Title: Intervention to Promote Survivor Resilience and Adjustment: Efficacy and Sustainability

VCU IRB Protocol Number: HM20011840

NCT03421964

The original grant was submitted to the IRB 11/15/2017 but the final version of the IRB approval for the study was 1/17/2018. When this study was initially reviewed by the Virginia Commonwealth University IRB, a separate protocol with the statistical analysis was not required. It is now. Sadly, this is the only way I can provide both documents.

Descriptive Title: Traumatic Brain Injury Model Systems

Submission Title: Traumatic Brain Injury Model System

Opportunity ID: HHS-2017-ACL-NIDILRR-DPTB-0204

Opportunity Title: Disability and Rehabilitation Research Projects (DRRP) Program: Traumatic Brain Injury (TBI) Model System Centers Program

Agency Name: Administration for Community Living

Table of Contents

OMB Number: 4040-0004
Expiration Date: 10/31/2019

Application for Federal Assistance SF-424

*1. Type of Submission:	*2. Type of Application	*If Revision, select appropriate letter(s):
[ ] Pre-application	[X] New	
[X] Application	[ ] Continuation	*Other (Specify):
[ ] Changed/Corrected Application	[ ] Revision	

*3. Date Received: 4. Applicant Identifier:

5.a. Federal Entity Identifier:	5.b. Federal Award Identifier:

State Use Only:

6. Date Received by State:	7. State Application Identifier:

8. APPLICANT INFORMATION:

*a. Legal Name: Virginia Commonwealth University

*b. Employer/Taxpayer Identification Number (EIN/TIN):	*c. Organizational DUNS:
1546001758A1	1053004460000

d. Address:

*Street 1: 800 East Leigh St, Suite 3200
Street 2: PO Box 980568
* City: Richmond
County:
* State: VA: Virginia
Province:
* Country: USA: UNITED STATES
* Zip/Postal Code: 23298-0568

e. Organizational Unit:

Department Name:	Division Name:

f. Name and contact information of person to be contacted on matters involving this application:

Prefix: * First Name: Jeffrey
Middle Name: S
* Last Name: Kreutzer
Suffix:

Title: Professor and Eminent Scholar

Organizational Affiliation:

* Telephone Number: 8048286772 Fax Number: 8048282521

* Email: dirospa@vcu.edu

OMB Number: 4040-0004
Expiration Date: 10/31/2019

Application for Federal Assistance SF-424

Version 02

9. Type of Applicant 1: Select Applicant Type:

H: Public/State Controlled Institution of Higher Education

Type of Applicant 2: Select Applicant Type:

Type of Applicant 3: Select Applicant Type:

Other (Specify):

* **10. Name of Federal Agency:**

Administration for Community Living

11. Catalog of Federal Domestic Assistance Number:

93.433

CFDA Title:

ACL National Institute on Disability, Independent Living, and Rehabilitation Research

* **12. Funding Opportunity Number:**

HHS-2017-ACL-NIDILRR-DPTB-0204

* **Title:**

Disability and Rehabilitation Research Projects (DRRP) Program: Traumatic Brain Injury (TBI) Model System Centers Program

13. Competition Identification Number:

HHS-2017-ACL-NIDILRR-DPTB-0204

Title:

Disability and Rehabilitation Research Projects (DRRP) Program: Traumatic Brain Injury (TBI) Model System Centers Program

14. Areas Affected by Project (Cities, Counties, States, etc.):

15. Descriptive Title of Applicant's Project:

Traumatic Brain Injury Model Systems

Attach supporting documents as specified in agency instructions.

OMB Number: 4040-0004
Expiration Date: 10/31/2019

Application for Federal Assistance SF-424

Version 02

16. Congressional Districts of:

* **Applicant:** VA-003 * **Program/Project:** VA-003

Attach an additional list of Program/Project Congressional Districts if needed.

17. Proposed Project:

* **a. Start Date:** 10/1/2017 4:00:00 AM * **b. End Date:** 9/30/2022 4:00:00 AM

18. Estimated Funding ($):

* **a. Federal**	$2,324,745.00
* **b. Applicant**	$914,932.00
* **c. State**	$0.00
* **d. Local**	$0.00
* **e. Other**	$0.00
* **f. Program Income**	$0.00
* **g. TOTAL**	$3,239,677.00

* **19. Is Application Subject to Review By State Under Executive Order 12372 Process?**

[ ] **a. This application was made available to the State under the Executive Order 12372 Process for review on**

[ ] **b. Program is subject to E.O. 12372 but has not been selected by the State for review.**

[X] **c. Program is not covered by E.O. 12372.**

* **20. Is the Applicant Delinquent On Any Federal Debt? (If "Yes", provide explanation.)**

[ ] Yes [X] No

If "Yes", provide explanation and attach

21. *By signing this application, I certify (1) to the statements contained in the list of certifications and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances** and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 218, Section 1001)**

[X] ** I AGREE

** The list of certifications and assurances, or an internet site where you may obtain this list, is contained in the announcement or agency specific instructions.**

Authorized Representative:

Prefix: * **First Name:** Andrea

Middle Name: J

* **Last Name:** Publow

Suffix:

* **Title:** Dir, OSP - Gov

* **Telephone Number:** 8048286772 **Fax Number: 8048282521**

* **Email:** dirospa@vcu.edu

* **Signature of Authorized Representative:** * **Date Signed:**

OMB Number: 4040-0010
Expiration Date: 10/31/2019

Project/Performance Site Location(s)

Project/Performance Site Primary Location

[ ] I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: Virginia Commonwealth University
DUNS Number: 1053004460000
Street 1: 800 East Leigh St, Suite 3200
Street 2: PO Box 980568
City: Richmond
State: VA: Virginia
Province:
Country: USA: UNITED STATES
ZIP / Postal Code: 23298-0568

County:

Project/Performance Site Congressional District: VA-003

Additional Location(s):

OMB Number: 4040-0006

Expiration Date: 07/30/2010

BUDGET INFORMATION – Non-Construction Programs

SECTION A – BUDGET SUMMARY

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	Total (g)
1. DRRP	93.433			$2,324,745.00		$2,324,745.00
2. DRRP					$914,932.00	$914,932.00
3.						$0.00
4.						$0.00
5. Totals		$0.00	$0.00	$2,324,745.00	$914,932.00	$3,239,677.00

SECTION B – BUDGET CATEGORIES

6. Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY				Total (5)
	(1) DRRP	(2) DRRP	(3)	(4)	
a. Personnel	$234,776.00	$133,372.00			$368,148.00
b. Fringe Benefits	$87,335.00	$49,614.00			$136,949.00
c. Travel	$5,000.00				$5,000.00
d. Equipment					$0.00
e. Supplies	$2,220.00				$2,220.00
f. Contractual					$0.00
g. Construction					$0.00
h. Other	$22,903.00				$22,903.00
i. Total Direct Charges (sum of 6a-6h)	$352,234.00	$182,986.00	$0.00	$0.00	$535,220.00
j. Indirect Charges	$112,715.00				$112,715.00
k. TOTALS (sum of 6i and 6j)	$464,949.00	$182,986.00	$0.00	$0.00	$647,935.00
7. Program Income					$0.00

SECTION C - NON-FEDERAL RESOURCES				
(a) Grant Program	**(b) Applicant**	**(c) State**	**(d) Other Sources**	**(e)TOTALS**
8. DRRP				$0.00
9. DRRP	$914,932.00			$914,932.00
10.				$0.00
11.				$0.00
12. TOTAL (sum of lines 8-11)	$914,932.00	$0.00	$0.00	$914,932.00

SECTION D - FORECASTED CASH NEEDS					
	Total for 1st Year	**1st Quarter**	**2nd Quarter**	**3rd Quarter**	**4th Quarter**
13. Federal	$464,948.00	$116,237.00	$116,237.00	$116,237.00	$116,237.00
14. Non-Federal	$182,984.00	$45,746.00	$45,746.00	$45,746.00	$45,746.00
15. TOTAL (sum of lines 13 and 14)	$647,932.00	$161,983.00	$161,983.00	$161,983.00	$161,983.00

SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT				
(a) Grant Program	**FUTURE FUNDING PERIODS (YEARS)**			
	(b)First	**(c) Second**	**(d) Third**	**(e) Fourth**
16. DRRP	$464,949.00	$464,949.00	$464,949.00	$464,949.00
17. DRRP				
18.				
19.				
20. TOTAL (sum of lines 16 - 19)	$464,949.00	$464,949.00	$464,949.00	$464,949.00

SECTION F - OTHER BUDGET INFORMATION	
21. Direct Charges: $1,761,170	**22. Indirect Charges:** $563,575
23. Remarks:	

OMB Approval No.: 4040-0007
Expiration Date: 07/30/2010

ASSURANCES - NON-CONSTRUCTION PROGRAMS

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE OFFICE OF MANAGEMENT AND BUDGET. SEND IT TO THE ADDRESS PROVIDED BY THE SPONSORING AGENCY.

NOTE: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant, I certify that the applicant:

1. Has the legal authority to apply for Federal assistance and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project cost) to ensure proper planning, management and completion of the project described in this application.
2. Will give the awarding agency, the Comptroller General of the United States and, if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted counting standards or agency directives.
3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.
4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.
5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§4728-4763) relating to prescribed standards for merit systems for programs funded under one of the 19 statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).
6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C.§§1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. §794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. §§290 dd-3 and 290 ee- 3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. §§3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and, (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.
7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally-assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.
8. Will comply, as applicable, with provisions of the Hatch Act (5 U.S.C. §§1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.

9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§276a to 276a-7), the Copeland Act (40 U.S.C. §276c and 18 U.S.C. §874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§327-333), regarding labor standards for federally-assisted construction subagreements.
10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more.
11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§1451 et seq.); (f) conformity of Federal actions to State (Clean Air) Implementation Plans under Section 176(c) of the Clean Air Act of 1955, as amended (42 U.S.C. §§7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended (P.L. 93-523); and, (h) protection of endangered species under the Endangered Species Act of 1973, as amended (P.L. 93-205).
12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.
13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. §470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. §§469a-1 et seq.).
14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.
15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. §§2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.
16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§4801 et seq.) which prohibits the use of lead-based paint in construction or rehabilitation of residence structures.
17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act Amendments of 1996 and OMB Circular No. A-133, "Audits of States, Local Governments, and Non-Profit Organizations."
18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations, and policies governing this program.

* SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	* TITLE
Completed on submission to Grants.gov	Dir, OSP - Gov
* APPLICANT ORGANIZATION	* DATE SUBMITTED
Virginia Commonwealth University	Completed on submission to Grants.gov

CERTIFICATE REGARDING LOBBYING

Certification for Contracts, Grants, Loans, and Cooperative Agreements

The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure of Lobbying Activities," in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly. This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,00 0 and not more than $100,000 for each such failure.

Statement for Loan Guarantees and Loan Insurance

The undersigned states, to the best of his or her knowledge and belief, that:

If any funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this commitment providing for the United States to insure or guarantee a loan, the undersigned shall complete and submit Standard Form-LLL, "Disclosure of Lobbying Activities," in accordance with its instructions. Submission of this statement is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required statement shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

* APPLICANT'S ORGANIZATION Virginia Commonwealth University
* PRINTED NAME AND TITLE OF AUTHORIZED REPRESENTATIVE Prefix: * First Name: Andrea Middle Name: J * Last Name: Publow Suffix: * Title: Dir, OSP - Gov
* SIGNATURE: Andrea.Publow *DATE:

OMB Number: 1894-0007
Expiration Date: 08/31/2017

U.S. DEPARTMENT OF EDUCATION
SUPPLEMENTAL INFORMATION
FOR THE SF-424

1. Project Director:

Prefix:	First Name:	Middle Name:	Last Name:	Suffix:
	Jeffrey	S	Kreutzer	

Address:

Street1: PO Box 980206
Street2:
City: Richmond
County:
State: VA: Virginia
Zip Code: 23298-0206
Country: USA: UNITED STATES

Phone Number (give area code) Fax Number (give area code)
8043271166

Email Address:
jeffrey.kreutzer@vcuhealth.org

2. Applicant Experience:

Are you a novice applicant as defined in the regulations in 34 CFR 75.225 (and included in the definitions page in the attached instructions)?

[ ] Yes [X] No [ ] Not applicable to this program

3. Human Subjects Research

a. Are any research activities involving human subjects planned at any time during the proposed project Period?

[X] Yes [ ] No

b. Are ALL the research activities proposed designated to be exempt from the regulations?

[ ] Yes Provide Exemption(s) #: [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 6

[X] No Provide Assurance #, if available: FWA0005287

c. If applicable, please attach your "Exempt Research" or "Nonexempt Research" narrative to this form as indicated in the definitions page in the attached instructions.

Nonexempt Research Narrative.pdf

HUMAN SUBJECTS NONEXEMPT RESEARCH NARRATIVE (FORM 424)

The VCU TBIMS proposal includes data collection from human subjects for three studies:

1. Data collection for the NIDILRR-funded TBIMS National Database
2. Intervention to Promote Survivor Resilience and Adjustment: Efficacy and Sustainability
3. Caregiver Resilience: A Longitudinal Investigation

Grouped by individual research project, are responses to each question regarding human subjects protection.

1. Data collection for the NIDILRR-funded TBIMS National Database

(1) Human Subjects Involvement and Characteristics: Provide a detailed description of the proposed involvement of human subjects. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children, children with disabilities, adults with disabilities, persons with mental disabilities, pregnant women, prisoners, institutionalized individuals, or others who are likely to be vulnerable.

Individuals included in this project will be adults (18 years or older) who have experienced a traumatic brain injury (TBI). We expect to enroll approximately 200 new research participants over the course of the grant. TBI often causes physical and mental disabilities. Thus, adults with physical and/or mental disabilities will be included. Pregnant women will also be enrolled, as there is no indication of additional risk to mother or fetus. Individuals in the following special classes will **not** be studied: children, prisoners, and institutionalized individuals.

(2) Sources of Materials: Identify the sources of research material obtained from individually living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Research materials will be comprised of data obtained through questionnaires, medical records review, interviews, and administration of neuropsychological tests. Information will be obtained specifically for the research purposes of the project.

(3) Recruitment and Informed Consent: Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the Institutional Review Board (IRB) has

authorized a modification or waiver of the elements of consent or the requirement for documentation of consent.

Participants will be solicited from inpatient admissions to the Brain Injury Rehabilitation Unit at the Virginia Commonwealth University Health System (VCUHS). Patients will be approached by Jennifer Marwitz, M.A. (TBIMS Project Coordinator) or Daniel Klyce, Ph.D. (the Brain Injury Rehabilitation Unit's neuropsychologist). A description of the project will be provided to patients. If the patient is interested in participating, Ms. Marwitz or Dr. Klyce will review the nature of the research (completion of questionnaires and neuropsychological testing). The consent form will be carefully reviewed with the patient and written consent obtained. Ms. Marwitz and Dr. Klyce will emphasize that participation is voluntary and the patient's decision to participate will not affect the quality of their medical care.

In any case where the investigator has concerns about the patient's ability to provide informed consent, formal assessment of decision-making capacity will be made using the MacArthur Competence Assessment Tool, Clinical Research version (MacCAT-CR). As allowed under Virginia state law, an alternative procedure will be used to consent persons lacking the capacity to give informed consent, as determined by the MacCAT-CR, or as judged by the investigators. Investigators will seek to obtain consent from a legally designated substitute decision maker. In every case, an effort will be made to obtain assent from the patient. Patients who decline to participate will **not** be enrolled regardless of their respective substitute decision maker's desire.

The consent form was approved for the 2012-2017 funding cycle of this project by the Institutional Review Board (IRB) (VCU internal code CCHR Protocol #00223) through March 31, 2018. No request has been made to modify or waive any of the elements of consent. Documentation of consent is required.

(4) Potential Risks: Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

There are minimal risks (physical, psychological, social, legal, or other) associated with human subjects use for this project. Some individuals may experience feelings of sadness or frustration when completing the tests. The only inconvenience to research participant will be the time it takes to answer the questionnaires and take the tests. Questions of a sensitive nature (e.g., substance use/abuse, criminal history) are included; however patients are given the option to omit questions

that they do not wish to answer.

5) Protection Against Risk: Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of the subjects.

This project is directed by a licensed clinical psychologist (Dr. Jeffrey Kreutzer). In the event that a patient is found to have significant psychological problems, Dr. Kreutzer will provide individual psychotherapy or refer the patient for further psychiatric intervention. Confidentiality of information will be guaranteed in the database. No names or social security numbers will be included - only identification numbers assigned by the Project Coordinator. The Project Coordinator and Research Assistants will keep any contact information for follow-up purposes separate from research data collected.

(6) Importance of the Knowledge to be Gained: Discuss the importance of the knowledge gained or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

The longitudinal National Database is the largest longitudinal database addressing outcomes after TBI. Knowledge gained regarding long-term outcomes is important to better serve persons with disabilities. There are minimal risks (physical, psychological, social, legal, or other) associated with the project. The possibility that some individuals may experience feelings of sadness or frustration during testing is outweighed by the potential benefits of the project. The VCU TBIMS places an emphasis on providing patients with psychological support and education to assist in recovery following TBI.

(7) Collaborating Site(s): If research involving human subjects will take place at collaborating site(s) or other performance site(s), name the sites and briefly describe their involvement or role in the research.

Not applicable.

2. Intervention to Promote Survivor Resilience and Adjustment: Efficacy and Sustainability

(1) Human Subjects Involvement and Characteristics: Provide a detailed description of the proposed involvement of human subjects. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children, children with disabilities, adults with disabilities, persons with mental disabilities, pregnant women, prisoners, institutionalized individuals, or others who are likely to be vulnerable.

Individuals included in this project will be adults (18 years or older) who have experienced a TBI. Participants with any of the following will be excluded from the study: imminent risk of psychiatric hospitalization, imminent danger of hurting themselves or others, or active substance abuse (e.g., intoxicated at intake), as judged by the investigators.

The proposed study will evaluate the benefits of the Resilience and Adjustment Intervention for improving resilience and emotional well-being after TBI. The study is a two-arm randomized controlled trial comparing the benefits of a basic resilience-building intervention (RAI) with an expanded, patient-centered resilience intervention (RAI+).

We expect to enroll approximately 154 participants over the course of the grant. TBI often causes physical and mental disabilities. Thus, adults with physical and/or mental disabilities will be included. Pregnant women will also be enrolled, as there is no indication of additional risk to mother or fetus. Individuals in the following special classes will **not** be studied: children, prisoners, and institutionalized individuals.

(2) Sources of Materials: Identify the sources of research material obtained from identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Research materials will be comprised of data obtained through questionnaires, interviews, and medical records review. Information will be obtained specifically for the research purposes of the project.

(3) Recruitment and Informed Consent: Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the Institutional Review Board (IRB) has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent.

Individuals who are referred for outpatient brain injury services will be contacted by Dr. Jeffrey Kreutzer (Principal Investigator), Jennifer Marwitz (Project Coordinator), Dr. Ana Mills, or Dr. Nancy Hsu (therapists) to determine their eligibility and interest in participation. The details of the study will be explained, and the consent form will be carefully reviewed with the eligible participant. Written consent will be obtained at the initial intake session. Project staff will emphasize that participation is voluntary and the individual's decision to participate will not affect the quality of their medical care.

In any case where the investigator has concerns about the person's ability to provide informed consent, formal assessment of decision-making capacity will be made using the MacArthur Competence Assessment Tool, Clinical Research version (MacCAT-CR).

As allowed under Virginia state law, an alternative procedure will be used to consent persons lacking the capacity to give informed consent, as determined by the MacCAT-CR, or as judged by the investigators. Investigators will seek to obtain consent from a legally designated substitute decision maker. In every case, an effort will be made to obtain assent from the patient. Patients who decline to participate will **not** be enrolled regardless of their respective substitute decision maker's desire.

The consent form is currently under review by the Institutional Review Board (IRB). No request has been made to modify or waive any of the elements of consent. Documentation of consent is required.

(4) Potential Risks: Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

There are minimal risks (physical, psychological, social, legal, or other) associated with human subjects use for this project. Some individuals may experience feelings of sadness or frustration when answering questions about their current status. Participants will be given the option to omit any questions that they do not wish to answer.

5) Protection Against Risk: Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of the subjects.

This project is directed by a licensed psychologist (Dr. Kreutzer). Dr. Kreutzer will be on call during each assessment and treatment session. He will be responsible for monitoring the status of enrolled participants and addressing urgent situations. When concerns arise, Dr. Kreutzer will make a clinical decision regarding the need for further evaluation, treatment, or referral.

Confidentiality of information will be guaranteed in the databases. No names or social security numbers will be included - only identification numbers assigned by the Project Coordinator. The Project Coordinator, Therapists, and Research Assistants will keep any contact information for follow-up purposes separate from research data collected.

(6) Importance of the Knowledge to be Gained: Discuss the importance of the knowledge gained or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

Empirical investigation of a structured, replicable, outpatient intervention to address resilience and emotional adjustment after TBI will guide clinicians serving individuals post-discharge, enabling more effective and efficient service delivery. There are minimal risks (physical, psychological, social, legal, or other) associated with the project. The possibility that some individuals may experience feelings of sadness and frustration during protocol implementation is outweighed by the potential benefits of the project. The VCU TBIMS places an emphasis on providing patients with psychological support and education to assist in recovery following TBI.

(7) Collaborating Site(s): If research involving human subjects will take place at collaborating site(s) or other performance site(s), name the sites and briefly describe their involvement or role in the research.

Not applicable.

3. Caregiver Resilience: A Longitudinal Investigation

(1) Human Subjects Involvement and Characteristics: Provide a detailed description of the proposed involvement of human subjects. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children, children with disabilities, adults with disabilities, persons with mental disabilities, pregnant women, prisoners, institutionalized individuals, or others who are likely to be vulnerable.

Individuals included in this project will be adults (18 years or older) who are caregivers of a TBIMS National Database (NDB) research participant. We expect to enroll approximately 78 research participants over the course of the grant. Adults with physical and/or mental disabilities will be included. Pregnant women will also be enrolled, as there is no indication of additional risk to mother or fetus. Individuals in the following special classes will **not** be studied: children, prisoners, and institutionalized individuals.

(2) Sources of Materials: Identify the sources of research material obtained from identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Research materials will be comprised of data obtained through questionnaires and interviews. Information will be obtained specifically for the research purposes of the project.

(3) Recruitment and Informed Consent: Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the Institutional Review Board (IRB) has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent.

Newly enrolled TBIMS NDB participants will be contacted after discharge and no more than six months postinjury by a research assistant (Marie Grace Martinez or Abigail Welch). NDB participants will be asked to identify a caregiver. The research assistant will then approach the caregiver, providing them with information about the project, and inviting study participation. If the caregiver agrees, the research assistant will then explain study details and obtain written informed consent. Information regarding the project's focus and the caregiver's right to decline to participate will be given both orally and in writing. Research assistants will emphasize that participation is voluntary and the caregiver's decision to participate will not affect the quality of the patient's medical care.

In any case where the investigator has concerns about the caregiver's ability to provide informed consent, formal assessment of decision-making capacity will be made using the MacArthur Competence Assessment Tool, Clinical Research version (MacCAT-CR).

As allowed under Virginia state law, an alternative procedure will be used to consent persons lacking the capacity to give informed consent, as determined by the MacCAT-CR, or as judged by

the investigators. Investigators will seek to obtain consent from a legally designated substitute decision maker. In every case, an effort will be made to obtain assent from the patient's caregiver. Caregivers who decline to participate will **not** be enrolled regardless of their respective substitute decision maker's desire.

Once collaborating centers are established, the study will be submitted for review and approval by the Institutional Review Board (IRB). No request will be made to modify or waive any of the elements of consent. Documentation of consent will be required.

(4) Potential Risks: Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

There are minimal risks (physical, psychological, social, legal, or other) associated with human subjects use for this project. Some individuals may experience feelings of sadness when answering questions or talking about their current status. The only inconvenience to research participants will be the time it takes to answer the questionnaires and complete the interviews. Questions of a sensitive nature (e.g., substance use/abuse) are included, and caregivers will be given the option to omit questions that they do not wish to answer.

5) Protection Against Risk: Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of the subjects.

This project is directed by a licensed psychologist (Dr. Kreutzer). In the event that a participant is found to have significant psychological problems, Dr. Kreutzer will provide individual psychotherapy or refer the patient for further psychiatric intervention. Confidentiality of information will be guaranteed in the databases. No names or social security numbers will be included - only identification numbers assigned by the Project Coordinator. The Project Coordinator and Research Associates will keep any contact information for follow-up purposes separate from research data collected.

(6) Importance of the Knowledge to be Gained: Discuss the importance of the knowledge gained or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

As a result of this research, we will better understand and conceptualize caregivers' experiences after TBI. Further, we will gain a new and better understanding of how caregiver attributes, namely resilience, relate to survivor outcomes and caregiver burden and needs. There are minimal risks (physical, psychological, social, legal, or other) associated with the project. The possibility that some individuals may experience feelings of sadness or frustration is outweighed by the potential benefits of the project. The VCU TBIMS places an emphasis on providing patients and family members/caregivers with psychological support and education to assist in recovery following TBI.

(7) Collaborating Site(s): If research involving human subjects will take place at collaborating site(s) or other performance site(s), name the sites and briefly describe their involvement or role in the research.

Not yet identified.

ATTACHMENTS FORM

Instructions: On this form, you will attach the various files that make up your grant application. Please consult with the appropriate Agency Guidelines for more information about each needed file. Please remember that any files you attach must be in the document format and named as specified in the Guidelines.

Important: Please attach your files in the proper sequence. See the appropriate Agency Guidelines for details

1) Table of Contents.pdf
2) Appendices.pdf
3) Data and Safety Monitoring Plan.pdf
4) VCU Indirect Rate Agreement.pdf
5)
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TRAUMATIC BRAIN INJURY MODEL SYSTEM

DISABILITY REHABILITATION RESEARCH PROJECT (DRRP)

FOR NEW AWARD FOR FISCAL YEAR 2017

HHS-2017-ACL-NIDILRR-DPTB-0204

United States Department of Health and Human Services

Administration for Community Living

CFDA No. 93.433

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May 9, 2017

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Data and Safety Monitoring Plan

For all proposed clinical trials, NIDILLR is requiring that applicants address the safety of human subjects. The VCU TBIMS proposal includes one clinical trial, our site-specific project:

Intervention to Promote Survivor Resilience and Adjustment: Efficacy and Sustainability

The monitoring of this study will involve a continuous and ongoing process of reviewing the conduct of the trial, including adherence to the study design and documentation of AEs/SAEs. The responsibility of monitoring the safety of participants is held primarily by Dr. Kreutzer as Project Director and Principal Investigator. Considering that the interventions in this study carry **less than minimal risk** to participants, and that Dr. Kreutzer and his research team have appropriate clinical skills and training to monitor for AEs/SAEs, it is appropriate for the research team to carry the primary responsibility for monitoring.

Monitoring the Safety of Participants: As noted above, a specific protocol will be used to monitor for and report AEs/SAEs. The Project Director, in collaboration with the Project Coordinator, are primarily responsible for monitoring the safety of participants, in collaboration with the study therapists (Dr. Mills and Dr. Hsu, both clinical psychologists), in the following ways:

- Monitor for Psychological AE (worsening depressive symptoms from one assessment time point to the next by 5 points on the BSI-18 Depression scale with no endorsement of suicidality):
  - Participants will be provided with the contact information for the Project Coordinator, Project Director, and therapist. They will be advised to call with any questions or concerns or to report any unusual emotional feelings; and
  - Research Assistants will be trained in the definition of AE (worsening depressive symptoms without endorsement of suicidality) and will report any obvious psychological changes in participants to the Project Director immediately.
- Monitor for Psychological SAE (suicidality):
  - The Project Coordinator will administer the MINI suicide module immediately to assess suicidality risk in any of the following situations:
    - a participant reports suicidal thoughts to study staff; and/or,
    - a participant endorses suicidality on the depression scale of the BSI-18 during data collection
  - If the suicide risk is low on the MINI ($\leq$8), the Project Coordinator will ask the participant to be in touch with his/her healthcare provider for follow-up. If the participant scores high for

suicide risk (9-17), the Project Coordinator will ensure that the participant is accompanied by a family member or friend to their healthcare provider or the local emergency department for immediate evaluation. The Project Coordinator will consult with Dr. Kreutzer (a clinical psychologist) regarding additional questions/concerns.

In all of the above cases, the Project Director will determine the severity of the AE/SAE and the relatedness to the intervention. The Project Director will document actions taken and outcomes. If any of these events occurs and are directly related to the intervention, the IRB and NIDILRR will be alerted.

Summary of Study Review Plan: Study progress and safety will be reviewed by the Project Director on a monthly basis, and more frequently if needed. Progress reports, including participant accrual, participant status and adherence data will be provided regularly to the Project Director. Data about AEs/SAEs will be reported with each occurrence. As part of the IRB continuing review, an Annual Report will be compiled and will include a list and summary of AEs/SAEs. In addition, the Annual Report will address (1) whether AEs/SAEs have been severe and related to the intervention; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; and (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study.

Validity and Integrity of Data: In collaboration with the research team, the Project Director will maintain responsibility for all aspects of data collection, entry, and analysis. The Project Director and study staff will review all data collected on an ongoing basis for completeness and accuracy, as well as protocol compliance. The frequency of data review is described below:

- Participant accrual: Review of the rate of participant accrual and compliance with inclusion/exclusion criteria will occur monthly during the recruitment phase to ensure that a sufficient number of participants are being enrolled and that they meet eligibility criteria.
- Participant status and Adherence data: Review of the status of enrolled participants will occur on a consistent basis throughout the study, including data on adherence to study visits and the intervention protocol. If there are concerns about whether adherence has reached a level that might inhibit the ability of the study to evaluate the specific aims, a conference call will be scheduled with Scientific Advisors and the Advisory Board to discuss methods for improving adherence.
- AEs and SAEs and rates: Review of every AE and SAE will be closely evaluated by the Project Director at each occurrence and reported in annual reviews.

Abstract

Virginia Commonwealth University's (VCU) Traumatic Brain Injury Model System (TBIMS) proposal is comprised of four major components. One component, a site-specific research project, is a two-arm randomized controlled trial comparing the benefits of a basic resilience-building intervention with an expanded, patient-centered, resilience intervention. Outcome measures will focus on resilience, emotional distress, adjustment, and stress management. The sustainability of treatment benefits will be investigated. A second component is focused on caregivers. The adverse impact of TBI on caregivers has been well-documented. Reflecting the recent focus on positive psychology, we propose to conduct a multi-center, longitudinal investigation of caregiver resilience. The module will examine caregiver factors associated with resilience including emotional well-being, needs, and perceived burden. Survivor characteristics, including emotional distress, functional status, resilience, and injury characteristics, will also be examined. A third major component relates to the National Database. VCU will continue to collect data for the National Database, and will lead and participate in multi-center, collaborative efforts to examine TBI outcomes and prognostic indicators. A fourth component of our proposal relates to dissemination. VCU will maintain a highly active dissemination program in collaboration with the Model Systems Knowledge Translation Center. As in the past, VCU's dissemination efforts will include a high volume of peer-reviewed publications and consumer-oriented outreach. In partnership with Brain Injury Services and the National Resource Center for TBI, the VCU TBIMS recently hosted our 41st TBI rehabilitation conference in Williamsburg, VA. The conference was the first and remains the longest running TBI rehabilitation conference in the world. The conference planning committee will continue to include research and researchers from other TBIMS sites in planning the next five years of conferences.

VCU has been a major provider of brain injury acute care and inpatient and outpatient rehabilitation services to a large, culturally diverse population for more than three decades. VCU Medical Center provides nearly one-third of Virginia's indigent care and is the largest provider of indigent care in the state. Uninsured patients represent 20 percent of all patients treated, substantiating our strong commitment to serve persons regardless of ability to pay. We have been an active collaborator in the TBIMS since 1987. Since program inception, we have: extended our system of care; developed new partnerships with service providers and advocacy organizations; improved outcome measurement techniques; and successfully developed innovative interventions. Consumer involvement, emphasis on community-based rehabilitation, relevance, and active dissemination to consumer and professional audiences have been cornerstones of program development and implementation. The nearly 400 model systems manuscripts published by our interdisciplinary research team in the past 30 years substantiates assertions that the urban, academic health center setting is ideal for scientific research, innovation, collaboration, and dissemination.

I. Importance of the Problem

Need and Target Population

With an estimated annual incidence rate of 1.7 million,[1] traumatic brain injury (TBI) continues to be a leading cause of death and disability in the United States.[2] Each year, TBI results in 2.5 million visits to the emergency department (ED).[3] One-third of all injury deaths in the U.S. are due to TBI,[4] and there are 3.2 to 5.3 million persons,[5] or ~1.1% of U.S. population living with permanent TBI-related disabilities.[6] The societal toll of TBI is enormous and growing. Since 2007, there has been a 56% increase in the rate of TBI-related ED visits.[5] The increase in TBI-related visits far outpaces the increase in total ED visits, representing an eight-fold greater increase.[7] Despite the magnitude, these numbers do not account for all occurrences of TBI because they do not include individuals who go without medical care, had outpatient or office-based visits, and those who received treatment at a federal facility.[5] Estimates place the annual indirect and direct financial costs near $76.5 billion.[8,9]

Brain injury causes drastic life changes, with losses affecting survivors, their families, and society.[9-12] TBI often results in a diversity of problems[13,14] and life-long impairments.[15,16] The complex and long-term nature of sequelae create special challenges.[17-19] Difficulties are well documented and have been categorized into at least five different areas, including: (1) functional status;[20-23] (2) neurological and medical status;[24-27] (3) neurobehavioral and emotional status;[16,28-30] (4) familial and marital adjustment;[31-34] and (5) vocational status.[35-37] For example, five years after inpatient rehabilitation, one-third of TBI survivors remain dependent for everyday activities and 12% are institutionalized.[14] While fewer people die from TBI, survivors must often contend with poorer health, including hastened neurodegenerative processes and increased risk for Parkinson's disease and Lewy body accumulation.[38] Emotional adjustment following TBI is fraught with high rates of depression (25-53%),[39-41] anxiety (21%),[42] and suicidal ideation (7-10%).[39] Return to work after TBI is suboptimal, with more than 60% of working age individuals being unemployed two years after completing rehabilitation.[36] Given these pervasive deleterious consequences, family members of survivors of TBI are especially burdened, frequently reporting emotional distress, lack of respite, financial stress, and lack of community support.[43-45] Of particular concern, caregiver

burden appears to increase over time, underscoring the need to care for these caregivers, including enhancing their resilience, as a critical effort in mitigating the chronic toll of TBI.[46]

Although the last decade has seen advances in TBI management,[47] much remains to be understood about how to effectively address the lifelong needs of this vulnerable population.[48-53] There have been marked improvements in reducing mortality and managing major medical complications, yet addressing the emotional and psychosocial needs of persons with TBI remains an area of development. Questions pertain to how to optimize rehabilitation services and effective psychological interventions along the continuum of care after inpatient rehabilitation.[5] For example, despite accumulating evidence about the importance of fostering resilience after TBI,[54] questions remain about the long-term trajectory of resilience postinjury and how it relates to other outcomes. Experts agree that additional research needs to be conducted on the efficacy of various rehabilitation treatments and strategies,[55-57] especially as there is greater appreciation for rehabilitation beyond the acute phase. More serious questions have arisen from the ranks of third-party payers. Long-term rehabilitation is expensive and efficacy questions have diminished the insurance industry's willingness to provide reimbursement.[58,59]

While an increasing number of researchers have focused their interests on TBI management during the past decade, many important questions remain unanswered, especially questions relating to treatment efficacy. Progress has been limited partly by funding and a lack of trained researchers. Many professionals choose to work solely as clinicians because they view the immediate needs of their clients as a priority. Progress has also been constrained by the use of retrospective designs and small samples.[60,61] In addition, few investigators have pursued systematic, long-term research plans.

Virginia Commonwealth University (VCU) researchers have been immersed in TBI rehabilitation research for nearly three decades. Our earliest studies were descriptive, focusing on cognitive and neurobehavioral functioning, emotional adjustment, employment, and family functioning (see *VCU Model Systems Publications,* Appendix F). Our more recent research, involving development and evaluation of psychological interventions for survivors and families, has produced promising results. Studies have yielded evidence of improved: (1) problem solving,

communication, and goal setting skills; (2) emotional well-being and stress management; and (3) knowledge about TBI.[62-66] Still, survivors face many additional challenges and more work remains. In moving forward, we firmly believe that standardized, targeted interventions focused on resilience and adjustment are key to helping survivors live meaningful and productive lives. Little is known about caregiver resilience, and better understanding will allow the opportunity to improve outcomes.[67,68] Feedback from patients and families, research participants, and Advisory Board members substantiates that VCU's proposed projects are relevant, worthy of investigation, and likely to improve the lives of survivors and caregiving family members.

Beneficial Impact on Target Population

The VCU TBI Model System (TBIMS) aims to conduct one new site-specific research project and new multi-site module project, continue to collect data for the TBIMS National Database, and carry out a wide variety of dissemination activities. A strong interest in benefiting consumers and professionals guided our choice and design of program activities. Specific information about the expected benefits of each activity is provided in respective sections of the grant (e.g., *Design of Research Activities; Design of Dissemination Activities*).

The overall expected benefits of the VCU TBIMS program are as follows:

1. Analysis of the National Database will identify characteristics of patients with optimal and sub-optimal outcomes. An understanding of factors that influence outcomes will aid in needs assessment and establishing priorities for program development and training.
2. Professionals often face uncertainty when choosing appropriate treatment outcome measures. The proposed research programs will help identify sensitive measures, allowing professionals to make more informed choices in selecting outcome measurement tools.
3. Progress in rehabilitation practice has been limited by concerns about the foundations of evidence-based practice. Increased knowledge about outcomes and the elements of efficacious treatment to improve resilience and adjustment will benefit practice, ultimately improving the lives of survivors and their caregivers.
4. Identifying the characteristics of treatment-resistant research participants will further development of effective treatment alternatives.
5. Improved outcomes for survivors will help alleviate the stress and distress that often affects caregivers and other family members, enabling them to live healthier lives.
6. A better understanding of caregiver resilience and how it relates to survivor outcomes and caregiver burden and needs will provide a foundation for more effective intervention development.
7. A strong, effective research dissemination plan will help rehabilitation professionals improve their practice and enable consumers to make more informed treatment choices.
8. All systems of care have resource limitations. Improved understanding of effective intervention strategies will enable systems to more efficiently allocate resources.

9. Within managed care systems, rehabilitation consumers often suffer great financial hardships partly because third-party payers are unwilling to pay for services with uncertain effectiveness. Demonstration of intervention effectiveness will increase the willingness of third-party payers to fund services.
10. New hypotheses will be generated for future intervention research focused on resilience, adjustment, and caregiving.

II. Responsiveness to Priorities

The VCU Health System (VCUHS) encompasses a long-standing, comprehensive multidisciplinary continuum of care that includes a full range of inpatient and outpatient follow-up services (see *Adequacy and Accessibility of Resources* and Appendix E). Emergency, acute, inpatient rehabilitation care, and post-acute services are centered in the region's only Level I trauma center. In partnership with other providers and agencies, a network of outpatient rehabilitation services is also offered in community-based settings. Consistent with priorities stated in the 2017 Federal Register, VCU researchers will generate novel information about intervention effectiveness and outcomes, providing a foundation for evidence-based clinical practice guidelines.

We are firmly committed to addressing the newly announced priorities, and a number of factors will enable success. First, the proposed projects will build upon a solid foundation of existing knowledge. We have thoroughly reviewed and analyzed the literature (*see Design of Research Activities - Literature Review, Rationale)*. Second, we were guided by extensive clinical experience to develop relevant projects most likely to advance treatments and improve outcomes for individuals with TBI and their families. Importantly, individuals with disabilities and their family members have participated in planning this proposal, helping to assure the relevance of our research program. Indeed, they will be integral to future planning, implementation, dissemination, and evaluation *(see Plan of Operation, Plan of Evaluation).*Third, our health system resources *(see Adequacy and Accessibility of Resources* and Appendix E*)*, highly qualified personnel *(see Project Staff)*, and practical experience gained through preliminary research in the proposed areas will ensure attainment of our objectives. Fourth, we have developed and will implement a rigorous program evaluation plan to prevent problems and make certain that objectives are accomplished in a timely, cost-efficient, and high quality manner.

Our site-specific project examines the short and longer-term benefits of a curriculum-based, skill-building, education, and psychological support intervention for persons with TBI. Our proposed module project will examine caregivers' well-being with a focus on resilience, emotional adjustment, burden, and needs. As such, VCU TBIMS research falls primarily within NIDILRR's *Health and Function* research domain, and secondarily in the *Participation and Community Living* domain. The selection and design of projects were guided by the need for methodological rigor, NIDILRR's Long-Range Plan, and our Advisory Board. Information regarding stage of research, sample size, power calculations, methodology, and quality control procedures is provided within the text of each research project. We are confident that the proposed research designs and sample sizes will enable us to achieve meaningful and robust findings. With the guidance of our Advisory Board and VCU colleagues, data collection instruments were selected based on their sensitivity and cultural relevance. With Richmond's culturally diverse population, we anticipate successfully enrolling persons from traditionally underserved populations. As in the past, guidance will also be sought from the National Data and Statistical Center (NDSC) and the Model Systems Knowledge Translation Center (MSKTC). We have worked and will continue to work closely with the NDSC and MSKTC, as outlined in their letters of support (see Appendix C).

High quality data collection, following established TBIMS National Database protocols, will remain a foundation of our project. VCU has been a member of the NIDILRR-funded TBIMS program since 1987. Data on over 700 patients has been collected thus far, and nearly 2,200 follow-up evaluations have been completed. VCU's data collection expertise has been recognized by the NDSC in many ways. For example, our staff have been involved in NDSC quality support visits, training other centers, developing prototype interview formats, and J. Marwitz serves as chair of the TBIMS Data Committee. We will apply our considerable expertise to ensure continued high quality data collection.

Considering our enrollment rate over the past five years (average of 44 patients per year), we anticipate accrual of no less than 35 participants per year for the National Database. Collaborative relationships with medical centers outside our region (e.g., University of Virginia, Mary

Washington, and Norfolk Sentara Hospitals) ensure our ability to recruit a substantial number of National Database participants. Further, VCU is now collaborating with Sheltering Arms Rehabilitation Hospital to build a 114-bed acute rehabilitation center in Richmond. Our analysis of admissions for both hospitals leaves us to anticipate a 50% increase in National Database enrollment with the merger. Descriptive statistics detailing VCU data collection and follow-up rates are provided in Appendix E. VCU researchers are uniquely positioned to continue following patients well beyond 25 years postinjury. Multiple TBIMS manuscripts have described long-term outcomes and trends in rehabilitation care up to ten years postinjury (see Appendix F), and VCU has contributed a considerable proportion of the data. As requested by NIDILRR, specific estimates for follow-up data collection costs are provided in the *Budget Narrative.*

As directed by NIDILRR, VCU will participate in at least one Module project. As specified in the *Budget Narrative,* no less than 15% of our annual budget will be reserved to fund module project operations. Also, as requested by NIDILRR, funds have been budgeted for participation in two annual, in-person Project Directors' meetings.

For nearly 25 years, we have actively collaborated with other TBIMS centers, organizations, and agencies in carrying out program activities. We have solidified relationships with the Virginia Department of Aging and Rehabilitative Services, Brain Injury Association of Virginia, VA Polytrauma Rehabilitation Centers, and Brain Injury Services of Virginia *(*see also Appendices C and E, *Letters of Commitment and Support* and *VCU Contribution to National Database and Continuum of Care)*. Information on collaborative mechanisms, entities, and coordination is provided in the *Collaboration* section of the proposal. A review of our publications list (see Appendix F) substantiates our many successes in collaborative research endeavors. For example, in the past five years, VCU has shared authorship with other model system centers in 22 peer-reviewed journal manuscripts published or in press.

A Guide for Reviewers

The following table was developed to help reviewers evaluate our application. The table indicates where in the grant text information relevant to the selection criteria are provided.

SELECTION CRITERIA	PRIMARY LOCATION WITHIN TEXT
Importance of the Problem	***Importance of the Problem***; **Rationale** and **Expected Beneficial Impact** sections provided in text of each project within ***Research Activities***
Responsiveness to Priorities	***Responsiveness to Priorities***; **Objectives/Research Questions, Rationale,** and **Expected Beneficial Impact** sections within ***Research Activities***
Design of Research Activities	***Research Activities***: ▪ Review of the Literature; Rationale; References in Appendix A ▪ Hypotheses and Objectives or Research Questions ▪ Sample, Power Analyses (see Data Analysis section) ▪ Feasibility: Project Staff, Potential Problems and Anticipated Solutions ▪ Input from Persons with Disabilities and Stakeholders (see Research Activities overview and individual projects) ▪ Data collection and measurement (Methodology section- intervention, measures, procedure, quality control) ▪ Data Analysis ▪ Stage of Research (see Methodology section) ▪ **Implementation Manual for Intervention** (Appendix G)
Design of Dissemination Activities	***Dissemination Activities***
Plan of Operation	***Plan of Operation;*** **Project Staff** section within ***Research Activities,***
Collaboration	***Collaboration***; **Letters of Commitment and Support** (Appendix C); **Model Systems Publications** (Appendix F)
Adequacy and Reasonableness of Budget	***Adequacy and Reasonableness of Budget***; ***Budget Narrative*** in front matter
Plan of Evaluation	***Plan of Evaluation***
Project Staff	***Project Staff***; **Project Staff** section within ***Research Activities,*****; Vitae, Biographical Sketches** (Appendix B, and D)
Adequacy and Accessibility of Resources	***Adequacy and Accessibility of Resources***; separate sub-sections entitled**, Quality of Past Grant Performance, Access to Clinical Populations; VCU Contribution to National Database and Continuum of Care** (Appendix E); **Model Systems Publications** (Appendix F)

III. Research Activities

Resilience is the theme of VCU's two proposed research projects. The site-specific project is entitled, **Intervention to Promote Survivor Resilience and Adjustment: Efficacy and Sustainability.** The second project, a "module," is entitled, **Caregiver Resilience: A Longitudinal Investigation.** Research will also include data collection for the National Database.

For several reasons, we are highly confident that our projects will: accomplish their stated objectives; represent a coherent, sustained approach to research in the field; and contribute substantially to the state-of-the-science. First, we have closely monitored, analyzed, and synthesized the literature to characterize the current state of knowledge, trends, and shortcomings. Second, we

have conducted a substantial amount of research in each area, affording us an invaluable fund of knowledge and expertise. Each proposed project builds on the findings of researchers within and outside the University. Third, **we have consulted with consumers, clinicians, and scientists, including Advisory Board members, to determine current needs and priorities.** For example, participants in the TBIMS National Database (NDB) and their family members provided input on site-specific and module project selection, project design, methods, and intervention content through in-person meetings, telephone interviews, and surveys. Our research projects were designed with the goal of providing new and useful information to consumer, research, and clinical audiences. VCU's proposed projects utilize the most rigorous applied-research designs possible. Finally, we have strong commitments of support from departmental, health system, university, and community organizations.

For the record, collecting and contributing data to the NIDILRR TBIMS NDB will be an integral part of our research program. As a past contributor to the NDB, we are well versed in enrollment, collection, and data submission procedures. We are certain we can enroll more than 35 participants annually and have done so on a regular basis. We are now collecting data on patients who are more than 25 years postinjury with excellent follow-up rates (e.g., 80-94% at each time point). Appendix E provides a summary of our contributions to the NDB, as well as information about our local database developed to track research participants and our continuum of care.

Intervention to Promote Survivor Resilience and Adjustment: Efficacy and Sustainability
Director: J. Kreutzer

Introduction and Review of the Literature

Persons with TBI across all degrees of injury severity often struggle mightily with cognitive,[69-71] emotional,[72-74] psychological,[75-77] and psychosocial[78-80] challenges, some for the remainder of their lives. A broad range of rehabilitation interventions have been designed in efforts to mitigate obstacles to complete recovery.[81-88] However, concerns about efficacy remain. Frequently, intervention outcomes are limited to specific domains or generate non-transferable skills,[13,87] cannot be reproduced,[89,90] or show transitory gains.[81] Without treatment approaches that can produce

sustainable, holistic gains, TBI survivors will continue to struggle to establish productive and meaningful lives postinjury.

The Resilience Framework: A recent paradigm shift in the field of psychology has led clinicians and researchers to explore the relationship between resilience and trauma outcomes.[91-93] Resilience has been defined as, "positive adaptation in the face of a traumatic event."[94] The exploration of resilience began with the study of individuals who emerge from various types of traumatic situations unharmed and even strengthened.[95,96] Although many of the skills associated with resilience correspond with seemingly static personality characteristics, a key feature of resilience lies in the distinction between skills and traits.[92] While traits are innate, skills can be promoted and developed throughout the life span. As indicated in the following table, researchers have identified core skill sets evident in resilient individuals.[97] Combined, these skills create a prototypical profile of resilience. Researchers in the area of resilience have determined that (a) the skills associated with a resilient and adaptive response to trauma are neither "superhuman" nor extraordinary; and, (b) resilient skills can be initiated and/or enhanced in individuals who have previously demonstrated non-resilient profiles.[94,98]

Common TBI Deficits and Challenges	Skills Necessary for Resilience
Anxiety / Depression[99-101]	Even Temperament / Stable Emotionality[102-104]
Survivor Focus on Deficits and a Comparison with Pre-Injury Functioning[105,106]	Positive Outlook / Optimism[107-109]
Irritability / Aggressive Behaviors[110,111]	Self-Regulatory Skills and Even-Tempered Behaviors[112-114]
Discomfort with Socialization[115,116]	Social Perception / Arousal of 'Liking Responses' in Others[109,117,118]
Impaired Self-Awareness[106,119,120]	Insightful Modification of Behavior[121-123]
Cognitive Deficits / Impaired Executive Functioning (hypothesizing, problem solving[124,125])	Good Problem Solving Skills[104,126,127]
Diminished Communication Skills[128-130]	Effective Communication[97,98,131]

Outcomes following trauma are inextricably linked to an individual's ability to consistently apply resiliency skills.[92,132] Having and applying highly resilient skills facilitates a competent and effective response to crisis.[92,133-135] Conversely, poor use of a resilient skill-set is related to instability and poor outcomes. Richardson's[96] metatheory of resilience clarifies the divergent paths an individual might take in response to trauma: "resilient reintegration" or "dysfunctional

reintegration." While individuals who achieve resilient reintegration are more likely to find meaning, be productive, and engage in life, those who follow the path of dysfunctional reintegration are unlikely to set goals, maintain a support system, or achieve stability.

Early on in the development of Resilience Theory, researchers recognized the possibility that resilience could be promoted in previously non-resilient individuals.[92,94] A seminal longitudinal study of resilience investigated children on the island of Kauai who had at least four predictors of negative outcomes (e.g., extreme poverty, mental illness in the family).[136] During the nearly 40 years of data collection, researchers discovered that a few of the children who did not exhibit resilience at early data-collection points were later able to demonstrate resilient skills and associated positive outcomes. These findings formed the basis of the notion that resilience is not an inborn trait, but rather, is a set of skills amenable to intervention. Subsequent studies support these conclusions.[96,137]

Over the last decade, researchers have begun to examine the hypothesis that resilience can be enhanced. In fact, the development of interventions designed to promote resilience in other populations has led to positive outcomes.[135] Research on adults facing cancer,[138,139] PTSD,[140,141] anxiety disorders,[142] diabetes,[143] and other illness and injury types[144] has demonstrated substantial gains on measures assessing degrees of resilience. More specifically, a number of the skill-deficits often associated with non-resilient profiles have shown significant improvement following resilience-promotion interventions. Measures of emotional well-being consistently improve, while indicators of psychological distress decline.[138,142,144,145] Furthermore, measures of injury/illness adjustment often show gains.[138,140,143,146] Improvement in ability levels on measures of problem solving, communication, and stress reduction are also frequently noted.[138,140,142-144] Moreover, health-behaviors and functional abilities have also improved following treatment.[140,143,144]

Resilience and TBI: Given the long-term challenges of TBI, many authors have asserted the critical need for developing a resilience-promotion approach to treatment in brain injury rehabilitation settings.[91,92,95,147] In a recent study, VCU researchers[93] investigated the relationship between resilience, emotional distress, and participation in a treatment-seeking, outpatient sample

with mild, moderate, and severe TBI. The investigators found a relationship between resilience, emotional adjustment, and depressive symptoms. Lower levels of resilience were associated with greater psychological distress. The authors concluded that interventions that successfully target resilience are likely to benefit emotional well-being. In a series of recent studies, Losoi and colleagues[148-150] and Sullivan and colleagues[151] examined postinjury resilience in patients with mild TBI. Greater resilience was associated with fewer post-concussion symptoms and better quality of life. Sullivan, in a later systematic review, reaffirmed that higher levels of resilience were associated with fewer post-concussion symptoms.[152]

In 2016, a TBIMS multi-center study led by VCU researchers examined resilience at three months postinjury among a sample of adults with moderate to severe TBI. The investigation yielded evidence that resilience levels were relatively low in comparison to the general population.[54] Investigators also showed that greater resilience was related to higher education, absence of pre-injury substance abuse, and lower anxiety. In the same year, Hanks and colleagues reported on resilience within 5 years following mild, moderate, and severe injury.[153] Generally, resilience was unrelated to injury or demographic factors, although the relationship to education approached significance, with higher education levels predicting greater resilience. In summary, there is consensus that resilience is a quality likely to help mitigate emotional distress after TBI.

Interventions Promoting Resilience: The parallel between common TBI deficits and the skills necessary for a resilient response to trauma elucidates the reasons why many survivors struggle to respond to injury in a resilient manner (see table on page 9). These challenges to resilience explain why the many existing post-TBI interventions have largely struggled to demonstrate sustained gains:[81] TBI diminishes an individual's ability to be resilient. Without specific efforts to engender resilience, survivors are unable to "bounce back" from the myriad of postinjury complications they are likely to face. White and colleagues[92] call for the generation of "specific interventions that could enhance factors of resilience" as a strategy to improve sustainable postinjury outcomes. Lefebvre and Levert[154] echo this sentiment, asserting that resilience is likely a primary factor in survivors' adjustment to injury and development of new competencies.

VCU Research: A Curriculum-Based Approach: One of the greatest challenges to designing a TBI resilience intervention is the need for a treatment modality that will effectively deliver the intervention content. Resilience Theory sets forth a specific set of skills to target to encourage resilience.[155-157] The American Psychological Association asserts that while everyone is able to become more resilient, individuals with cognitive, emotional, or psychological challenges need multi-faceted intervention models which consider the specific needs of the population.[94] Due to the cognitive limitations and lability which often accompany TBI,[70,72,158] the specific needs of survivors call for an integrative approach to the design and delivery of therapeutic interventions.

VCU researchers have had great success in implementing effective interventions for TBI survivors. Through the use of Curriculum-Based (C-B) approaches, studies have demonstrated efficacy for interventions focused on inpatient neurobehavioral functioning,[62,159,160] return to work,[161] and caregiver needs.[63,64,66,162] The C-B approach to intervention development was designed to specifically address the unique needs of persons with TBI.[159,161,162] The fundamental structures included in C-B interventions are tripartite: (1) education regarding a challenge or issue; (2) psychological support; and (3) skill building of abilities associated with improvement in the targeted domain.[64,66,162] This three-part intervention structure has proven to be an appropriate and effective design to meet the needs of individuals challenged with post-TBI complications.

In 2012, with NIDILRR TBIMS funding, VCU researchers developed a structured C-B intervention to promote postinjury resilience and adjustment: the Resilience and Adjustment Intervention (RAI).[163] The intervention development project, which was designed to address post-acute TBI needs, concerns, and challenges (e.g., common injury effects, coping with loss and change, one's role in recovery, problem solving, communication, and stress management), emphasized education, skill building, and psychological support. Our site-specific investigation was also implemented to test the feasibility of the intervention and measurement protocol.

Outpatients (n=160) with mild to severe TBI were randomly assigned to either a treatment (RAI) or wait list control (WLC) group. Treatment was delivered in seven one-hour sessions with outcome measurement pre- and post-treatment, and three months after treatment completion.

Outcome measures included the Connor-Davidson Resilience Scale (CD-RISC),[97] Mayo Portland Adaptability Inventory-4 (MPAI-4),[164] Brief Symptom Inventory-18 (BSI-18),[165] and 13 Item Stress Test.[162] As indicated in the table that follows, treatment group participants showed improvement in outcomes, whereas controls did not. At three months post-treatment, improvements were maintained relative to pre-treatment.

Outcome	Group	Baseline Mean (SD)	Post-treatment Mean (SD)	Follow-up Mean (SD)
CD-RISC	RAI	21.1 (8.1)	28.4 (6.9)	25.5 (7.8)
	WLC	23.4 (9.0)	23.7 (8.1)	-
MPAI-4: Adjustment Index	RAI	55.4 (9.1)	51.2 (9.5)	50.7 (10.0)
	WLC	55.8 (10.5)	54.5 (9.2)	-
MPAI-4: Ability Index	RAI	55.0 (9.7)	51.0 (8.3)	50.7 (9.5)
	WLC	53.5 (10.8)	54.2 (9.5)	-
BSI-18	RAI	63.8 (11.7)	57.2 (10.6)	58.7 (10.4)
	WLC	64.1 (10.7)	64.0 (9.4)	-
Stress	RAI	6.7 (3.3)	4.5 (3.4)	5.0 (3.1)
	WLC	6.5 (3.5)	6.0 (3.3)	-

A linear mixed-effect model was used to model each outcome, with the time point (baseline, post-treatment, 3-month follow-up), treatment, and interaction as explanatory variables. Each of these models was also adjusted for education level, time postinjury, and injury severity. The table below displays between group outcome differences from baseline to post-treatment, as well as changes from baseline to 3-month follow-up for the RAI group.

	RAI – WLC at Post-treatment		3-Month Follow-up – Baseline for RAI	
Outcome	Difference (95% CI)	P	Difference (95% CI)	P
CD-RISC	6.70 (4.96, 8.43)	<0.001	4.36 (2.42, 6.30)	<0.001
MPAI-4: Adjustment	-2.48 (-4.55, -0.41)	0.019	-4.61 (-6.95, -2.27)	<0.001
MPAI-4: Ability	-3.75 (-5.85, -1.65)	<0.001	-4.05 (-6.41, -1.69)	<0.001
BSI-18	-6.51 (-8.73, -4.30)	<0.001	-5.01 (-7.52, -2.50)	<0.001
Stress	-1.50 (-2.23, -0.77)	<0.001	-1.60 (-2.40, -0.81)	<0.001

Overall, analyses suggest that intervention benefits are sustained for three months and perhaps longer. Important questions remain regarding the sustainability of treatment benefits. First, are treatment benefits sustained beyond three months? Second, are there patient characteristics that predict longevity of benefits? Qualitative feedback from research participants was carefully reviewed to provide direction for further development of the RAI. Every single participant stated that they would recommend the program to others. However, a number of participants wanted more sessions with additional time to focus on individual needs. Input was also sought from our Scientific

Advisors, Advisory Board members, and NDB participants, who agreed that the clinical research program should be continued with their recommended changes. For example, recommendations were made to increase the duration and include more individualized content, suggesting that the addition of booster sessions could be of great benefit.

By definition, booster sessions are follow-up sessions implemented after program completion to help maintain benefits over time. Boosters provide an opportunity for individuals to review course content, consolidate gains, and discuss challenges. Given the high rate of cognitive impairments following TBI, booster sessions can provide an important opportunity to reinforce learning and ameliorate the impact of memory deficits on skills acquisition. Booster sessions have been shown to be beneficial across an array of therapy targets, including reducing anxiety and depression,[104] facilitating role transition,[166] improving communication skills,[167] and enhancing relationship skills.[168] There is also evidence that booster sessions may promote resilience in treating individuals with panic disorder.[104] In the only known study to utilize psychotherapy booster sessions for individuals with TBI, Ponsford and colleagues examined the impact of modified cognitive-behavioral therapy with three booster sessions provided between 21 and 30 weeks post-recruitment.[169] The booster program was associated with reduced anxiety and depression and increased psychosocial functioning.

The development and inclusion of booster sessions increases the extent to which the intervention is patient-centered. The addition is well in line with an established literature on the additional benefits of patient-centered treatment over and above those of standardized interventions.[170-174] As such, patient-centered care has been championed as a mark of high quality healthcare by both the Institute of Medicine[175] and U.S. Congress.[176] The essence of the patient-centered approach entails eliciting as well as mindfully and flexibly responding to the individual's needs and preferences.[177] Patient-centered care has been examined among persons with TBI, with positive findings showing that not only is it feasible for individuals with compromised cognitive skills to participate in their care, they are also more satisfied with their treatment when they do

so.[178] Additional work is needed to quantify the increased benefits of patient-centered interventions in TBI research, and the proposed project will address this knowledge gap.

A. Rationale: The Need for Effective Interventions to Promote Resilience and Adjustment

Along with difficulties in obtaining effective care, research shows that survivors encounter a wide variety of lingering injury-related challenges. For example, many survivors know little about the common consequences of injury and have trouble coping with loss and change. Some have difficulty taking an active role in treatment, and impatience with the recovery process is common. Poor problem solving, emotional regulation, stress management, and communication skills further exacerbate the challenges of maintaining/rebuilding positive relationships. Research shows that the many experience depression[41,179,180] and are unable to maintain employment,[35,181] which speaks to the breadth of chronic struggles faced by persons with TBI. Consequently, many survivors become discouraged and have difficulty maintaining a positive outlook.

The Resilience and Adjustment Intervention (RAI) is a standardized educational, support, and skill-building program developed for persons with TBI. A preliminary analysis of data derived from the VCU TBIMS intervention development project has yielded promising findings. The proposed investigation is a logical next step in advancing our understanding of standardized interventions designed to promote recovery.

The proposed investigation differs from prior VCU research in several important ways. First, in response to recommendations made by research participants, Scientific Advisors, and Advisory Board members, the intervention period has been extended with three booster sessions. Boosters will be patient-focused and personalized to address the original RAI topics that were most relevant to the individual, as described in the *Intervention* section which follows. Furthermore, the project will thoroughly evaluate the sustainability of treatment gains by extending the follow-up period from three to nine months. The research design will compare the benefits of the original intervention (RAI) to an expanded, more person-centered intervention (RAI+).

B. Objectives

1. to evaluate the short and long-term efficacy of two structured outpatient intervention programs (RAI vs. RAI+) on resilience
2. to evaluate the short and long-term impact of intervention on emotional well-being and postinjury adjustment with the RAI vs. the RAI+
3. to evaluate the short and long-term impact of the RAI and the RAI+ on abilities including problem solving, communication, and stress management
4. to determine if demographic, lifestyle, injury, or treatment response information can predict maintenance of gains

C. Hypotheses

1. **Primary:** Participants receiving the booster (RAI+ group) will report higher levels of resilience in comparison to individuals in the standard RAI group.
2. Participants in the RAI+ group will show better adjustment and lower levels of emotional distress as compared to persons in the standard RAI group.
3. Additionally, participants in the RAI+ group will report greater abilities in the areas of problem solving, communication, and stress management relative to persons in the standard RAI group.
4. A participant's demographic, lifestyle, injury, and treatment response information will be predictive of maintenance ability.

D. Methodology

D1. Stage of Research

VCU's previous work with the RAI was best labeled as an "Intervention Development" project. The present proposal is best labeled as falling within the "Intervention Efficacy" stage of research, as the primary goal is to evaluate whether the RAI+ is feasible, practical, and has the potential to yield sustainable and positive outcomes over and above the benefits of the RAI. The present proposal also seeks to identify individual characteristics associated with positive outcomes. The success of the proposed research program will allow for the "scaling up" of the RAI in hopes that the evidence-based intervention will be widely adopted in practice.

D2. Sample

Information regarding inclusion and exclusion criteria, enrollment rate, and participant incentives is provided herein. Recruitment information is provided in the *Procedure* section.

Inclusion criteria: Individuals 18 years of age and older with mild, moderate, or severe TBI who are able to understand and provide consent will be eligible to participate. The standard TBIMS brain injury definition will be used: damage to brain tissue caused by an external mechanical force as evidenced by loss of consciousness due to brain trauma, post-traumatic amnesia (PTA), skull

fracture, or objective neurological findings that can be reasonably attributed to TBI on physical examination or mental status examination. Since there is no reason to believe that treatment effectiveness varies with chronicity, no maximum has been set for time postinjury.

Exclusion criteria: Active substance abusers (e.g., intoxicated at arrival to intake), individuals at imminent risk of psychiatric hospitalization or in imminent danger of hurting themselves or others, as judged by the investigators, will be excluded from the study. Records will be kept indicating the number and type of exclusions. The data will be evaluated to help ascertain the representativeness of the final sample.

Enrollment rate: Considering the inclusion and exclusion criteria and past research experience at VCUHS, average monthly accrual rates are estimated to range between 3-4 participants. Considering potential attrition rates (e.g., 10%), we conservatively estimate an accrual rate of no less than 154 participants over the 46-month enrollment period. As noted in the *Data Analysis* section, power analyses indicate our anticipated sample size exceeds recommended minimums.

Participant incentives: Participants will be provided therapy, educational materials, and referral services at no cost. Each participant will receive up to a total of $140. Individuals will receive $25 for completing each of the first two assessments (pre- and post-treatment) and $30 each for the latter three (pre- and post-booster, and long-term follow-up). For participants traveling more than 60 miles roundtrip, funds will be provided to offset travel costs (IRS mileage rate of 19 cents per mile driven).

D3. Intervention

The RAI was developed over the last decade based upon research review and more than 20 years' clinical experience. The RAI is a structured, resilience-based approach to helping persons with TBI successfully manage their most common needs, concerns, and challenges.[91,182,183]

Assumptions underlying the RAI: Helping persons with TBI adjust, cope, and resume normal lives is a formidable challenge. Successful intervention requires a clear understanding of commonly encountered challenges. For example, survivors must cope with unexpected and unfamiliar problems soon after the injury, and in many cases, for years afterward. Many experience frustration,

struggling with their intense desire to recover quickly and completely. Finally, many survivors strive for normalcy, yearning for their former lives. Though there are commonalities, survivors differ in the extent to which they face and overcome each of these challenges. Intervention can be more effective when clinicians appreciate **five important guiding assumptions:**

1. Successful survivorship is based in individual resilience. Survivors who possess or learn to adopt traits identified as key to resilient living will find increasing success in their recovery, and growing satisfaction with their postinjury lives.[184]
2. Achieving emotional wellness after TBI requires a clear understanding of injury-related symptoms, commonly encountered challenges, and the recovery process.[160,178,185]
3. A key feature of resilience is developing insight into one's own behavioral response to trauma.[121,122,186,187] Survivors who are more aware of their strengths and limitations are more likely to lead productive and meaningful lives.[188,189]
4. Resilient individuals are adept at problem solving, goal setting, communication, and managing stress and intense emotions.[112,127] Helping survivors develop these skills benefits their ability to be productive and maintain quality relationships.
5. Survivors are more likely to improve when they develop resilient traits, such as being actively engaged in recovery,[126,131] and are able to maintain a positive outlook.[107,127]

Intake and treatment planning: Treatment begins with an intake session that helps shape the intervention process. Information is gathered using both quantitative and qualitative methods. Via interview, participants will be asked about their injury, progress in recovery, and their home, family, and work situation. They will be asked about their emotional well-being as well as their personal needs, goals, and priorities. Additionally, participants will complete a series of measures (see *Measures* section for a complete description).

Intervention modalities: The RAI is a curriculum-based intervention which has three major components: (1) skill-building: helping clients enhance existing skills and develop new skills; (2) psychological support: counseling participants and offering empathy, encouragement, and hope; and (3) education via instruction, discussion, and bibliotherapy.

Several strategies will be used to extend the benefits of in-person sessions. Participants will be provided with copies of the book, *Getting Better and Better after Brain Injury: A Guide for Survivors, 2nd ed.*[183] The book, developed by the VCU TBIMS's National Resource Center for TBI, contains key elements of the RAI curriculum and self-assessment tools. Participants will be asked to review materials and complete self-assessments in advance of, during, or after therapy sessions. Post-session discussion with close family members and friends regarding participants' self-

assessment responses and reactions to written materials will be encouraged. Participants will also be asked to practice skills and test solutions to problems outside of therapy sessions, as a means of consolidating in-session learning.

The RAI curriculum: Research and clinical experience have taught us that survivors differ in how they are affected and how they adjust to injury, yet there are many common problems. Delivered in seven 60-minute sessions over seven weeks, the RAI curriculum was developed to provide a solid foundation for continuing recovery. Enhancing resilience and helping survivors overcome commonly encountered issues, concerns, and challenges are key objectives. The following table specifies the RAI content areas to be covered (see Implementation Manual in Appendix G for more details).

Session I: Understanding the Effects of Brain Injury *will help survivors…* 1. Understand the typical consequences of brain injury 2. Appreciate the difference between emotional and physical recovery 3. Cope effectively with loss and change
Session II: Active Engagement in Recovery *will help survivors…* 4. Realize the important role they have in their recovery 5. Recognize what they can do to help themselves and feel better
Session III: Setting Reasonable Goals *will help survivors…* 6. Appreciate that success is relative 7. Improve their ability to be patient 8. Understand and implement effective goal setting strategies
Session IV: Solving Problems Effectively *will help survivors…* 9. Learn and use more effective problem solving strategies
Session V: Managing Stress, Anger, and Other Intense Emotions *will help survivors…* 10. Monitor and manage stress more effectively 11. Better manage intense emotions including frustration, anger, and fear
Session VI: Communicating Effectively and Rebuilding Relationships *will help survivors…* 12. Rebuild relationships and overcome loneliness 13. Learn and apply more effective communication skills 14. Develop strategies for comfortably discussing their injury with others
Session VII: Maintaining a Positive Outlook *will help survivors…* 15. Avoid a negative focus, feeling guilty, or blaming others 16. Appreciate positive aspects of their new lives, develop a positive attitude, and consolidate gains and move forward

In response to consistent feedback from past RAI participants and Advisory Board recommendations, **the original RAI protocol has been expanded for the present investigation**. One of the most consistent recommendations and requests was to lengthen the duration of the

program and to include more person-centered content within the pre-established curriculum. For half of study participants (RAI+ group), three 60-minute follow-up booster sessions are planned three months after completion of the RAI. The goal of providing booster sessions is to consolidate gains achieved in the core treatment, ameliorate the impact of cognitive deficits on learning, and address ongoing or new challenges in rehabilitation. In other populations, booster sessions have been shown to improve problem-solving, enhance communication, and strengthen relationship skills[167,168] and in persons with TBI, boosters are associated with improved emotional and psychosocial functioning.[169] Reflecting a person-centered approach, a framework for the format and content of each booster session follows. More information on booster session content and implementation is provided in Appendix G.

Update on Living Situation, Changes, and Life Events At the beginning of each session, participants will be asked to give an update on their living situation with reference to relationships, work, and activities. Information about ongoing medical care and participation in rehabilitation services will also be sought.
Review of Next Steps for Improvement as specified in RAI Session VII The therapist will review the list of 'Important Things You Can Do to Keep Getting Better,' completed in Session VII that identifies the most important things participants learned during the course of treatment and the steps needed to continue improvement. The therapist and participant will review the successes and failures in achieving these goals, with an emphasis on consolidating gains by continuing to use the most effective coping strategies.
Review of Concerns Expressed During Previous RAI Sessions The therapist will review primary issues and concerns identified by the participant during previous RAI sessions. The status of efforts to resolve difficulties will be discussed. Effective and ineffective strategies will be distinguished.
Identification of Ongoing Issues and Concerns Participants will be asked to identify new issues or concerns that have arisen since the most recent intervention session.
Problem Solve and Implement Strategies for Improvement Where multiple concerns are identified, priorities will be established and a plan for resolution will be formulated. Previously learned skills and strategies (e.g., problem solving; managing stress and intense emotions; effective goal setting) will be applied to achieve solutions.

During the third and final booster session, the therapist will again review the list of 'Important Things You Can Do to Keep Getting Better,' completed in Session VII. Together, the therapist and participant will develop a revised list to reflect new learning and new plans for next steps to continue getting better.

D4. Measures

The measures chosen for the present investigation were selected because they: (1) are relevant to project objectives and hypotheses; (2) have substantial evidence of reliability and validity; (3) are included in the NDB; and (4) are included in the Common Data Elements (CDE).[190-192]

Patient demographics and history: Information will be collected including: age, gender, ethnicity, marital status, household income, living situation, education, pre- and postinjury occupational status, and hours worked per week. Additionally, information will be obtained about pre- and postinjury substance abuse (Behavioral Risk Factor Surveillance System, BRFSS) and mental health treatment.

Injury characteristics: The following information will be obtained from medical records: date of injury, etiology, admission Glasgow Coma Scale (GCS) score, duration of unconsciousness and post-traumatic amnesia, duration of hospitalization, time postinjury, and history of neurosurgical intervention.

Connor-Davidson Resilience Scale (CD-RISC): During the past decade, researchers have developed resilience measurement scales, and research suggests that Connor and Davidson have been most successful.[193,194] The authors first developed a 25-item scale (CD-RISC) reflecting resilience characteristics identified by Kobasa and Rutter.[195,196] Normative studies including factor analyses indicated that the CD-RISC is reliable, valid, and sensitive to treatment effects.[97] More recently, a 10-item version was developed using exploratory and confirmatory factors analyses.[197] Respondents are presented with a series of descriptors (e.g., "I am able to adapt and change," "Coping with stress can strengthen me") and rate themselves on a 0-4 scale ranging from rarely true (0) to true nearly all the time (4). Campbell-Sills and colleagues have characterized the 10-item version, to be used in the present study, as demonstrating excellent psychometric properties, namely reliability, internal consistency, and construct validity.[197,198]

Mayo Portland Adaptability Inventory-4 (MPAI-4): Included as a CDE-recommended global outcome measure, the MPAI-4 is comprised of 30 items rated from 0-4, with higher scores indicating greater problem severity. The proposed project will focus on the Adjustment and Ability

indices.[164] The Adjustment Index items relate to anxiety, depression, irritability, anger, social interaction, and self-awareness. The Ability Index includes items relating to verbal and nonverbal communication and problem solving ability. T-scores are obtained based on norms derived from a brain injury sample. Research has provided evidence of good concurrent, construct, and predictive validity, as well as satisfactory internal consistency.[164,199] Sensitivity to treatment-related change has also been substantiated.[200]

13 Item Stress Test: This self-report measure was developed more than a decade ago for clinical research studies on stress management with survivors and caregiving family members.[162] Sample items include, "I have more to do than I can handle," "I'm pushing myself too hard," and "I can't stand living like this." Items are rated as True (+1) or False (0) with higher scores indicating higher stress levels.[201] The measure has been shown to be sensitive to family intervention after TBI.[63,64] The Total Score will be the measure of interest in the present investigation.

Brief Symptom Inventory-18 (BSI-18): This 18-item self-report instrument is the abbreviated version of the Symptom Checklist-90-Revised (SCL-90-R) developed to quantify psychological distress in the general population.[165] A number of investigators have used the measure to quantify distress after TBI. In particular, researchers have used the BSI to monitor change in psychological status in response to treatment[202] and general change in status over time.[203] The BSI-18 is often used because of its sound psychometric properties,[165] brevity, ease of administration, and global assessment of psychological issues commonly found in individuals with TBI.[191] The measure is included in the TBI CDE as a gauge of psychiatric and psychological status.

Frequency ratings for items in three primary symptom dimensions are added to yield scores for Somatization, Depression, and Anxiety. The Global Severity Index (GSI) reflects the sum of scores for the three symptom dimensions. T-scores for each dimension and the GSI are calculated based on community norms. GSI scores, reflecting overall distress levels, will be the focus of the present investigation. A study examining the psychometric properties of the GSI with a TBI sample characterized the GSI as having good internal consistency with excellent reliability and validity.[204]

D5. Research Setting

Screening, assessment, and intervention will be centralized in the Brain Injury Outpatient Research Center, located on the third floor of West Hospital. In operation for more than 25 years, the center is centrally located on the VCUHS campus and is fully accessible to individuals with disabilities. The center contains a waiting area and central office where patients will be greeted and checked in. The center also houses eight private offices, which are ideal for interviews, testing, and therapy. Inpatient psychiatric, emergency, and rehabilitation services are located within 500 yards of the outpatient center. The offices also house password-protected computers for secure data entry, management, and statistical analysis. Locked file cabinets and offices also ensure data security.

D6. Procedure

Patients will be self-referred or referred by professionals within and outside VCUHS, organizations (e.g., Brain Injury Association of Virginia), and agencies (e.g., Virginia Department of Aging and Rehabilitative Services). N. Moadab will facilitate recruitment at VCUHS outpatient clinics. When persons with TBI contact the Brain Injury Outpatient Research Center, an intake session will be scheduled.

During the intake, a therapist (e.g., Dr. Mills, Dr. Hsu) will provide information about the research program, and determine eligibility and interest in participation. Staff will explain study details and obtain informed consent. When there are concerns about the individual's ability to provide informed consent, formal assessment of decision-making capacity will be made using the MacArthur Competence Assessment Tool, Clinical Research version (MacCAT-CR). An instrument derived from pioneering multi-center studies of treatment capacity,[205] the MacCAT-CR has excellent content validity. Some consider the measure to be the only available instrument that assesses the full range of abilities relevant to capacity for giving informed consent for research participation.[206]

The MacCAT-CR has previously been used with persons having dementia,[207] depression,[208] schizophrenia,[209] and other psychiatric disorders.[210] For the present investigation, minimum values on each scale of the MacCAT-CR will be established as two standard deviations below the mean for

the normal population.[206] This criterion is commonly used in assessment of decision-making capacity[211-213] and has been shown to be more stringent than expert assessment of capacity.[206] Generally, 15 to 20 minutes is required for completion.[214]

As allowed under Virginia state law, an alternative procedure will be used to consent persons lacking the capacity to give informed consent, as determined by the MacCAT-CR or judged by the investigators. Investigators will seek to obtain consent from a legally designated substitute decision-maker. In every case, an effort will be made to obtain assent from the patient. Patients who decline to participate will not be enrolled regardless of their respective substitute decision-maker's desire. Readers should note, the protocol for this project has been submitted for review and approval to the VCU Office of Research Subjects Protection and formal approval is pending. More detailed information regarding human subjects protection and safety monitoring procedures is detailed in the *Human Subjects Narrative* (Form 424) and the *Data and Safety Monitoring Plan*. Readers should also note that, once approved, the study will be registered with ClinicalTrials.gov.

On giving informed consent, participants will be given baseline assessment materials to complete. Estimated time for the completion of baseline measures is 30-40 minutes. Project staff will make accommodations for persons with visual, motor, and other impairments.

Using randomization tables provided by our Biostatistician, Dr. Sima, participants will be randomly assigned to either of two groups: (1) RAI or (2) RAI+. After randomization, a second appointment will be scheduled. Participants will begin treatment during their second appointment.

The RAI consists of seven 60-minute sessions scheduled over seven weeks as described in the *Intervention* section. During the first session, participants will receive an empty loose-leaf binder to store and organize completed self-assessments, reading materials, and homework assignments from each session. Participants will also receive a copy of the curriculum, *Getting Better and Better after Brain Injury: A Guide for Survivors, 2nd edition*.[183] They will be asked to review materials and complete worksheets between sessions. The RAI will be implemented by two experienced, licensed therapists (Dr. Mills, Dr. Hsu). Within each treatment condition, participants will be randomly assigned to one of the two therapists. Data will be analyzed to identify any therapist effects.

For the RAI+ participants, three booster sessions will be implemented as described in the *Intervention* section of this proposal. The three weekly booster sessions will be scheduled to start three months following completion of Session VII.

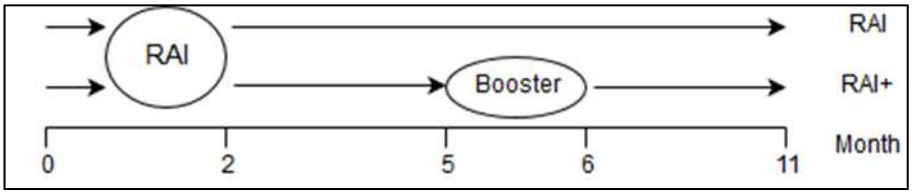
Implementation of quality control procedures: A protocol has been established to ensure the quality and standardization of treatment implementation across therapists.

During the two-month project start-up period, the therapists (A. Mills, N. Hsu), and J. Kreutzer will meet to review the manual and discuss implementation and standardization procedures.
Following, each therapist will meet with volunteer participants, and implement Session I of the RAI curriculum. Informed written consent for digital audio-recording will be obtained. Afterward, the intervention audio-recordings will be reviewed with Dr. Kreutzer, with the manual in hand, to make certain that all steps are faithfully completed. Additionally, Dr. Kreutzer will assure that therapists have covered the bolded content areas in the manual, which are considered to be key elements of treatment (see Appendix G). Strategies for improving consistency between therapists will be discussed and implemented. Changes will be made in the implementation manual (e.g., clarification of procedures) as needed.
The two therapists will meet again with the same volunteer participants, and implement the remaining six sessions of the RAI curriculum. Again, the audio-recordings will be reviewed with Dr. Kreutzer, and strategies for adherence to the manual will be discussed and implemented after each session.

Every six months thereafter, the complete quality control procedure will be reapplied.

Additional quality control procedures will be implemented for booster sessions with each therapist. As indicated in the *Intervention* section, booster sessions are person-centered and thereby highly individualized. Audio-recordings will be made for the three booster sessions and reviewed with Dr. Kreutzer to ensure that key areas are covered as outlined in the manual. Every six months thereafter, quality control procedures will be repeated.

Data collection procedures: Demographic, injury severity, and history information will be collected at baseline using TBIMS standard procedures. For RAI and RAI+ participants, outcome measures will be obtained prior to treatment (baseline) and following completion of the RAI. Outcome measures for RAI+ participants will be obtained at the start and completion of the booster, and six months following completion of the booster sessions. Measures for RAI participants will be obtained at three, four, and nine months post-RAI treatment. Data collection will occur within the same timeframe for both RAI and RAI+ participants as outlined in the figure that follows.



Project timeline: The major activities for the research project are sequentially delineated in the *Plan of Operation* section.

E. Data Analysis

Descriptive statistics (e.g., means, standard deviations, proportions) will be calculated for all measures at designated time intervals. Analyses will be performed using the university licensed statistical program SAS v.9.3 (© 2002- 2010; SAS Institute Inc.; Cary, NC). The following table provides a description of major statistical analysis procedures, emphasizing priority areas related to research hypotheses. Information is provided regarding statistical hypotheses, statistical methods, power analysis and sample size estimates. Analyses evaluating the RAI+ are based on the intent-to-treat principle if drop-out is assumed as missing at random or missing completely at random.

Hypothesis 1 – Primary: Participants receiving the booster (RAI+ group) will report higher levels of resilience in comparison to individuals in the standard RAI group.
Statistical Methods: A linear mixed-effects model will be used to model the CD-RISC scores over time for the RAI and RAI+ groups. The model will include fixed-effects for time at RAI+Booster initiation, conclusion, and long-term follow-up (e.g. 5, 6, and 11 months), group (RAI or RAI+) and the interaction between group and time. The model will also adjust for fixed-effects for injury severity, time postinjury, and education. Within-subject correlations in the CD-RISC scores over time will be modeled using a spatial power covariance pattern structure. Specific contrast statements will be used to test for a difference in the CD-RISC change scores between the treatment groups at both RAI+Booster initiation and conclusion as well as RAI+Booster initiation and long-term follow-up at a significance level of .05.
Power Analysis: Data obtained by our group indicated that the mean CD-RISC increased from a baseline value of 21.1 units to a mean of 28.4 units post-treatment (Difference=7.3), followed by a decline to 25.5 at the 3-month follow-up (Difference=2.9), with a standard deviation (SD) of the change score equal to 5.0. Considering a conservative SD of 6.0, this study will require 138 participants (n=69 per group) using a two-sample t-test performed at the 0.05 significance level to achieve 80% power. This effect translates to an effect size d=2.9/6.0=0.48, which is typically considered a moderate effect size.
Hypothesis 2: Participants in the RAI+ group will show better adjustment and lower levels of emotional distress as compared to persons in the standard RAI group.
Statistical Methods: Separate mixed-effects models, similar to that outlined in the methods for Hypothesis 1, will be used to model the responses for the MPAI-4 Adjustment Index and the BSI-18 GSI scores over time for each group. Specific contrast statements will be used to test the hypotheses of interest, each assuming a significance level of .05. Using a similar 40% decrease between the baseline to post-treatment values observed in our pilot study, we would expect the RAI+ to ameliorate declines in the MPAI-4 Adjustment and BSI-18 GSI scores by 1.7 and 2.6 points, respectively. Considering a conservative SD of 7.0, the 138 participants enrolled would provide power of 29% and 58% for the two outcomes, if analyzed by a two-sample t-test at the 0.05 level.
Hypothesis 3: Participants in the RAI+ group will report greater abilities in the areas of problem solving, communication, and stress management relative to persons in the standard RAI group.
Statistical Methods: Two additional mixed-effect models, similar to the first three, will be used to

model the MPAI-4 Ability scores and the 13-Item Stress Test scores over time for each group. Again, a specific contrast statement will be used to test the hypothesis of interest at a significance level of $\alpha = .05$. In a similar fashion to Hypothesis 2, a 40% decrease between the observed baseline to post-treatment values yields differences of 1.6 and 0.9 for the MPAI-4 Ability Index and the 13-Item Stress Test. Considering a conservative SD of 7.0 and 2.0, respectively, the 138 participants enrolled would provide power of 27% and 75% for the two outcomes, if analyzed by a two-sample t-test at the 0.05 level.
Hypothesis 4 (exploratory): A participant's demographic, lifestyle, injury, and treatment response information will be predictive of maintenance ability. **Statistical Methods:** Separate linear regression models will be used to determine the relationship between each of the demographic, lifestyle, injury, and initial RAI response characteristics and both the change in the 5 and 6 month CD-RISC scores, as well as the change in the 5 and 11 month CD-RISC scores. Assuming 69 participants in the RAI group complete the study and 8 predictor variables are in the linear regression model, this analysis will have 80% power to detect effect sizes of f^2=0.12, which is considered a moderate effect size.

Power analyses relating to the primary hypothesis indicate minimum group sizes of 69 participants. If we allow for a maximum of 10% attrition, then an additional 8 individuals per treatment group (16 individuals total) should be recruited (138/(1-0.1)-138 = 15.3) for a total sample size of 154.

F. Feasibility

F1. Project Staff

Personnel effort levels are based on thorough consideration of our prior experience conducting similar projects. Following is information on responsibilities of personnel allocating >5% effort:

J. Kreutzer, Ph.D. (12% effort): (1) assume primary administrative responsibility for the project; (2) staff training, supervision, and performance monitoring; (3) formulation of data collection protocols; (4) obtaining informed consent; (5) being present or on call during each assessment and treatment session or ensuring another psychologist is on call throughout the study period; (6) analysis, interpretation, and dissemination of findings; (7) completion of progress reports.
A. Mills, Psy.D. (30% effort): (1) intervention implementation; (2) assist with analysis and interpretation of findings; (3) assist in preparing reports, presentations, and publications.
N. Hsu, Psy.D. (30% effort): (1) intervention implementation; (2) assist with analysis and interpretation of findings; (3) assist in preparing reports, presentations, and publications.
J. Marwitz, M.A. (15% effort): (1) database development; (2) supervision of data coding and entry; (3) data management and quality control.
A. Welch, B.A. (45% effort): (1) obtaining informed consent; (2) coordination and scheduling of appointments, providing appointment reminders; (3) collection of assessment and outcome data; (4) tracking and maintaining high follow-up rates; (5) medical records review; (6) data coding/entry.

Dr. Sima, M. Martinez, and N. Moadab will also have a role in the project (each 5% effort). Dr. Sima will supervise statistical analysis, conducting a subset of the analyses, and interpreting the results for reports and dissemination. M. Martinez will serve as back-up to A. Welch. N. Moadab will assist with participant screening and recruitment in outpatient clinics.

F2. Potential Problems and Anticipated Solutions.

Our confidence in successful completion of this project stems from our long history of success conducting intervention research programs. In consultation with the Advisory Board and R. Rawlins, project consultant, potential obstacles have been identified and discussed. Following are descriptions of potential problems and proposed solutions.

Accrual rates may be lower than anticipated. Based on our past research success, we are confident in accrual rate estimates, particularly given commitments from the director of the Brain Injury Association of Virginia (BIAV) to facilitate recruitment. BIAV's Executive Director helped develop the treatment protocol, and has expressed optimism about the protocol's helpfulness. BIAV is in an excellent position to assist with recruitment because of their close, daily contacts with individuals with TBI and their families. Individuals often contact BIAV to request information about treatment alternatives and referral information. BIAV has agreed to help encourage participation in our research by dissemination of information in their newsletters and at conferences and workshops they sponsor. BIAV will also help disseminate information about the need for research participants to professionals and agencies. Advisory Board members, representing a variety of organizations (e.g., Department of Aging and Rehabilitative Services, Brain Injury Services, Mill House) and service providers (e.g., Tree of Life, Concussion Care Centre of Virginia), have also agreed to disseminate information about the project and the potential benefits of treatment (see Appendix C for letters of support).
Individuals with TBI may have difficulty completing measures because of difficulties with fatigue, vision, motor functioning, or other impairments. Failure to include participants with severe disabilities may also create a biased sample. Based on our experience, we anticipate that fewer than 10% of individuals who are three or more months postinjury will have significant difficulty completing the proposed measures. To reduce the likelihood of sample bias, we will invite participants to indicate whether they have difficulties and we will offer a variety of accommodations. Accommodations may include reading questionnaire items to the person or recording responses for them. A record will be kept of accommodations made for each person, allowing an evaluation of whether accommodations affected response patterns.
A number of participants may be unavailable for follow-up. The accrual numbers presented in this proposal are based upon a review of data collection rates in past studies conducted at VCU. Furthermore, with more than 25 years of experience conducting follow-up studies, we have developed an effective follow-up system. The cornerstones of the system include: (a) providing high quality clinical follow-up services; (b) maintaining up-to-date contact information; and (c) employing an efficient appointment reminder system. Our system employs a combination of in-person, written, and telephone reminders. Most of our studies have included annual follow-ups, and follow-up rates have ranged between 90-95%.
Participants may be involved in concurrent individual psychotherapy or support groups or may be taking psychotropic medications. Individuals will be eligible for this study regardless of concurrent mental health treatment. As a matter of ethical practice, psychiatric consultation will be offered to individuals requesting services or who appear to be in need. Information about concurrent treatment will be obtained during each assessment session and recorded for each participant. Statistical analysis will be implemented to assess the relationship between concurrent therapy participation and treatment (RAI) outcome.
Interventions may not be completed within the proposed timeframe. Ideally, the RAI will be completed in seven weeks. For RAI+ participants, ideally booster sessions begin three months after completion of the RAI and will be completed in three weeks. Unforeseen delays may arise (e.g., related

to illness, transportation) that may affect timelines. We have built in windows that allow a modicum of flexibility. We will record completion dates and statistically evaluate how outcome data are affected by deviation from prescribed time intervals.

G. Expected Beneficial Impact

▪ An effective intervention for survivors will improve psychological outcomes and provide a means of counteracting the adverse, far-reaching effects of reduced inpatient lengths of stay.
▪ Use of effective patient-focused intervention and outcome tracking will provide an empirical foundation for utilizing person-centered interventions.
▪ All systems of care have resource limitations. Improved understanding of effective skill building, support, and education strategies will help systems more efficiently allocate resources.
▪ Identifying the attributes of participants who are treatment-resistant will facilitate development of effective alternative treatments.
▪ Effective treatment to promote resilience and adjustment will reduce the adverse impact on family members who are often in a caregiving role.
▪ Providing empirically-based guidance to clinicians serving participants will enable them to deliver more effective and efficient services.
▪ Development of a structured, replicable intervention will allow treatment providers and advocacy organizations to provide services in more settings.
▪ New hypotheses will be generated for future treatment studies.
▪ Empirically-based research findings will provide a rationale for requiring third party payers to cover the cost of intervention services, previously dismissed as having uncertain efficacy.

Caregiver Resilience: A Longitudinal Investigation

Introduction and Review of Literature

Many persons with moderate to severe TBI require assistance from a caregiver for months or years postinjury.[215] A caregiver is an individual who provides help, support, guidance, or supervision to a person in need. Caregivers for persons with TBI are typically female and a parent or spouse of the survivor.[216,217] While there is some evidence caregivers have positive feelings about their role,[218,219] many report emotional distress,[43,220-222] perceived burden[44,223] and life dissatisfaction.[224] One of the most widely-cited studies of caregiver distress was a TBIMS, multi-center prospective study.[43] Investigators found clinically significant rates of depression (19%), anxiety (18%), and somatic symptoms (24%), with one in ten caregivers exceeding the cut-offs on all three scales.

A shift in the field of psychology has led to a focus on the positive facets of postinjury adjustment, notably, resilience. Unfortunately, little is known about caregiver resilience after TBI. To date, only two studies have explored caregivers' postinjury resilience.[67,68] Las Hayas and colleagues[67] found that Spanish caregivers' resilience was positively correlated with quality of life

and negatively correlated with perceived burden. However, the study aimed to describe the psychometric properties of a new resilience questionnaire, and caregivers' resilience levels were not described. Simpson and Jones[68] found that higher levels of resilience among Australian caregivers were associated with lower rates of negative affect and caregiver burden. Using Wagnild's criteria, the resilience level of Simpson's sample would be characterized as "moderately low to moderate."[225] Las Hayas' and Simpson's studies are limited by small sample sizes and use of cross-sectional data from a single center.

Given the scarce literature on TBI caregivers, we examined studies of resilience among caregivers of persons with dementia. Although dementia differs from TBI in several important ways, caregivers of persons with dementia take on somewhat comparable caregiving roles, such as support of self-care, instrumental activities of daily living, cognitive functioning, and emotional well-being.[226] Thus, findings from this literature can offer insight into resilience among TBI caregivers. In a Brazilian study of dementia caregivers, investigators found higher levels of resilience were related to lower levels of emotional distress. Caregiver resilience was unrelated to caregiver gender or patients' clinical or sociodemographic characteristics.[227] Elnasseh and colleagues[226] found that for Argentinian caregivers, higher levels of resilience were associated with empathy, optimism, and fewer family problems. Fitzpatrick and Vacha-Haase[228] found that resilience was unrelated to marital satisfaction, but was related to self-efficacy. In a study of Alzheimer's caregivers, Wilks found that younger age and African-American ethnicity were associated with higher levels of resilience. Marital status, gender and relation to caregiver recipient were unrelated to resilience levels.[229]

In summary, the literature on resilience among caregivers of persons with dementia is generally characterized by small sample sizes[227,228] and measurement at a single time point.[226-228] Most studies did not fully describe resilience levels, leaving questions about the quality of caregivers' resilience unanswered. Of the two studies that did provide mean resilience values,[227,229] resilience levels were considered to be moderate to moderately low based on general population norms.[225] Nevertheless,

the evidence from both the literature on caregivers in TBI and dementia is clear – resilience is associated with emotional well-being[67,68,227] and perceived burden.[67,68]

A. Rationale: The Need for Research

Caregivers provide integral support to survivors, especially after hospital discharge. Concerns have been expressed that many survivors go home to family members who are ill-prepared to manage commonly encountered problems.[230] Caregiving places a great burden on family members that is manifested in high rates of depression, anxiety, and somatic concerns.

Until recently, research on caregivers had focused on only the negative correlates of caregiving. A greater appreciation of strengths-based approaches in psychology mandates that we take a more holistic view of caregiving. Whereas there have been several studies exploring resilience among survivors of TBI, very little has been written about resilience in their caregivers. As with other types of illness, improving outcomes for persons with TBI may be predicated on the well-being of their support persons.[231,232] Research to quantify and characterize the nature of caregivers' resilience postinjury is a cornerstone to advancing the evidence base on adjustment after TBI. Thus, the primary purpose of the proposed study is to investigate TBI caregivers' resilience over time. Understanding factors relating to resilience will likely help identify components of a resilience-building intervention for caregivers and ultimately help to improve outcomes for survivors.

B. Research Questions

For the past 30 years, we have had a strong interest in understanding and serving families after TBI. As clinicians, we have interviewed hundreds of caregivers and assessed their needs, concerns, and desires for resources. For the past 25 years, we have performed clinical research on family functioning, needs, life satisfaction, and emotional well-being with a focus on caregivers after TBI. For the past five years, we have been conducting research on resilience, focused on survivors. To develop the proposed module, we considered the comments and feedback from caregivers in our family practice. Further, the proposed module was also shaped by our Advisory Board, NDB participants, and NDB caregivers. Their feedback affirms that our new focus on caregiver resilience

is timely, relevant and complements our prior research. From our discussions, interviews and review of the current literature, a series of important questions have emerged:

1. What is the trajectory of caregiver resilience over the first two years postinjury? Does resilience change over time for some caregivers? If yes, what patient and caregiver factors are related to decline or improvement?
2. What is the relationship between caregivers' resilience and their emotional well-being? Can the proposed longitudinal, multi-center study reproduce results from several single-center, small-sample studies with TBI and dementia caregivers?
3. A few TBI caregiver studies found a relationship between caregiver resilience and perceived burden. In addition to perceived burden, do other caregiver factors (e.g., needs, time spent caring for the patient) relate to resilience?
4. What is the relationship between caregiver resilience and patient characteristics, including resilience, emotional distress, and functional status?

C. Methodology

C1. Stage of Research

The proposed module project is best labeled as falling within the "Exploration and Discovery" stage of research. The present investigation is intended to generate hypotheses and theories through analysis of prospective, multi-center, longitudinal data. There is little information to aid our understanding of the construct of resilience in caregivers after TBI, despite the potential relevance to patients' rehabilitation and recovery. Research suggests that resilience can be improved with training, and we anticipate that the results of this project will facilitate the development of effective interventions that benefit caregivers and patients.

C2. Sample

Information regarding inclusion and exclusion criteria, enrollment rate, and participant incentives is provided herein. Recruitment information is provided in the *Procedure* section.

Inclusion criteria: Caregivers age 18 and older, identified within six months postinjury by TBIMS NDB participants (survivors) will be included. Participants will include relatives, friends, or other acquaintances involved in providing care, support, or other meaningful assistance to the survivor. In cases where there is more than one caregiver available, first priority will be given to the caregiver who is providing the most care to the survivor. A script will be developed for data collectors, allowing them to better identify a single caregiver for each survivor.

Exclusion criteria: Survivors who are unable to identify a relative, friend, or other caregiver will not be enrolled in the study. Formal caregivers, those who are a paid professional, will not be included in the study. Records will be kept indicating the number and type of exclusions. The data will be evaluated to help ascertain the representativeness of the final sample.

Enrollment rate: Considering the proposed eligibility criteria and past experience with similar research, we estimate accrual of no less than two caregivers per month, for a total of at least 26 annually. We anticipate three additional TBIMS centers will participate in this module with similar accrual rates. Conservatively, 78 VCU participants and 234 partner site participants will be enrolled for a total of 312 participants over the 36-month enrollment period. As noted in the *Data Analysis* section, the power analysis indicates our anticipated sample size is more than adequate.

Participant incentives: Caregiver participants will be given $50 for completing each of the three assessments. Survivors will be given $50 for completing the first assessment, as it falls outside of NDB protocol. Survivors will receive NDB protocol compensation ($50) for the second and third assessments.

C3. Measures

The measures chosen for the present investigation were selected because they: (1) are relevant to project research questions; (2) have substantial evidence of reliability and validity; and (3) are included in the NDB.

Connor-Davidson Resilience Scale (CD-RISC): A full description of the CD-RISC can be found in the site-specific project (*Intervention to Promote Survivor Resilience and Adjustment* Measures section). As mentioned previously, normative studies including factor analyses indicated that the CD-RISC has excellent psychometric properties, including reliability, internal consistency, and construct validity.[97,197,198] The scale has been effectively used with a wide variety of populations, including caregivers of relatives with Alzheimer's disease.[229,233] The CD-RISC will be completed by both survivor and caregiver.

Patient Health Questionnaire-9 (PHQ-9): The PHQ-9 is used to assess depressive symptom severity and identify depression based on diagnostic criteria.[234] The 9-item scale assesses frequency

of symptoms on a scale of "0" (not at all) to "3" (nearly every day). [234] Depression severity can be determined by calculating the total score, ranging from 0-27, with interpretation cut-off scores of 0-4 (minimal), 5-9 (mild), 10-14 (moderate), 15-19 (moderately severe) and >20 (severe).[234] The PHQ-9 has good reliability and validity across clinical and racial/ethnic groups, including individuals with a history of TBI.[234-236] This widely used measure of depression is also sensitive to change over time.[237] The PHQ-9 will be completed by both survivor and caregiver.

Generalized Anxiety Disorder-7 (GAD-7): The GAD-7 is used to screen for generalized anxiety disorder and assess symptom severity.[238] The 7-item scale is based on diagnostic criteria and review of existing measures.[238] Frequency of symptoms are assessed on a scale of "0" (not at all) to "3" (nearly every day). Total scores range from 0-21, with increasing scores indicating more severe levels of anxiety.[238] The GAD-7 is a reliable and valid measure of anxiety in the general population and in individuals with TBI.[238-240] Both survivor and caregiver will complete the measure.

Family Needs Questionnaire (FNQ): The FNQ is a 37-item questionnaire developed to measure family members' perceived needs after a survivor's brain injury.[241] The items were designed to address diverse postinjury psychosocial and educational needs. Caregivers rate the degree to which each need has been met (not met, partly met, or met). An early investigation provided evidence of content and construct validity. Internal consistency was indicated by a Spearman-Brown split-half reliability of .75.[242] A later factor analytic investigation revealed six independent factors comprising six scales: Health Information, Emotional Support, Instrumental Support, Professional Support, Community Support Network, and Involvement with Care.[243] Internal consistency for individual factors was indicated by Cronbach's alpha's ranging from 0.78 to 0.89. For the present investigation, the proportion of needs rated as met, converted to a 10-point scale, for the four scales most relevant to post-acute needs will be used (e.g., Emotional Support, Instrumental Support, Professional Support, Community Support Network).

Zarit Burden Interview (ZBI): The ZBI was originally developed as a 22-item questionnaire designed to quantify caregiving burden and is the most commonly used measure of such.[244] Caregivers are asked to describe perceived changes in their emotional or physical health, social life,

and financial status as a result of caring for a relative. Items are rated on a 5-point Likert scale, ranging from 0 (never) to 4 (nearly always). A total score is derived, representing the extent of burden, with higher scores denoting greater burden. Research has evaluated the utility of a 12-item version.[245] The correlations between the short and full version ranged from .92 - .97, substantiating the comparability of both versions. In a study among three caregiving populations (advanced cancer, dementia, and acquired brain injury), the 12-item ZBI had excellent validity (rho = .95-.97).[246] Both the 12- and 22-item versions have been used with adult and pediatric TBI populations.[66,219,223,247] The present investigation will utilize the 12-item version.

Caregiver demographics and history: Demographic data collected will consist of age, gender, race/ethnicity, marital status, household income, years of education, occupational status, and nature and length of relationship with survivor. To help characterize relationships, the caregiver will also be asked to indicate: (a) whether they are living with the survivor; (b) the number of hours spent caring for them daily; and (c) and the average number of days per week the caregiver sees the survivor. Additionally, information will be obtained about current and past mental health treatment and substance abuse, using the same variables as the NDB.

Survivor demographics and history: Data from the NDB protocol will be used. In addition, at the 6-month follow-up, the Disability Rating Scale and PART (Participation Assessment with Recombined Tools-Objective) will be collected.

Injury characteristics: The following information will be used from the NDB data collection: date of injury, etiology, admission GCS score, duration of unconsciousness and post-traumatic amnesia, duration of hospitalization, and history of neurosurgical intervention (e.g., craniotomy/craniectomy, ICP monitoring).

C4. Procedure

This will be a multi-center, prospective longitudinal investigation. Newly enrolled TBIMS NDB participants will be contacted after discharge and no more than six months postinjury and asked to identify a caregiver. Caregivers will be approached, provided with information about the project, and invited to participate. Informed consent will be obtained. At six months postinjury (+/-

two weeks), caregivers will be asked to complete baseline assessment materials and TBIMS participants will complete measures as well. Caregiver participants will be contacted again at 12 and 24 months postinjury and asked to complete primary outcome measures. TBIMS participants will be contacted per standard NDB protocols. Data will be collected via telephone, in person, or by mail at the time points specified in the following table.

Content Area/Measure	6 months	12 months	24 months
Demographics (caregiver)	x		
Functional Outcome (DRS, PART)	x	x	x
Resilience (CD-RISC)	x	x	x
Emotional wellbeing (PHQ-9 and GAD-7)	x	x	x
Family Needs (FNQ)	x	x	x
Burden (ZBI)	x	x	x

Estimated time for caregivers to complete measures is 20-30 minutes. Additional time required of survivors, beyond the standard NDB protocol, is 10-15 minutes. Project staff will make accommodations for persons with visual, motor, and other impairments. To maintain confidentially, data collected from the caregiver will not be shared with the survivor, and data collected from the survivor will not be shared with the caregiver. The same procedures will be employed at collaborating centers.

With regard to safety monitoring at VCU, Dr. Kreutzer will be on call during each assessment. He will monitor the status of enrolled participants and address urgent situations. When concerns arise, Dr. Kreutzer will be contacted immediately to make a clinical decision regarding the need for further evaluation, treatment, or referral. In-person assessments will be conducted in the hospital where a full range of mental health services are available. Once collaborating centers are identified, the project will be submitted to the VCU Office of Research Subjects Protection for review and approval. More detailed information regarding human subjects protection and safety monitoring procedures is detailed in the *Human Subjects Narrative* (Form 424).

Implementation of quality control procedures: A standard protocol will be implemented to maintain consistency and timeliness of data collection across centers. Each center will have a management team consisting of a project director and project coordinator. With assistance from the coordinator, the director will have primary responsibility for ensuring:

▪ enrollment of appropriate participants with respect to inclusion and exclusion criteria
▪ proper administration of measures
▪ completion of assessments within specified timeframes
▪ accurate entry of data

In collaboration with the NDSC, VCU will develop the project database. Computer scoring will be used to eliminate errors in calculating and converting scale scores. Data entry programs will be set up to eliminate the possibility of entering out-of-range values.

D. Data Analysis

Descriptive information will be computed for each of the variables measured in this study. Separate summaries will be provided for those measures collected at each follow-up. Caregivers will be classified as having increasing, decreasing, or stable resilience based on a 3-unit change in CD-RISC scores. The 3-unit cutoff was chosen since it is approximately the level of decrease we found in our previous research focused on postinjury resilience (manuscript under review, *Archives of Physical Medicine and Rehabilitation*). ANOVA and Pearson chi-square tests will be used to determine if caregiver characteristics are related to resilience score changes. Additionally, a latent class linear mixed model (LCLMM) predicting the longitudinal CD-RISC values will be used to identify groups of caregivers that have similar trajectories over time and the characteristics related to these groups.[248-251] Since data from a maximum of three time points will be available, only quadratic trajectories will be considered. The number of latent groups will be chosen by selecting the model with the smallest Bayesian information criterion (BIC), while limiting the model to include no more than 10 trajectories. After identification of the optimal model, a 3-step process will be used to classify and determine the relationship of both caregiver and patient characteristics with the latent trajectories.[252]

Following our strategy with previous longitudinal studies of resilience (under review, *Archives of Physical Medicine and Rehabilitation*), individual growth curve analyses will be used to assess the relationships between caregivers' resilience and the longitudinal caregiver and patient characteristics. These models will include correlated random intercept and slope effects. Separate models will be fit with time, each caregiver and patient characteristic, and the interaction of these variables. Similar models will be fit without the interactions, and any interaction or individual

characteristic significant at the 0.05 level will be candidates to be entered into the final model. A backwards selection procedure will be performed so that all remaining characteristics have a p-value <0.05. The continuous time variable will remain in the model regardless of statistical significance. A random effect will be included to adjust for the different study sites and all inferences will be adjusted for the estimation of the random effects using a Kenward-Rogers adjustment.[253]

The SAS software will be used for all analyses except the LCLMM analysis, which will be performed using the 'lcmm' package in R.[251] All inferences will be made at the 0.05 level and all statistical models, with the exception of the ANOVA and Pearson chi-squared tests, are able to incorporate data that is missing at random. An adjustment for multiple comparisons will not be made due to the exploratory nature of the study.[254]

Power Analysis: Conservatively, assuming that 85% of caregivers (N=266) will complete the two year follow-up, a one-way ANOVA will be able to detect effect sizes of f=0.19 with 80% power. A Pearson's chi-square test will have power to detect an effect size of ω=0.19 or ω=0.20 for characteristics with two levels and three levels, respectively. Each of these are considered small effect sizes. Since we do not have an *a priori* idea of the number or structure of the latent trajectories, it is extremely difficult to determine the achieved power of LCLMM analysis. One conservative metric indicates that no fewer than ten observations per variable should be obtained for adequate power and specificity, while others have suggested that > 500 observations are required.[255,256] By either metric, our study will achieve recommended samples sizes, even if we restrict ourselves to caregivers that contributed data at all three time points (266 participants x 3 time points=798 observations). Lastly, a linear mixed effect model with a 3-level covariate will have 80% power to detect a covariate by time interaction of effect size f=0.10 at the 0.05 level assuming a small correlation between time points of 0.25. Two-level variables and continuous variables will both be able to detect smaller effect sizes under similar conditions.

E. Feasibility

E1. Project Staff

Personnel effort levels are based on thorough consideration of our prior experience conducting similar projects. Following is information on responsibilities of personnel:

J. Kreutzer, Ph.D. (6% effort): (1) assume primary administrative responsibility for the proposed project; (2) staff training, supervision, and performance monitoring; (3) formulation of data collection protocols; (4) being present or on call during each assessment session or ensuring another psychologist is on call throughout the study period; (5) analysis, interpretation, and dissemination of findings; (6) completion of progress reports.
J. Marwitz, M.A. (20% effort): (1) preparation of syllabus and procedures manual; (2) in collaboration with NDSC, develop data entry and scoring quality control procedures; (3) scheduling multi-center teleconferences and meetings for training, quality control, and dissemination planning; (4) supervision of local data collection and entry; (5) assistance with data analysis.
M. Martinez, B.A. (20% effort): (1) obtaining informed consent; (2) coordination and scheduling of appointments, providing appointment reminders; (3) data collection and entry; (4) tracking and maintaining high follow-up rates.
A. Sima, Ph.D. (8% effort): (1) supervise statistical analysis; (2) conducting a subset of analyses; (3) interpreting the results for reports and dissemination.

E2. Potential problems and solutions

In consultation with the Advisory Board and Scientific Advisors, potential problems with procedures in this investigation have been considered to prevent and address them effectively. Following are descriptions of potential problems and proposed solutions.

Accrual rates may be lower than anticipated. We are confident in accrual rate estimates, given the success of previous module projects we have managed (e.g., resilience module, caregiver module). A variety of strategies will be used to ensure successful recruitment and enrollment. Accrual rates will be closely monitored, allowing us to be aware of failures and successes early on. Early identification of accrual problems will enable early implementation of corrective actions. A variety of mechanisms (e.g., regular conference calls and meetings, list server) will be used to promote sharing of information about effective and ineffective recruitment strategies. Sample size calculations are based on collaborating with three other centers. Based on prior experience leading modules, we anticipate a high likelihood that more than three other centers will participate as collaborators, allowing for increased accrual.
A significant number of participants will be unavailable for follow-up. Our twenty-five years of TBI research experience has led us to develop effective follow-up systems. The cornerstones of the system include: (a) providing high quality clinical follow-up services; (b) maintaining up-to-date contact information; (c) employing an efficient written and telephone appointment reminder system; and (d) communication (e.g., sending birthday and holiday greeting cards) and sharing research news (e.g., via quarterly newsletter). VCU follow-up rates at one and two years postinjury have ranged from 90-95%. With regard to collaborating centers, our expectations about follow-up rates are based upon a review of data collection rates for previous modules in which we have participated. Furthermore, the TBIMS has established guidelines for optimal follow-up and all centers will adhere to these guidelines for the module effort.

F. Expected Beneficial Impact

▪ A focus on resilience offers a promising opportunity to better understand and conceptualize caregivers' experiences after TBI.
▪ We will gain a new and better understanding of how caregiver attributes, namely resilience, relate to survivor outcomes and caregiver burden and needs.
▪ New hypotheses will be generated for future caregiver intervention development.
▪ The development of empirically-based interventions for caregivers has the potential to benefit outcomes for survivors.

IV. Dissemination Activities

Disseminating relevant, accurate information about TBI and dispelling public misinformation are important goals for this proposal. The following methods and formats will be employed to meet these objectives: (a) lectures, workshops, conferences; (b) publications; (c) web sites; (d) technical assistance; and (e) internships, practica, and research training experiences. We will disseminate at least five categories of information: research knowledge (results of scientific investigations, methods of design and analysis), program development (methods of rehabilitation program planning and development), evaluation (methods of medical, functional, cognitive, psychosocial, and vocational assessment; program evaluation), rehabilitation practice (medical care and rehabilitation methods), and resources (identifying appropriate support and rehabilitation services).

Several factors will help assure that dissemination activities are **effective, useful, and of high quality**. To plan each dissemination activity, input regarding format, content, and quality will be solicited from relevant sources, including consumers served by the TBIMS, Advisory Board Members, the MSKTC, and intended audiences. Feedback relating to past activities will also be reviewed. After completing each activity, feedback will be solicited and used to guide later dissemination activities.

As indicated in their letters of support, BIAV and DARS have agreed to serve an important role in dissemination activities. Both organizations' leaders are members of our Advisory Board. They will have planning, implementation, and evaluation roles, ensuring that dissemination activities are relevant, useful, and of high quality. BIAV and DARS routinely conduct needs assessments and have agreed to share the results with us. Through collaborative dissemination projects, VCU has also developed a close working relationship with BrainLine and WETA-TV (see Appendix C, letter

from N. Gunther). WETA is the flagship PBS station in Washington, D.C. We will continue to support WETA in developing programming and their website, and we will solicit feedback from them regarding VCU projects.

Kelli Williams Gary, Ph.D., MPH, OTR/L, will serve as Dissemination Coordinator. As a person with a disability and over 20 years of experience in the field of TBI rehabilitation, Dr. Gary is well-qualified to serve in this capacity. Additionally, she is on the Board of Directors for BIAV. Her close working relationships with other regional organizations will enable her to successfully solicit feedback about dissemination activities. Dr. Gary's credentials and responsibilities are detailed in the *Project Staff* and *Plan of Operation* sections.

To enhance the usability and accessibility of dissemination materials, program materials will be made available in multiple formats with sensitivity to issues of culture, language, literacy, and disability. Before, during, and after each activity, individuals will be welcomed to identify desired accommodations or modifications to increase their likelihood of benefit. We are strongly committed to doing our best to accommodate the needs of all individuals. Further, VCU's Spanish/English Translation and Interpretation Service (SETI) will help translate materials into Spanish and facilitate planning of dissemination activities for Spanish-speaking individuals.

Dissemination Methods and Objectives

Following are descriptions of dissemination methods and planned activities. Use of multiple methods and activities will increase usability and accessibility for persons with different needs.

A. Conferences: Conference activities will incorporate lectures, workshops, case presentations, panel presentations, and invited peer-reviewed papers and posters. Materials normally produced for each conference will include a syllabus, and often, audiotapes or videotapes of presentations.

VCU Sponsored Interdisciplinary Conferences for Professionals
Annual ("Williamsburg") Conference on Rehabilitation of the Adult and Child with Brain Injury. For 40 years, this international conference has been held in central Virginia. Interdisciplinary faculty interact with audiences of 200-300. The VCU TBIMS program has co-sponsored the 2-3 day conference since 1992, reaching a total audience of nearly 5,500. Each year, more than 50 hours of instruction are provided, and conference faculty from other collaborating TBIMS programs play a vital role in presentations. Continuing education credits are offered to attendees by professional certification organizations (e.g., CRC, NASW, CCM, APA). Annual conferences are planned during the five-year period, and TBIMS program information dissemination will remain a major objective.

Conferences for Persons with TBI and Family Members
The Getting Better and Better after Brain Injury Workshops have been provided to consumers and family members since 1998. Typically, two to four workshops per year have been completed across the state. Moving educational programs to rural areas has allowed us to reach underserved persons. We will continue to offer regional workshops relating to self-advocacy, adjustment to injury, and accessing resources during the proposed funding period. The workshops offer an opportunity to provide education and training, as well as a platform to inform individuals about ongoing TBIMS research projects. Program staff have routinely served as faculty and program planning committee members at the invitation of DARS, BIAV, Brain Injury Services, and other state organizations. We are committed to continuing to serve in this capacity.
Conferences Sponsored by Rehabilitation Providers, Professional Organizations, and Universities
Project staff have routinely been invited to lecture nationally and internationally because of their relevant interests, publication records, and public speaking skills. More than 200 presentations were given in the last five years by TBIMS staff. Every effort will be made to continue.

B. Publications will include books, manuals, and manuscripts in peer-reviewed journals. We will continue supporting the National Rehabilitation Information Center (NARIC), providing them with copies of materials and responding to inquiries. In addition, we are committed to working with the MSKTC and the Brain Injury Association of America (BIAA) to meet organization objectives, and will continue to share newly developed program materials with them. Our campaigns to promote dissemination of accurate information about TBI in the news and social media (e.g., Twitter, Facebook) will also continue. The following table highlights aspects of our publication plans:

Publications for professionals. Project personnel selection has partly been based on productivity. Examination of *curriculum vitae* (see Appendix B) clearly shows historically high productivity records. The VCU TBIMS has greatly exceeded previous commitments to disseminate findings. For example, in the successful 2012-2017 TBIMS application, a commitment was made to publish at least 40 manuscripts during the five-year funding period. More than 45 publications, including books and manuscripts, were completed. Since 2000, project personnel have published 19 books on TBI rehabilitation (e.g., community integration, vocational rehabilitation, behavioral management, cognitive rehabilitation). The books and many of the journal manuscripts emphasize practical treatment approaches and NIDILRR priority areas.
Project personnel are editors of major rehabilitation journals and serve on a number of editorial boards. J. Kreutzer is Co-Editor-In-Chief of two international journals, *Brain Injury* and *NeuroRehabilitation*. As indicated in CV's, key personnel also serve on journal editorial boards. Here, key personnel will enhance accessibility of TBIMS literature. For example, an entire issue of *Brain Injury* (2012; volume 26, issue 11) was allocated to presentation of information regarding NIDILRR's TBIMS research and programs.
Publications on special topics for consumers. We are committed to developing educational materials for consumers that provide practical solutions to commonly encountered problems. The VCU TBIMS has developed and disseminated a wide variety of written and audiovisual materials. For example, we developed the *25 Ideas Series,* a series of four books that provide practical information relating to TBI, recovery, resources, and self-advocacy with the second edition of *Getting Better and Better after Brain Injury: A Guide for Survivors* released in 2012. Two additional books were written, *Memory Matters* and *Recovering Relationships after Brain Injury.* Four of our books have been converted to audio CD

for persons with visual impairments. Other educational materials developed include the *Help You Need Guides*, seven tri-fold brochures on topics relevant to TBI. A similar series of guides was also developed to address the needs of family members and friends. **For the new funding cycle** agreements have been reached with BIAV and DARS to identify additional topics and aid in dissemination. When completed, multiple copies of each guide will be sent to BIAA, all state-affiliated BIA's, and DARS regional brain injury resource centers. Guides and other materials will also be distributed at regional conferences and workshops. Furthermore, materials are provided to all persons with TBI receiving services at VCUHS.
Quarterly Newsletter. *TBI Today* is in its fifteenth year of production. The newsletter provides educational information to consumers and families. Distribution by regular mail is over 800, with issues also emailed to over 2,000 subscribers and posted on the VCU TBIMS website, http://model.tbinrc.com/newsletters. Staff will continue to produce *TBI Today* during the next funding cycle.
BIAV Newsletter. *Headway* is published quarterly. In each newsletter J. Kreutzer and colleagues are contributors and have a long-term agreement to publish at least one new article in each issue. We will continue to publish articles describing our research findings.
Dissemination of Information to Local and National Media through Newspapers, Magazines, Radio, and Television. The media provides opportunities to educate a large public audience. The VCU News Services Office has assigned the TBIMS a media consultant, Erin Lucero. Ms. Lucero, an experienced journalist, has worked with us in the past and is very knowledgeable about TBI and rehabilitation (see Appendix D for biographical information). Notably, VCU's TBIMS experienced significant media attention (e.g., front page of the January 10, 2012 *NY Times* Science section; and WETA-TV). Through regular contacts and press releases, Ms. Lucero will continue to distribute information about the TBIMS in the proposed funding cycle.

C. Web Sites: For more than a decade, the VCU TBIMS program has worked to make electronic communication and information sharing a helpful resource for consumers and professionals. We have established and maintain three active web sites, *The National Resource Center for TBI* (www.tbinrc.com), and *The VCU TBI Model System* (http://model.tbinrc.com), and *VCU Family Support Research* (www.tbifamilyresearch.com). In addition, we provide support for *The Center for Outcome Measurement on Brain Injury* (COMBI, www.tbims.org/combi). We will continue to support the COMBI and serve as the designated expert for the Family Needs Questionnaire, the Neurobehavioral Functioning Inventory, and the Service Obstacles Scale.

The *National Resource Center for TBI* and *VCU TBI Model System* sites were created in 1999. Following are descriptions of site content information. Site content will be reviewed, updated, and improved throughout the project funding period.

▪ **Mailing list subscription** - individuals can subscribe to the web sites' mailing lists to receive regular e-mails. Subscribers will receive updated information about project activities and *TBI Today* newsletters.
▪ **Frequently Asked Questions (FAQ's) -** an extensive listing with responses from regional and national experts; topic areas include networking to locate services, general information on TBI, rehabilitation options, cultural issues, return to work, women's issues, family adjustment, behavioral

issues, and self-advocacy. Responses to questions will be solicited from TBIMS staff and Advisory Board members.
▪ **VCU TBIMS information -** a description of research programs along with list of publications.
▪ **"Chat with Pat" -** a support and advice column for everyday problems and concerns.
▪ **TBI Today -** quarterly newsletter for the VCU TBIMS described in section B, Publications.
▪ **Links to other locations -** users can review listings of other helpful sites organized by topic.
▪ **Announcements of conferences and upcoming meetings -** information for both professionals and consumers is provided for state, regional, and national conferences and meetings.
▪ **E-mail -** users can directly contact all persons listed at the site, directly through links or indirectly by mailing the site manager (J. Marwitz).

The *VCU Family Support Research* web site provides information for professionals working with families after TBI. Publications, links to resources, and training videos on family intervention and education are available. Further content development is planned.

D. Response to inquiries by phone and correspondence: TBIMS staff receive and respond to 200-350 inquiries annually from consumers, family members, and professionals. Some request copies of publications. Others request referral information or technical assistance (e.g., information about selection, administration, or scoring of measures). Continuing responsiveness to inquiries will enable us to meet a greater diversity of needs and better gauge the needs of the general public.

E. Internship, Practica and Research Training Experiences: Students enrolled in our training programs disseminate information to their mentors and colleagues. Information about their research will be disseminated through conference presentations and publications.

▪ VCU was awarded a NIDILRR Advanced Rehabilitation Research Training (ARRT) Grant in September 1992, with additional 5 year awards in 1997, 2004, 2009, and 2015. Current funding will run through September 2020. The TBIMS setting serves as the primary foundation for post-graduate brain injury rehabilitation research training.
▪ Eight dissertations and five master's theses were completed within our system during the past twenty years. A similar rate of future accomplishment is anticipated.
▪ Our relationship with students has extended beyond VCU, and includes University of Richmond, the College of William and Mary, University of Virginia, Eastern Virginia Medical School, Washington and Lee University, and University of Mary Washington students. We will continue to work with universities to provide opportunities for research and clinical training.

Information Products and Production Rates

An active web site and mailing list substantially increase our ability to provide information and technical assistance. Including web site visits, emails, and phone calls, we anticipate responding to 5,000-10,000 information requests. Serving as a benchmark, the following table depicts the *minimum* number of major products we intend to develop and distribute annually, beginning Year 1:

Annual Production	Information Product Type
6-10	Peer reviewed publications, book chapters, and books
20-30	Presentations at regional and national meetings
8-12	Special topic reports, reference lists, *Help You Need Guides.*
4-8	Newsletter, newspaper and magazine articles

Our Dissemination Coordinator, Dr. Gary, will compile and maintain a listing of products completed and in preparation. The list will be updated monthly and revisions will be posted online. Completion of new products will be announced via newsletters, mailing lists, and social media.

Expected Beneficial Impact

Information developed through the VCU TBIMS has been and will be used to directly extend and improve the continuum of care in our region. Successful dissemination will ensure that benefits also accrue for persons outside our geographic area. The following primary benefits are anticipated:

▪ Increased knowledge about TBI and rehabilitation resources
▪ Improvement in consumers' ability to self-advocate and serve actively in rehabilitation planning
▪ Increased accessibility to appropriate rehabilitation and support services
▪ Improved communication between consumers and professionals
▪ Increased inclusion of persons with disabilities through reduction and removal of barriers created by negative stereotypes and misinformation
▪ Improved life satisfaction for survivors and their families as a result of increased knowledge
▪ Greater levels of support for effective rehabilitation programs

V. Plan of Operation

The management plan will make certain that all project objectives are accomplished within budget, on time, and with integrity. The plan is based on the following activities and principles:

- Clear designation of responsibilities for all personnel including Advisory Board members
- Designation of authority lines with clear hierarchies
- Establishment of clear, coordinated timelines for all project activities
- Coordinated use of resources to maintain operations within budget and in a cost-effective manner
- Designation of responsibilities for organizational entities
- Establishment of clear research and dissemination objectives towards achieving project goals

Organizational entities integral to this project and their major responsibilities are described below:

NIDILRR – Project Officer and other personnel provide guidance and leadership, monitor project's rate and quality of accomplishments.
Senior Management Team – senior project personnel responsible for management and quality monitoring of research and dissemination activities; share primary responsibility for assuring objectives

are accomplished within timeframes and within budget, assure cost-effective utilization of resources
Research Project Directors – highly experienced, senior faculty responsible for managing day-to-day project operations and staff; each research project has been assigned a director
Project Associates – highly qualified medical center faculty and personnel, integral to the system of care, serving as clinical research advisors
SOM-Tech (School of Medicine Technology Services) - will maintain computer software, hardware and back-up systems; design and implement protocols for system security, data integrity, capacity planning, and computer performance; and provide ongoing staff consultation and training
Advisory Board – includes persons with brain injury, family members, scientists, professionals, and representatives of advocacy organizations (will help develop and implement relevant, innovative, and high quality research; evaluate and monitor progress toward research and dissemination objectives; and provide ongoing feedback)
Scientific Advisors – leading interdisciplinary scientists, based in VCU's Center for Rehabilitation Science and Engineering (CERSE), will provide expertise relating to project management, research methodology, data analysis, and interpretation of findings
Project Evaluator – Dr. Kim, from outside the TBIMS, will monitor program progress, provide feedback for improvement, and ensure the quality and timely accomplishment of program objectives
TBIMS NDSC – monitors VCU NDB contributions including enrollment and follow-up rates; also conducts quality support visits to ensure that data is collected per established protocols

Project oversight will be shared by members of the **Senior Management Team** whose responsibilities are described below. An organizational chart depicting the framework of authority for this project is presented following descriptions of the Senior Management Team.

Principal Investigator - Jeffrey S. Kreutzer, Ph.D. will assume primary administrative responsibility for the proposed project, including: (1) maintaining adherence to federal and state regulations; (2) monitoring budgetary expenditures; (3) coordinating research program development; and (4) monitoring program activities to ensure progress toward stated objectives. Dr. Kreutzer will take an active leadership role in project development, implementation, quality control, and dissemination. Identifying, allocating, and helping to coordinate resources will be a major responsibility. Dr. Kreutzer, with Dr. Cifu, will maintain close communication with NIDILRR representatives, the Project Evaluator, and the project Advisory Board.

Co-Principal Investigator - David X. Cifu, M.D., Chairman, VCU Department of Physical Medicine and Rehabilitation (PM&R), will work closely with Dr. Kreutzer to manage the TBIMS program. Dr. Cifu will share primary administrative responsibility for coordinating fiscal, research, and clinical program activities. Supervising medical programs and maintaining quality assurance of medical and follow-up data for the NDB will be important and unique roles.

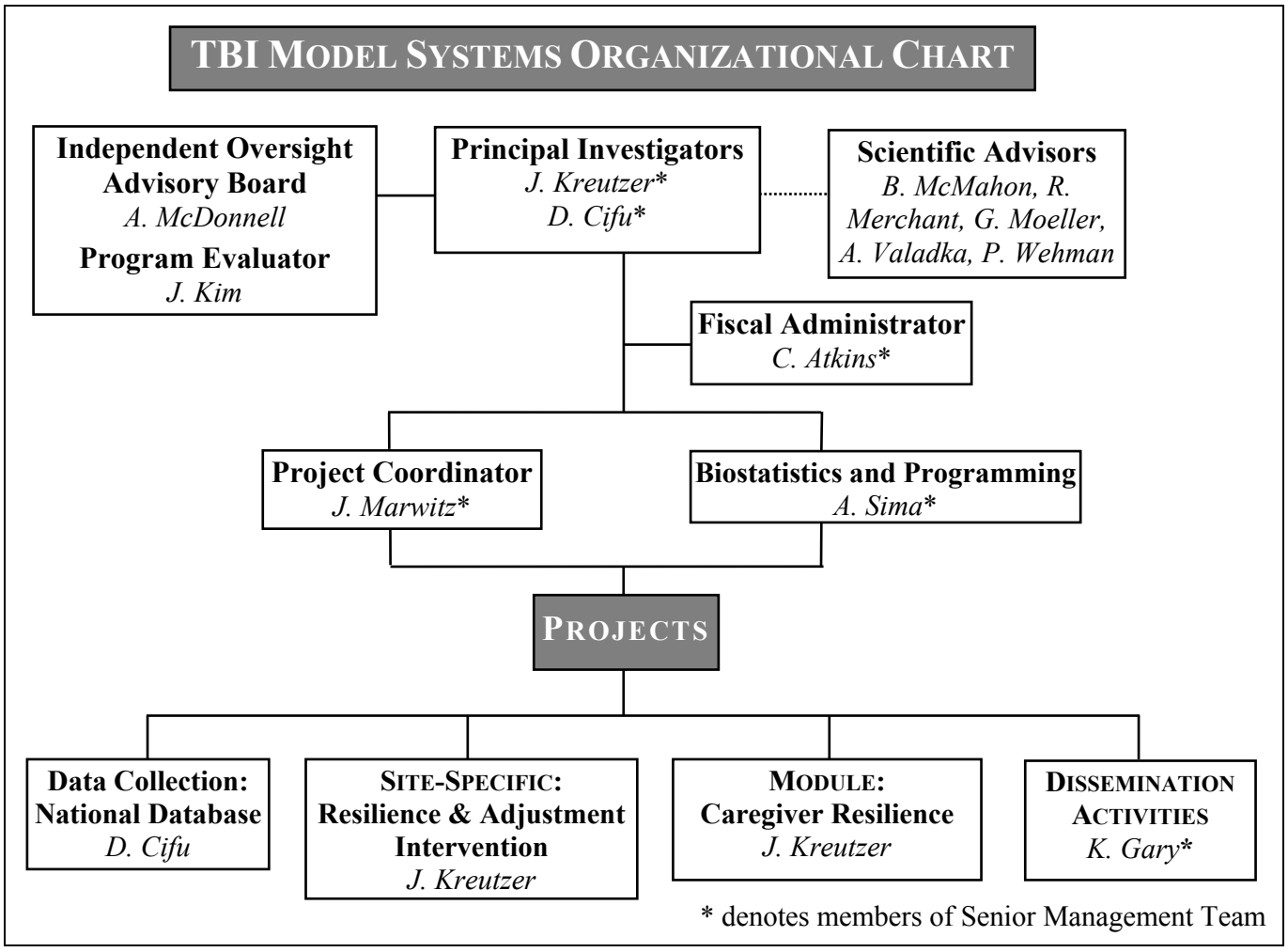
Project Coordinator - Jennifer H. Marwitz, M.A., under the direction of the Principal Investigators, will help: (1) coordinate and implement research activities including NDB data collection; (2) coordinate resource allocation; (3) serve as a liaison between project staff, advisory groups, community agencies, survivors, and family members; (4) monitor progress toward program objectives; (5) supervise research assistants and address staff training needs; and (6) coordinate and synthesize program evaluation procedures. Database creation and management responsibilities include setting up and maintaining reliable data entry systems, developing data tracking and reporting systems.

Biostatistician – Adam P. Sima, Ph.D. will provide and supervise statistical analysis for research projects and have a critical role in manuscript preparation. He will identify and apply appropriate statistical methodologies necessary to address hypotheses based on factors such as measurement scaling, data distribution, and sample size. In addition to completing sophisticated statistical modeling and analysis, he will assist with methodological and design issues as they arise.

Dissemination Coordinator – Kelli Williams Gary, Ph.D., MPH, OTR/L will: (1) help develop, facilitate, and coordinate dissemination activities, including social media, in collaboration with project staff and Advisory Board members; (2) respond to requests for information; and (3) monitor progress toward dissemination objectives. Dr. Gary will identify audience needs and make certain that TBIMS information is made available in alternative formats. Dr. Gary will have a primary role in making certain that dissemination activities are relevant, innovative, high quality, and implemented in a timely, cost-efficient manner.

Grant Administrator – Christie Atkins will have responsibility for initial review of purchase orders, organizing and maintaining financial records, coordination of equipment purchases, and review of expenditures to ensure adherence to University and federal guidelines. Working closely with the Principal Investigators, she will facilitate communication with University, federal, and departmental fiscal representatives. As Grant Administrator, Ms. Atkins will have a primary role in assuring the cost-efficient utilization of resources.

The VCU TBIMS **Senior Management Team** will meet weekly. Monitoring progress toward meeting objectives, making sure that activities are completed as scheduled, and maintaining fiscal control and accountability are essential responsibilities shared by the team. The team will also evaluate progress of individual research projects and data collection for the TBIMS NDB. Initial meetings will focus on staffing and training issues, project development, quality assurance standards, and establishing communication networks. As depicted at the end of this section, a Project Work Plan details major activities with corresponding timeframes and objectives. The work plan will facilitate project evaluation and coordination of resources.



Project Directors and Project Personnel - The directors for each project are shown in the *TBIMS Organizational Chart*. Their responsibilities include: (1) coordinating and supervising day-to-day operations; (2) coordinating and monitoring allocation of individual project resources; (3) hiring,

training, supervising, and evaluating staff; (4); monitoring progress and preparing written reports for the Senior Management Team; and (5) maintaining ongoing communication with the Senior Management Team. Project Directors will assist the Project Coordinator (J. Marwitz) and facilitate dissemination activities for individual projects.

Research Associates assigned to each project will meet regularly with their respective individual Project Directors who will serve as team leaders. Team meetings will provide an opportunity to problem solve and plan. Project teams will meet with the Senior Management Team on a monthly basis for the first 12 months of the grant, and on a quarterly basis thereafter. Written reports regarding progress and adherence to timelines will be provided on a quarterly basis as well.

Research Associates and Assistants will have an active role in many of the team meetings. Following is a general description of Research Associates' responsibilities relating to the individual program and to the TBIMS NDB:

- Collecting data from medical records
- Scheduling appointments and completing interviews for research participants and caregivers
- Carrying out neuropsychological, psychological, and vocational evaluations
- Data entry and verification
- Completing coding forms necessary for TBIMS NDB
- Assisting in literature reviews and manuscript preparation
- Compiling information for written publication and dissemination on the Internet
- Completing basic summaries of statistical analyses and reporting on analyses
- Implement treatment protocols (doctoral level Research Associates)
- Assist with statistical analyses, interpretation, dissemination (doctoral level Research Associates)
- Managing project web sites and social media accounts

The Advisory Board will play a major role in project implementation, helping make certain that TBIMS programs are relevant, innovative, and of high quality. Bringing a multi-cultural perspective, this diverse group is composed of survivors with advanced degrees, family members of persons with disabilities, and interdisciplinary professionals who are nationally known leaders in the field. This highly qualified group will meet as a whole with the Senior Management Team three times during the first year of operation and at least twice annually thereafter. Meetings with individual board members or groups of members will also take place as needed.

Meetings will provide an important opportunity for communication, soliciting input, reviewing progress, and planning. On a quarterly basis, Advisory Board members will be updated on project

activities and accomplishments. Board members will be provided with copies of all dissemination materials including manuscripts and reports. They have agreed to collaborate and participate in training and other educational activities. Board members have also agreed to regularly solicit and convey feedback from their constituents about goals and products developed through the grant.

The following table delineates board members and qualifications. Per NIDILRR's request, initials rather than full names are provided. Letters of commitment and support from board members are provided in Appendix C. **Anne McDonnell, MPA, OTR/L**, Executive Director of BIAV, will serve as Advisory Board Chair. A member of the VCU TBIMS Advisory Board since 2001, Ms. McDonnell has over 25 years of experience in TBI rehabilitation across a continuum of hospital and community-based settings. She holds a clinical faculty position in the VCU School of Occupational Therapy and also serves as a consultant to state agencies.

Board Member	Qualifications
Anne McDonnell, MPA,OTR/L Chair, Advisory Board	Executive Director, Brain Injury Association of Virginia. Expertise: community integration, survivor and family members' perspectives, survivor and family support and education programs.
Rosemary Rawlins, B.A., Consultant	Author, lecturer, and spouse of a survivor. Expertise: Caregiver and spousal needs and services, family and survivor adjustment.
JM, M.S.	Survivor, Rehabilitation Counselor. Expertise: post-acute rehabilitation services, consumers' needs and perspectives.
JC, B.A.	Survivor. Expertise: survivor needs, continuum of care.
KB, M.Ed,CBIS	Executive Director, Brain Injury Services. Expertise: community-based needs assessment and intervention, networking.
CG, RN,MScN,AAMFT	Family Therapist, Holland Bloorview Kids Rehabilitation Hospital. Expertise: solution focused therapy after TBI, clinical program development, rehabilitation science and methodology.
PG, Ed.S.	Coordinator of Brain Injury Services, Commonwealth of Virginia Department of Aging and Rehabilitative Services. Expertise: program development and evaluation, community needs assessment, employment and disability, and regional TBI resources.
CL, MSW,CBIS	Case Manager, Community Futures Foundation. Expertise: community program development, case management, and program evaluation.
LS, Ph.D.,LCP	Principal Investigator, McGuire VAMC TBIMS program; Psychologist. Expertise: adjustment to injury and resilience in both civilian and veteran populations.

Scientific Advisors, drawn from CERSE, will serve as an important resource to the Senior Management Team. They will provide ongoing guidance regarding design, methodology, data

analysis, and interpretation. Biographical sketches (P. Wehman, B. McMahon, R. Merchant, G. Moeller, and A. Valadka) are provided in Appendix D.

Dr. Jeong Han Kim will serve as **Program Evaluator** to assess progress in implementing the plan of operation, meeting objectives and timelines, and achieving proposed outcomes. He is adept at program evaluation and will independently evaluate implementation, impact, and efficiency. The principal investigators will translate his recommendations into an effective action plan.

Rosemary Rawlins, B.A. will serve as a **Program Consultant** and Advisory Board member. The spouse of a survivor and an accomplished author, Ms. Rawlins is uniquely qualified to guide TBIMS program activities. She will have a significant role in program planning and evaluation, with Dr. Kim (see *Plan of Evaluation* section). Ms. Rawlins will help judge the relevance, quality, and impact of research and dissemination activities.

Administrative and Fiscal Management Procedures: We are firmly committed to careful fiscal monitoring given the magnitude of funds involved and the scope of work. Management procedures will meet the highest standards. Examination of key personnel's vitae substantiates our experience managing large scale grant funding. Previous grants awarded have been audited by the state budget office, as a matter of routine procedure, over the last 25 years. Historically, no deficiencies have been identified.

The University and the Commonwealth of Virginia have built an effective checks and balances system to maintain budgets and monitor compliance. Purchase orders for expenditures and travel reimbursement procedures will be initiated, approved, and later verified by the Principal Investigators. They will share responsibilities for personnel recruitment, management, and payroll. For monitoring purposes, bi-annual effort certification forms are issued by the University's budget office for all personnel. Effort reports will be routinely checked by Dr. Kreutzer and Ms. Atkins to verify accuracy and posting to appropriate accounts.

All financial expenditures for the proposed project will be recorded by the Grant Administrator in our offices and also recorded in the University's Office of Grants and Contracts. The Office of Grants and Contracts will have major budgetary oversight responsibility. The Principal

Investigators will communicate regularly with the Grants and Contracts staff to maintain compliance with state and federal policies.

The partial duplication of effort between the Office of Grants and Contracts and the Senior Management Team will ensure scrutiny of expenditures and careful adherence to agency guidelines. The project's Grant Administrator will work closely with the University Office of Grants and Contracts to maintain communication and coordination of fiscal monitoring activities.

Following is a detailed project work plan for key activities by time (in months). The overall goal for the VCU TBIMS is to advance our knowledge of resilience relating to persons with TBI and their caregivers, with the ultimate hope of improving health and function and community participation.

Months **Project and Major Tasks**	1-6	7-12	13-18	19-24	25-30	31-36	37-42	43-48	49-54	55-60
Program Management Activities (J. Kreutzer)										
Weekly Senior Management Team meetings	x	x	x	x	x	x	x	x	x	x
Review monthly project progress reports	x	x	x	x	x	x	x	x	x	x
Quarterly Implementation Assessment meeting	x	x	x	x	x	x	x	x	x	x
Advisory Board meeting	x	x	x	x	x	x	x	x	x	x
Annual Performance Reports		x		x		x		x		x
Site-Specific Project: Intervention to Promote Survivor Resilience and Adjustment (J. Kreutzer)										
Review project management and implementation plans with staff.	x									
Develop data collection, treatment coordination, and scheduling plans.	x									
Format, complete, and duplicate written protocols for data collection.	x									
Train staff to implement the RAI as required in research protocols.	x									
Quality control procedures	x		x		x		x		x	
Begin database development to accommodate data elements.	x									
Complete databases to accommodate data elements for all participants	x									
Enroll study participants	x	x	x	x	x	x	x	x		
Deliver intervention	x	x	x	x	x	x	x	x		
Follow-up assessment protocol implemented	x	x	x	x	x	x	x	x	x	x
Review data accrual rates and summarize data collected		x		x		x		x		x
Preliminary data analysis and summarize results						x				
Initiate formal dissemination activities relating to results									x	x
Prepare final project report for NIDILRR										x

Project and Major Tasks / Months	1-6	7-12	13-18	19-24	25-30	31-36	37-42	43-48	49-54	55-60
Module Project: Caregiver Resilience (J. Kreutzer)										
Develop and distribute multi-center project implementation manual and syllabus	x									
All centers will submit final protocol for review and approval to respective IRB's	x									
Develop database to accommodate data elements for participants at all centers	x									
Multi-center project staff teleconferences	x	x	x	x	x	x	x	x	x	x
Enroll study participants	x	x	x	x	x	x				
Complete follow-up data collection		x	x	x	x	x	x	x	x	x
Prepare and distribute accrual, follow-up, and quality control reports		x		x		x		x		x
Preliminary data analysis and summarize results						x				
Initiate formal dissemination activities relating to results									x	x
Prepare final project report for NIDILRR										x
Dissemination Activities (K. Gary)										
Produce quarterly newsletter	x	x	x	x	x	x	x	x	x	x
Update project web site and social media posts	x	x	x	x	x	x	x	x	x	x
Prepare presentations for national conferences		x	x	x	x	x	x	x	x	x
Prepare manuscripts and submit for publication		x	x	x	x	x	x	x	x	x
Implement annual TBI rehabilitation conference		x		x		x		x		x
Implement consumer workshops		x	x	x	x	x	x	x	x	x
National Database (D. Cifu)										
Enroll and follow-up with NDB participants	x	x	x	x	x	x	x	x	x	x

VI. Collaboration

This project will involve collaboration between a variety of programs and service organizations within and outside the University. Ongoing close communication, shared interests in achieving optimal outcomes, focus on constructive solutions, and mutual respect and support are principles shared by the VCU TBIMS Senior Management Team. These principles are the philosophical cornerstones of effective collaborative efforts. Within the University system, collaboration will occur between clinical programs, University departments, and administrative offices.

Outside of VCU, we will collaborate with health care providers, survivors, family members, advocacy organizations, other TBIMS centers, the MSKTC and other federally-funded programs. The following table illustrates involvement of entities necessary for effective completion of research and dissemination activities. Letters of commitment to collaborate, offered by program directors and leaders who will serve on our Advisory Board, are provided in Appendix C.

VCU MANAGED PROGRAMS	PROGRAMS SPONSORED BY PARTNERS
On-Campus Services ▪ Emergency Room ▪ Neuroscience Intensive Care Unit ▪ Acute Neuroscience Care Unit ▪ Acute Inpatient Rehabilitation ▪ Outpatient Rehabilitation Clinics/Services ▪ Psychiatric and Mental Health Services including the Substance Abuse Program	**Community-Based Medical Services** ▪ Emergency Medical Transport Services ▪ Polytrauma Rehab Center at McGuire VAMC **Community-Based Rehab Services** ▪ BIAV and affiliated support programs ▪ Brain Injury Association of America ▪ Brain Injury Services ▪ Central Virginia Center for Independent Living ▪ Community Futures Foundation ▪ Concussion Care Center of Virginia ▪ Tree of Life Supported Living Center ▪ Virginia DARS ▪ Virginia Institute of Neuropsychiatry
Off-Campus Medical Services ▪ Neurologic Recovery (subacute) Care Unit at Retreat Hospital ▪ Neuroscience, Orthopaedic, & Wellness Center	
Community-Based Rehab Services ▪ Supported Employment Program ▪ Sheltering Arms Day Rehabilitation Centers	

A variety of factors will help assure that collaborative efforts are successful:

- Model systems activities involve building and expanding on existing positive relationships. All the collaborative relationships have existed for many years.
- On a local, state-wide, and regional level, we are collaborating with many other organizations on projects hosted by them. The model systems effort provides an excellent opportunity to enhance the reciprocity of relationships.
- All collaborators value high-quality service, and all were involved in the planning of this proposal. Each collaborator has a vested interest in the success of this project. Commitments have been made to refer potential participants for involvement in individual research projects, and to provide guidance to ensure that projects remain innovative, relevant, and scientifically sound.
- For almost 30 years, the VCU TBIMS program has worked productively with other NIDILRR-funded model systems and the VCU Rehabilitation Research and Training Center on Employment of People with Physical Disability. Our many joint publications with other TBIMS centers affirms our ability to collaborate successfully (see Appendix F).
- Many of our proposed research projects share data elements with the NIDILRR TBIMS NDB. Shared data elements will enhance opportunities for future collaboration. As in the past, we will invite other model systems to collaborate with us in our new data collection efforts. Involvement in dissemination activities will be invited as well.

- As outlined in the *Dissemination* section of the proposal, we will continue to collaborate with other centers by contributing information to the Center for Outcome Measurement on Brain Injury (COMBI). The VCU TBIMS has contributed information on the Family Needs Questionnaire (FNQ), the Neurobehavioral Functioning Inventory (NFI), and the Service Obstacles Scale (SOS). We will continue to provide technical assistance to persons who inquire about the measures through the COMBI.
- VCU has a long history of research collaboration with other medical and rehabilitation centers including NIDILRR-funded centers. Since 1987, we have collaborated with fellow rehabilitation centers in the production of 109 peer-reviewed publications. Our history of successful collaboration provides the groundwork for future partnerships.
- We are committed to working with the NIDILRR-funded MSKTC. We have taken a primary role in developing fact sheets and educational videos with the MSKTC. In fact, VCU, working with the MSKTC, received a Bronze Telly Award for producing the video, *Relationships after TBI*. We will continue to work with the MSKTC, generating new ideas and developing new products for dissemination (see MSKTC letter of support and collaboration, Appendix C).

In summary, we are confident that collaborative efforts will be successful for three reasons. First, we have a long-standing history of successful partnerships with other agencies and organizations. Second, we and our partners firmly agree that collaboration is in the best interests of all parties. Third, we have secured written commitments detailing the specifics of collaboration from agency and organizational leaders, who will comprise a major component of our Advisory Board.

VII. Adequacy and Reasonableness of the Budget

Reasonableness of Costs

Detailed information on proposed costs is provided in the *Budget Narrative* section in the front matter of the proposal. We believe the proposed costs are reasonable in relation to project activities for a number of reasons. We will build on a solid foundation of resources, most of which have been in place for many years. Evolving in response to Virginians' health care needs, VCU Medical Center is a centerpiece for medical care and education in Virginia. As Virginia's largest university,

VCU has a vast array of resources to meet the needs of more than 30,000 students. As members of the academic community, VCU TBIMS researchers have complete access to the university's resources. Detailed information regarding university resources is provided in the *Adequacy and Accessibility of Resources* section.

To assure that our goals are achieved in a cost-effective manner, we have selected highly competent, diligent, and experienced staff. Project personnel were selected because their expertise is highly relevant to program requirements and goals. Key personnel and most staff members have a long history of working in the VCU TBIMS program. Dr. Kreutzer has been the Principal Investigator since 1987, and Dr. Cifu has been Co-Principal Investigator since 1992. J. Marwitz has 29 years of experience with the program. Reflecting on past accomplishments, we are confident that responsibilities will be efficiently and effectively carried out.

Salaries of all proposed staff are reasonable relative to the local labor market. Proposed effort of project staff has been closely scrutinized and allocated to ensure that program activities are completed capably and on time.

An array of university and departmental checks and balances are in place to ensure that proposed costs are reasonable and appropriate. Staff salary requirements, effort levels, and all other proposed expenditures have been evaluated and agreed upon by the VCU Office of Sponsored Programs, the Principal Investigators, the Grant Administrator (C. Atkins), and the Chairman of the Department of PM&R's Research Division (P. Wehman).

As evidence of the university's strong commitment to support TBIMS research, a substantial amount of cost share has been allocated. In fact, each year, for five years, **VCU will contribute $182,986, a total of $914,932.** The cost share amount equals 38.3% of the total funding amount requested from NIDILRR. In addition, the **university has agreed to reduce the on-campus Facilities and Administrative (F&A) rate from 55% to 32%** on Modified Total Direct Costs (MTDC) for this project. The reduction represents an additional $404,963 in financial support from VCU.

VIII. Plan of Evaluation

We are firmly committed to ongoing project evaluation to make certain that objectives are fully realized. The Plan of Operation provides a foundation for the evaluation process. VCU TBIMS staff share the philosophy that effective program evaluation requires: (1) clearly delineating evaluation objectives; (2) creating entities responsible for program evaluation with clearly delineated responsibilities; (3) developing and monitoring performance measures according to established timetables; and (4) developing and implementing plans for identifying and remedying deficiencies.

Evaluation Objectives

Major objectives and primary organizational entities are presented in the following table. Timetables for accomplishing project tasks are provided in the *Plan of Operation* section.

1. Early and continuing assessment of the extent to which the plan of operation has been activated and proposed organizational structures have been established (Senior Management Team, Advisory Board, Program Evaluator)
2. Ongoing collection of quantitative and qualitative performance measures (Project Directors, Senior Management Team, Program Evaluator, NDSC)
3. Assessment of adherence to proposed timelines (Project Directors, Senior Management Team, Advisory Board, Program Evaluator, NDSC)
4. Assessment of project impact on consumers' needs and on the quality of regional resources (Senior Management Team, Program Evaluator, Advisory Board, feedback from project participants and individuals requesting information and services)
5. Utilization of designated, independent evaluation to determine: (a) the reliability of data collection; (b) the integrity of methodology; (c) the degree to which consumers and family members report that programs are relevant; and (d) overall program effectiveness (Program Evaluator, Advisory Board, Scientific Advisors, NDSC, NIDILRR)
6. Prevention and early remediation of problems (Senior Management Team, Project Directors)

Entities Responsible for Developing and Implementing Performance Measures

A number of entities within and outside the TBIMS program will have important roles in achieving evaluation plan objectives. Complementary evaluation activities will take place at different organizational levels and with varying levels of formality. Following are descriptions of program evaluation **entities within the VCU TBIMS program:**

- **Project Directors.** The research Project Directors and the Dissemination Coordinator will monitor progress on a day-to-day basis, providing monthly written reports on accomplishments

relative to timelines to the Senior Management Team. Information about research project accrual rates and reasons for discontinuations or refusals to participate will be included in reports.

- **Senior Management Team.** The Senior Management Team will formally review the progress of each project on a monthly basis. Weekly meetings to review project implementation will also include an evaluation component.

Entities outside the TBIMS program will have a critical role. Roles of the VCU TBIMS Program Evaluator (J. Kim), Program Consultant (R. Rawlins), Advisory Board, Scientific Advisors, VCU's Senior Leadership, and NIDILRR program officials are delineated in the following text.

With primary responsibility, Dr. Kim, **Program Evaluator,** will maintain a centralized monitoring and evaluation system for the project. He will carefully monitor successes and identify challenges as the project moves forward. In conjunction with the Principal Investigators, he will make certain that organizational entities fully participate in the evaluation process. Dr. Kim will also assist in documenting the impact of research and dissemination activities by providing:

- Quarterly Implementation Assessments to determine the extent to which research and dissemination activities occur as specified in the timeline, (see *Plan of Operation* section).
- Annual Impact Assessments to determine the extent to which expected beneficial impacts have been achieved.

The Implementation Assessment will represent the more formative component of the evaluation process throughout the five-year funding period. The Senior Management Team will meet with Dr. Kim and Ms. Rawlins quarterly to conduct progress reviews. Reviews will identify necessary mid-course adjustments in project implementation. The results of the quarterly implementation assessments will be documented by Dr. Kim and included in a formal report, the Quarterly Implementation Progress Report. Progress reports will also be used as a monitoring tool to systematically identify barriers to full implementation and strategies for their removal. Dr. Kim will consult with the Scientific Advisors on an as-needed basis.

The Impact Assessment will be more summative in nature and address the extent to which the TBIMS project meets the overall goal of generating new research knowledge to improve treatment

and service delivery outcomes for individuals with TBI. The Senior Management Team, along with Dr. Kim, will formally assess the successes of the TBIMS project annually. Final conclusions about the overall success and impact of the project will be made in the last six months of funding, when research and dissemination activities are nearing completion.

Advisory Board Members will formally review the progress of all project activities at least three times during the first year of operation, and at least twice each year thereafter. Individual board members will take on evaluation responsibilities relevant to their expertise and interest. Evaluations will consist of reviewing and rating activities as specified by Dr. Kim. Advisory Board members will be provided with copies of evaluation reports as they are completed.

VCU Senior Leadership (Francis Macrina, Ph.D. and Peter Buckley, M.D.) is fully committed to making certain that objectives are completed in a timely fashion and within budget (see *Letters of Commitment and Support*, Appendix C). These individuals have enthusiastically offered their support and have fully committed the breadth of University resources. The Principal Investigators will keep University leadership fully informed about progress. When difficulties are encountered but not promptly remedied, senior leadership officials have offered their personal assistance to guarantee resolution.

National Data and Statistical Center will monitor quality of data contributed to the NDB (e.g., enrollment and follow-up rates; missing data and error reports). Their quarterly reports will be reviewed by the Senior Management Team and the Program Evaluator. The NDSC will assist in developing plans to address deficiencies, if needed.

NIDILRR Program Officials will be kept abreast of program advancement through verbal and quarterly written progress reports. Their direct involvement and advice to improve operations will be sought at appropriate times.

Feedback and guidance will also be sought from Directors and staff of other TBIMS and NIDILRR-funded programs, particularly when issues relate to their special expertise or mutual concerns. For example, Directors of projects with similar foci and objectives will be contacted for

guidance relating to preventing or resolving problems. The following table depicts important additional external sources of evaluative feedback:

▪ Reviewers of manuscripts; journal and book editors; conference program committees ▪ Evaluation forms completed by participants at sponsored conferences ▪ Feedback normally solicited and received during the course of close working relationships with BIAA ▪ Program visitors from other agencies and organizations ▪ Survey and e-mail information provided by Web site visitors ▪ Program accreditation site visitors

Performance Measures

Measures reflecting intended outcomes have been developed for program administration, research projects, and dissemination. The project work plan presented in the *Plan of Operation* section provides an important benchmark for evaluating progress. Following are descriptions of primary performance measures:

Program Administration
▪ the extent to which expenditures are consistent with the proposed budget
▪ the success of recruitment and retention of highly qualified, competent, and diverse applicants
▪ the success of training staff to effectively carry out responsibilities
Research Activities
▪ quarterly enrollment numbers (e.g., meets minimum specified for project)
▪ consent (> 80%) and follow-up rates (> 90%)
▪ completeness of data collection forms (e.g., < 5% missing data)
▪ error rates for data collection and entry (e.g., < 5%)
▪ fidelity of intervention maintained as described in Methodology, Implementation of Quality Control Procedures sections of *Research Activities*
Dissemination
▪ annual number of publications, presentations, and other products as specified in *Design of Dissemination Activities* section

The expected beneficial impacts for each major project activity were identified earlier in this proposal (see *Importance of the Problem* and *Design of Research and Dissemination Activities* sections). To ascertain success, Advisory Board members, including the Program Consultant, will rate the extent to which benefits have been achieved. Ratings will be compiled by Dr. Kim and presented in the annual Impact Assessment Reports.

Timetable for Completing Performance Measures

The following table depicts measurement activities which will be conducted by each entity and the frequency with which they will be completed.

Program Evaluation Entities	Performance Measurement Activities	Frequency
Project Directors	▪ Prepare written progress reports and submit to Senior Management Team	Monthly
Senior Management Team	▪ Review and evaluate written progress reports from Project Directors ▪ Review and analyze Implementation Assessments ▪ Review and analyze Impact Assessments	Monthly Quarterly Annually
Program Evaluator	▪ Prepare Implementation Assessments ▪ Prepare Impact Assessments	Quarterly Annually
Advisory Board Members	▪ Review and evaluate progress reports and dissemination materials ▪ Review Implementation and Impact Assessments	2-3 times Annually Quarterly/ Annually
VCU Senior Leadership	▪ Review and analyze Implementation and Impact Assessments and other reports	Quarterly
NDSC	▪ Prepare reports addressing benchmarks	Quarterly
NIDILRR	▪ Monitor progress and address concerns	As needed

Problem Identification and Remediation

With assistance from Scientific Advisors and Advisory Board members, we will be proactive by anticipating potential problems. Within the text of the research projects are sections entitled *Potential Problems and Solutions*. All staff involved in program evaluation will be alert to the concerns that have been outlined and the need to address them quickly and effectively. Our strategy for effective problem solving emphasizes:

- identifying potential problems through ongoing monitoring and routine assessment
- preventing problems before they occur
- carefully monitoring the success of proposed solutions
- addressing problems rapidly and effectively, using a team problem solving approach

In summary, the evaluation plan requires attentively monitoring progress, interrelating resources, and addressing concerns proactively. Effective organizational and management strategies will be identified and promoted within all aspects of the system. Internal and external groups will actively participate in a deliberate and systematic evaluation process focused on clearly delineated performance measures. Communication between group members and among groups is viewed as essential to program effectiveness. The VCU TBIMS will strive toward continuous improvement, diligently applying lessons learned from overcoming challenges to ensure future success.

IX. Project Staff

The success of this project depends on the qualities and capabilities of personnel. Consequently, personnel selection and assignments were based on a careful review of training, experience, and past productivity. Staff competencies are closely matched to project objectives. Considering our experience, we firmly believe that the knowledge, experience, ability, and time commitment of staff are more than sufficient to complete the formidable goals we have proposed.

Herein, detailed information is provided on recruitment practices, faculty, and staff. Selected biographical sketches are presented below; CV's for key personnel are presented in Appendix B. Detailed biographical sketches of Project Associates are provided in Appendix D. Specific time commitments of paid personnel were carefully considered and allocated as indicated in the table following project staff descriptions. Additional information regarding effort and funding allocations is provided in the *Budget Narrative* and *Project Staff* sections within each research project.

Recruitment Practices

We will work with other entities (e.g., DARS, BIAV, VCU Department of Rehabilitation Counseling) to recruit a diverse staff, including individuals with disabilities. Because Richmond is a large, diverse community, we are confident that we can effectively recruit a diversity of well-qualified individuals. VCU is an equal opportunity/affirmative action institution and does not discriminate on the basis of race, color, sex, sexual orientation, gender identity, age, religion, national origin, or disability. As a matter of policy and history, VCU is clearly dedicated to hiring individuals from under-represented groups, including individuals with disabilities, and providing training and advancement opportunities. For example, VCU enables all full-time employees to take up to six hours of academic credit each semester free of charge. Employment counseling, mentoring, and Employee Assistance Program (EAP) services are available and readily accessible.

The VCU TBIMS program has made a special effort to recruit and promote individuals with diverse backgrounds and we have been successful**.** For example, among our 14 proposed staff are four persons from minority backgrounds (K. Gary, J. Kim, M. Martinez, N. Hsu). Two proposed primary staff are persons with disabilities (K. Gary, J. Kim). With more than 15 years of experience

in the field of TBI, Dr. Gary will serve as our Dissemination Coordinator. Dr. Kim will serve as Program Evaluator for the TBIMS. Over the years, our TBIMS program has successfully recruited a number of other highly qualified research team members with disabilities (R. Everley, L. Brown, D. Bruer, B. Greenwald, T. Naumann, D. West). All but two of these individuals remain employed in the rehabilitation field with more responsibility and better pay.

Although all positions are currently filled, we have an established recruitment process for vacated positions built on the following cornerstones -

close working relationships with organizations and agencies serving persons with disabilities
development and implementation of clear, fair, and helpful policies that address the training needs of persons with disabilities
widespread dissemination of information about our policies to potential applicants and sources of applicants (e.g., internship and residency programs, university departments)

As part of the state personnel system in Virginia, VCU carefully follows all rules and regulations of affirmative action and equal employment opportunity (EEO). Recruitment for vacant positions is done through the VCU Human Resources and Equity and Access Services Offices with approval for hiring from the Dean. The search process and committee must be approved by the Dean and Provost prior to advertising for a position. Job notices are placed in a diversity of journals, newsletters, and newspapers, including *Insight to Diversity*. To further disseminate information about available positions, position descriptions are sent to leading University departments with programs in medicine, allied health, psychology, and education. Position availability notices are posted in at least one publication directed towards minority populations. Monitoring and compliance procedures provide a full system of checks and balances. The VCU Equity and Access Services Office routinely guides personnel searches. In addition, the Dean's Office will use the Inclusion and Enhancement Fund to augment salaries for new hires from diverse backgrounds as a way to continue to increase the diversity of our faculty and staff.

Personnel

Principal Investigator - Jeffrey S. Kreutzer, Ph.D., ABPP (key personnel) is a tenured Professor in the Departments of PM&R, Neurosurgery, and Psychiatry. Dr. Kreutzer completed a one year internship with Dr. Muriel Lezak in Portland, Oregon before graduating with a clinical psychology

doctoral degree. Following, he completed a one year postdoctoral fellowship in Clinical Neuropsychology and Rehabilitation Psychology at VCU. Dr. Kreutzer was a founding member of BIAV and the 2010 recipient of the National Academy of Neuropsychology's Lifetime Contribution to Neuropsychology Award. In 2013 he received the Innovations in Treatment Award from the North American Brain Injury Society. In 2017 he received the Jennett Plum Award for Clinical Achievement in the Field of Brain Injury Medicine, presented by the International Brain Injury Association. Since 1987, he has served as the Principal Investigator of the VCU TBIMS project. Dr. Kreutzer has been the lead investigator of two successful multi-center, module projects. His extensive research and grant administration experience also includes four years as a Co-Investigator for the National Traumatic Coma Data Bank and five years as Research Director of the VCU Rehabilitation Research and Training Center (RRTC) on Severe TBI. For more than 25 years, Dr. Kreutzer has conducted research on family response to TBI. He has spent the last decade developing and evaluating skill-building, psychological support, and educational interventions for survivors, couples, and families. With 170 peer-reviewed journal publications, 18 published books, and more than 500 conference presentations, his strong commitment to innovation and research advancement is evident.

Co-Principal Investigator - David Cifu, M.D. (key personnel) is Chairman and the Herman J. Flax, MD Professor of the Department of PM&R at VCU, Chief of PM&R Services of the VCU Health System, Founding Director of the VCU-Center for Rehabilitation Sciences and Engineering (VCU-CERSE), and Senior TBI Specialist for the U.S. Department of Veterans Affairs. He has been Co-Director of the VCU TBIMS program since 1991, and was instrumental in arranging the inter-agency agreement between NIDILRR and the VA Polytrauma Centers for collection of TBIMS data on veterans as well as civilians. Dr. Cifu is also the Principal Investigator of the VA/DoD $62.2 million Chronic Effects of Neurotrauma Consortium (CENC). In his more than 25 years as an academic physiatrist, he has delivered more than 525 national and international lectures, published more than 215 scientific articles, and co-authored or edited 30 books and book chapters.

He served as Editor-in-Chief of the 5th Edition of Braddom's Physical Medicine and Rehabilitation textbook (2015) and Braddom's Handbook of Rehabilitation Medicine (2017).

Project Coordinator - Jennifer Marwitz, M.A. (key personnel) is an Associate Professor in the Department of PM&R. She has served as the Project Coordinator for the VCU TBIMS since 1990 with intimate knowledge of data collection, quality assurance, and database systems. Ms. Marwitz is a member of the TBIMS Executive Committee (2002-present). She serves as Chair for the Data Management Committee (2012-present) and was Co-Chair from 2002-12. Recently, Ms. Marwitz has been an NDSC data quality site visitor and provided data collection training to the Richmond VA Polytrauma Center. She also served as Research Coordinator for the NIDRR-funded RRTC on Severe TBI. Ms. Marwitz has co-authored 48 peer-reviewed journal articles and made 40 presentations specifically related to TBI. Her diligence, scientific knowledge, efficiency, and organizational skills are well known to the rehabilitation community. Ms. Marwitz's highly developed interpersonal skills allow her to readily establish rapport with patients/families, and carry out responsibilities as liaison between university programs, collaborating agencies, and consumers.

Medical Director – William Walker, M.D. is an endowed Professor of PM&R and academic physician with board certification in PM&R. For more than a decade, he has been Medical Director of the VCU Concussion Care Clinic and Brain Injury Rehabilitation Services, and Principal Investigator for the Richmond Defense and Veterans Brain Injury Center (DVBIC) at McGuire Veterans Affairs Medical Center (VAMC). He has a strong track record of clinical research including leadership positions on large grants, including several multi-center studies, and over 50 peer-reviewed publications. Dr. Walker was recently awarded a NIH R21 grant, "Practical Prognostics: building clinically useful predictive models for long-term functional outcome after TBI," funding to complete secondary analyses of the TBIMS NDB.

Biostatistician – Adam Sima, Ph.D. is an Assistant Professor of Biostatistics at VCU whose work includes development of statistical methods used in clinical trials, longitudinal datasets, and model selection. Dr. Sima teaches and advises graduate students in applied statistics and statistical consulting, and also mentors post-doctoral fellows and junior faculty who are new to research,

including those interested in TBI rehabilitation. He has provided advanced statistical consultation to faculty, staff, and students and served as the biostatistician for the VCU TBIMS since 2013. He continues to work on several TBIMS NDB studies in addition to the site-specific projects. Dr. Sima is the lead statistician on two additional grants: a NIH-funded grant exploring predictive modeling for 1, 2, and 5 year outcomes using the TBIMS, and an armed services-funded clinical trial exploring the use of hyperbaric oxygen therapy for Marines who have sustained a TBI and have PTSD. He has 30 manuscripts published or under review in peer-reviewed journals including nine relating to rehabilitation for patients with TBI. In addition, Dr. Sima serves as Senior Statistical Consultant for two international journals, *Brain Injury* and *NeuroRehabilitation.*

Research Associate – Nancy Hsu, Psy.D. is an Assistant Professor and board certified rehabilitation psychologist in the Department of PM&R at VCU. She joined the faculty in 2007 after completing a two-year postdoctoral fellowship as a NIDILRR-funded Advanced Rehabilitation Research and Training (ARRT) fellow, under the supervision of Dr. Jeffrey Kreutzer. As the assistant director of the Neuropsychology and Rehabilitation Psychology clinic, Dr. Hsu is involved in the evaluation and treatment of children and adults with TBI, cancer, stroke, and other neurological disorders. She has served as a research interventionist for VCU's TBIMS RAI project. Furthermore, Dr. Hsu serves as the consulting neuropsychologist on the DOD and VA-funded Chronic Effects of Neurotrauma Consortium and participates in the NINDS-funded, multi-center Transforming Research and Clinical Knowledge in TBI (TRACK-TBI) study as a neuropsychologist, administering neurocognitive tests to participants. Dr. Hsu has published peer-reviewed manuscripts, co-authored book chapters, and presented at professional conferences.

Research Associate – Ana Mills, Psy.D. is a licensed clinical psychologist and Assistant Professor in the Department of PM&R at VCU. Dr. Mills received her doctoral degree from the Institute for Graduate Clinical Psychology at Widener University in 2012 and then completed a NIDILRR-funded ARRT post-doctoral fellowship at VCU. She specializes in the neurocognitive evaluation and psychotherapeutic treatment of individuals with acquired neurological disorders, with emphasis on TBI. She also regularly consults with the Departments of Neurology and Neurosurgery for the

pre-surgical evaluation of patients with epilepsy and Parkinson's disease. Dr. Mills' research activities include investigating the efficacy of novel psychoeducational interventions and promoting resilience after TBI. She is currently a co-investigator on a Michael J. Fox Foundation-funded study to examine the feasibility of novel DBS intervention to treat cognitive symptoms in Parkinson's disease. She has authored a number of peer-reviewed articles, book chapters, and presentations on neuropsychology, TBI, and rehabilitation. Additionally, she is a referee for the journals *Brain Injury* and *Journal of Neurotrauma*, and a support group facilitator for BIAV.

Research Associate – Daniel Klyce, Ph.D. is a licensed clinical psychologist and Assistant Professor in the Department of PM&R. Dr. Klyce completed a fellowship in rehabilitation psychology in the Department of PM&R at the University of Washington, where he was based at Seattle's Harborview Medical Center. He has co-authored articles published in the *Journal of Head Trauma Rehabilitation* and *Archives of Physical Medicine and Rehabilitation* related to resource facilitation for individuals with TBI and coping skills training for individuals with TBI and family caregivers. Dr. Klyce is an active member of professional organizations such as the American Psychological Association's Division for Rehabilitation Psychology and the American Congress of Rehabilitation Medicine. Since 2013, he has served as the rehabilitation psychologist for the inpatient brain injury rehabilitation unit at VCU. In this role he works daily with individuals with TBI and their family members, while also making substantive contributions to VCU's teaching, research, and service missions.

Program Evaluator – Jeong Han Kim, Ph.D., CRC is an Assistant Professor in the Department of Rehabilitation Counseling. Dr. Kim obtained his doctoral degree from the University of Wisconsin-Madison, and served as Program Director of the Rehabilitation Counseling Program at Ball State University prior to joining VCU. His research and scholarly accomplishments include 26 peer-reviewed publications and numerous regional and national presentations. Dr. Kim's research expertise relates to methodology and program evaluation in the following areas: 1) quantitative research methodology; 2) inferential statistics; 3) design and execution of psychosocial research; 4) use of various statistical packages; 5) psychometric validation of psychological instruments; and 6)

managing and collaborating with research teams to execute multiple projects in a timely manner. He has worked in a variety of settings including independent living centers, vocational rehabilitation agencies, VAMC's, and long-term health care agencies. In addition, Dr. Kim served as PI of an RSA long-term training grant. Perhaps most relevant to the present application is his experience as program evaluator for the VCU TBIMS grant activities (2012-17). Dr. Kim is a retired first Lieutenant from the Republic of Korea Army with firsthand experience of disability after being treated for burns, undergoing an amputation, and living with hearing loss after a bomb explosion in 1997. As a member of a minority community and as an individual who has gone through the rehabilitation process, Dr. Kim will bring an invaluable perspective to the VCU TBIMS program.

Dissemination Coordinator – Kelli Williams Gary Ph.D., MPH, OTR/L, has 20 years' experience in the rehabilitation field, including working as an occupational therapist in two academic medical centers and a VAMC, as well as serving as rehabilitation director in a skilled nursing facility. During her 3-year tenure with VCU PM&R's Advanced Rehabilitation Research Training grant, Dr. Gary completed research projects relating to judgment and safety issues, and racial and ethnic differences in receipt of services after TBI. Her personal experience has allowed her to develop a special sensitivity to the needs of minority group members and persons with disability. Dr. Gary sustained a severe TBI in 1990 and subsequently completed requirements to obtain BS, MPH, MS, and Ph.D. degrees after her injury. She worked extensively with Dr. Niemeier's Acute Cognitive and Neurobehavioral Intervention research team, preparing project reports and developing research publications. Dr. Gary is actively involved in the brain injury community. She co-facilitates a brain injury support group for BIAV and was a member of the Virginia Brain Injury Council (VBIC) from 2007-2011, for which she served as Vice-Chair. Currently, she is on the Board of Directors of BIAV.

Research Assistant – Abigail Welch, B.S., B.A. obtained bachelors' degrees in both Psychology and Gender, Sexuality, and Women's Studies from VCU. She has worked in the Department of PM&R for the past year and a half, and is responsible for the Form 1 and Form 2 data collection and entry for the TBIMS NDB, as well as working on our site-specific projects. Before joining the

Department, Ms. Welch gained research experience by studying racial discrimination in health and food service industries, and gained job experience by counseling children with special needs.

Research Assistant – Marie Grace Martinez, B.A. obtained bachelors' degrees in both Psychology and French from the University of Virginia, where she gained research experience focused on implicit social psychology and developmental psychology. She has worked on the VCU TBIMS for almost a year and is responsible for data collection for the TBIMS NDB, including the coordination of patient interviews and collection, preparation, and entry of Form 1 and Form 2 data.

Research Assistant – Naghmeh Moadab, M.S. obtained her Master's degree in Clinical Psychology from Virginia State University. She has been employed in the Department of PM&R since 2014. Under Dr. Kreutzer's supervision, Ms. Moadab provides neuropsychological testing services to persons with TBI. Related to the currently funded TBIMS, she inspects the TBI database for prior research completion and provides extensive review of records for each patient seen in the clinic to determine eligibility. When deemed eligible, she provides the patients with pertinent packets of information and notifies senior staff.

Grant Administrator – Christie Atkins is Finance Manager for the Department of PM&R and manages all budgetary, administrative, and contractual aspects of department research programs. Ms. Atkins has ten years' experience in sponsored research and budget administration. Currently, she works closely with project directors, managing several million dollars in grant funding. Ms. Atkins has had primary accounting and support responsibilities for the VCU TBIMS project.

The proposed project involves participation in five major program activities: (1) Administration and Dissemination; (2) National Database; (3) Resilience and Adjustment Intervention; and (4) a multi-center Collaborative Module. The following table provides staff time commitments.

	Administration Dissemination	**National Database**	**Resilience Intervention**	**Collaborative Module**	**Total**
Kreutzer	10%	2%	12%	6%	30%
Cifu	5%	5%	-	-	10%
Marwitz	25%	20%	15%	20%	80%
Walker	-	10%	-	-	10%
Sima	-	2%	5%	8%	15%
Hsu	-	-	30%	-	30%
Mills	-	-	30%		30%

	Administration Dissemination	National Database	Resilience Intervention	Collaborative Module	Total
Klyce	-	8%	-	-	8%
Kim	5%	-	-	-	5%
Gary	15%	-	-	-	15%
Welch	-	35%	45%	-	80%
Martinez	-	75%	5%	20%	100%
Moadab	-	-	5%	-	5%
Atkins	4.5%	-	-	-	4.5%

Project Associates:

Project Associates will be involved in many important aspects of program implementation. The group includes Research Associates, Allied Health Professionals, Psychologists, Educators, Data Collectors, and Dissemination Facilitators. Some will contribute time to the TBIMS, as outlined in their University job descriptions which emphasize devotion to service, education, and research activities. Many associates describe the VCU TBIMS program as an excellent opportunity to be involved in exciting scientific research with beneficial outcomes. A listing of all project associates is provided in the table below. Detailed biographical sketches are provided in Appendix D.

Woodford Beach, PhD CCC/SP	Alice Jesudian, MD	Randall Merchant, PhD
Karen Brooke, MT	John Kregel, EdD	F. Gerard Moeller, MD
William Carne, PhD	Richard Kunz, MD	Cynthia Rolston, PhD
Karen Chandler, MSW	Erin Lucero, BA	Macon Sizemore, PT, MHA
Benjamin, Darter, PT, PhD	Paul Mazmanian, PhD	Alex Valadka, MD
Charlotte Gilman, RN, BSN	Scott McDonald, PhD	John Ward, MD, MSHA
Robert S. Graham, MD	Patrick McGowan, MD	Paul Wehman, PhD
Katherine Inge, PhD, OTR	Brian McMahon, PhD	Harold F. Young, MD

In summary, VCU TBIMS staff are a diverse group of highly trained, experienced, and knowledgeable interdisciplinary professionals. Each is committed to making certain that program objectives are accomplished effectively and efficiently.

X. Adequacy and Accessibility of Resources

VCU is a public research university with 12 major schools, including the School of Medicine which manages the VCU Health System (VCUHS). Receiving more than $156 million a year in sponsored research funding, the University has an impressive infrastructure to support researchers. Operating since 1838, VCUHS is the only academic medical center in Central Virginia and a national leader. With the region's only Level I trauma center, 805 inpatient beds and a network of

outpatient clinics, 750 physician/faculty members offer state-of-the-art care in more than 200 specialty areas. VCUHS records over 50,000 admissions and more than 630,000 outpatient visits annually, and is the largest single provider of indigent care in the state (providing nearly one-third of Virginia's indigent care). Uninsured patients represent 20 percent of all patients treated, substantiating the strong commitment to serve persons regardless of ability to pay.

Department of Physical Medicine and Rehabilitation. The Department of PM&R is chaired by Dr. Cifu, TBIMS Co-PI. Dr. Cifu will ensure that project staff have full access to space, equipment, and administrative support to complete their work. The Department is one of the oldest, most well-established university PM&R departments in the country. Comprehensive inpatient and outpatient services are provided to patients with a variety of neurological, musculoskeletal, and other conditions, including TBI, stroke, spinal cord injury, burns, and cancer.

Housed within the Department of PM&R is CERSE, the VCU Center for Rehabilitation Science and Engineering. Funded by VCU's Office of Research and the School of Medicine, CERSE provides infrastructure for interdisciplinary research project design, implementation, and management. Staff have advanced expertise in rehabilitation research design, statistical analysis, database development, participant enrollment and tracking, and grants management. The expertise of CERSE faculty and staff will be readily available to the TBIMS. For example, Dr. Sima, CERSE Statistical Services Director, will also serve as the biostatistician for the present proposal.

Interdepartmental Relationships. One of the major strengths of our ongoing TBI research and clinical program is the quality of interdepartmental and interdisciplinary relationships. This fact is probably best exemplified by our relationships with Neurosurgery. Underlying this relationship is a mutual commitment to basic science, clinical research, and academic excellence. This commitment is evident in funding allocations through federal grants and pharmaceutical research projects.

Excellent relationships have also been developed with a diversity of other medical and therapy departments including Psychiatry, Neurology, Physiology, Anatomy, Rehabilitation Counseling, Internal Medicine, Occupational Therapy, Speech-Language Pathology, Physical Therapy, and

Nursing. A complete spectrum of learning opportunities is available to staff through these departments via regularly scheduled seminars, grand rounds presentations, and conferences. VCU faculty and staff have access to the Center for Health Disparities resources, a partnership between VCUHS and the University. The Center facilitates research, education, access to health care services, and workforce diversity initiatives to eliminate health disparities.

Quality of Past Grant Performance

In September 1987, VCU was funded by NIDRR as one of five TBIMS centers. In 1992, 1998, 2002, 2007, and 2012 NIDRR again funded VCU as a TBIMS. Dr. Kreutzer has served as the Principal Investigator for the nearly 30 years of funding managed through the Department of PM&R. J. Marwitz has served as chair or co-chair of the TBIMS Data Committee since 2002. For the NDB, VCU has collected data about outcomes throughout the continuum of care for more than 700 research participants (for more information, see Appendix E, *VCU Contribution to National Database and Continuum of Care*). Over the years, VCU has developed empirically-based programs for academic and vocational reentry, community support, resilience and adjustment, prevention of substance abuse and neurobehavioral dysfunction, and family/caregiver/couples support. Collaboration with local schools, BIAV, and DARS has helped us improve academic success, increase socialization opportunities, and improve community integration and family functioning.

VCU served as the coordination site for neuropsychological outcome data among the Model Systems from 1987-1997, developing quality control and documentation procedures, and facilitating communication between the systems. VCU also developed a test administration, scoring, and interpretation manual for use by other TBIMS centers. Preparation of neuropsychological data summaries for all centers was an important responsibility. More recently, VCU served as the lead for the Emotional Module of the TBIMS, leading a six-center, collaborative study on caregiver distress and satisfaction with life. In the current grant cycle, VCU serves as lead for the Resilience Module, a five-center, collaborative study on resilience in the first year postinjury. J. Kreutzer and J. Marwitz developed the research proposals and protocols, data collection forms, questionnaires,

and a syllabus. In addition, J. Kreutzer led meetings at Project Directors' meetings and regular teleconferences, and prepared data reports and publications related to the studies.

Besides multi-center collaborative research, staff from the VCU TBIMS project have completed research on neurobehavioral issues, substance abuse, balance and ambulation disorders, re-hospitalization, employment outcome, family functioning, headache, and pharmacologic approaches to treatment of depression and seizures. The quality of VCU's leadership has been officially recognized by the TBIMS Project Directors. Every two years, the TBIMS presents an award for "Best Scientific Publication using the NIDILRR TBI Model System National Database." Two awards have been given to VCU (Walker and Kreutzer).[43,257]

In addition to the TBIMS, the Department of PM&R has had numerous grant awards including: NIH-funded RO1 on Acute Neurobehavioral and Cognitive Intervention for TBI (2008-2012), Virginia Incarcerated Youth with Brain Injury Program (Commonwealth Neurotrauma Initiative, 2009-2012), and NIH-funded TBI Clinical Trials Network center grant (2002-2011). Dr. Kreutzer manages a NIDILRR-funded Advanced Rehabilitation Research Training Grant (1987-2003, 2005-present). In addition, Dr. Cifu serves as PI for the Chronic Effects of Neurotrauma Consortium (CENC) jointly funded by the Departments of Defense (DOD) and Veterans Affairs (VA) for $62.175 million (2010-present). Clearly, VCU has a long and successful history of completion of research and training grants. Following is a listing of currently funded TBI research programs within the Department of PM&R.

Ongoing Funded TBI Research Projects
Advanced Rehabilitation Research Training (ARRT); funding source NIDILRR
Biomarkers of Injury and Outcome in Pro-TECT III (BIO-ProTECT); funding source NIH/NINDS
The Chronic Effects of Neurotrauma Consortium (CENC); funding source DOD and VA
COSBID: Cooperative Study on Brain Injury Depolarizations; funding source DOD
Defense and Veterans Brain Injury Center, funding source DOD through subcontract with General Dynamics Information Technology (GDIT)
Evaluation and Diagnosis of Potential Research Subjects with TBI; funding source DOD through subcontract with GDIT
Longitudinal Study of Outcomes for CENC; funding source DOD and VA
Minimally Invasive Surgery plus rt-PA for ICH Evacuation (MISTIE III); funding source NIH/NINDS

Ongoing Funded TBI Research Projects
Practical Prognostics: Building Clinically Useful Predictive Models for Long-term Functional Outcome after TBI; funding source NIH
Progesterone for TBI: Experimental Clinical Treatment Trial (ProTECT III); funding source NIH/NINDS
A Randomized, Double-Blind, Placebo-Controlled, Dose-Escalation Study of NNZ-2566 in Patients with TBI; funding source Neuren Pharmaceuticals Ltd. and DoD
A Randomized Clinical Trial of Glyburide (RP-1127) for TBI; funding source DOD
Rehabilitation Research and Training Center (RRTC) on Employment for Persons with Physical Disabilities; funding source NIDILRR
Safety and effectiveness of the PoNS™ 4.0 Device for Cranial Nerve Noninvasive Neuromodulation (CN-NINM) Training in Subjects with a Chronic Balance Deficit Due to Mild-to-Moderate TBI; funding source DOD and Private Industry (Helius Medical Technologies)
Targeted Transcranial Magnetic Stimulation for Cognitive Rehabilitation after TBI; funding source Commonwealth of VA, Dept. of Aging & Rehabilitation Services (Commonwealth Neurotrauma Initiative Trust Fund)
Transforming Research and Clinical Knowledge in TBI II (TRACK-TBI II); funding source NIH/NINDS

Access to Clinical Populations

VCU provides a comprehensive continuum of care for persons with TBI and their families. VCUHS is one of five Level I trauma centers in Virginia and the only one in the region. The Level I designation indicates the most severe cases of TBI are treated here. Our system of care includes individuals with mild, moderate, and severe injuries. Comprehensiveness, interdisciplinary communication, and integration of a continuum of services are important philosophies which have guided program development at VCU. Guided by consumer needs assessments, the VCU system of care continues to evolve, and partnerships with other rehabilitation agencies are growing.

As outlined in the *Research Activities* section, we will have appropriate access to individuals with TBI starting in the Intensive Care Unit. Neurosurgery nursing staff (C. Gilman, R.N.) and PM&R consult staff (P. McGowan, M.D.) will identify all persons with a TBI diagnosis admitted to VCUHS. Dr. Cifu and Dr. Walker both have joint appointments within McGuire VA Medical Center's Defense and Veterans Brain Injury Center. Drs. Cifu and Walker can ensure that McGuire VAMC will provide access to their outpatients for our proposed site-specific project.

A review of VCUHS records indicates that our ED receives an average of 120 TBI-related visits per month. Of those ED visits, one-third are mild (admission GCS 13-15) and not admitted. Of

hospital admissions, 30-40 per month are categorized as moderate-severe TBI with the TBI listed as primary reason for admission.

The table that follows provides data regarding the number of patients with mild, moderate and severe injuries admitted to the Brain Injury Rehabilitation Unit since 2014. As previously mentioned, VCU is collaborating with Sheltering Arms Rehabilitation Hospital to build a 114-bed acute rehabilitation center. Estimated completion date is 2019. Based on data from Sheltering Arms, we expect a 50% increase in TBI admissions.

Year	Severe Injury	Moderate Injury	Mild Injury	Total Number
2014	51	24	4	79
2015	66	15	7	88
2016	60	19	8	87

Patients also enter the VCUHS system of care through referrals from health professionals outside the system. Information regarding the number of patients with mild, moderate and severe injuries seen at the Brain Injury Outpatient Services Center are provided below.

Year	Severe Injury	Moderate Injury	Mild Injury	Total Number
2014	48	41	124	213
2015	55	36	149	240
2016	61	29	138	228

Budget Narrative

Budget information for the five year funding period is presented in spreadsheet format on the following pages. The first spreadsheet, "NIDILRR Budget," details funding requested from the U.S. Department of Health & Human Services (DHHS). As indicated, the requested Total Direct Cost is $352,234 per year for five years. Total Indirect Costs are $112,715 per year for five years, and the Total Costs is $464,949 per year for a cumulative total of $2,324,745. The second spreadsheet "Overall TBIMS Budget," indicates effort levels for personnel with information regarding proposed federally supported effort, VCU cost share supported effort, and Total Effort. In planning this proposal, funding and effort allocations were carefully considered by project management and administrative staff. Effort and funding allocations reflect program activity requirements and timelines, staff responsibilities, and our nearly 30 years' experience as a TBIMS center.

Cost Share:

Virginia Commonwealth University (VCU) is firmly committed to supporting the proposed TBIMS as indicated by the cost share amounts shown on the third spreadsheet "VCU Cost Share Budget". Each year, for five years, the university will contribute $182,986, a total of $914,932. The cost share amount equals 28% of the total amount requested from NIDILRR. The Total Budget for the five year project, inclusive of both federal funds and cost-shared funds, is $3,239,676.

Cost share is used entirely to support faculty effort. The VCU Cost Share budget details supported effort as well as cost share supported annual salary, fringe benefits, and total costs. Fringe benefits are calculated at the current VCU/DHHS negotiated rate of 37.2% of salaries. The fringe benefit package includes: annual and medical leave; health, dental, and life insurance; workman's compensation; retirement savings; and social security. VCU will cost share $49,614 annually in fringe benefits, a total of $248,072 over the course of the project.

Major Project Activities and Effort Allocations:

The fourth spreadsheet, "Staff Effort Allocation," details each of the five major program activities: (1) Administration and Dissemination; (2) National Database; (3) Resilience and Adjustment Intervention; and (4) Collaborative Module. NIDILRR has indicated that module

project activities will be determined after the announcement of awards. The agency has required that at least 15% of the total budget should be set aside for the Collaborative Module project. NIDILRR's requirements and the resources necessary to successfully complete program activities have been carefully considered to determine effort allocations.

Program Income:

Any program income funds generated under this award will be utilized under the additional cost method as set forth at 34 CFR 74.24(b)(1), which allows the income to be used for costs which are in addition to the allowable costs of the project and further the broad objectives of the Federal statute under which the grant was made. Estimated program income for project year one will be approximately $3,000. We anticipate that the program income generated each year will increase as new products (e.g., educational guides, manuals) are produced for dissemination. Program income funds will be utilized to defray costs above the funding level provided by DHHS. In addition, program income funds will be expended for other costs identified as necessary to ensure that project activities are completed and expanded to the greatest extent possible, furthering the objectives of the Federal statute of this award.

Follow-Up Data Collection Costs:

Within the grant application package, NIDILRR has requested an estimate of the costs for follow-up data collection. Staff effort allocations for the National Database are indicated on the Staff Effort Allocation spreadsheet. Considering effort levels, the number of patients requiring follow-up, and the cost of research incentives, we estimate the need for $244,265 annually, a sum of $1,269,136 over the five year project funding period.

Requested Funds

The following narrative provides information on funds requested from the DHHS. Information is provided regarding personnel and salary allocations, fringe benefits, travel, supplies, and other costs.

1. Personnel

As indicated in the *Project Staff* section, VCU TBIMS key personnel have been a very stable entity. Dr. Kreutzer has been the Principal Investigator since 1987, Dr. Cifu has been Co-Principal Investigator since 1992, and Ms. Marwitz has more than 25 years of experience as Project Coordinator. The NIDILRR Budget spreadsheet for this section provides detailed information regarding federally supported effort and salary. Annual salary costs of $234,776 per year are requested, a sum of $1,173,879 over the five year funding period.

Following are descriptions of personnel including information about: (1) requested and **cost share funding**; (2) effort; and (3) primary responsibilities. Detailed information regarding staff responsibilities and qualifications is provided in the *Plan of Operation* and *Project Staff* sections, as well as in the individual descriptions of the research projects (see "Project Staff" in *Research Activities*).

- Principal Investigator – Jeffrey S. Kreutzer, Ph.D., will devote a total of 30% effort to the TBIMS program. Funds are requested for 5% of Dr. Kreutzer's time. He will serve as primary manager of the VCU TBIMS program as well as Director of the Resilience and Adjustment project. Dr. Kreutzer will be responsible for all administrative and dissemination activities. He will oversee staff training, data collection and quality control for research activities. Funds requested for salary support of Dr. Kreutzer are $9,350 annually. Total funds requested for Dr. Kreutzer salary support are $46,750 over a period of five years. An additional 25% effort annually will be supported by cost share.
- Co-Principal Investigator – David X. Cifu, M.D. has a joint appointment with VCU and VAMC. He will devote 10% contributed effort from his VCU appointment to this project. As Co-Principal Investigator, Dr. Cifu will share primary program management responsibilities with

Dr. Kreutzer. He will share responsibility for administrative and dissemination activities. Dr. Cifu will also be responsible for coding CT scans and ensuring the quality of medical data collection for the National Database. Dr. Cifu's entire effort will be provided to the grant via university cost share.

- Project Coordinator - Jennifer Marwitz, M.A., will devote 80% effort to the proposed project. Her substantial effort, and prior experience as coordinator, will ensure the successful completion of program activities. Ms. Marwitz will have a major role in helping the Principal Investigators manage, implement, and coordinate program activities. She will coordinate and implement data collection activities, monitor follow-up and enrollment rates, and help supervise Research Assistants (M. Martinez, A. Welch and N. Moadab). Funds requested for salary support of Ms. Marwitz are $78,668 in years one through five. Total salary requested is $393,340.
- Medical Director – William Walker, M.D., will devote 10% contributed effort to the project annually. Dr. Walker will introduce eligible patients to the TBIMS research projects and assist Research Associates with data collection. He will also help Research Associates contact "hard to reach" participants for follow-up data collection. Finally, Dr. Walker will participate in dissemination activities related to publicity of research. Dr. Walker's entire effort will be provided to the grant via university cost share.
- Biostatistician – Adam Sima, Ph.D., will devote 15% effort to the research project. Dr. Sima will provide and supervise statistical analyses, and interpret the results for reports and dissemination. Funds requested for salary support of Dr. Sima are $15,450 annually. Total funds requested for Dr. Sima are $77,250.
- Research Associate - Ana Mills, Ph.D. will devote a total of 30% effort to the project. Funds are requested to support 20% of Dr. Mills' time. She will serve as an interventionist for the Resilience and Adjustment project. Salary support is requested at $19,200 annually. Total funds requested for Dr. Mills' are $96,000. In addition, 10% of Dr. Mills' effort will be supported via university cost share.

- Research Associate - Nancy Hsu, Ph.D. will devote a total of 30% effort to the project. Funds are requested to support 20% of Dr. Hsu's time. She will serve as an interventionist for the Resilience and Adjustment project. Salary support is requested at $22,337 annually. Total funds requested for Dr. Hsu are $111,684. In addition, 10% of Dr. Hsu's effort will be supported via university cost share.
- Research Associate – Daniel Klyce, Ph.D., will devote 8% effort to the research project. Dr. Klyce will coordinate inpatient rehabilitation enrollment and data collection for the National Database. Funds requested for salary support for Dr. Klyce are $7,580 annually. Total funds requested for Dr. Klyce are $37,900.
- Project Evaluator – Jeong Han Kim, Ph.D., will devote 5% effort to the proposed project. Dr. Kim will plan, implement, and oversee program evaluation activities. An amount of $4,692 is requested for years one through five for a total of $23,460.
- Dissemination Coordinator – Kelli Williams Gary, Ph.D., MPH, OTR/L will devote 15% effort to the proposed project. Dr. Gary has primary responsibility for the development and implementation of dissemination activities. Funds requested for salary support are $13,650 annually. Total funds requested for Dr. Gary are $68,250 over the five year project span.
- Research Assistant – Marie Grace Martinez, B.A. will devote 100% effort to this project. Her responsibilities will include data collection and follow-up for the National Database. She will also coordinate patient interviews and the collection, preparation, and entry of Form I and Form II data. In addition, she will assist Ms. Welch with project activities for the Resilience & Adjustment project. The sum of $33,000 annually is requested for salary support. Total funds requested for Ms. Martinez are $165,000.
- Research Assistant – Abigail Welch, B.S., B.A. will devote 80% effort to the project. Her primary responsibilities will include the Form I and Form II data collection and entry for the TBIMS National Database, as well as helping coordinate and carry out the Resilience & Adjustment project. Salary support of $26,400 annually is requested. Total funds requested for Ms. Welch are $132,000.

- Research Assistant – Naghmeh Moadab, M.S., will devote 5% effort to the project. Based in the Brain Injury Outpatient Center, she will help recruit research participants and serve as a liaison between clinical and research staff. Salary support of $1,785 annually is requested. Total funds requested for Ms. Moadab are $8,925.
- Grant Administrator – Christie Atkins, will devote 4.5% effort to the proposed project. Working closely with the Principal Investigator, she will provide support in the areas of fiscal administration and purchasing. The amount of $2,664 is requested annually, a total of $13,320 over the five year funding period.

2. Fringe Benefits

Fringe Benefits are calculated at the current VCU/DHHS negotiated rate of 37.2% of salaries for full-time faculty and classified personnel and 7.9% for hourly personnel. VCU's fringe benefit package includes annual and medical leave; health, dental, and life insurance; workman's compensation; retirement savings; and social security. Funds in the amount of $87,335 annually; a total of $436,675 is requested over five years to cover fringe benefits costs for the project.

3. Travel

A sum of $5,000 annually is required to pay travel costs for project staff to attend semi-annual Project Directors' meetings, professional meetings and conferences, and other dissemination-related activities. The projected costs relate to airfare, lodging, meals, airport parking, taxi or other transportation at the destination. All travel expense will be reimbursed in accordance with the State of Virginia travel regulations at the approved rates in effect at the time of travel.

4. Equipment

VCU is not requesting funds for the purchase of equipment. Equipment needed for project implementation, including computers, networking software and hardware, and telecommunication equipment are provided through the VCU infrastructure. Additional information about VCU resources is provided in the *Adequacy and Accessibility of Resources* section of this proposal.

5. Supplies

The supply budget will be utilized to support the development of dissemination materials and other consumable supplies and materials required by project staff. Supplies will be needed to produce reports, technical assistance materials, journal articles, and conference presentation materials. Supplies will include printer toner, paper, envelopes, file folders, pens, pencils, staples, paper clips, CD's, and DVD's. Supplies have been budgeted at $2,220 in years one through five, a total of $11,100 over the five year funding period.

6. Contractual:

Duplication, Printing, etc. - Funds in the amount of $1,800 per year in years one through five are requested to support printing, duplication, and other project-related contractual charges. Funds will be utilized for the printing, duplication, and dissemination of items such as newsletters, research reports, informational booklets, project announcements, and program brochures for consumer and professional audiences. Small items such as one or two-page documents will be processed through the VCU print shop. Others will be competitively bid to obtain the best price available and to ensure quality materials are procured under the project. Additionally funds will be utilized to purchase books, training materials, and videos produced by other agencies useful to staff for completion of project objectives. The total for contractual expenses requested over the five year funding period is $9,000.

7. Construction

No funds for construction are requested.

8. Other:

- Advisory Board – Annually, $1,000 is requested, to provide board members an honorarium. Board members will be reimbursed for their time and travel expenses related to attending board, planning, and other meetings.
- Publications – Funds in the amount of $3,319 annually is requested to support the costs of open access publications and other publication- related charges. The publications will be peer reviewed, published by a journal and will arise from data analyzed in this project.

- Consultants – An amount of $1,200 is requested annually to support the activities of one program consultant, R. Rawlins. She will provide 16 hours of effort to the project each year. The funds will be used to reimburse her for her time and travel.
- Research Incentives – Ensuring that research participants return for follow-up visits can be challenging. Some have concerns about travel costs, while others prefer not to take off time from work. To increase compliance with measurement and follow-up protocols, we will provide each participating individual $50 - $200 for completing each measurement protocol, depending on travel costs. Detailed information about research incentives is provided in the *Research Activities* section. Considering anticipated accrual and attrition rates, the following sums are budgeted annually for the National Database ($7,800), Resilience and Adjustment Intervention ($3,864), and Collaboration Module ($3,120). Annually, a total of $14,784 has been budgeted for a total of $73,920 for the five year project funding period.
- Long Distance Telephone – Funds are requested to support telephone expenses relating to necessary project staff communication with research participants, collaborating researchers outside the university, Advisory Board members outside the local region, and with NIDILRR program staff. VCU employees are provided with a telephone authorization code, which ensures that TBIMS-related calls are appropriately charged. VCU utilizes the SCATS system that results in substantial savings for long distance. Funds of $800 per year are budgeted to support long distance and conference call costs.

9. Total Direct Costs

The total annual direct cost requested for years one through five is $352,234. The five-year total direct costs will be $1,761,170.

10. Indirect Costs

VCU has an approved DHHS Federal Rate Agreement on-campus Facilities and Administrative (F&A) rate of 55% of Modified Total Direct Cost (MTDC). However, **VCU is firmly committed to supporting the proposed TBIMS and has agreed to reduce the on-campus Facilities and**

Administrative (F&A) rate to 32% on Modified Total Direct Costs (MTDC) for this project. The **$404,963 reduction** is a further indication of VCU's support for the project. The requested F&A for year one of this project equals $112,715 and the five-year total project requested F&A is $563,575. Per VCU policy, F&A is not charged on rent, equipment over $5,000, tuition, and is only charged to the first $25,000 of a subcontract.

11. Training Stipends

VCU is not requesting funds for training stipends.

12. Total Costs

A total of $464,949 is requested annually for years one through five. The five-year total funding request is $2,324,745.

In conclusion, we believe that project operations will be cost effective for several reasons. First, we will build on well established resources. Second, in order for the stated outcomes and accompanying benefits to occur, we will utilize highly competent, diligent, and experienced staff. To enhance the value of our efforts, we will focus on widespread dissemination and develop programs that can easily be replicated by others.

Traumatic Brain Injury (TBI) Model Systems
CFDA Number: HHS-2017-ACL-NIDILRR-DPTB-0204
National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)
Principal Investigator: Jeffrey Kreutzer, PhD
2017 Application-Proposed

NIDILRR BUDGET

Budget Period: 10/01/2017 - 09/30/2022

PERSONNEL	Title	NIDILRR EFFORT	Federal YEAR 1 BUDGET	Federal YEAR 2 BUDGET	Federal YEAR 3 BUDGET	Federal YEAR 4 BUDGET	Federal YEAR 5 BUDGET	TOTAL Federal BUDGET
J. Kreutzer	Principal Investigator	5%	$ 9,350	$ 9,350	$ 9,350	$ 9,350	$ 9,350	$ 46,750
D. Cifu	Co-Principal Investigator	0%	$ -					$ -
J. Marwitz	Project Coordinator	80%	$ 78,668	$ 78,668	$ 78,668	$ 78,668	$ 78,668	$ 393,340
W. Walker	Medical Director	0%	$ -					$ -
A. Sima	Statistician	15%	$ 15,450	$ 15,450	$ 15,450	$ 15,450	$ 15,450	$ 77,250
A. Mills	Research Associate	20%	$ 19,200	$ 19,200	$ 19,200	$ 19,200	$ 19,200	$ 96,000
N. Hsu	Research Associate	20%	$ 22,337	$ 22,337	$ 22,337	$ 22,337	$ 22,337	$ 111,684
D. Klyce	Research Associate	8%	$ 7,580	$ 7,580	$ 7,580	$ 7,580	$ 7,580	$ 37,900
J. Kim	Project Evaluator	5%	$ 4,692	$ 4,692	$ 4,692	$ 4,692	$ 4,692	$ 23,460
K. Gary	Dissemination Coordinator	15%	$ 13,650	$ 13,650	$ 13,650	$ 13,650	$ 13,650	$ 68,250
M. Martinez	Research Assistant	100%	$ 33,000	$ 33,000	$ 33,000	$ 33,000	$ 33,000	$ 165,000
A. Welch	Research Assistant	80%	$ 26,400	$ 26,400	$ 26,400	$ 26,400	$ 26,400	$ 132,000
M. Moadab	Research Assistant	5%	$ 1,785	$ 1,785	$ 1,785	$ 1,785	$ 1,785	$ 8,925
C. Atkins	G & C Administrator	4.5%	$ 2,664	$ 2,664	$ 2,664	$ 2,664	$ 2,664	$ 13,320
Subtotal Personnel			**$ 234,776**	**$ 234,776**	**$ 234,776**	**$ 234,776**	**$ 234,776**	**$ 1,173,879**
Fringes at		37.2%	**$ 87,335**	**$ 87,335**	**$ 87,335**	**$ 87,335**	**$ 87,335**	**$ 436,675**
Total Personnel & F/B			**$ 322,111**	**$ 322,111**	**$ 322,111**	**$ 322,111**	**$ 322,111**	**$ 1,610,554**
								$ -
OTHER COSTS								$ -
Travel			$ 5,000	$ 5,000	$ 5,000	$ 5,000	$ 5,000	$ 25,000
Supplies			$ 2,220	$ 2,220	$ 2,220	$ 2,220	$ 2,220	$ 11,100
Publication Costs			$ 3,319	$ 3,319	$ 3,319	$ 3,319	$ 3,319	$ 16,595
Contractual -Duplication/Printing			$ 1,800	$ 1,800	$ 1,800	$ 1,800	$ 1,800	$ 9,000
Other:								
Consultants			$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 6,000
Advisory Board			$ 1,000	$ 1,000	$ 1,000	$ 1,000	$ 1,000	$ 5,000
Research Incentives			$ 14,784	$ 14,784	$ 14,784	$ 14,784	$ 14,784	$ 73,920
Telephone			$ 800	$ 800	$ 800	$ 800	$ 800	$ 4,000
Subtotal Other Costs			$ 30,123	$ 30,123	$ 30,123	$ 30,123	$ 30,123	$ 150,615
Total Direct Costs			$ 352,234	$ 352,234	$ 352,234	$ 352,234	$ 352,234	$ 1,761,170
F&A/Indirect at		32%	$ 112,715	$ 112,715	$ 112,715	$ 112,715	$ 112,715	$ 563,575
TOTAL COST			**$ 464,949**	**$ 464,949**	**$ 464,949**	**$ 464,949**	**$ 464,949**	**$ 2,324,745**

Traumatic Brain Injury (TBI) Model Systems
CFDA Number: HHS-2017-ACL-NIDILRR-DPTB-0204
National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)
Principal Investigator: Jeffrey Kreutzer, PhD
2017 Application-Proposed

OVERALL TBIMS BUDGET

Budget Period: 10/01/2017 - 09/30/2022

PERSONNEL	Title	NIDILRR EFFORT	VCU Cost Share EFFORT	Total EFFORT	Federal YEAR 1 BUDGET	Federal YEAR 2 BUDGET	Federal YEAR 3 BUDGET	Federal YEAR 4 BUDGET	Federal YEAR 5 BUDGET	TOTAL Federal BUDGET
J. Kreutzer	Principal Investigator	5%	25%	**30%**	$ 59,361	$ 59,361	$ 59,361	$ 59,361	$ 59,361	$ 296,804
D. Cifu	Co-Principal Investigator	0%	10%	**10%**	$ 33,087	$ 33,087	$ 33,087	$ 33,087	$ 33,087	$ 165,436
J. Marwitz	Project Coordinator	80%		**80%**	$ 78,668	$ 78,668	$ 78,668	$ 78,668	$ 78,668	$ 393,340
W. Walker	Medical Director	0%	10%	**10%**	$ 29,506	$ 29,506	$ 29,506	$ 29,506	$ 29,506	$ 147,529
A. Sima	Statistician	15%		**15%**	$ 15,450	$ 15,450	$ 15,450	$ 15,450	$ 15,450	$ 77,250
A. Mills	Research Associate	20%	10%	**30%**	$ 28,800	$ 28,800	$ 28,800	$ 28,800	$ 28,800	$ 144,000
N. Hsu	Research Associate	20%	10%	**30%**	$ 33,505	$ 33,505	$ 33,505	$ 33,505	$ 33,505	$ 167,526
D. Klyce	Research Associate	8%		**8%**	$ 7,580	$ 7,580	$ 7,580	$ 7,580	$ 7,580	$ 37,900
J. Kim	Project Evaluator	5%		**5%**	$ 4,692	$ 4,692	$ 4,692	$ 4,692	$ 4,692	$ 23,460
K. Gary	Dissemination Coordinator	15%		**15%**	$ 13,650	$ 13,650	$ 13,650	$ 13,650	$ 13,650	$ 68,250
M. Martinez	Research Assistant	100%		**100%**	$ 33,000	$ 33,000	$ 33,000	$ 33,000	$ 33,000	$ 165,000
A. Welch	Research Assistant	80%		**80%**	$ 26,400	$ 26,400	$ 26,400	$ 26,400	$ 26,400	$ 132,000
N. Moadab	Research Assistant	5%		**5%**	$ 1,785	$ 1,785	$ 1,785	$ 1,785	$ 1,785	$ 8,925
C. Atkins	G & C Administrator	4.5%		**4.5%**	$ 2,664	$ 2,664	$ 2,664	$ 2,664	$ 2,664	$ 13,320
Subtotal Personnel					**$ 368,148**	**$ 368,148**	**$ 368,148**	**$ 368,148**	**$ 368,148**	**$ 1,840,739**
Fringes at		37.2%			**$ 136,949**	**$ 136,949**	**$ 136,949**	**$ 136,949**	**$ 136,949**	**$ 684,747**
Total Personnel & F/B					**$ 505,097**	**$ 505,097**	**$ 505,097**	**$ 505,097**	**$ 505,097**	**$ 2,525,486**
										$ -
OTHER COSTS										$ -
Travel					$ 5,000	$ 5,000	$ 5,000	$ 5,000	$ 5,000	$ 25,000
Supplies					$ 2,220	$ 2,220	$ 2,220	$ 2,220	$ 2,220	$ 11,100
Contractual -Duplication/Printing					$ 3,319	$ 3,319	$ 3,319	$ 3,319	$ 3,319	$ 16,595
Publications					$ 1,800	$ 1,800	$ 1,800	$ 1,800	$ 1,800	$ 9,000
Other:										
Consultants					$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 1,200	$ 6,000
Advisory Board					$ 1,000	$ 1,000	$ 1,000	$ 1,000	$ 1,000	$ 5,000
Research Incentive:					$ 14,784	$ 14,784	$ 14,784	$ 14,784	$ 14,784	$ 73,920
Telephone					$ 800	$ 800	$ 800	$ 800	$ 800	$ 4,000
Subtotal Other Costs					$ 30,123	$ 30,123	$ 30,123	$ 30,123	$ 30,123	$ 150,615
Total Direct Costs					$ 535,220	$ 535,220	$ 535,220	$ 535,220	$ 535,220	$ 2,676,101
F&A/Indirect at 32%		32%			$ 112,715	$ 112,715	$ 112,715	$ 112,715	$ 112,715	$ 563,575
TOTAL COST					**$ 647,935**	**$ 647,935**	**$ 647,935**	**$ 647,935**	**$ 647,935**	**$ 3,239,676**

Traumatic Brain Injury (TBI) Model Systems
CFDA Number: HHS-2017-ACL-NIDILRR-DPTB-0204
National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)
Principal Investigator: Jeffrey Kreutzer, PhD
2017 Application-Proposed

VCU COST SHARE

Budget Period: 10/01/2017 - 09/30/2022

PERSONNEL	Title	Cost-Share EFFORT	Year 1	Year 2	Year 3	Year 4	Year 5	Cost Share Total
J. Kreutzer	Principal Investigator	25%	$ 50,011	$ 50,011	$ 50,011	$ 50,011	$ 50,011	$ 250,054
D. Cifu	Co-Principal Investigator	10%	$ 33,087	$ 33,087	$ 33,087	$ 33,087	$ 33,087	$ 165,436
W. Walker	Medical Director	10%	$ 29,506	$ 29,506	$ 29,506	$ 29,506	$ 29,506	$ 147,529
A. Mills	Research Associate	10%	$ 9,600	$ 9,600	$ 9,600	$ 9,600	$ 9,600	$ 48,000
N. Hsu	Research Associate	10%	$ 11,168	$ 11,168	$ 11,168	$ 11,168	$ 11,168	$ 55,842
D. Klyce	Research Associate	0%	$ -	$ -	$ -	$ -	$ -	$ -
Subtotal Personnel			**$ 133,372**	**$ 133,372**	**$ 133,372**	**$ 133,372**	**$ 133,372**	**$ 666,860**
Fringes at	37.2%		**$ 49,614**	**$ 49,614**	**$ 49,614**	**$ 49,614**	**$ 49,614**	$ 248,072
Total Personnel with Fringes			**$ 182,986**	**$ 182,986**	**$ 182,986**	**$ 182,986**	**$ 182,986**	$ 914,932
								$ -
Other								$ -
Total VCU Direct Costs			$ 182,986	$ 182,986	$ 182,986	$ 182,986	$ 182,986	$ 914,932
			$ -	$ -	$ -	$ -	$ -	$ -
TOTAL COST SHARE			**$ 182,986**	**$ 182,986**	**$ 182,986**	**$ 182,986**	**$ 182,986**	**$ 914,932**

Traumatic Brain Injury (TBI) Model Systems
CFDA Number: HHS-2017-ACL-NIDILRR-DPTB-0204
National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)
Principal Investigator: Jeffrey Kreutzer, PhD
2017 Application-Proposed

STAFF EFFORT ALLOCATION

Budget Period: 10/01/2017 - 09/30/2022

	Administration Dissemination	National Database	Resilience Intervention	Collaborative Module	Total
Kreutzer	10%	2%	12%	6%	30%
Cifu	5%	5%	-	-	10%
Marwitz	25%	20%	15%	20%	80%
Walker	-	10%	-	-	10%
Sima	-	2%	5%	8%	15%
Hsu	-	-	30%	-	30%
Mills	-	-	30%		30%
Klyce	-	8%	-	-	8%
Kim	5%	-	-	-	5%
Gary	15%	-	-	-	15%
Welch	-	35%	45%	-	80%
Martinez	-	75%	5%	20%	100%
Moadab	-	-	5%	-	5%
Atkins	4.5%	-	-	-	4.5%

Budget Narrative
Traumatic Brain Injury Model Systems
Jeffrey Kreutzer, Principal Investigator

Year 1 **10/1/2017-9/30/2018**

Object Class Category	Federal Funds	Non-Federal Funds Cash	Non-Federal In-Kind	Total	Justification
Personnel	$234,776	$133,372	$0	$368,148	Principal Investigator (Jeffrey Kreutzer) = .05 FTE @ $187,100/yr = $9,350 (Salary is more than the DHHS Salary Cap Threshold so the amount budgeted is at the current applicable salary cap) Project Coordinator (Jennifer Marwitz) = .80 FTE @ $98,335/yr = $78,668 Statistician (Adam Sima) = .15 FTE @ $103,000/yr = $15,450 Research Associate (Ana Mills) = .20 FTE @ $96,000/yr = $19,200 Research Associate (Nancy Hsu) = .20 FTE @ $111,684/yr = $22,337 Research Associate (Daniel Klyce) = .08 FTE @ $94,749/yr = $7,580 Project Evaluator (Jeong Han Kim) = .05 FTE @ $93,840/yr = $4,692 Dissemination Coordinator (Kelli Williams Gary) .15 FTE @ $91,000/yr = $13,650 Research Assistant (Marie Grace Martinez) 1 FTE @ $33,000/yr = $33,000 Research Assistant (Abigail Welch) .80 FTE @ $33,000/yr = $26,400

					Research Assistant (Naghmeh Moadab) .05 FTE @ $35,700/yr = 1,785 G&C Administrator (Christie Atkins) .045 FTE @ $59,200/yr = $2,664 **Non-Federal Cash** Principal Investigator (Jeffrey Kreutzer) = .25 FTE @ $200,043/yr = $50,011 Co-Principal Investigator (David Cifu) = .10 FTE @ $330,871/yr = $33,087 Medical Director (William Walker) = .10 FTE @ $295,058/yr = $29,506 Research Associate (Ana Mills) = .10 FTE @ $96,000/yr = $9,600 Research Associate (Nancy Hsu) = .10 FTE @ $111,684/yr = $11,168 **Total: $368,148**
Fringe Benefits	$87,335	$49,614	$0	$136,949	Principal Investigator at 37.2% = $3,478 Project Coordinator at 37.2% = $29,265 Statistician at 37.2% = $5,747 Research Associate at 37.2% = $7,143 Research Associate at 37.2% = 8,309 Research Associate at 37.2% = $2,819 Project Evaluator at 37.2% = $1,745 Dissemination Coordinator at 37.2% = $5,078

					Research Assistant at 37.2% = 12,275 Research Assistant at 37.2% = 9,821 Research Assistant at 37.2% = $664 G&C Administrator at 37.2% = $991 Retirement (11.45%) FICA (6.65%) Group Life (1.32%) Health Insurance (14.20%) Health Insurance Credit (1.17%) Unemployment (0.15%) Workers Compensation (0.35%) Long-Term Disability (0.47%) VRS Long-Term Disability (0.40%) Faculty-Staff Tuition Waivers (0.55%) Cash Match Plan (0.49%) **Non-Federal Cash** Principal Investigator at 37.2% = $18,604 Co-Principal Investigator at 37.2% = $12,308 Medical Director at 37.2% = $10,976 Research Associate at 37.2% = 3,571 Research Associate at 37.2% = 4,155 Retirement (11.45%) FICA (6.65%) Group Life (1.32%) Health Insurance (14.20%) Health Insurance Credit (1.17%) Unemployment (0.15%) Workers Compensation (0.35%) Long-Term Disability (0.47%) VRS Long-Term Disability (0.40%)

					Faculty-Staff Tuition Waivers (0.55%) Cash Match Plan (0.49%) **Total: $136,949**
Travel	$5,000	$0	$0	$5,000	Travel for project staff to attend Semi-Annual Project Directors' meeting, professional meetings, conferences and other dissemination-related activities Mileage: 210 miles roundtrip to Arlington, VA x $0.535 per mile x 2 trips x 2 people = $449.40 Per Diem: $69 Full Days x 10 / $51.75 Travel Day x 20 = $1,725 Airfare: 1 out of state conference for PI - $523.30 Lodging: $182 per night plus 15% taxes = $209.30 x 11 nights = $2,302.30 **Total: $5,000.00**
Equipment	$0	$0	$0	$0	No Equipment Requested
Supplies	$2,220	$0	$0	$2,220	Project supplies and materials **Total: $2,220**
Contractual	$0	$0	$0	$0	No Contractual Requested
Other	$22,903	$0	$0	$22,903	Advisory Board: $1,000 Consultants: $1,200 Duplication/Printing: $1,800 Publication Costs: $3,319 University Services (telecommunications): $800 Research Incentives: $14,784 **Total: $22,903**
Indirect Charges	$112,715	$0	$0	$112,715	32% of Modified Direct Costs = $112,715
Total	$464,949	$182,986	$0	$647,935	

Year 2 **10/1/2018-9/30/2019**

Object Class Category	Federal Funds	Non-Federal Funds Cash	Non-Federal In-Kind	Total	Justification
Personnel	$234,776	$133,372	$0	$368,148	Principal Investigator (Jeffrey Kreutzer) = .05 FTE @ $187,100/yr = $9,350 (Salary is more than the DHHS Salary Cap Threshold so the amount budgeted is at the current applicable salary cap) Project Coordinator (Jennifer Marwitz) = .80 FTE @ $98,335/yr = $78,668 Statistician (Adam Sima) = .15 FTE @ $103,000/yr = $15,450 Research Associate (Ana Mills) = .20 FTE @ $96,000/yr = $19,200 Research Associate (Nancy Hsu) = .20 FTE @ $111,684/yr = $22,337 Research Associate (Daniel Klyce) = .08 FTE @ $94,749/yr = $7,580 Project Evaluator (Jeong Han Kim) = .05 FTE @ $93,840/yr = $4,692 Dissemination Coordinator (Kelli Williams Gary) .15 FTE @ $91,000/yr = $13,650 Research Assistant (Marie Grace Martinez) 1 FTE @ $33,000/yr = $33,000 Research Assistant (Abigail Welch) .80 FTE @ $33,000/yr = $26,400 Research Assistant (Naghmeh Moadab) .05 FTE @ $35,700/yr = 1,785

					G&C Administrator (Christie Atkins) .045 FTE @ $59,200/yr = $2,664 **Non-Federal Cash** Principal Investigator (Jeffrey Kreutzer) = .25 FTE @ $200,043/yr = $50,011 Co-Principal Investigator (David Cifu) = .10 FTE @ $330,871/yr = $33,087 Medical Director (William Walker) = .10 FTE @ $295,058/yr = $29,506 Research Associate (Ana Mills) = .10 FTE @ $96,000/yr = $9,600 Research Associate (Nancy Hsu) = .10 FTE @ $111,684/yr = $11,168 **Total: $368,148**
Fringe Benefits	$87,335	$49,614	$0	$136,949	Principal Investigator at 37.2% = $3,478 Project Coordinator at 37.2% = $29,265 Statistician at 37.2% = $5,747 Research Associate at 37.2% = $7,143 Research Associate at 37.2% = 8,309 Research Associate at 37.2% = $2,819 Project Evaluator at 37.2% = $1,745 Dissemination Coordinator at 37.2% = $5,078 Research Assistant at 37.2% = 12,275

					Research Assistant at 37.2% = 9,821 Research Assistant at 37.2% = $664 G&C Administrator at 37.2% = $991 Retirement (11.45%) FICA (6.65%) Group Life (1.32%) Health Insurance (14.20%) Health Insurance Credit (1.17%) Unemployment (0.15%) Workers Compensation (0.35%) Long-Term Disability (0.47%) VRS Long-Term Disability (0.40%) Faculty-Staff Tuition Waivers (0.55%) Cash Match Plan (0.49%) **Non-Federal Cash** Principal Investigator at 37.2% = $18,604 Co-Principal Investigator at 37.2% = $12,308 Medical Director at 37.2% = $10,976 Research Associate at 37.2% = 3,571 Research Associate at 37.2% = 4,155 Retirement (11.45%) FICA (6.65%) Group Life (1.32%) Health Insurance (14.20%) Health Insurance Credit (1.17%) Unemployment (0.15%) Workers Compensation (0.35%) Long-Term Disability (0.47%) VRS Long-Term Disability (0.40%) Faculty-Staff Tuition Waivers (0.55%) Cash Match Plan (0.49%)

					Total: $136,949
Travel	$5,000	$0	$0	$5,000	Travel for project staff to attend Semi-Annual Project Directors' meeting, professional meetings, conferences and other dissemination-related activities Mileage: 210 miles roundtrip to Arlington, VA x $0.535 per mile x 2 trips x 2 people = $449.40 Per Diem: $69 Full Days x 10 / $51.75 Travel Day x 20 = $1,725 Airfare: 1 out of state conference for PI - $523.30 Lodging: $182 per night plus 15% taxes = $209.30 x 11 nights = $2,302.30 **Total: $5,000.00**
Equipment	$0	$0	$0	$0	No Equipment Requested
Supplies	$2,220	$0	$0	$2,220	Project supplies and materials **Total: $2,220**
Contractual	$0	$0	$0	$0	No Contractual Requested
Other	$22,903	$0	$0	$22,903	Advisory Board: $1,000 Consultants: $1,200 Duplication/Printing: $1,800 Publication Costs: $3,319 University Services (telecommunications): $800 Research Incentives: $14,784 **Total: $22,903**
Indirect Charges	$112,715	$0	$0	$112,715	32% of Modified Direct Costs = $112,715
Total	$464,949	$182,986	$0	$647,935	

Year 3 **10/1/2019-9/30/2020**

Object Class Category	Federal Funds	Non-Federal Funds Cash	Non-Federal In-Kind	Total	Justification
Personnel	$234,776	$133,372	$0	$368,148	Principal Investigator (Jeffrey Kreutzer) = .05 FTE @ $187,100/yr = $9,350 (Salary is more than the DHHS Salary Cap Threshold so the amount budgeted is at the current applicable salary cap) Project Coordinator (Jennifer Marwitz) = .80 FTE @ $98,335/yr = $78,668 Statistician (Adam Sima) = .15 FTE @ $103,000/yr = $15,450 Research Associate (Ana Mills) = .20 FTE @ $96,000/yr = $19,200 Research Associate (Nancy Hsu) = .20 FTE @ $111,684/yr = $22,337 Research Associate (Daniel Klyce) = .08 FTE @ $94,749/yr = $7,580 Project Evaluator (Jeong Han Kim) = .05 FTE @ $93,840/yr = $4,692 Dissemination Coordinator (Kelli Williams Gary) .15 FTE @ $91,000/yr = $13,650 Research Assistant (Marie Grace Martinez) 1 FTE @ $33,000/yr = $33,000 Research Assistant (Abigail Welch) .80 FTE @ $33,000/yr = $26,400 Research Assistant (Naghmeh Moadab) .05 FTE @ $35,700/yr = 1,785 G&C Administrator (Christie Atkins) .045 FTE @ $59,200/yr = $2,664

					Non-Federal Cash Principal Investigator (Jeffrey Kreutzer) = .25 FTE @ $200,043/yr = $50,011 Co-Principal Investigator (David Cifu) = .10 FTE @ $330,871/yr = $33,087 Medical Director (William Walker) = .10 FTE @ $295,058/yr = $29,506 Research Associate (Ana Mills) = .10 FTE @ $96,000/yr = $9,600 Research Associate (Nancy Hsu) = .10 FTE @ $111,684/yr = $11,168 **Total: $368,148**
Fringe Benefits	$87,335	$49,614	$0	$136,949	Principal Investigator at 37.2% = $3,478 Project Coordinator at 37.2% = $29,265 Statistician at 37.2% = $5,747 Research Associate at 37.2% = $7,143 Research Associate at 37.2% = 8,309 Research Associate at 37.2% = $2,819 Project Evaluator at 37.2% = $1,745 Dissemination Coordinator at 37.2% = $5,078 Research Assistant at 37.2% = 12,275 Research Assistant at 37.2% = 9,821

					Research Assistant at 37.2% = $664 G&C Administrator at 37.2% = $991 Retirement (11.45%) FICA (6.65%) Group Life (1.32%) Health Insurance (14.20%) Health Insurance Credit (1.17%) Unemployment (0.15%) Workers Compensation (0.35%) Long-Term Disability (0.47%) VRS Long-Term Disability (0.40%) Faculty-Staff Tuition Waivers (0.55%) Cash Match Plan (0.49%) **Non-Federal Cash** Principal Investigator at 37.2% = $18,604 Co-Principal Investigator at 37.2% = $12,308 Medical Director at 37.2% = $10,976 Research Associate at 37.2% = 3,571 Research Associate at 37.2% = 4,155 Retirement (11.45%) FICA (6.65%) Group Life (1.32%) Health Insurance (14.20%) Health Insurance Credit (1.17%) Unemployment (0.15%) Workers Compensation (0.35%) Long-Term Disability (0.47%) VRS Long-Term Disability (0.40%) Faculty-Staff Tuition Waivers (0.55%) Cash Match Plan (0.49%) **Total: $136,949**

Travel	$5,000	$0	$0	$5,000	Travel for project staff to attend Semi-Annual Project Directors' meeting, professional meetings, conferences and other dissemination-related activities Mileage: 210 miles roundtrip to Arlington, VA x $0.535 per mile x 2 trips x 2 people = $449.40 Per Diem: $69 Full Days x 10 / $51.75 Travel Day x 20 = $1,725 Airfare: 1 out of state conference for PI - $523.30 Lodging: $182 per night plus 15% taxes = $209.30 x 11 nights = $2,302.30 **Total: $5,000.00**
Equipment	$0	$0	$0	$0	No Equipment Requested
Supplies	$2,220	$0	$0	$2,220	Project supplies and materials **Total: $2,220**
Contractual	$0	$0	$0	$0	No Contractual Requested
Other	$22,903	$0	$0	$22,903	Advisory Board: $1,000 Consultants: $1,200 Duplication/Printing: $1,800 Publication Costs: $3,319 University Services (telecommunications): $800 Research Incentives: $14,784 **Total: $22,903**
Indirect Charges	$112,715	$0	$0	$112,715	32% of Modified Direct Costs = $112,715
Total	$464,949	$182,986	$0	$647,935	

Year 4 **10/1/2020-9/30/2021**

Object Class Category	**Federal Funds**	**Non-Federal Funds Cash**	**Non-Federal In-Kind**	**Total**	**Justification**

Personnel	$234,776	$133,372	$0	$368,148	Principal Investigator (Jeffrey Kreutzer) = .05 FTE @ $187,100/yr = $9,350 (Salary is more than the DHHS Salary Cap Threshold so the amount budgeted is at the current applicable salary cap) Project Coordinator (Jennifer Marwitz) = .80 FTE @ $98,335/yr = $78,668 Statistician (Adam Sima) = .15 FTE @ $103,000/yr = $15,450 Research Associate (Ana Mills) = .20 FTE @ $96,000/yr = $19,200 Research Associate (Nancy Hsu) = .20 FTE @ $111,684/yr = $22,337 Research Associate (Daniel Klyce) = .08 FTE @ $94,749/yr = $7,580 Project Evaluator (Jeong Han Kim) = .05 FTE @ $93,840/yr = $4,692 Dissemination Coordinator (Kelli Williams Gary) .15 FTE @ $91,000/yr = $13,650 Research Assistant (Marie Grace Martinez) 1 FTE @ $33,000/yr = $33,000 Research Assistant (Abigail Welch) .80 FTE @ $33,000/yr = $26,400 Research Assistant (Naghmeh Moadab) .05 FTE @ $35,700/yr = 1,785 G&C Administrator (Christie Atkins) .045 FTE @ $59,200/yr = $2,664 **Non-Federal Cash**

					Principal Investigator (Jeffrey Kreutzer) = .25 FTE @ $200,043/yr = $50,011 Co-Principal Investigator (David Cifu) = .10 FTE @ $330,871/yr = $33,087 Medical Director (William Walker) = .10 FTE @ $295,058/yr = $29,506 Research Associate (Ana Mills) = .10 FTE @ $96,000/yr = $9,600 Research Associate (Nancy Hsu) = .10 FTE @ $111,684/yr = $11,168 **Total: $368,148**
Fringe Benefits	$87,335	$49,614	$0	$136,949	Principal Investigator at 37.2% = $3,478 Project Coordinator at 37.2% = $29,265 Statistician at 37.2% = $5,747 Research Associate at 37.2% = $7,143 Research Associate at 37.2% = 8,309 Research Associate at 37.2% = $2,819 Project Evaluator at 37.2% = $1,745 Dissemination Coordinator at 37.2% = $5,078 Research Assistant at 37.2% = 12,275 Research Assistant at 37.2% = 9,821 Research Assistant at 37.2% = $664

					G&C Administrator at 37.2% = $991 Retirement (11.45%) FICA (6.65%) Group Life (1.32%) Health Insurance (14.20%) Health Insurance Credit (1.17%) Unemployment (0.15%) Workers Compensation (0.35%) Long-Term Disability (0.47%) VRS Long-Term Disability (0.40%) Faculty-Staff Tuition Waivers (0.55%) Cash Match Plan (0.49%) **Non-Federal Cash** Principal Investigator at 37.2% = $18,604 Co-Principal Investigator at 37.2% = $12,308 Medical Director at 37.2% = $10,976 Research Associate at 37.2% = 3,571 Research Associate at 37.2% = 4,155 Retirement (11.45%) FICA (6.65%) Group Life (1.32%) Health Insurance (14.20%) Health Insurance Credit (1.17%) Unemployment (0.15%) Workers Compensation (0.35%) Long-Term Disability (0.47%) VRS Long-Term Disability (0.40%) Faculty-Staff Tuition Waivers (0.55%) Cash Match Plan (0.49%) **Total: $136,949**
Travel	$5,000	$0	$0	$5,000	Travel for project staff to attend Semi-Annual Project Directors' meeting, professional meetings,

					conferences and other dissemination-related activities Mileage: 210 miles roundtrip to Arlington, VA x $0.535 per mile x 2 trips x 2 people = $449.40 Per Diem: $69 Full Days x 10 / $51.75 Travel Day x 20 = $1,725 Airfare: 1 out of state conference for PI - $523.30 Lodging: $182 per night plus 15% taxes = $209.30 x 11 nights = $2,302.30 **Total: $5,000.00**
Equipment	$0	$0	$0	$0	No Equipment Requested
Supplies	$2,220	$0	$0	$2,220	Project supplies and materials **Total: $2,220**
Contractual	$0	$0	$0	$0	No Contractual Requested
Other	$22,903	$0	$0	$22,903	Advisory Board: $1,000 Consultants: $1,200 Duplication/Printing: $1,800 Publication Costs: $3,319 University Services (telecommunications): $800 Research Incentives: $14,784 **Total: $22,903**
Indirect Charges	$112,715	$0	$0	$112,715	32% of Modified Direct Costs = $112,715
Total	$464,949	$182,986	$0	$647,935	

Year 5 **10/1/2021-9/30/2022**

Object Class Category	**Federal Funds**	**Non-Federal Funds Cash**	**Non-Federal In-Kind**	**Total**	**Justification**
Personnel	$234,776	$133,372	$0	$368,148	Principal Investigator (Jeffrey Kreutzer) = .05 FTE @ $187,100/yr = $9,350 (Salary is more than the

					DHHS Salary Cap Threshold so the amount budgeted is at the current applicable salary cap) Project Coordinator (Jennifer Marwitz) = .80 FTE @ $98,335/yr = $78,668 Statistician (Adam Sima) = .15 FTE @ $103,000/yr = $15,450 Research Associate (Ana Mills) = .20 FTE @ $96,000/yr = $19,200 Research Associate (Nancy Hsu) = .20 FTE @ $111,684/yr = $22,337 Research Associate (Daniel Klyce) = .08 FTE @ $94,749/yr = $7,580 Project Evaluator (Jeong Han Kim) = .05 FTE @ $93,840/yr = $4,692 Dissemination Coordinator (Kelli Williams Gary) .15 FTE @ $91,000/yr = $13,650 Research Assistant (Marie Grace Martinez) 1 FTE @ $33,000/yr = $33,000 Research Assistant (Abigail Welch) .80 FTE @ $33,000/yr = $26,400 Research Assistant (Naghmeh Moadab) .05 FTE @ $35,700/yr = 1,785 G&C Administrator (Christie Atkins) .045 FTE @ $59,200/yr = $2,664 **Non-Federal Cash** Principal Investigator (Jeffrey Kreutzer) = .25 FTE @ $200,043/yr = $50,011

					Co-Principal Investigator (David Cifu) = .10 FTE @ $330,871/yr = $33,087 Medical Director (William Walker) = .10 FTE @ $295,058/yr = $29,506 Research Associate (Ana Mills) = .10 FTE @ $96,000/yr = $9,600 Research Associate (Nancy Hsu) = .10 FTE @ $111,684/yr = $11,168 **Total: $368,148**
Fringe Benefits	$87,335	$49,614	$0	$136,949	Principal Investigator at 37.2% = $3,478 Project Coordinator at 37.2% = $29,265 Statistician at 37.2% = $5,747 Research Associate at 37.2% = $7,143 Research Associate at 37.2% = 8,309 Research Associate at 37.2% = $2,819 Project Evaluator at 37.2% = $1,745 Dissemination Coordinator at 37.2% = $5,078 Research Assistant at 37.2% = 12,275 Research Assistant at 37.2% = 9,821 Research Assistant at 37.2% = $664 G&C Administrator at 37.2% = $991 Retirement (11.45%) FICA (6.65%)

					Group Life (1.32%) Health Insurance (14.20%) Health Insurance Credit (1.17%) Unemployment (0.15%) Workers Compensation (0.35%) Long-Term Disability (0.47%) VRS Long-Term Disability (0.40%) Faculty-Staff Tuition Waivers (0.55%) Cash Match Plan (0.49%) **Non-Federal Cash** Principal Investigator at 37.2% = $18,604 Co-Principal Investigator at 37.2% = $12,308 Medical Director at 37.2% = $10,976 Research Associate at 37.2% = 3,571 Research Associate at 37.2% = 4,155 Retirement (11.45%) FICA (6.65%) Group Life (1.32%) Health Insurance (14.20%) Health Insurance Credit (1.17%) Unemployment (0.15%) Workers Compensation (0.35%) Long-Term Disability (0.47%) VRS Long-Term Disability (0.40%) Faculty-Staff Tuition Waivers (0.55%) Cash Match Plan (0.49%) **Total: $136,949**
Travel	$5,000	$0	$0	$5,000	Travel for project staff to attend Semi-Annual Project Directors' meeting, professional meetings, conferences and other dissemination-related activities

					Mileage: 210 miles roundtrip to Arlington, VA x $0.535 per mile x 2 trips x 2 people = $449.40 Per Diem: $69 Full Days x 10 / $51.75 Travel Day x 20 = $1,725 Airfare: 1 out of state conference for PI - $523.30 Lodging: $182 per night plus 15% taxes = $209.30 x 11 nights = $2,302.30 **Total: $5,000.00**
Equipment	$0	$0	$0	$0	No Equipment Requested
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Contractual	$0	$0	$0	$0	No Contractual Requested
Other	$22,903	$0	$0	$22,903	Advisory Board: $1,000 Consultants: $1,200 Duplication/Printing: $1,800 Publication Costs: $3,319 University Services (telecommunications): $800 Research Incentives: $14,784 **Total: $22,903**
Indirect Charges	$112,715	$0	$0	$112,715	32% of Modified Direct Costs = $112,715
Total	$464,949	$182,986	$0	$647,935	

Project Narrative File(s)

Project Narrative File Attachments:

ProjectNarrative.pdf

Study Identification

1. * **Select the Principal Investigator:**
   Nancy Hsu

2. * **Study Title:**
   Intervention to Promote Survivor Resilience and Adjustment: Efficacy and Sustainability

3. * **Is this a student or trainee project in which activities will be carried out by that individual under your supervision (for example, dissertation or degree-required projects):**
   - ○ Yes
   - ● **No**

4. * **Please select the primary department or center that this study is being conducted under:**
   Physical Medicine and Rehabilitation

5. **Select the VCU IRB numbers assigned to studies that are:**
   1. **Associated with this study**
   2. **Research registries this study will utilize**
   3. **Previously submitted versions of this study (closed, withdrawn, auto-withdrawn studies)**

ID	Title	PI

There are no items to display

6. **Select all individuals who are permitted to edit the IRB protocol and should be copied on communications (study staff will be entered later). These individuals will be referred to as protocol editors:**

Last Name	First Name	E-Mail	Phone	Mobile
Abbasi	Katherine	kwalker33@vcu.edu	8048283703	
Brown	Rochelle	brownr25@vcu.edu	8048284230	
Frey	Carolyn	cafrey@vcu.edu	8042299143	
Hsu	Nancy	nhhsu@vcu.edu		
Marwitz	Jennifer	jhmarwit@vcu.edu	8048283704	

7. * **Select one of the following that applies to the project (selection will branch to new pages):**
   Note: VCU IRB offers guidance for many types of studies, including secondary data analysis studies, internet research, registries, EFIC, HUD, and Emergency Use protocols.
   See *https://research.vcu.edu/human_research/guidance.htm*
   - ● **Research Project or Clinical Investigation [*most exempt, expedited, and full board research studies]**
   - ○ Exception from Informed Consent (EFIC) for Planned Emergency Research
   - ○ Humanitarian Use of Device for Treatment or Diagnosis
   - ○ Humanitarian Use of Device for Clinical Investigation
   - ○ Emergency Use of Investigational Drug, Biologic or Device
   - ○ Treatment Use (Expanded Access to Investigational Product for Treatment Use)
   - ○ Center or Institute Administrative Grant Review

- ○ Request for Not Human Subject Research Determination (i.e. request a letter confirming that IRB review is not required)

Federal Regulations

1. * Is this a FDA regulated study?

FDA regulated research includes all clinical investigations involving a test article and a human subject(s) that has been submitted for approval to the FDA or may be submitted in the future.
Check Yes if
• the study involves an IND/IDE, abbreviated IDE, IND/IDE exemption, HUD, expanded access, or is otherwise subject to 21 CFR 56,
• the study involves a test article being administered or dispensed to subjects NOT according to a clinicians' medical judgment but rather, per the study protocol, OR
• the study does not involve a test article but intends to provide safety or efficacy data to the FDA.

- ○ Yes
- ● **No**

2. * Is this study supported by the Department of Defense (DoD):

- ○ Yes
- ● **No**

3. * Check if any of the following funding sources apply to this research (including Direct and/or Indirect funding):

- ☐ Department of Education
- ☐ Department of Justice
- ☐ Environmental Protection Agency
- ☑ **None of the above**

IRB Panel Setup

1. * **To which IRB is this study being submitted for review?**

- (●) **VCU IRB**
- ( ) WCG IRB
- ( ) NCI Central IRB
- ( ) Advarra IRB
- ( ) Other IRB

2. * **Is this study transitioning to review by another IRB?**

- ( ) Yes - transitioning from VCU IRB to an external IRB (WCG, CIRB, Other)
- ( ) Yes - transitioning from an external IRB (WCG, CIRB, Other) to VCU IRB
- (●) **No or not applicable**

HM20011840 - Nancy Hsu
Intervention to Promote Survivor Resilience and Adjustment: Efficacy and Sustainability

Review Setup

1. * **Select which study type best describes the majority of the study. Your response will help determine which IRB panel should review this.**
   - ○ Bio-Medical Research
   - ● **Social/Behavioral/Education (SBE) Research**

2. * **Which option(s) best describe the way(s) this study's procedures will be conducted? (Select all that apply.) This information may be used by the IRB in triaging studies during an emergency.**
   - ☐ In-person interactions / interventions with participants
   - ☐ Remote interactions / interventions with participants
   - ☐ Secondary data/specimen analyses with or without contact with study participants

3. * **Does this study involve greater than minimal risk:**
   - ○ Yes ● **No**

4. * **Review type requested: (subject to IRB approval):**
   - ○ Full Board
   - ● **Expedited**
   - ○ Exempt

5. * **Is this study initiated by a VCU investigator or a sponsor:**
   - ○ VCU Investigator initiated
   - ○ Sponsor or industry initiated

The IRB has determined that the selected types of anticipated individual and social benefit apply to this study

The below information is read-only to investigators, and the categories are set by the IRB during review. All categories will appear blank until the IRB has made a determination. If a category is not checked, it does not apply to this study. This information may be used by the IRB in triaging studies during an emergency situation.
There are no items to display

The following information applies to studies being reviewed by the VCU IRB.

The IRB has determined that the selected Exempt and/or Expedited categories apply to this study.

The below information is read-only to investigators, and the categories are set by the IRB during review. All categories will appear blank until the IRB has made a determination. If a category is not checked, it does not apply to this study or the study is being reviewed by an external IRB.

6. **For Expedited Studies:**

Category 5	Nonresearch Data Collection	Involves materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes including medical treatment or diagnosis.
Category 6	Research Data Collection	Involves the collection of data from voice, video, digital, or image recordings made for research purposes.
Category 7	Behavioral	Is research that will be performed on individual or group characteristics or behavior OR will employ a survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Initial Setup Complete

Protocol Progress:
● **INITIAL SETUP**
② BACKGROUND, RATIONALE & GOALS
③ RESEARCH PLAN
④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Background, Rationale and Goals

1. * **Describe the study's background and what is currently known from the scientific literature, including citations, or upload a citation list in document upload. Use lay language whenever possible.**

Though persons with traumatic brain injury (TBI) often confront a variety of long-term challenges, inpatient and outpatient services are often limited or unavailable. Review of recent TBI Model Systems National Database reports provides evidence that lengths of stay in inpatient rehabilitation settings have declined over the last two decades. Professionals, family members, and survivors have been alarmed by reductions, restrictions, and limitations on inpatient rehabilitation stays. Concerns have also been expressed that many survivors are discharged home with serious problems to family members who are not adequately equipped to help. In fact, many communities do not offer specialized outpatient rehabilitation. Where outpatient rehabilitation is available, insurance companies are often reluctant to fund services.

In addition to the difficulties in obtaining effective care, research and clinical experience suggest that survivors experience a wide variety of lingering injury-related challenges. For example, early on, many survivors know little about the common consequences of injury and have trouble coping with loss and change. Some have difficulty taking an active role in treatment, while impatience with the recovery process is common. Diminished problem solving, emotional regulation, stress management, and communication skills add further to the challenges of maintaining and rebuilding positive relationships. Research suggesting that a majority of survivors experience depression and are unable to maintain employment illustrates the breadth of struggles brain injury survivors continue to face in the long-term. Consequently, many survivors become discouraged and struggle to maintain a positive outlook.

Clinical psychology researchers have recently turned their attention to resilience, an individual characteristic that allows persons who experience trauma to successfully adjust, adapt, and, in many cases, thrive despite adversity. Researchers have learned that resilience is not a trait, but rather a set of skills which can be developed and enhanced. A number of studies involving children, adolescents, and adults with anxiety disorders, depression, PTSD, and learning disabilities have demonstrated the efficacy of resilience-based interventions.

In 2012, with NIDILRR TBIMS funding, VCU researchers developed a structured C-B intervention to promote postinjury resilience and adjustment after TBI: the Resilience and Adjustment Intervention (RAI) (Godwin et al, 2015). The intervention development project, which was designed to address post-acute TBI needs, concerns, and challenges (e.g., common injury effects, coping with loss and change, one’s role in recovery, problem solving, communication, and stress management), emphasized education, skill building, and psychological support. Our investigation was also implemented to test the feasibility of the intervention and measurement protocol. Outpatients with mild to severe TBI were randomly assigned to either a treatment (RAI) or wait list control (WLC) group. Treatment was delivered in seven one-hour sessions with outcome measurement pre- and post-treatment, and three months after treatment completion. Treatment group participants showed improvement in outcomes, whereas controls did not. At three months post-treatment, improvements were maintained relative to pre-treatment.

Important questions remain regarding the sustainability of treatment benefits. First, are treatment benefits sustained beyond three months? Second, are there patient characteristics that predict longevity of benefits? Qualitative feedback from research participants was carefully reviewed to provide direction for further development of the RAI. Every single participant stated that they would recommend the program to others. However, a number of participants wanted more sessions with additional time to focus on individual needs, suggesting that the addition of booster sessions could be of great benefit.

By definition, booster sessions are follow-up sessions implemented after program completion to help maintain benefits over time. Boosters provide an opportunity for individuals to review content, consolidate gains, and discuss challenges. Given the high rate of cognitive impairments following TBI, booster sessions can provide an important opportunity to reinforce learning and ameliorate the impact of memory deficits on skills acquisition. Booster sessions have been shown to be beneficial across an array of therapy targets, including reducing anxiety and depression (Wesner et al., 2015), improving communication skills (Braukhaus, et al, 2003) and enhancing relationship skills (Vaterlaus et al, 2012). In the only known study to utilize psychotherapy booster sessions for individuals with TBI, Ponsford and colleagues examined the impact of modified cognitive-behavioral therapy with three booster sessions provided between 21 and 30 weeks post-recruitment (Ponsford et al., 2016). The booster program was associated with reduced anxiety and depression and increased psychosocial functioning.

The development and inclusion of booster sessions increases the extent to which the intervention is patient-centered. The addition is well in line with an established literature on the additional benefits of patient-centered treatment over and above those of standardized interventions (McMillan et al., 2013; Rathert et al, 2013). As such, patient-centered care has been championed as a mark of high quality healthcare by both the Institute of Medicine (Institute of Medicine, 2001) and U.S. Congress (U.S. Congress, 2010). The essence of the patient-centered approach entails eliciting as well as mindfully and flexibly responding to the individual’s needs and preferences (Sidani et al, 2006). Patient-centered care has been examined among persons with TBI, with positive findings showing that not only is it feasible for individuals with compromised cognitive skills to participate in their care, they are also more satisfied with their treatment when they do so (Pegg et al., 2005). Additional work is needed to quantify the increased benefits of patient-centered interventions in TBI research, and the proposed project will address this knowledge gap.

Braukhaus, C., Hahlweg, K., Kroeger, C., Groth, T., & Fehm-Wolfsdorf, G. (2003). The effects of adding booster sessions to a prevention training program for committed couples. Behavioural and Cognitive Psychotherapy, 31(3), 325-336.

Godwin, E. E., Lukow II, H. R., & Lichiello, S. (2015). Promoting resilience following traumatic brain injury: Application of an interdisciplinary, evidence-based model for intervention. Family Relations: An Interdisciplinary Journal of Applied Family Studies, 64(3), 347-362.

Institute of Medicine. (2001). Institute of medicine: Crossing the quality chasm. Washington, DC.

McMillan, S. S., Kendall, E., Sav, A., King, M. A., Whitty, J. A., Kelly, F., & Wheeler, A. J. (2013). Patient-centered approaches to health care: A systematic review of randomized controlled trials. Medical Care Research and Review: MCRR, 70(6), 567-596.

Pegg Jr., P. O., Auerbach, S. M., Seel, R. T., Buenaver, L. F., Kiesler, D. J., & Plybon, L. E. (2005). The impact of patient-centered information on patients' treatment satisfaction and outcomes in traumatic brain injury rehabilitation. Rehabilitation Psychology, 50(4), 366-374.

Ponsford, J., Lee, N. K., Wong, D., McKay, A., Haines, K., Alway, Y., . . . O'Donnell, M. L. (2016). Efficacy of motivational interviewing and cognitive behavioral therapy for anxiety and depression symptoms following traumatic brain injury. Psychological Medicine, 46(5), 1079-1090.

Rathert, C., Wyrwich, M. D., & Boren, S. A. (2013). Patient-centered care and outcomes: A systematic review of the literature. Medical Care Research and Review, 70(4), 351-379.

Sidani, S., Epstein, D., & Miranda, J. (2006). Eliciting patient treatment preferences: A strategy to integrate evidence-based and patient-centered care. Worldviews on Evidence-Based Nursing, 3(3), 116-123.

U.S. Congress. (2010). Patient protection and affordable care act. Public Law, 111, 48.

Vaterlaus, J. M., Allgood, S. M., & Higginbotham, B. J. (2012). Stepfamily education booster sessions. Social Work with Groups: A Journal of Community and Clinical Practice, 35(2), 150-163.

Wesner, A. C., Gomes, J. B., Detzel, T., Guimaraes, L. S., & Heldt, E. (2015). Booster sessions after cognitive-behavioural group therapy for panic disorder: Impact on resilience, coping, and quality of life. Behavioural and Cognitive Psychotherapy, 43(5), 513-525.

2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
1. Primary: Participants receiving the booster (RAI+ group) will report higher levels of resilience in comparison to individuals in the standard RAI group.

2. Participants in the RAI+ group will show better adjustment and lower levels of emotional distress as compared to persons in the standard RAI group.

3. Additionally, participants in the RAI+ group will report greater abilities in the areas of problem solving, communication, and stress management relative to persons in the standard RAI group.

4. A participant's demographic, lifestyle, injury, and treatment response information will be predictive of maintenance ability.

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
1. to evaluate the short and long-term efficacy of two structured outpatient intervention programs (RAI vs. RAI+) on resilience

2. to evaluate the short and long-term impact of intervention on emotional well-being and postinjury adjustment with the RAI vs. the RAI+

3. to evaluate the short and long-term impact of the RAI and the RAI+ on abilities including problem solving, communication, and stress management

4. to determine if demographic, lifestyle, injury, or treatment response information can predict maintenance of gains

4. * **Describe the scientific benefit or importance of the knowledge to be gained:**

Empirical investigation of a structured, replicable, outpatient intervention to address resilience and emotional adjustment after TBI will guide clinicians serving individuals post-discharge, enabling more effective and efficient service delivery. There are minimal risks (physical, psychological, social, legal, or other) associated with the project. The possibility that some individuals may experience feelings of sadness and frustration during protocol implementation is outweighed by the potential benefits of the project. The VCU TBIMS places an emphasis on providing patients with psychological support and education to assist in recovery following TBI.

5. * **Describe any potential for direct benefits to participants in this study:**
Participants may or may not gain any direct benefit from being in this study. They receive written information about TBI, including available services or programs that might be helpful.

6. * **Describe any potential for direct social impact in this study . For example, any engagement with specific communities to respond to community-identified needs, or ways the study will strengthen the well-being of the specific communities if applicable:**

7. Upload a supporting citation list if applicable:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent Form	RAI+ consent_2021 05 25 clean.pdf	0.15	5/27/2021 11:20 AM	Jennifer Marwitz	Consent/Assent/Information Sheet	Yes
View	Assent Form	RAI+ assent_2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Jennifer Marwitz	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Consent Script	COVID Contingency Consent Script RAI+ 2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Courtney Roberts	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Consent Form	COVID Contingency Consent Info Sheet RAI+ 2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Courtney Roberts	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Protocol	COVID Contingency Protocol v6 HM20011840 2021 05 25.docx	0.06	5/25/2021 2:35 PM	Elicia Preslan	Research Protocol	Yes
View	Flyer	RAI+ Study_Flyer 2021 05 25 clean.doc	0.03	5/25/2021 2:35 PM	Jennifer Marwitz	Recruitment/Advertising	Yes
View	Hsu PI Change Form	Hsu PI Change Form 2021 05 11.pdf	0.01	5/25/2021 2:33 PM	Jennifer Marwitz	Other	Yes
View	Hsu CV	Hsu CV 2020 Dec.pdf	0.01	5/25/2021 2:33 PM	Jennifer Marwitz	CV/Biosketch	Yes
View	Marwitz CV	Marwitz,Jennifer CV 2020 12 18.docx	0.01	1/6/2021 2:45 PM	Jennifer Marwitz	CV/Biosketch	Yes
View	Script for cases where follow-up done by phone	Script follow-ups done by phone 2017 12 17.doc	0.01	12/17/2017 3:24 PM	Jennifer Marwitz	Research Measure	Yes
View	Grant Proposal	grantsApplication.pdf	0.01	11/15/2017 2:35 PM	Jennifer Marwitz	Funding Proposal	Yes
View	Data Collection Forms	RAI+ Measures.pdf	0.01	10/30/2017 5:24 PM	Jennifer Marwitz	Research Measure	Yes
View	RAI+ Implementation Manual	RAI+ Manual 2017 05 08.pdf	0.01	10/30/2017 5:22 PM	Jennifer Marwitz	Research Measure	Yes
View	MacCAT-CR (Consent Evaluation)	MacCAT-CR 2017 10.doc	0.01	10/30/2017 5:22 PM	Jennifer Marwitz	Research Measure	Yes
View	CV/Biosketch-Kreutzer	JSK CV 2017 10 04.docx	0.01	10/25/2017 12:56 PM	Jennifer Marwitz	CV/Biosketch	Not Applicable

Study Population

1. * **Provide the maximum number of individuals that**

   1. May participate in any study interaction or intervention (Including screening, consenting, and study activities)
   AND/OR
   2. You obtain any data/specimens about (regardless of identifiability)

   at VCU and at other sites under the VCU IRB's oversight. See the help text for additional guidance.
   192

2. **If this is a multi-Center Project, what is the maximum anticipated number of subjects across all sites?**

3. * **Provide justification for the sample size by explaining how you arrived at the expected number of participants and why this number is adequate for answering the research questions:**
   Power analyses relating to the primary hypothesis indicate minimum group sizes of 69 participants. If we allow for a maximum of 28% attrition, then an additional 27 individuals per treatment group (54 individuals total) should be recruited (138/(1-0.28)-138 = 53.67), yielding a sample size of 192.

4. * **List the study inclusion criteria:**
   Individuals meeting the following:

   Eighteen years of age and older.

   Mild, moderate, or severe TBI defined as: damage to brain tissue caused by an external mechanical force as evidenced by loss of consciousness due to brain trauma, post-traumatic amnesia (PTA), skull fracture, or objective neurological findings that can be reasonably attributed to TBI on physical examination or mental status examination.

   At least 3 months post-TBI.

   Since there is no reason to believe that treatment effectiveness varies with chronicity, no maximum has been set for time postinjury.

5. * **List the study exclusion criteria:**
   Active substance abusers (e.g., intoxicated at arrival to intake).

   Individuals at imminent risk of psychiatric hospitalization, or in imminent danger of hurting themselves or others, as judged by the investigators, will be excluded from the study.

6. * **Will individuals with limited English proficiency be included in or excluded from this research?**
   - ○ Included
   - ○ Excluded - safety concerns if participants are unable to communicate with the study team
   - ○ Excluded - instruments/measures only validated in English
   - ○ Excluded - no prospect of direct benefit to individual participants
   - ● **Excluded - minimal risk study**
   - ○ Excluded - lack of budget/resources for translation and interpretation [provide an explanation in next question]
   - ○ Excluded - other reason [provide an explanation in next question]

7. **Justify the inclusion and exclusion criteria if you are either targeting, or excluding, a particular segment of the population / community. Provide a description of the group/organization/community and provide a rationale.**
   Individuals with limited English proficiency are excluded, as this is a minimal risk study. Further, the intervention involves working with an English-speaking interventionist and use of measures that have only been validated in the English language.

Background, Rationale & Goals Section Complete

Protocol Progress:
● **INITIAL SETUP**
● **BACKGROUND, RATIONALE & GOALS**
③ RESEARCH PLAN
④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Study Procedures

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
1. Primary: Participants receiving the booster (RAI+ group) will report higher levels of resilience in comparison to individuals in the standard RAI group.

2. Participants in the RAI+ group will show better adjustment and lower levels of emotional distress as compared to persons in the standard RAI group.

3. Additionally, participants in the RAI+ group will report greater abilities in the areas of problem solving, communication, and stress management relative to persons in the standard RAI group.

4. A participant's demographic, lifestyle, injury, and treatment response information will be predictive of maintenance ability.

2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
1. to evaluate the short and long-term efficacy of two structured outpatient intervention programs (RAI vs. RAI+) on resilience

2. to evaluate the short and long-term impact of intervention on emotional well-being and postinjury adjustment with the RAI vs. the RAI+

3. to evaluate the short and long-term impact of the RAI and the RAI+ on abilities including problem solving, communication, and stress management

4. to determine if demographic, lifestyle, injury, or treatment response information can predict maintenance of gains

3. * **Choose all types of recruitment materials that may be used <u>and upload them below</u>:**
- [ ] E-mail invitations
- [ ] Phone Solicitation scripts (i.e. cold calls or random-digit-dialing)
- [x] **Flyers, Mailed Letters or Newspaper/TV/Radio Ads**
- [ ] TelegRAM announcements
- [x] **Website text**
- [ ] Study-specific web sites (provide the design and text)
- [ ] Social Media
- [ ] EPIC MyChart Patient Portal research study descriptions
- [ ] Psychology Research Participant Pool (SONA) study descriptions
- [ ] Scripts for announcements made to groups
- [ ] Other recruitment document
- [ ] No recruitment materials

4. * **Describe the study procedures/methods for identifying and recruiting participants. Address all of the following three aspects of recruitment in your response.**

1. Identification of potentially eligible participants or secondary data/specimens of interest.
- What database(s) will be queried to identify secondary data/specimens
- How VCU Informatics or VCU IRDS will be used for cohort identification (when applicable, see help text)
- How potential participants' contact information will be obtained

2. Recruitment procedures to invite participation in the study (when applicable):
- How each of the written or verbal recruitment materials and reminders (selected above) will be used
- Who will contact, approach, or respond to potential participants
- Locations where recruitment procedures will take place
- The timing and frequency of recruitment attempts

3. Eligibility screening prior to consent and how those activities will be carried out (when applicable)

See the help text for additional guidance.
Potential subjects will be identified in several ways. Flyers advertising the study (attached) will be distributed via local brain injury support organizations, through PM&R Outpatient Brain Injury (ACC 6) and Neuropsychology VCUHS (Stony Point) Clinics and on VCU PM&R websites which target both brain injury clinicians (for flyer distribution) and brain injury survivors. Flyers will direct interested patients to contact the Research Coordinator for more information. Secondly, the Interventionists and other healthcare providers will take referrals from potential participants at the Neuropsychology Clinic. Once participants have been identified and express an interest, they will either meet with the PI or a Research Assistant that day at the clinic to discuss the study, or they will be contacted by the Research Assistant by phone to further discuss participation and ensure that they meet the criteria for participation.

5. * **Does this study have a separate protocol document (i.e. a multisite or sponsor's protocol) that contains a detailed description of the study's methodology?**

   ○ Yes

   ● **No**

6. * **Since a separate protocol document is not uploaded, describe the proposed research using language understandable to those IRB committee members whose expertise is not scientific. The description must include:**

   1. A statement explaining the study design
   2. A detailed description of all the procedures that will be followed to carry out the study, preferably in sequential order, and in sufficient detail that the study's methods could be replicated
   3. The schedule and frequency of when and how procedures will be conducted (e.g. in person, online, phone, paper, etc.)
   4. A description of all research measures/tests/interventions that will be used, including analyses/tests conducted on specimens/biological samples (if applicable)

   See the help text for additional guidance
   Participants will be self-referred or referred by professionals within and outside VCUHS, organizations (e.g., Brain Injury Association of Virginia), and agencies (e.g., Virginia Department of Rehabilitative Services). When persons with TBI contact the Department of Physical Medicine and Rehabilitation's (PM&R's) Neuropsychology Service regarding the study, an intake session will be scheduled.

   During the intake, the Interventionist, Research Coordinator or Research Assistant will provide information about the research program, and determine eligibility and interest in participation. Staff will explain the study details and obtain informed consent.

   On giving informed consent, participants will complete intake assessment materials. Average estimated time for the completion of measures is 30 minutes. Information from medical record review will be included on the intake form, specifically acute care and inpatient rehabilitation length of stay, time to follow commands, time to emerge from post-traumatic amnesia, neurosurgical intervention, Glasgow Coma Scale score, and severity of injury (mild vs moderate-severe).

   Using randomization tables, participants will be assigned to either of two treatment groups: (1) Resilience and Adjustment Intervention (RAI), or (2) RAI+. After randomization, a second appointment will be scheduled. All participants will begin the 7-session treatment during their second appointment. The intervention consists of seven 60-minute sessions scheduled over seven weeks (see attached RAI Implementation Manual). During the first session, participants will receive an empty loose leaf binder to store and organize completed self-assessments, reading materials, and homework assignments from each session. They will be asked to review materials and complete worksheets between sessions. The intervention will be implemented by experienced, licensed therapists (Ph.D. level Interventionists). Participants will be randomly assigned to one of the therapists.

   The RAI and RAI+ groups will both complete the post-treatment measures immediately after the seventh treatment session and then 3, 4, and 9 months later. Data collection at 3, 4, and 9 months post-treatment will be completed in-person, unless the participant requests to complete via phone.

   Furthermore, the RAI+ group will complete 3 booster sessions, spaced approximately 7-10 days apart, beginning 3 months after completion of the seventh treatment session (booster sessions will occur between the 3 and 4 month data collection described above).

   Data will be analyzed to identify any therapist effects, as well as treatment effects. For the RAI and RAI+ groups, demographic, injury severity, and history information will be collected at intake using standard procedures and protocols. All participants will complete the 4 outcome measures (Connor-Davidson Resilience Scale, CD-RISC; Mayo Portland Adaptability Inventory-4, MPAI-4; 13 Item Stress Test; and Brief Symptom Inventory-18, BSI-18) at 5 time points (intake, post-treatment, and 3, 4 and 9 month follow-up).

   The RAI is not a standard of care at VCU. Both the RAI and the RAI+ are experimental interventions. Any information collected during the intervention sessions (e.g., questionnaires, lists generated) is part of the experimental intervention, not part of the research data.

7. * **The IRB only reviews research activities, so indicate for each of the study activities described in the question above or in the protocol which activities are:**

   - Being performed exclusively for research purposes (i.e. they would not otherwise be done apart from this study) VERSUS.

- Alterations of routine activities/procedures (e.g. the study is altering the timing, frequency, method, location, amount, etc.) VERSUS.
- Being done for other purposes and whose data/results will be used secondarily in the study (e.g. standard medical or psychological tests, routine education practices, quality improvement initiatives, etc.).
See the help text for additional guidance

All data is collected specifically for research purposes.

8. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:**
Potential participants will be given referral information for mental health services if they are not interested in participating in research.

9. **Upload any supporting tables or documents (e.g. protocol documents, figures/tables, data collection forms, study communications/reminders):**

Upload ALL instruments/guides that will be used or that participants will experience (i.e. see, hear, complete), including measures, scripts/questions to guide interviews, surveys, questionnaires, observational guides, etc,:

Upload ALL recruitment and screening materials, including such as ads, flyers, telephone or in-person scripts, letters, email invitations, TelegRAM announcements, and postcard reminders, screening scripts, screening forms, and screening measures:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent Form	RAI+ consent_2021 05 25 clean.pdf	0.15	5/27/2021 11:20 AM	Jennifer Marwitz	Consent/Assent/Information Sheet	Yes
View	Assent Form	RAI+ assent_2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Jennifer Marwitz	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Consent Script	COVID Contingency Consent Script RAI+ 2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Courtney Roberts	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Consent Form	COVID Contingency Consent Info Sheet RAI+ 2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Courtney Roberts	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Protocol	COVID Contingency Protocol v6 HM20011840 2021 05 25.docx	0.06	5/25/2021 2:35 PM	Elicia Preslan	Research Protocol	Yes
View	Flyer	RAI+ Study_Flyer 2021 05 25 clean.doc	0.03	5/25/2021 2:35 PM	Jennifer Marwitz	Recruitment/Advertising	Yes
View	Hsu PI Change Form	Hsu PI Change Form 2021 05 11.pdf	0.01	5/25/2021 2:33 PM	Jennifer Marwitz	Other	Yes
View	Hsu CV	Hsu CV 2020 Dec.pdf	0.01	5/25/2021 2:33 PM	Jennifer Marwitz	CV/Biosketch	Yes
View	Marwitz CV	Marwitz,Jennifer CV 2020 12 18.docx	0.01	1/6/2021 2:45 PM	Jennifer Marwitz	CV/Biosketch	Yes
View	Script for cases where follow-up done by phone	Script follow-ups done by phone 2017 12 17.doc	0.01	12/17/2017 3:24 PM	Jennifer Marwitz	Research Measure	Yes
View	Grant Proposal	grantsApplication.pdf	0.01	11/15/2017 2:35 PM	Jennifer Marwitz	Funding Proposal	Yes
View	Data Collection Forms	RAI+ Measures.pdf	0.01	10/30/2017 5:24 PM	Jennifer Marwitz	Research Measure	Yes
View	RAI+ Implementation Manual	RAI+ Manual 2017 05 08.pdf	0.01	10/30/2017 5:22 PM	Jennifer Marwitz	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	MacCAT-CR (Consent Evaluation)	MacCAT-CR 2017 10.doc	0.01	10/30/2017 5:22 PM	Jennifer Marwitz	Research Measure	Yes
View	CV/Biosketch-Kreutzer	JSK CV 2017 10 04.docx	0.01	10/25/2017 12:56 PM	Jennifer Marwitz	CV/Biosketch	Not Applicable

Project Details

An intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

An interaction includes communication or interpersonal contact between investigator and subject. It may include in-person, online, written, or verbal communications.

Secondary information/biospecimens are information or biospecimens that have been or will be collected for some other "primary" or "initial" activity and that will be used secondarily in the research study.

1. * **Select all of the following types of interventions that apply to this study (selections will branch):**
   - [x] **Social/Behavioral interventions or experimentation / Tasks / Environmental manipulations**
   - [ ] Deception (misleading participants through false or incomplete information)
   - [ ] Drug(s) / Biologics / Supplement(s) / Other Compounds (investigational products or products whose administration is dictated by the study protocol and not per the physician's clinical judgment)
   - [ ] IV contrast administration for research-related imaging (will branch to the Drugs page)
   - [ ] Placebos
   - [ ] Safety and/or effectiveness evaluation of Bio-Medical Device(s), including in-vitro diagnostic devices/assays, mobile medical apps, software functions, and HUDs used in clinical investigations
   - [ ] Washout Periods
   - [ ] Expanded Access – Treatment Use of an Investigational Product
   - [ ] Medical or Surgical Procedures (eg: physical exam, clinical procedures, scans, etc)
   - [ ] Specimen/biological sample collection
   - [ ] None of the Above

2. * **Select all of the following types of interactions and methods of data collection that apply to this study (selections will branch):**
   - [x] **Surveys / Questionnaires /Written responses to questions (including data entry)**
   - [ ] Active Internet data collection (i.e. using the internet to collect data, including online surveys, data collection via Zoom, apps, etc.)
   - [ ] Passive Internet data collection (i.e. passively observing online behavior, bots)
   - [ ] Interviews / Focus Groups / Verbal responses to questions
   - [x] **Audio / Video recording or photographing participants**
   - [ ] Observations
   - [ ] Educational Settings/Assessments/Procedures
   - [ ] None of the Above

3. * **Select all types of recordings that will be made:**
   - [x] **Audio**
   - [ ] Video
   - [ ] Photographs

4. * **Describe the purpose of the recordings, who will be recorded and when such recordings will occur:**
   A protocol has been established to ensure the quality and standardization of treatment implementation across interventionists.

   Each interventionist will meet with one volunteer participant, and implement Session I of the RAI curriculum. Informed written consent for audio-recording will be obtained. Audio recording consent is addressed within the study consent form. Afterward, the intervention audio-recordings will be reviewed with the PI, with the manual in hand, to make certain that all steps are completed. Additionally, the PI will assure that interventionists have covered the bolded

content areas in the manual, which are considered to be key elements of treatment (see uploaded RAI manual). Strategies for improving consistency between interventionists will be discussed and implemented. Changes will be made in the implementation manual (e.g., clarification of procedures) as needed.

The interventionist will meet again with the same volunteer participant, and implement the remaining six sessions of the RAI curriculum. Again, the audio-recordings will be reviewed with the PI, and strategies for adherence to the manual will be discussed and implemented after each session.

Every six months thereafter, the complete quality control procedure will be reapplied by each interventionist.

Additional quality control procedures will be implemented for booster sessions with each interventionist. Audio-recordings will be made for the three booster sessions and reviewed with the PI to ensure that key areas are covered as outlined in the manual. Every six months thereafter, quality control procedures will be repeated.

5. * **Select all types of secondary information and/or specimens that apply to this study (selections will branch): See the help text for definitions.**

- [x] **Individually Identifiable Health Information (PHI)**
- [x] **Secondary data/specimens NOT from a research registry or repository**
- [ ] Information/specimens from a research registry or repository (Usage Protocol)
- [ ] Information/specimens originally collected for a previous research study
- [ ] Publicly available information/specimens
- [ ] Government-generated or collected information that was or will be obtained for nonresearch activities [only applicable to research conducted by or on behalf of a Federal department or agency]
- [ ] No secondary data/specimens will be used

Behavioral Intervention/Task Details

This page asks for details about the social/behavioral intervention, task, or environmental manipulation in the research.

Interventions include both physical procedures by which information is gathered and manipulations of the subject or the subject's environment that are performed for research purposes. This might include activities such as playing computer games, performing a task, thought/cognition activities, environmental manipulations, and educational activities.

If the study only involves surveys, interviews, or secondary data collection, go back to the Project Details page and uncheck “Social/Behavioral interventions or experimentation / Tasks / Environmental manipulations” in Question 1.

1. * **Describe the duration of the social/behavioral intervention, task, or environmental manipulation:**
   The intervention consists of seven 60-minute sessions scheduled over seven weeks, as well as three additional "booster" sessions scheduled weekly 3 months after completion of the seven sessions.

2. * **Describe any potential harms or discomforts that participants could experience during the intervention activity:**
   Feelings of mental/emotional discomfort may arise when discussing postinjury changes.

3. * **Will the intervention activity be physically invasive or painful?**
   - ○ Yes
   - ● **No**

4. * **Describe the impact the intervention activity will have on participants, including the nature and duration of any impact(s):**
   Feelings of discomfort are common when stressed individuals talk about postinjury changes. However, our experience is that people generally appreciate the opportunity to discuss their life situations. Participants will have the opportunity to omit or decline to answer any questions. The VCU TBIMS places an emphasis on providing participants with psychological support and education to assist in recovery following TBI. The duration of discomfort is not expected to last longer than the duration of the session.

5. * **In the investigator's opinion, is there any reason to think that the participants will find the intervention activity offensive or embarrassing? Explain why or why not.**
   There is no reason to think that participants will find the intervention offensive or embarrassing. The emphasis is on psychological support and education.

Secondary Data/Specimen Details

1. * **Describe the source(s) and nature of the information/specimens being obtained. This response should:**

   a. Identify where the data/specimens will come from (e.g., another researcher's registry, pathology lab, commercial source, medical records, etc.); and
   b. List what types of specimens will be obtained (when applicable); and/or
   c. List all data elements that will be obtained (when applicable). A data collection form or other documentation may be uploaded and referenced here.
   Data is collected from medical records (information regarding injury severity). Data is accessed through Cerner.

   Specific data points include: acute care and inpatient rehabilitation length of stay, time to follow commands, time to emerge from post-traumatic amnesia, neurosurgical intervention, Glasgow Coma Scale score, and severity of injury (mild vs moderate-severe).

2. * **Describe whether any agreement exists between you and data/specimen provider that states you will never have access to the ability to identify the participants (i.e. access to identifiers or the code key) and that you will not attempt to re-identify individuals.**
   Actual date of injury is provided by the participant, though it will be verified in Cerner.

3. * **When the information/specimens were originally collected, did individuals provide consent for secondary research use of their data/specimens (i.e. consent to another research study or to a research registry)?**
   - (●) **Yes**
   - ( ) No

Costs to Participants

1. * **Select all categories of costs that participants or their insurance companies will be responsible for:**
   - [x] **Participants will have no costs associated with this study**
   - [ ] Study related procedures that would be done under standard of care
   - [ ] Study related procedures not associated with standard of care
   - [ ] Administration of drugs / devices
   - [ ] Study drugs or devices
   - [ ] Other

Compensation

It is recommended that investigators consult with VCU Procurement Services before proposing a compensation plan (monetary or non-monetary) to the IRB to ensure the plan will comply with VCU policies. Refer to WPP XVII-2 for the IRB's guidelines about compensating research participants.

1. * **Describe any compensation that will be provided including:**
   1. **total monetary amount**
   2. **type (e.g., gift card, research pre-paid card, cash, check, merchandise, drawing, extra class credit)**
   3. **how it will be disbursed**
   4. **how you arrived at this amount**
   5. **What identifiers and tax forms will be required for compensation purposes (i.e. W-9 form, SSN, V#, addresses, etc.)**

   Participants will be provided therapy, educational materials, and referral services at no cost. Each participant will receive a total of $140. Participants will receive a payment each time measures are completed: $25 for completing the intake session and post-treatment session surveys, and $30 at each of the remaining 3 survey data time points (3, 4, and 9 months after the post-treatment session).

   If participants travel more than 60 miles roundtrip, funds will be provided to offset travel costs (IRS mileage rate of 19 cents per mile driven).

   When data collection is completed by phone, a payment form is mailed to the participant with instructions on completion and a postage-paid business reply envelope. Participants complete the payment form and then return the form in the self-addressed envelope. Payment forms are then processed at VCU and a check is mailed to the participant.

   When data collection is completed in person, the participant completes the payment form and then receives cash for their participation.

   As described previously, the payment form requires the following PHI: name, social security number, address, and phone number.

2. **If compensation will be pro-rated, explain the payment schedule.**

Contingency Plan

This page will be used by the IRB in the event that an institution-wide emergency situation arises that requires contingency plans.

A contingency plan describes the alternative procedures that a study would want to use in case of an emergency that prevented normal study activities from occurring. It is a form of adaptive protocol. It enables the VCU IRB to quickly approve alternative study activities along with criteria for when those activities would or would not be put into effect. For example, in 2020, some studies had a COVID-19 Contingency Protocol approved that described alternative remote procedures that they would switch to whenever the University restricted in-person research activities.

In all studies, investigators are strongly encouraged to plan prospectively and build flexibilities into their regular protocols (regardless of whether an emergency situation exists) as well as think about what they would do in an emergency situation. For example, windows for timed study visits, ranges instead of exact values, flexibilities in inclusion criteria, etc. Flexibility and adaptations that are built into the protocol will reduce the number of changes that have to be submitted to the IRB and should reduce the number of incidents of deviations and noncompliance by investigators.

Further instructions and smartform questions on this page will be released from the IRB in the event of such an institution-wide emergency situation.

Research Complete

Protocol Progress:
● **INITIAL SETUP**
● **BACKGROUND, RATIONALE & GOALS**
● **RESEARCH PLAN**
④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

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Consent Process

1. * List all consent groups:

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
View	Participants with TBI	Signed Consent by Participant Signed Assent by Child or Decisionally Impaired Adult Signed Parent/Guardian Permission or Legally Authorized Representative Consent	No Waivers Requested	Other Research Coordinator Research Assistant	Interventionist		Participants will consent in the facilities housing the Department of Physical Medicine and Rehabilitation, Division of Neuropsychology and Rehabilitation Psychology Research Offices, located in West Hospital on the 3rd floor.		Individuals are afforded as much time as they wish to decide about participation, and they may schedule a follow-up appointment with the study team if they wish to take the consent form home to discuss with others prior to deciding.	If the individual's cognitive status improves during the course of this study, then consent will be sought.

2. Upload any consent / assent documents:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent Form	RAI+ consent_2021 05 25 clean.pdf	0.15	5/27/2021 11:20 AM	Jennifer Marwitz	Consent/Assent/Information Sheet	Yes
View	Assent Form	RAI+ assent_2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Jennifer Marwitz	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Consent Script	COVID Contingency Consent Script RAI+ 2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Courtney Roberts	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Consent Form	COVID Contingency Consent Info Sheet RAI+ 2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Courtney Roberts	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Protocol	COVID Contingency Protocol v6 HM20011840 2021 05 25.docx	0.06	5/25/2021 2:35 PM	Elicia Preslan	Research Protocol	Yes
View	Flyer	RAI+ Study_Flyer 2021 05 25 clean.doc	0.03	5/25/2021 2:35 PM	Jennifer Marwitz	Recruitment/Advertising	Yes
View	Hsu PI Change Form	Hsu PI Change Form 2021 05 11.pdf	0.01	5/25/2021 2:33 PM	Jennifer Marwitz	Other	Yes
View	Hsu CV	Hsu CV 2020 Dec.pdf	0.01	5/25/2021 2:33 PM	Jennifer Marwitz	CV/Biosketch	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Marwitz CV	Marwitz,Jennifer CV 2020 12 18.docx	0.01	1/6/2021 2:45 PM	Jennifer Marwitz	CV/Biosketch	Yes
View	Script for cases where follow-up done by phone	Script follow-ups done by phone 2017 12 17.doc	0.01	12/17/2017 3:24 PM	Jennifer Marwitz	Research Measure	Yes
View	Grant Proposal	grantsApplication.pdf	0.01	11/15/2017 2:35 PM	Jennifer Marwitz	Funding Proposal	Yes
View	Data Collection Forms	RAI+ Measures.pdf	0.01	10/30/2017 5:24 PM	Jennifer Marwitz	Research Measure	Yes
View	RAI+ Implementation Manual	RAI+ Manual 2017 05 08.pdf	0.01	10/30/2017 5:22 PM	Jennifer Marwitz	Research Measure	Yes
View	MacCAT-CR (Consent Evaluation)	MacCAT-CR 2017 10.doc	0.01	10/30/2017 5:22 PM	Jennifer Marwitz	Research Measure	Yes
View	CV/Biosketch-Kreutzer	JSK CV 2017 10 04.docx	0.01	10/25/2017 12:56 PM	Jennifer Marwitz	CV/Biosketch	Not Applicable

Consent Plan Complete

Protocol Progress:
- **INITIAL SETUP**
- **BACKGROUND, RATIONALE & GOALS**
- **RESEARCH PLAN**
- **CONSENT PLAN**

⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Risks, Discomforts, Potential Harms and Monitoring

1. * **Describe the risks of each research procedure to participants or others. For each identified risk, provide an assessment of the anticipated seriousness and likelihood of the risk. Some examples of possible risks include but are not limited to:**

   - **Physical risks (e.g. bodily harms or discomforts, side effects, etc.)**
   - **Psychological risks (e.g. emotional, mental, or spiritual harms or discomforts, changes to thoughts, beliefs, or behaviors, etc.)**
   - **Research data risks (e.g. loss of confidentiality and privacy)**
   - **Social or legal risks (e.g. impacts on relationships or reputation, legal or criminal justice actions for self or others, etc.)**
   - **Financial risks (e.g. impacts on income, employability, or insurability, loss of services, etc.)**
   - **Other risks (e.g. unforeseeable risks of experimental procedures, risks related to particular study designs (randomization, washout, placebo, withholding care/services, deception), etc.)**

   See the help text for additional guidance.

   There is less than minimal risk (physical, psychological, social, legal, or other) associated with enrollment in the study.

   The primary potential risk is the feeling of mental/emotional discomfort that may arise when discussing post-TBI changes. These types of feelings may be common when stressed individuals are talking about postinjury changes. However, our experience with data collection indicates that people generally appreciate the opportunity to discuss their life situations. Participants will have the opportunity to omit or decline to answer any questions. The VCU TBIMS places an emphasis on providing participants with psychological support and education to assist in recovery following TBI.

   Another potential risk is a breach in confidentiality and breach in privacy with regard to data collection. The de-identification and coding process is the safeguard in place to minimize risk of breach in confidentiality, and research activities are completed in a private clinical setting to minimize risk related to breach in privacy

2. * **Describe how each of the risks/harms/discomforts identified above will be minimized:**
   The research staff will pay particular attention to and attempt to minimize any risks that may occur as a result of participation in this study. For this study, risks to subjects are less than minimal. Potential risk is mitigated in several ways. Research staff who collect the data are well trained and very familiar with the population. The de-identification and coding process is the safeguard in place to minimize risk of breach in confidentiality. And, research activities are completed in a private clinical setting to minimize risk related to breach in privacy.

3. * **Describe any potential risks or harms to a community or a specific population based on study findings (e.g. information that could be stigmatizing or derogatory):**
   None.

4. **Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects:**
   The PI is on call during each interview is responsible for monitoring the status of enrolled participants and addressing urgent situations. When concerns arise, the PI is contacted immediately to make a clinical decision regarding the need for further evaluation, treatment, or referral.

5. * **Describe criteria for when the investigator would withdraw an individual participant from the study; such as safety or toxicity concerns, emotional distress, inability to comply with the protocol, etc.:**
   If the participant experiences significant emotional distress during the intervention sessions, the Interventionist may recommend study withdrawal in order for the person to seek a more appropriate and intensive treatment for mental health problems. Referrals will be made to the VCUHS Neuropsychology Clinic located at Stony Point. If the participant's emotional difficulties improve, they may return to complete the study.

6. * **Summarize any pre-specified criteria that would trigger the investigator/sponsor/monitoring committee to stop or change the study protocol due to safety concerns:**
   None.

   Data and Safety Monitoring
   Data and safety monitoring is a system for checking the study's data at regular intervals over the study period to identify and address issues that could affect the safety of research participants. This requirement is in accordance with 45 CFR 46.111.

The purpose of data and safety monitoring plan is to set forth study team procedures for monitoring/addressing:
- Participant safety (physical, psychological, etc.)
- Data validity
- Early stopping (termination) based upon changes in risks and benefits.

7. * **Indicate if this study will have a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Plan (DSMP): [Required for all greater than minimal risk studies]**

- [ ] DSMB
- [x] **DSMP**
- [ ] No DSMB/DSMP [Note: This response is not applicable for greater than minimal risk studies]

8. * **Describe your Data Safety Monitoring Plan for monitoring the study's data to ensure the safety of participants. This plan should include (but is not limited to) the following elements:**
1. Who will monitor data
2. What data and/or processes will be reviewed
3. When and how frequently monitoring will occur
4. What report/documentation will be submitted to the IRB at the time of continuing reviews

See the help text for additional guidance.

The monitoring of this study will involve a continuous and ongoing process of reviewing the conduct of the trial, including adherence to the study design and documentation of AEs/SAEs. The responsibility of monitoring the safety of participants is held primarily by the PI. Considering that the interventions in this study carry less than minimal risk to participants, and that the PI and the research team have appropriate clinical skills and training to monitor for AEs/SAEs, it is appropriate for the research team to carry the primary responsibility for monitoring.

Monitoring the Safety of Participants: A specific protocol will be used to monitor for and report AEs/SAEs. The PI, in collaboration with the Research Coordinator, are primarily responsible for monitoring the safety of participants, in collaboration with the study interventionists, in the following ways:

Monitor for Psychological AE (worsening depressive symptoms from one assessment time point to the next by 5 points on the BSI-18 Depression scale with no endorsement of suicidality):
- Participants will be provided with the contact information for the Research Coordinator, PI, and interventionist. They will be advised to call with any questions or concerns or to report any unusual emotional feelings; and
- Research Assistants are trained in the definition of AE (worsening depressive symptoms without endorsement of suicidality) and will report any obvious psychological changes in participants to the PI immediately.

Monitor for Psychological SAE (suicidality):
- The Research Coordinator will administer the MINI suicide module immediately to assess suicidality risk in any of the following situations: a participant reports suicidal thoughts to study staff; and/or, a participant endorses suicidality on the depression scale of the BSI-18 during data collection.
- If the suicide risk is low on the MINI (<8), the Research Coordinator will ask the participant to be in touch with his/her healthcare provider for follow-up. If the participant scores high for suicide risk (9-17), the Research Coordinator will ensure that the participant is accompanied by a family member or friend to their healthcare provider or the local emergency department for immediate evaluation. The Research Coordinator will consult with one of the interventionists (clinical psychologists) regarding additional questions/concerns.

In all of the above cases, the PI or the interventionists will determine the severity of the AE/SAE and the relatedness to the intervention. The PI will document actions taken and outcomes. If any of these events occurs and are directly related to the intervention, the IRB and NIDILRR will be alerted.

Summary of Study Review Plan: Study progress and safety will be reviewed by the PI on a monthly basis, and more frequently if needed. Progress reports, including participant accrual, participant status and adherence data will be provided regularly to the PI. Data about AEs/SAEs will be reported with each occurrence. As part of the IRB continuing review, an Annual Report will be compiled and will include a list and summary of AEs/SAEs. In addition, the Annual Report will address (1) whether AEs/SAEs have been severe and related to the intervention; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; and (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study.

Validity and Integrity of Data: In collaboration with the research team, the PI will maintain responsibility for all aspects of data collection, entry, and analysis. PI and study staff will review all data collected on an ongoing basis for completeness and accuracy, as well as protocol compliance. The frequency of data review is described below:
- Participant accrual: Review of the rate of participant accrual and compliance with inclusion/exclusion criteria will occur monthly during the recruitment phase to ensure that a sufficient number of participants are being enrolled and that they meet eligibility criteria.
- Participant status and Adherence data: Review of the status of enrolled participants will occur on a consistent basis throughout the study, including data on adherence to study visits and the intervention protocol. If there are concerns about whether adherence has reached a level that might inhibit the ability of the study to evaluate the specific aims, a conference call will be scheduled with Scientific Advisors and the Advisory Board to discuss methods for improving adherence.
- AEs and SAEs and rates: Review of every AE and SAE will be closely evaluated by the PI at each occurrence and reported in annual reviews.

Privacy

Privacy refers to an individual's right to control how others view, record, or obtain information about them. When privacy is violated it can involve such things as

- Being asked personal questions in a public setting;
- Being publicly identified as having a particular characteristic or diagnosis;
- Being seen entering a place that might be stigmatizing;
- Being photographed, videotaped or observed without consent;
- Disclosure of personal information to unauthorized people

Privacy is not the same as confidentiality because privacy protections apply to people, and confidentiality protections apply to data. Confidentiality protections should be described on the Data Confidentiality page of this form, not here.

Instructions for this page:

Select all the applicable ways that the research team will protect participants' privacy throughout the course of the study. The options listed include some of the most common best practices. Not all will be applicable to every study.

****The IRB will expect studies to operationalize all selected checkboxes into the conduct of the research.**

To elaborate on any response, also click the "Other Protections" checkbox to provide further explanation in the last free-text question.

Read the entire page before filling out the form.

1. * Protections when conducting one-on-one in-person interventions or interactions (for groups see Q2 below):

- [x] **Conducting study activities in locations that maximize privacy (limited people around, closing doors, drawing drapes around beds, monitoring voice volume, etc.)**
- [x] **Verifying identity before discussing personal information.**
- [x] **Asking the participant if they are comfortable answering questions in that location**
- [x] **Asking the participant if they are comfortable with having other people present (if any)**
- [x] **Moving away from other people when conducting activities in public spaces or offering a private space**
- [x] **Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing) if uncomfortable verbally responding**
- [x] **Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics**
- [ ] Other protections not listed in this question – describe below
- [ ] N/A – study has no in-person interventions or interactions with participants

2. * Protections when conducting group interventions or interactions:

- [ ] Conducting study activities in locations that maximize privacy (limited people passing by, closing doors, monitoring voice volume, etc.)
- [ ] Moving to a more private area to answer questions or to discuss concerns
- [ ] Discussing privacy with the participants and the importance of not talking outside the group about what other people say during the group session
- [ ] Allowing participants to use a pseudonym or limiting use of individuals' names during the group activity
- [ ] Asking everyone in a public group setting (e.g. classrooms, workshops) to turn something in (blank or filled) so participants do not have to self-identify when turning in materials
- [ ] Collecting paper forms in a closed box or envelope rather than passing to others or leaving in an open area
- [ ] Limiting participant identifiers that would be visible on paper documents (i.e. using study IDs instead of direct identifiers)
- [ ] Allowing people to distance themselves from other participants during group activities

- [ ] Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing instead of speaking)
- [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
- [ ] Ensuring non-participating individuals are not captured on recordings or in photos
- [ ] Other protections not listed in this question – describe below
- [x] **N/A – study has no group interventions or interactions**

3. * **Protections when conducting remote interventions or interactions (e.g. phone, text, email, video-conference, tele-health, online, etc.):**
   - [x] **Conducting study activities in locations where study staff can maximize their own privacy (limited people around, closing doors, monitoring voice volume, etc.)**
   - [x] **Leaving/sending generic messages that avoid using study and participant identifiers, such as names, study titles, clinics, study topics, etc.**
   - [x] **Obtaining permission prior to sending text messages**
   - [x] **Advising the participant to move to a location where they are comfortable answering questions and will not be overheard - incorporate this instruction into your study materials**
   - [x] **Advising online participants to complete the activity at a time and location where they will be comfortable answering questions - incorporate this instruction into your study materials**
   - [x] **Ensuring non-participating individuals are not captured on recordings or in photos**
   - [x] **Offering other options of ways to complete the activity (i.e. online, paper, phone) if more privacy is desired**
   - [x] **Offering a way to save and return later to the online activity if privacy is compromised**
   - [ ] Other protections not listed in this question – describe below
   - [ ] N/A – study has no remote interventions or interactions with participants

4. * **Protections when mailing study materials to/from participants:**
   - [x] **Obtaining permission to mail study materials**
   - [x] **Confirming/verifying the accuracy of addresses before mailing items**
   - [x] **Ensuring the participant is able to personally receive mailed materials and has a way to protect their own privacy if they do not want others to know they are receiving research communications (i.e. notifying participants of when to expect it)**
   - [x] **Using return address labels and document headers that avoid study identifiers, such as study names, clinics, study topics, etc.**
   - [x] **Avoiding or limiting use of participant identifiers and health information on mailed documents (i.e. using study IDs instead of direct identifiers)**
   - [x] **Providing a return mailing address label or pre-addressed envelope to ensure returned items are sent to the correct address**
   - [x] **Communicating receipt of mail from participants and/or asking them to notify you when they mail it to ensure study documents are not lost in transfer**
   - [ ] Offering other options of ways to complete the activity (i.e. by phone or online) if desired
   - [ ] Other protections not listed in this question – describe below
   - [ ] N/A – not mailing any materials to/from participants

5. * **Protections when analyzing or disseminating study data** *Applicable to all studies*:
   - [x] **Working only in locations where the study team can ensure privacy (not working in close proximity to non-study personnel, closing doors, closing/putting away documents/files before leaving, etc.)**
   - [x] **Securing physical materials only in locations that ensure privacy (access limited to authorized study personnel)**
   - [ ] Obtaining explicit parental permission before disseminating or sharing recordings or photos of children
   - [ ] Blurring/redacting/hiding faces and other identifiable features/marks (tattoos, scars, birthmarks, distinctive voice, etc.) in recordings or photos prior to disseminating or sharing
   - [ ] Only publishing or presenting aggregate results or findings (i.e. no individual-level information)
   - [ ] Taking additional steps to protect participant identities when publishing or presenting individual-level information, quotations, results, images – describe below

☐ Other protections not listed in this question – describe below

6. Describe any other way(s) that the research team will protect participants' privacy. *See the help text for additional guidance*.

Consent and completion of data collection will be conducted in a private room or office.

All participants will be informed that their responses will be held in confidence by research staff and that their comments will not be shared. Participants will also be told that all research staff are compelled by law to report incidences of abuse or threat of harm to self or others.

Further, participants are informed that the information from the study may be published in medical journals. Assurance is given that publications will not reveal participants' identities.

Data Confidentiality and Storage

Confidentiality refers to the way private, identifiable information about a participant or defined community is maintained and shared. It describes how the study's research materials (data, specimens, records, etc.) are protected from unauthorized access.

Instructions for this page:
Select all the ways that the research team will keep the study materials and data confidential throughout the course of the study. Not all will be applicable to every study.
To elaborate on any response, also click the "Other Protections" checkbox to provide further explanation in the last free-text question.

Read the entire page before filling out the form.

1. * **Protections for paper research materials:**

- [x] **Maintaining control of paper documents at all times, including when at an off-campus location**
- [x] **Limiting or avoiding use of participant identifiers on paper documents (i.e. using study IDs instead of direct identifiers)**
- [x] **Storing paper documents in a secure location accessible only to authorized study personnel**
- [ ] Promptly transcribing, scanning, or abstracting data from paper into electronic platforms with destruction of the paper copy
- [ ] Proper destruction of paper records (and obtaining prior permission when required) in accordance with VCU Records Management policies
- [ ] Other protection not listed in this question – describe below
- [ ] N/A – no paper research materials

2. * **Protections for research specimens:**

- [ ] Maintaining control of specimens at all times, including when at an off-campus location
- [ ] Storing specimens in a secure location accessible only to authorized study personnel
- [ ] Labeling specimens with subject ID or other coded information instead of direct identifiers
- [ ] Final destruction of specimens will be in accordance with VCU policies and specimen containers will be devoid of any identifiable information
- [ ] Other protection not listed in this question – describe below
- [x] **N/A – no research specimens**

3. * **Protections for electronic files/data - See https://ts.vcu.edu/about-us/information-security/data-management-system/**

- [x] ***Required for all studies* Use VCU-approved methods of data storage, transmission, and transfer (see https://dms.vcu.edu)**
- [x] **Remotely accessing VCU network storage to store data when at off-campus locations**
- [x] **Ensuring unauthorized individuals who might share a device do not have access to study materials (e.g. individual logins, separate accounts)**
- [ ] Using VCU-approved data collection tools and apps (e.g. REDCap) and storing exported analysis files in VCU-approved storage locations (see https://dms.vcu.edu)
- [ ] When using non-VCU-approved electronic data collection tools, storage locations, data transfer platforms, and mobile apps (e.g. Dropbox, Box, Survey Monkey, Fitbits, novel apps, multi-site data collection platforms):
  • consulting with VCU Information Security on proper data management (see https://ts.vcu.edu/askit/essential-computing/information-security/);
  • advising participants about the terms of use and privacy policies of those sites/apps;
  • limiting or avoiding use of identifiers; and
  • removing data promptly from the external location after transferring it to a VCU storage location
- [x] **De-identifying the research data by replacing subjects' names with assigned subject IDs**
- [x] **Storing the study's linkage key in a password-protected and VCU-approved storage location (see https://dms.vcu.edu)**
- [ ] When analyzing particularly sensitive information, using computers that are unconnected from the internet.
- [ ] Proper destruction of electronic records (and obtaining prior permission when required) in accordance with VCU Records Management policies

- [ ] Other protection not listed in this question – describe below

4. * **Protections for computers and research devices/apps that are provided to participants for use in the study and taken out of the lab (i.e., giving participants a phone or iPad to take home, wearable trackers, apps, etc.):**
   - [ ] Transferring data promptly from the device/app given to the participant to a VCU storage location
   - [ ] Setting strong passwords on computers and research devices (when applicable) that leave VCU with participants
   - [ ] Device/app set up by VCU Information Security
   - [ ] When providing devices or mobile apps to children, informing parents about the settings and how to manage them (if applicable), internet access, and any other installed apps on the device
   - [ ] Other protection not listed in this question – describe the device/app and protection below
   - [x] **N/A – no computers or devices/apps being provided for participant use outside the lab**

5. * **Protections for email/online communications**
   - [x] **Only using VCU/VCU Health email addresses for study-related communications**
   - [x] **Only using VCU/VCU Health–approved methods of teleconferencing or video conferencing (e.g. Zoom) (for studies involving HIPAA, contact VCU or VCU Health Information Security [as appropriate] about HIPAA-compliant systems)**
   - [ ] Other protection not listed in this question – describe below
   - [ ] N/A – no email/online communications

6. **Specify any other places where this study's paper and electronic research data and/or physical specimens will be stored and any other ways they will be secured from improper use and disclosure.**

   See the help text for additional guidance.
   Each participant is assigned a unique identification number, which is used on all paper-based records, so that no participant may be identified by name. All paper-based records are secured in locked cabinets in a Research Assistant's locked office, separate from clinical records. Only the PI, Interventionists, Research Coordinator and Research Assistants have access to the data.

   A master list of participant names and identification numbers, along with contact information is kept in a password-protected database, accessible by only by the research staff. Each person has their own unique username and password to access the electronic database.

   The research database is also kept in a password-protected database, accessible by only by the research staff. Each person has their own unique username and password to access the electronic database.

7. * **If research data/specimens will be sent/released to person(s) or group(s) outside of the VCU study team or the PI's department for the conduct of this protocol (not for future sharing),**
   1) identify the data/specimen recipient(s) along with their VCU department or other institutional or organizational affiliation(s).
   2) give a description of what identifiers and/or codes will accompany the data/specimens.
   If data/specimens are not being sent/released outside of the VCU study team or the PI's department, state that:
   None of the 18 HIPAA identifiers will be released to persons or groups outside of the VCU study team.

8. * **Select all identifiers that will be collected at any time as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized:**
   - [x] **Names**
   - [x] **Geographic Locators Below State Level**
   - [x] **Social Security Numbers**
   - [x] **Dates (year alone is not an identifier)**
   - [x] **Ages over 89 (age under 89 is not an identifier)**
   - [x] **Phone Numbers**
   - [ ] Facsimile Numbers
   - [x] **E-mail Addresses**
   - [x] **Medical Record Numbers**
   - [ ] Device Identifiers
   - [ ] Biometric Identifiers
   - [ ] Web URLs

- [ ] IP Addresses
- [ ] Account Numbers
- [ ] Health Plan Numbers
- [ ] Full Face Photos or Comparable Images
- [ ] License/Certification Numbers
- [ ] Vehicle ID Numbers
- [ ] Other Unique Identifier
- [ ] No Identifiers
- [ ] Employee V#

9. * **If the study will code (i.e. de-identify) the research data by replacing subjects' names and/or other identifiers with assigned subject IDs, explain the following aspects of the coding process:**

   - The process for how subject IDs will be generated/assigned (e.g. random, sequential)
   - Whether there will be a key that links the subject ID with direct identifiers. If there will be no linkage key, state that.

   If a key will be created, describe
   - The place where the key will be stored
   - The role(s) of all individuals who will have access to the key
   - When the key will be destroyed

   See the help text for guidance.
   Each participant is assigned a unique identification number (sequentially) by the Research Coordinator or a Research Assistant. Within an electronic database, a key linking participant names and identification numbers, along with contact information is kept in a password-protected database, accessible by only the research staff. Each person has their own unique username and password to access the electronic database. Because this study has a follow-up component, the key will not be destroyed until after the study is completed.

Data Retention

1. * **Select all of the ways that individually identifiable information obtained during pre-screening and/or screening will be handled for individuals who DO NOT qualify for the study:**
   - [ ] N/A - study does not require screening procedures
   - [x] **Immediately destroy the information and identifiers (no data collected)**
   - [ ] Immediately destroy the identifiers connected with the data (anonymization)
   - [ ] Store until the end of study & then destroy
   - [ ] Use as "screening failure" data by members of the study team
   - [ ] Provide to others outside of the research team (with the participant's permission)
   - [ ] Request permission from participant to maintain and use the identifiable information
   - [ ] Other

2. * **Will participants be able to withdraw their data (paper, electronic, or specimens) from the study (e.g. ask that it be destroyed or returned) if they no longer wish to participate? (FDA-regulated studies should select No – see help text)**
   - (●) **Yes**
   - ( ) No

3. * **If Yes , describe the process (oral, written, email, letter, etc.) that participants should use to request withdrawal of their data/specimens. Identify if there is a timepoint when withdrawal will no longer be an option and/or if the amount of data that can be withdrawn is reduced at different points in the study.**
   Participants may request that their data be withdrawn orally. Research staff will keep a written record of the withdrawal.

4. * **What will happen to the research materials (e.g. data, specimens, documents, etc.) when the research has been completed?**
   - (●) **Stored indefinitely with identifiers removed**
   - ( ) Stored indefinitely with identifiers attached
   - ( ) Destroyed at the end of study once the minimum time required for data retention has been met per VCU Data Retention Policy and/or sponsor retention requirements
   - ( ) Destroyed when notified by sponsor but not less than the minimum time required for data retention per VCU Data Retention Policy
   - ( ) Other

5. * **Will audio/video recordings and full face photographs be destroyed?**
   - (●) **Yes**
   - ( ) No

6. **If yes, describe at what point and how recordings will be destroyed:**
   After review with the PI, the audio-recordings will be destroyed.

7. **If no, explain why the recordings need to be maintained:**

Sharing Plan

This page addresses times when investigators may be required to share information about participants or may desire to share their research information/specimens with the aim of advancing science. This page creates a plan for when and how information/specimens could be shared.

Try to anticipate all reasonably foreseeable sharing so that the consent document can also reflect that information. However, it is acceptable to amend this page later and explain either how re-consent of previously and currently enrolled participants will occur or why re-consent should not be required.

The IRB reviews this page against the consent document (if one exists) to demonstrate the ethical principle of Respect for Persons by confirming that plans for sharing do not go against what participants would understand about the use of their data/specimens.

The IRB also ensures there are adequate protections for the privacy of participants and the confidentiality of participants' data/specimens when data is shared with others.

1. * **Is it likely investigators could discover information about child/elder abuse or neglect that would require mandatory reporting by the investigators or staff?**

   The Code of Virginia requires that most medical personnel and all employees of institutions of higher education report suspected child/elder abuse or neglect.

   - (●) **Yes**
   - ( ) No

2. * **Is it likely investigators could discover a previously unknown reportable disease or condition that would require mandatory reporting by the investigators or staff (i.e., HIV , coronavirus, hepatitis, etc.)?**

   ( ) Yes ( ) No

3. * **Will the sponsor or investigator obtain a Certificate of Confidentiality for this study?**

   Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH), the FDA and CDC to protect identifiable research information from forced disclosure. All human subject research studies regardless of funding can qualify to receive a CoC. A CoC is automatically issued for research that was ongoing on December 13, 2016. or initiated after that date. For more information, see https://humansubjects.nih.gov/coc/

   - (●) **No – Will not obtain CoC for this study**
   - ( ) Yes – CoC has been obtained or issued automatically
   - ( ) Yes – CoC request is pending

4. * **Select the way(s) that information or biospecimens (including DNA) may be used <u>by the VCU PI or VCU study team for other future research projects</u> (i.e. analyses beyond/apart from the aims of this study)?**
   See help text for definitions.

   - [ ] Will use directly identifiable information or specimens.

     ('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research is treated as a registry by the VCU IRB. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. VCU IRB studies will be asked more questions about this on a later page)

   - [ ] Will use de-identified or indirectly identifiable information or specimens.

     ('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. When the researcher holds both the data and the key, the VCU IRB considers the subjects to be readily identifiable. Maintaining identifiable data for future research uses is treated by the IRB as a registry. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. VCU IRB studies will be asked more questions about this on a later page)

Will use anonymized information or specimens.

☐ *('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified, i.e. no direct or indirect identifiers or identifiable combinations of variables. The VCU IRB considers uses of anonymized data/specimens to not be human subject research.)*

Will use aggregate results (summary-level results), not individual-level information or specimens.

☐ *(The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects.)*

Will contribute to an existing registry or repository

☐ *(VCU IRB studies will be asked more questions about this on a later page.)*

☐ Will not use information/specimens for purposes beyond this study.

☑ **Not sure and will submit an amendment when known**

☐ Other use(s) of individual-level information in a way not listed above

5. * **Select the way(s) the VCU PI/study team may share information or biospecimens (including DNA) with other researchers who are not on this study team (i.e. for analyses beyond/apart from the aims of this study).** ***See help text for definitions.***

Will share directly identifiable information or specimens with other researchers.

☐ *('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research uses is treated by the VCU IRB as a registry. The data recipient's use of identifiable data would require them to obtain IRB review. VCU IRB studies will be asked more questions about this on a later page.)*

Will share de-identified or indirectly identifiable information or specimens with other researchers.

☐ *('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. The VCU researcher maintains the key but does not share it with any other researchers. The recipient's use of de-identified data/specimens may not be human subject research if there is documentation that the key will never be shared with the recipient, but they should check with their own IRB about review requirements. VCU IRB studies will be asked more questions about this on a later page.)*

Will share anonymized information or specimens with other researchers.

☐ *('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified (i.e. no direct or indirect identifiers or identifiable combinations of variables). The VCU IRB considers uses of anonymized data/specimens by other researchers to not be human subject research, but the recipient should check with their own IRB about review requirements.)*

Will only share aggregate results (summary-level results), not individual-level information or specimens.

☐ *(The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects. The data recipient should check with their own IRB about review requirements.)*

☐ Will contribute to an existing registry or repository (VCU IRB studies will be asked more questions about this on a later page.)

☐ Will submit data to an NIH genomic data repository (VCU IRB studies will be asked more questions about this on a later page.)

☑ **Will not share information/specimens with other researchers.**

☐ Not sure and will submit an amendment when known

☐ Other sharing of individual-level information with other researchers

6. * **The Principal Investigator certifies that after the study has been closed with the VCU IRB, the following conditions will be met whenever individual level research information and/or specimens are used or shared:**

- The identities of participants who are represented in the dataset/specimens will not be readily ascertainable or otherwise re-identifiable by the recipient;
- If a linkage/code key is created, it will be maintained at VCU and not shared with the recipient under any circumstances;
- The PI will have no knowledge that the remaining information could be used alone or in combination with any other information to identify the individuals represented in the data; and
- The PI agrees to abide by this sharing plan even after the study has been closed with the VCU IRB.

- ○ Yes
- ○ No
- ● **N/A - No sharing will occur**

Pertinent Results and Incidental Findings

1. * **Is it likely investigators could discover a participant's previously unknown condition (e.g. pregnancy, disease, suicidal thoughts, wrong paternity, genetic results, or other findings that may be of importance to health or well-being) or if a participant is engaging in illegal or reportable activities:**
   - (●) **Yes**
   - ( ) No

2. * **Describe what possible pertinent results or incidental findings stemming from research-only procedures may be discovered.**
   With regard to participants' health or well-being, we will not learn of any pertinent and/or incidental findings that the participant has not disclosed themselves.

   As mentioned above, participants could share concerns about depression/suicidal ideation.

   There is the possibility that research participants may, over the course of data collection, report to research staff incidences of intent to harm others or of committing abuse.

3. * **Explain what actions or procedures research personnel should take to inform the PI of such a discovery :**
   The research staff have resource and referral information for participants asking for medical or mental health care. If a participant indicates severe depression or suicidal ideation, the research staff will contact the PI. The PI is on call during each interview is responsible for monitoring the status of enrolled participants and addressing urgent situations. When concerns arise, the PI is contacted immediately to make a clinical decision regarding the need for further evaluation, treatment, or referral.

4. * **Will findings be disclosed to participants and/or any other person/group outside of the study team?**
   - ( ) Yes
   - (●) **No**

5. **If pertinent and/or incidental findings will not be disclosed, explain why not:**
   We will not learn of any pertinent and/or incidental findings that the participant has not disclosed themselves.

   In the case of participant-reported severe depression or suicidal ideation, the PI is contacted immediately to make a clinical decision regarding the need for further evaluation, treatment, or referral.

   In the case of participants reporting child or elder abuse or intent to harm others, the consent form clearly indicates that research staff are required to contact authorities.

Risk Benefit Complete

Protocol Progress:
● **INITIAL SETUP**
● **BACKGROUND, RATIONALE & GOALS**
● **RESEARCH PLAN**
● **CONSENT PLAN**
● **RISKS, PRIVACY & CONFIDENTIALITY**
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Populations with Special Considerations

1. * Check all participant groups that will be either

a) Specifically included in this study or

b) Discernable in the research data/specimens.

(Selections will branch)

- [ ] Children
- [ ] Emancipated minors
- [ ] Wards of the State
- [x] **Pregnant women or fetuses**
- [ ] Neonates or Post-delivery Materials
- [ ] Prisoners
- [x] **Decisionally Impaired Adults**
- [x] **VCU Health System or VCU Dental Care patients**
- [x] **VCU / VCUHS students or trainees**
- [x] **VCU / VCU Health System employees**
- [ ] Individuals with limited English proficiency
- [ ] Active military personnel
- [ ] Student populations in K-12 educational settings or other learning environments
- [ ] Members of a federally recognized American Indian and Alaska Native tribe
- [ ] None of the Above

2. * Check all of the following categories that apply to this research:

[x]	**45 CFR 46.204**	**Research involving pregnant women or fetuses.**
[ ]	45 CFR 46.205(a) and (b)	Research involving neonates of uncertain viability.
[ ]	45 CFR 46.205(a) and (c)	Research involving nonviable neonates
[ ]	45 CFR 46.205(d)	Research involving viable neonates.
[ ]	45 CFR 46.206	Research involving, after delivery, the placenta, the dead fetus, or fetal material.
[ ]	45 CFR 46.207	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

3. Additional considerations for student populations:
*** Select all who will be research participants in the study:**

- [x] **VCU Students**
- [x] **K-12 Students**
- [x] **Parents/Guardians of Students**
- [x] **Teachers**
- [x] **Administrators**

☐ Other

4. **If applicable, describe any alternative activities for students (including VCU students) who choose not to participate in the research.**

5. * **Describe how the study will minimize the possibility of coercion to participate.**
The purpose of the study is to evaluate the efficacy of a structured, curriculum-based intervention to promote postinjury resilience and adjustment. The study is not specifically focused on students, but there is no reason to exclude those who are students from participating. This is a survey study, and research personnel conducting informed consent will emphasize the voluntary nature of participation.

6. **Additional considerations for VCU/VCU Health System employees:**

* **Describe how the study will minimize the possibility of coercion to participate.**
The purpose of the study is to evaluate the efficacy of a structured, curriculum-based intervention to promote postinjury resilience and adjustment. The study is not specifically focused on VCU employees, but there is no reason to exclude those who are employees from participating. This is a survey study, and research personnel conducting informed consent will emphasize the voluntary nature of participation.

Pregnant Women or Fetuses

1. * **When scientifically appropriate, briefly describe any preclinical studies (including studies on pregnant animals) and clinical studies (including studies on nonpregnant women) that have provided data for assessing potential risks to pregnant women and fetuses [45 CFR 46.204(a)].**
   There is no additional risk to the pregnant woman or fetus. This is a survey study to evaluate the efficacy of a structured, curriculum-based intervention to promote postinjury resilience and adjustment.

2. * **Select the condition that is applicable to this study [45 CFR 46.204(b)]:**
   - ○ The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.
   - ● **If there is no prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.**

3. * **Provide protocol-specific information to support the selected condition above [45 CFR 46.204(b)].**
   Not applicable.

4. * **Describe how the risk is the least possible for achieving the objectives of the research [45 CFR 46.204(c)].**
   There is no additional risk to the pregnant woman or fetus. This is a survey study to evaluate the efficacy of a structured, curriculum-based intervention to promote postinjury resilience and adjustment.

5. * **Describe how consent will be obtained from the pregnant woman if the research may:**
   _directly benefit the pregnant woman,
   _directly benefit the pregnant woman and the fetus, or
   _offer no benefit for the woman nor the fetus (when risk to the fetus is not greater than minimal) and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means [45 CFR 46.204(d)].
   Not applicable.

6. **If the research may directly benefit the fetus only, describe how the consent of the pregnant woman and the father will be obtained. [45 CFR 46.204(e)]**

   Note: The father's consent is not required if he is unable to consent because he is unavailable, incompetent, temporarily incapacitated, or the pregnancy resulted from rape or incest.

   Not applicable.

7. * **Describe how each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate [45 CFR 46.204(f)].**
   There is no additional risk to the pregnant woman or fetus. This is a survey study to evaluate the efficacy of a structured, curriculum-based intervention to promote postinjury resilience and adjustment.

8. **For children who are pregnant, describe how you will obtain assent from the child and permission from the parent(s) of the pregnant child [45 CFR 46.204(g)].**
   Not applicable.

9. * **Will inducements, monetary or otherwise, be offered to terminate a pregnancy [45 CFR 46.204(h)]?**
   - ○ Yes
   - ● **No**

10. * **Will individuals engaged in the research have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy [45 CFR 46.204(i)]?**
    - ○ Yes
    - ● **No**

11. * **Will individuals engaged in the research have any part in determining the viability of a neonate [45 CFR 46.204(j)]?**
    - ○ Yes
    - ● **No**

Decisionally Impaired Adults

1. * **Choose the nature of the decisional impairment participants will have:**
   - ○ Temporarily Incompetent to Give Consent
   - ○ Permanently Incompetent to Give Consent
   - ● **Unknown**

2. * **Explain why this population is necessary for the conduct of the study.**
   The purpose of the study is to evaluate the efficacy of a structured, curriculum-based intervention to promote post-injury resilience and adjustment. TBI often causes physical and mental disabilities. Thus, adults with physical and/or mental disabilities are included.

3. * **Describe methods for determining whether participants are capable of providing consent or assent.**
   In any case where the research staff have concerns about the individual's ability to provide informed consent, formal assessment of decision-making capacity is made using the MacArthur Competence Assessment Tool, Clinical Research version (MacCAT-CR). This is a second-generation instrument based on pioneering multicenter studies of treatment capacity (Appelbaum, 1995). It has excellent content validity, and is the only current instrument that assesses the full range of abilities relevant to capacity for giving informed consent to participate in research (Kim, 2001). It has previously been used in persons with schizophrenia (Carpenter, 2000), depression (Appelbaum, 1999), and dementia (Kim, 2001). Minimum values on each scale of the MacCAT-CR are established as two standard deviations below the norms of competent persons from the community, which have previously been published. (Kim, 2001) Such an approach is commonly used in assessment of decision-making capacity (Grisso, 1995; Grisso, 1998; Marson, 1995) and has been shown to be more stringent than expert assessment of capacity (Kim, 2001). It generally requires 15 to 20 minutes to administer and is easily learned by investigators (Appelbaum, 1999; Kim, 2001).

   Appelbaum PS, Grisso T. The MacArthur Treatment Competence Study, I: Mental illness and competence to consent to treatment. Law Hum Behav 1995; 19:109-126.
   Appelbaum PS, Grisso T, Frank E, O'Donnell S, Kupfer DJ. Competence of depressed patients for consent to research. Am J Psychiatry 1999; 156:1380-1384.
   Carpenter WT Jr, Gold J, Lahti A, Queern C, Conley R, Bartko J, Kovnick J, Appelbaum PS. Decisional capacity for informed consent in schizophrenia research. Arch Gen Psychiatry 2000; 57:533-538.
   Grisso T, Appelbaum PS. Assessing Competence to Consent to Treatment: A Guide for Physicians and Other Health Professionals. New York: Oxford University Press, 1998.
   Grisso T, Appelbaum PS, Mulvey EP, Fletcher K. The MacArthur Treatment Competence Study, II: Measures of abilities related to competence to consent to treatment. Law Hum Behav 1995; 19:127-148.
   Kim SYH, Caine ED, Currier GW, Leibovici A, Ryan JM. Assessing the competence of persons with Alzheimer's disease in providing informed consent for participation in research. Am J Psychiatry 2001; 158:712-717.
   Marson DC, Ingram KK, Cody HA, Harrell LE. Assessing the competency of patients with Alzheimer's disease under different legal standards: a prototype instrument. Arch Neurol 1995; 52: 949-954.

4. * **If a participant is capable of exercising some judgment concerning the nature of the study, describe how assent will be obtained.**
   In cases where the patient is too impaired to consent, but family members wish for the person to participate in the intervention, consent will be obtained by a legally authorized representative (LAR) on behalf of the patient. Assent will then be sought from the patient. If the patient chooses not to participate, they will not be enrolled in the study.

5. **Describe, if applicable, how the individuals' ability to give consent will be assessed throughout the study and how consent will be obtained when appropriate.**
   At the 3, 4, and 9 month follow-ups, the Research Coordinator or Research Assistant will review the study details with the participant. Research staff will confirm that the participant remains interested in continuing their participation. If the individual's cognitive status improves during the course of the study, then consent will be sought. Participants may withdraw from the study at any time.

6. * **Describe how and when consent will be obtained from participants' legally authorized representative (LAR).**
   For persons lacking capacity in the judgment of investigators, consent is obtained from substitute decision makers (LAR) as allowed under Virginia law.

Populations with Special Considerations Section Complete

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- **POPULATIONS WITH SPECIAL CONSIDERATIONS**

⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Study Funding

1. * Have you applied for funding:

- (●) **Yes**
- ( ) No

2. Is this study already funded:

- (●) **Yes**
- ( ) No

3. * Select all funding sources for this study (pending or awarded):

- [ ] Industry
- [x] **Direct Federal**
- [ ] Indirect Federal
- [ ] State/Local Government
- [ ] Non-Profit - Sponsored Project
- [ ] Non-Profit - Gift
- [ ] Internal Grant
- [ ] Investigator/Departmental Funds
- [ ] None
- [ ] Other

4. * In addition to providing funding support, what is the funding source's role in this study? Select all that apply:

- [ ] Solely providing funding support
- [ ] Providing resources (e.g. study drug, device)
- [ ] Providing guidance to the researcher but does NOT make decisions about study design
- [ ] Study design/Creation of the study protocol
- [ ] Collaborator in the research (helps design and/or conduct the study) [list the funder as a site on the Types of Sites page]
- [ ] Data or sample analysis regardless of identifiability

5. Select all related funding proposals and contracts that have been submitted through the Division of Sponsored Programs (DSP):

RAMS-SPOT ID# (FP/PT/PD#)	Direct Sponsor	PI	Title	Status	Start	End
FP00003652	Department of Health & Human Services	Jeffrey Kreutzer	Traumatic Brain Injury Model Systems Centers	Funded		

6. If the following conditions are ALL met, provide the index code where the HRPP will charge Single IRB (sIRB) fees associated with this review:
1. The study is externally funded (fees do not apply if the study is not funded), AND
2. Multiple sites are executing the same research protocol (i.e. multicenter research), AND
3. VCU IRB will provide IRB review on behalf of one or more non-VCU sites

7. * Does the funder require the IRB to review this proposal for grant congruence?

- (●) **Yes**
- ( ) No

8. **If grant congruence review is requested, upload the entire grant proposal (exclusive of budget and appendices).**

   If Industry was selected above, upload the DSP Subject Injury Language Memo or other documentation from DSP approving the consent form's subject injury language.

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent Form	RAI+ consent_2021 05 25 clean.pdf	0.15	5/27/2021 11:20 AM	Jennifer Marwitz	Consent/Assent/Information Sheet	Yes
View	Assent Form	RAI+ assent_2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Jennifer Marwitz	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Consent Script	COVID Contingency Consent Script RAI+ 2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Courtney Roberts	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Consent Form	COVID Contingency Consent Info Sheet RAI+ 2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Courtney Roberts	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Protocol	COVID Contingency Protocol v6 HM20011840 2021 05 25.docx	0.06	5/25/2021 2:35 PM	Elicia Preslan	Research Protocol	Yes
View	Flyer	RAI+ Study_Flyer 2021 05 25 clean.doc	0.03	5/25/2021 2:35 PM	Jennifer Marwitz	Recruitment/Advertising	Yes
View	Hsu PI Change Form	Hsu PI Change Form 2021 05 11.pdf	0.01	5/25/2021 2:33 PM	Jennifer Marwitz	Other	Yes
View	Hsu CV	Hsu CV 2020 Dec.pdf	0.01	5/25/2021 2:33 PM	Jennifer Marwitz	CV/Biosketch	Yes
View	Marwitz CV	Marwitz,Jennifer CV 2020 12 18.docx	0.01	1/6/2021 2:45 PM	Jennifer Marwitz	CV/Biosketch	Yes
View	Script for cases where follow-up done by phone	Script follow-ups done by phone 2017 12 17.doc	0.01	12/17/2017 3:24 PM	Jennifer Marwitz	Research Measure	Yes
View	Grant Proposal	grantsApplication.pdf	0.01	11/15/2017 2:35 PM	Jennifer Marwitz	Funding Proposal	Yes
View	Data Collection Forms	RAI+ Measures.pdf	0.01	10/30/2017 5:24 PM	Jennifer Marwitz	Research Measure	Yes
View	RAI+ Implementation Manual	RAI+ Manual 2017 05 08.pdf	0.01	10/30/2017 5:22 PM	Jennifer Marwitz	Research Measure	Yes
View	MacCAT-CR (Consent Evaluation)	MacCAT-CR 2017 10.doc	0.01	10/30/2017 5:22 PM	Jennifer Marwitz	Research Measure	Yes
View	CV/Biosketch-Kreutzer	JSK CV 2017 10 04.docx	0.01	10/25/2017 12:56 PM	Jennifer Marwitz	CV/Biosketch	Not Applicable

Types of Sites

VCU Site Information

1. * **Select all VCU sites that will be utilized in this study:**
   - ☐ Children's Hospital of Richmond at VCU
   - ☐ Clinical Research Services Unit (CRSU)
   - ☐ Massey Cancer Center
   - ☐ VCU Health Community Memorial Hospital
   - ☐ VCU Health Tappahannock Hospital
   - ☑ **VCU Medical Center**
   - ☐ Other VCU Health Location
   - ☐ VCU Monroe Park Campus
   - ☐ VCU Qatar
   - ☐ Other VCU Site

Non-VCU Site Information

Non-VCU sites should be selected whenever any of the following situations apply:
a) Non-VCU sites that will be collaborating on a VCU-led study (i.e. involved in conducting the research, including being involved in the study interpretation or analysis of data and/or authorship of presentations or manuscripts related to the research.)
b) Non-VCU sites that will be deferring to the VCU IRB for IRB review
c) Non-VCU sites where VCU investigators will be overseeing study interventions or interactions
d) Non-VCU sites/locations where VCU investigators will conduct study activities

2. * **Select any of the following non-VCU sites utilized in this study:**
   - ☐ McGuire VAMC
   - ☐ Foreign Sites
   - ☐ Other Non-VCU Sites
   - ☑ **No Non-VCU Sites**

3. * **Is this a multi-center study being led by VCU?**
   - ○ Yes ● **No**

4. **For Non-VCU Sites: For each site or institution listed as "Site Engaged -- Requests to Rely on VCU IRB Review," upload:**

- Completed Local Context Form for Relying on VCU's IRB
- Site specific informed consent form(s) and HIPAA authorization(s), if applicable

For Foreign Sites: For each Cultural Consultant upload a CV/Biosketch that includes a clear description of cultural expertise:

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View	Consent Form	RAI+ consent_2021 05 25 clean.pdf	0.15	5/27/2021 11:20 AM	Jennifer Marwitz	Consent/Assent/Information Sheet	Yes
View	Assent Form	RAI+ assent_2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Jennifer Marwitz	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Consent Script	COVID Contingency Consent Script RAI+	0.10	5/27/2021 11:20 AM	Courtney Roberts	Consent/Assent/Information Sheet	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
		2021 05 25 clean.pdf					
View	COVID Contingency Consent Form	COVID Contingency Consent Info Sheet RAI+ 2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Courtney Roberts	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Protocol	COVID Contingency Protocol v6 HM20011840 2021 05 25.docx	0.06	5/25/2021 2:35 PM	Elicia Preslan	Research Protocol	Yes
View	Flyer	RAI+ Study_Flyer 2021 05 25 clean.doc	0.03	5/25/2021 2:35 PM	Jennifer Marwitz	Recruitment/Advertising	Yes
View	Hsu PI Change Form	Hsu PI Change Form 2021 05 11.pdf	0.01	5/25/2021 2:33 PM	Jennifer Marwitz	Other	Yes
View	Hsu CV	Hsu CV 2020 Dec.pdf	0.01	5/25/2021 2:33 PM	Jennifer Marwitz	CV/Biosketch	Yes
View	Marwitz CV	Marwitz,Jennifer CV 2020 12 18.docx	0.01	1/6/2021 2:45 PM	Jennifer Marwitz	CV/Biosketch	Yes
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Personnel

1. * **List all VCU/VCUHS personnel who are key study personnel.**

Key personnel are defined as including:
- **Conflict of interest investigators, including**
- **the PI**
- **the Lead Student/Trainee Investigator,**
- **medically/Psychologically responsible investigator(s)**
- **FDA Form 1572 investigators, and**
- **Other personnel whose roles are essential to the conduct of the research.**

Note: Individuals who are not key personnel are not required to be listed here, but PIs still bear the responsibility to document the delegation of responsibilities in the study records.

PIs may elect to use the Study Roster activity button in RAMS-IRB (available after approval) as an alternative way to document study staff involvement and delegation of responsibilities. Personnel changes made to the non-key personnel listed in the separate Study Roster activity do not require an amendment.

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
View	Jeffrey Kreutzer	Consultant		Data Analysis Study Design		Experience - Research Experience - Clinical Education and/or Professional Preparation		no
View	Ana Mills	Other	Interventionist	Participant Consent Participant Identification Participant Recruitment Intervention Services Data Collection - Interviews/Surveys		Experience - Research Experience - Clinical Education and/or Professional Preparation		no
View	Nancy Hsu	Other Principal Investigator	Interventionist	Data Analysis Participant Consent Participant Identification Study Design Participant Recruitment Intervention Services Data Collection - Interviews/Surveys		Experience - Research Experience - Clinical Education and/or Professional Preparation		yes
View	Kristin Graham	Other	Interventionist	Participant Consent Participant Recruitment		Experience - Research Experience - Clinical		no

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
				Intervention Services Data Collection - Interviews/Surveys		Education and/or Professional Preparation		
View	Laura Albert	Research Assistant		Participant Consent Data Collection - Clinical Data Entry Data Coding Data Collection - Interviews/Surveys		Experience - Research Experience - Clinical Education and/or Professional Preparation		no
View	Ronald Seel	Co/Sub-Investigator		Data Analysis		Experience - Research Experience - Clinical Education and/or Professional Preparation		no

2. **Identify all independent investigators and key personnel at non-VCU sites who will be engaged in this study AND who DO NOT have IRB approval for this study from their own institution.**

Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator

There are no items to display

3. If independent investigators or community engaged investigators are listed above,**describe the human subjects training these individuals will complete and the process that will be used to ensure that all persons assisting with the research are adequately informed about the protocol and their research related duties and functions:**
All members of the research team meet quarterly, at a minimum. The PI meets weekly with the Research Coordinator, and the Research Coordinator meets weekly with the Research Assistants. In addition, email is used to notify research team members about any issues related to the project. The Research Coordinator manages a database which has primary and secondary contact information for all research staff.

4. * **Upload a CV or Biosketch for the PI, Medically/Psychologically Responsible Investigators and the lead Student/Trainee Investigators. Do not upload CVs or Biosketches for other individuals.**

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Conflict of Interest

The PI should ask the questions on this page of all research personnel who are engaged in the research, including subrecipient investigators and personnel.

1. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a financial interest related to this study?**
   Financial interest include utilizing your licensed intellectual property in the study; serving as a paid consultant, or advisory board member, or officer/director with a related entity; and equity or business ownership in a company that is related to this project
   ○ Yes ● **No**

2. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a non-financial interest related to this study?**
   Non-financial Interests could include such things as:
   - utilizing your unlicensed intellectual property in the study,
   - serving as an unpaid advisory board member or officer/director with a related entity, and
   - equity or business ownership in a company that has yet to make a profit and is related to this project
   - conflict of time/effort,
   - personal and professional relationships/affiliations,
   - intellectual passions or personal beliefs
   - other factors that could create bias in the study
   ○ Yes ● **No**

3. **Describe any institutional conflict of interest that you or any member of the research team are aware of that pertains to this research:**

   An institutional conflict of interest is a situation in which financial interests of the University or University leadership may affect research activities at VCU.
   None.

Other VCU Requirements

This page asks questions on behalf of other ancillary offices, committees and departments at VCU regarding institutional requirements that could apply to this research. In some cases, these requirements could also impact the consent process or other aspects of the IRB's review.

Based upon answers provided earlier in this form, certain ancillary sections below may not have questions displayed if those requirements are not applicable to this study.

1. Cost Coverage Analysis

Information on coverage analysis requirements and processes can be found through VCU's Clinical Research Compliance Program at https://research.vcu.edu/human-research/clinical-research/vcu-clinical-research-coverage-analysis/

1. * **VCU requires that all clinical research studies be evaluated to determine if a Coverage Analysis is required. Has your study been evaluated by an institutionally designated Coverage Analysis Specialist?**
   - (●) **Yes**
   - ( ) No
   - ( ) Not Applicable

2. ClinicalTrials.gov Program & OnCore

For guidance, see https://cctr.vcu.edu/support/consultation/clinical-trials-gov/ or email CCTRCTGOV@vcu.edu

1. * **Is this a Clinical Trial?**
   (●) **Yes** ( ) No
2. * **ThePI acknowledges awareness of the following requirements for posting clinical trial consent forms:**

   - Each clinical trial under the 2018 Common Rule that is conducted or supported by a Federal department or agency must post one IRB-approved consent form that was used to enroll subjects on a publicly available Federal website [45 CFR 46.116(h)].
   - When engaged in multi-site research, the VCU PI is responsible for confirming with the lead site who is responsible for posting the informed consent form.
   - When VCU is the lead site, the VCU PI is responsible for posting the informed consent form (unless the federal department or agency will post it).

   (●) **Yes** ( ) No

3. Community Engagement

For more information, see https://community.vcu.edu/

1. * **Is this a community engaged research study? (See help text for definitions)**
   - ( ) Yes
   - (●) **No**

4. Family Educational Rights and Privacy Act (FERPA) Requirements

For guidance, see https://rar.vcu.edu/records/family-educational-rights-and-privacy-act/

1. * **Does this study involve obtaining information from VCU students' educational records (see help text)?**
   - ( ) Yes
   - (●) **No**

5. Research Data Privacy Requirements

Contact the VCU Research Data Privacy Office with questions: https://research.vcu.edu/integrity-and-compliance/compliance/research-data-privacy/

1. * **Does this study involve the VCU site (regardless of the IRB of record), or any sites under the VCU IRB"s oversight, obtaining data in, or from, a foreign country?**
   ◯ Yes ◯ No

6. Information Security
For guidance, see https://ts.vcu.edu/askit/essential-computing/information-security/

1. * **Using the VCU Data Classification Tool, please determine the appropriate data classification category for the data that will be collected or used in this research.**

   Note: if the data falls into Category 1, a data security management plan is required by University Information Security Office.

   See help text for information on accessing the VCU Data Classification Tool, and for information on creating a data security management plan at https://dms.vcu.edu**.**
   ● **Category 1: all data that require breach notifications in the event of improper release, including personally identifiable information covered by HIPAA and Commonwealth of Virginia regulations.**
   ◯ Category 2: all proprietary data that if improperly released has the potential to cause harm to the institution, its mission or its reputation that do not require breach notifications.

2. * **I confirm use of the VCU Data Classification Tool at** https://go.vcu.edu/dataclassification **in determining the data classification category selected in Question 1:**
   ● **Yes**
   ◯ No

3. * **The PI is aware that if the study's data is classified as Category 1, a Data Management Plan must be submitted to and approved by VCU Information Security prior to IRB approval. See** https://ts.vcu.edu/askit/essential-computing/information-security/data-management-system/
   ◯ Yes ◯ No

4. * **I confirm that any use of external technology has been submitted to Information Security in the study's Data Management Plan. If this study uses any technology platforms, apps, services, etc. that are maintained external to VCU or hosted by another institution and are NOT currently listed in the DMS system as an approved service for the storage, processing, or transmission of VCU data, I am required to have VCU Information Security conduct a security review of that technology. I may contact infosec@vcu.edu with questions.**

   I also confirm that if the study involves use of external technology and VCUHS HIPAA data, I must also seek security review from the VCUHS Data Governance group (contact Mary Harmon at mary.harmon@vcuhealth.org):
   ◯ Yes
   ◯ No
   ◯ N/A - not using external technology

7. Massey Cancer Center Protocol Review and Monitoring Committee (PRMC)
For guidance, see https://www.masseycancercenter.org/research/~/link.aspx?_id=ee49e95faa8b44d09b6e89d8e3b48b57&_z=z

1. * **Does this study involve any of the following?**
   - Research involving patients with cancer, their families or their health care providers
   - Research involving cancer screening, diagnosis or prevention
   - Secondary data collected from cancer patients or their medical records
   - Cancer-related surveys (e.g., attitudes about risk, prevention and treatment) of the general population
   ◯ Yes
   ● **No**

8. VCU ONETRAC Protocol Review Oversight Committees (PROCs) For guidance, see https://onetrac.vcu.edu/

1. * **Does this study involve research with any of the following?**

   - VCU Health System patients

   - VCU Health System facilities

- VCU Health System data

- ◯ Yes
- ◯ No

If Yes, upload documentation of approval or review by the PROC or PRMC in this study's topic area. If you do not have PROC or PRMC approval, please visit onetrac.vcu.edu for additional information and to submit your project for review.

9. VCU Health Department of Patient Centered Services

1. * **Does your study involve a satisfaction survey administered to VCUHS patients (*See Help Text):**
   - ◯ Yes
   - ● **No**
   - ◯ Not Applicable

10. VCU Faculty-Held IND or IDE

For guidance, see **https://research.vcu.edu/human-research/regulatory-affairs/**.

Questions related to if you need an IND or IDE for your study should be emailed to: indide@vcu.edu. Please submit a copy of your FDA
submission prior to submitting to the FDA to https://redcap.vcu.edu/surveys/?s=NR7K7LR4JW.

11. VCU Health System locations

1. * **Will research activities occur in patient care areas of the VCU Health System (including at CHoR, Community Memorial Hospital, Tappahannock Hospital, VCU Medical Center and Massey Cancer Center)?**
   - ◯ Yes
   - ● **No**

12. VCUHS Department of Pathology

Learn more about requesting and establishing an account with Pathology here: See https://pathology.vcu.edu/research-services/

1. * **I have contacted VCUHS Department of Pathology to determine feasibility if my study involves the following:**
   - Storage of Microbiology isolates
   - New instrumentation provided by clinical trial/study sponsor, or
   - Non-routine specimen processing (examples include but aren't limited to the following: addition of reagents to samples/aliquots, buffy coat processing, DNA sample processing)
   - ◯ Yes
   - ◯ No
   - ◯ N/A - my study does not involve any of the listed processes.
2. * **If my study involves specimen retrieval from the Pathology laboratory, I have established a process with Pathology to deidentify and retrieve specimens.**
   - ◯ Yes
   - ◯ No
   - ◯ N/A - my study won't involve specimen retrieval from Pathology

13. VCU Institutional Biosafety Committee (IBC)

To contact the Biosafety Office see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

1. * **Does this project involve any of the following hazardous biological agents ("biohazardous agents") that have NOT been FDA approved? These may include, but are not limited to, any of the following. If you are unsure, please contact the Biosafety Office:**

   - Any functional recombinant viruses (especially viruses that may integrate into the patients' genome).

- Expression or administration of biological toxins.

- Live pathogenic or potentially pathogenic organisms of plants or animals (bacteria, fungi, wild-type viruses, parasites, etc.), that are, or potentially may be, in experimental products.

- Introduction or expression of rDNA or synthetic nucleic acids

- Use of a product (e.g., monoclonal antibodies, recombinant cytokines) produced from virally infected mammalian cells.

- Use of a product (purified growth factors, cytokines) produced from mammals or their cells.

○ Yes ● **No**

14. VCU Radiation Safety Committee (RSC)

To contact the Radiation Safety Section see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

1. * **Does this study involve radiation exposure and/or scans involving radiation (e.g.: PET, MRA, CT, DXA, nuclear medicine, etc.)?**

○ Yes

● **No**

15. VCU Scientific Review Committee (SRC)

For guidance, see https://cctr.vcu.edu/support/consultation/scientific-review-committee/

1. * **Has this human subjects protocol (not the grant application) already been reviewed by the funder of a sponsored project (e.g. a federal, state or non-profit funding sponsor)?**

○ Yes

● **No**

16. Upload any documents requested in the questions above:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent Form	RAI+ consent_2021 05 25 clean.pdf	0.15	5/27/2021 11:20 AM	Jennifer Marwitz	Consent/Assent/Information Sheet	Yes
View	Assent Form	RAI+ assent_2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Jennifer Marwitz	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Consent Script	COVID Contingency Consent Script RAI+ 2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Courtney Roberts	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Consent Form	COVID Contingency Consent Info Sheet RAI+ 2021 05 25 clean.pdf	0.10	5/27/2021 11:20 AM	Courtney Roberts	Consent/Assent/Information Sheet	Yes
View	COVID Contingency Protocol	COVID Contingency Protocol v6 HM20011840 2021 05 25.docx	0.06	5/25/2021 2:35 PM	Elicia Preslan	Research Protocol	Yes
View	Flyer	RAI+ Study_Flyer 2021 05 25 clean.doc	0.03	5/25/2021 2:35 PM	Jennifer Marwitz	Recruitment/Advertising	Yes
View	Hsu PI Change Form	Hsu PI Change Form 2021 05 11.pdf	0.01	5/25/2021 2:33 PM	Jennifer Marwitz	Other	Yes
View	Hsu CV	Hsu CV 2020 Dec.pdf	0.01	5/25/2021 2:33 PM	Jennifer Marwitz	CV/Biosketch	Yes
View	Marwitz CV	Marwitz,Jennifer CV 2020 12 18.docx	0.01	1/6/2021 2:45 PM	Jennifer Marwitz	CV/Biosketch	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Script for cases where follow-up done by phone	Script follow-ups done by phone 2017 12 17.doc	0.01	12/17/2017 3:24 PM	Jennifer Marwitz	Research Measure	Yes
View	Grant Proposal	grantsApplication.pdf	0.01	11/15/2017 2:35 PM	Jennifer Marwitz	Funding Proposal	Yes
View	Data Collection Forms	RAI+ Measures.pdf	0.01	10/30/2017 5:24 PM	Jennifer Marwitz	Research Measure	Yes
View	RAI+ Implementation Manual	RAI+ Manual 2017 05 08.pdf	0.01	10/30/2017 5:22 PM	Jennifer Marwitz	Research Measure	Yes
View	MacCAT-CR (Consent Evaluation)	MacCAT-CR 2017 10.doc	0.01	10/30/2017 5:22 PM	Jennifer Marwitz	Research Measure	Yes
View	CV/Biosketch-Kreutzer	JSK CV 2017 10 04.docx	0.01	10/25/2017 12:56 PM	Jennifer Marwitz	CV/Biosketch	Not Applicable

HIPAA

In order for VCUHS to meet HIPAA regulations regarding accounting of disclosures, data retention, and data destruction requirements for PHI data obtained without patient authorization, members of the study team (including principal investigators) are directed to consult with VCU Informatics to obtain any VCUHS data. This does not include obtaining data for which the study team has patient authorization. [VCU Health System Authority and Affiliates Policy COMP-014]

For data requests, including preparatory to research and research with decedents, submit a request for the desired PHI, or for a consultation on alternate methods to obtain the data, at https://informatics.vcu.edu.

HIPAA Privacy Board Requirements

For guidance, see https://www.vcuhealth.org/our-story/who-we-are/compliance-services/compliance-services

1. * **Select the source of the Individually Identifiable Health Information. See help text for definitions.**
   - [x] **PHI associated with or derived from (i.e. obtained from or entered into) VCU Health medical records or VCU Dental Care records**
   - [x] **Research Health Information (RHI) created or received by a study and kept solely in study records (e.g. self reported or the result of research tests and not entered into health records)**
   - [ ] PHI associated with or derived from (i.e. obtained from or entered into) a non-VCU HIPAA covered entity's health records

2. * **Summarize the types of health information that will be obtained or used in this research. Do not describe only the identifiers that you will collect or use during the study.**
   Data collected from participants is obtained through review of medical records, patient interview, and completion of payment forms for participation in the research. Participants' VCUHS medical records are reviewed to obtain date of injury and date of birth. In cases where the participant was not seen at VCU for initial treatment after TBI, this information is collected directly from the participant. During participant interviews, research staff collect the following information, so that participants can be contacted for follow-up interviews: name, address, phone numbers, and email addresses. Payment forms for research participation require social security number, name, address, and phone number, as mandated by University policy.

3. * **Describe the source(s) of the protected health information (e.g. Informatics or which clinical databases):**
   VCU medical records (Cerner)
   Interview with the participant
   Payment form for participation

4. * **Does the PI certify that this study's access to and use of the protected health information is limited to the minimum amount necessary to be able to effectively conduct the research?**
   - (●) **Yes** ( ) No

5. * **Select all pathways this research will employ to use or access PHI (selections will branch):**
   - [ ] De-Identified Data (none of the 18 identifiers are recorded or associated with the research data)
   - [ ] Limited Data Set
   - [ ] Waiver of Authorization
   - [ ] Partial Waiver of Authorization (temporary waiver for recruitment purposes and/or waiver of some elements of Authorization)
   - [x] **Signed Authorization Combined with Consent Form**
   - [ ] Signed Authorization as Stand-Alone Form

Institutional Requirements Complete

Protocol Progress:
- **INITIAL SETUP**
- **BACKGROUND, RATIONALE & GOALS**
- **RESEARCH PLAN**
- **CONSENT PLAN**
- **RISKS, PRIVACY & CONFIDENTIALITY**
- **POPULATIONS WITH SPECIAL CONSIDERATIONS**
- **INSTITUTIONAL REQUIREMENTS**
- ⑧ DOCUMENTS

Click Continue below to go to the next section

HM20011840 - Nancy Hsu
Intervention to Promote Survivor Resilience and Adjustment: Efficacy and Sustainability

Documents

1. **Upload any documents that the VCU IRB will need to conduct a review of this submission:**
   A list of potential documents is given in the help text.

NOTE: The delete function should only be used if an incorrect document is uploaded or added to the system AND that document has not been reviewed and approved by the IRB. Do NOT delete documents that the IRB previously reviewed and approved.

Once you have uploaded a document to RAMS-IRB, any changes to that document (i.e. different versions of the same document) should be added to the IRB submission by using the Update button. To provide updated documents, follow these steps:
- Click the Update button located to the left of the document to be updated.
- In the Add Document window, click the Choose File or Browse button, select the file you are adding, and click on the Open button.
- Click OK to close the Add Document window, and the system will upload the revised document. RAMS-IRB will automatically provide a version number for the document.

To access previous versions of a document in RAMS-IRB you must use the History link associated with the document.
- Click the View or Update button located to the left of the document you wish to access.
- In the Add/View Document window, click the "History" hyperlink located to the right of the file name.
- A separate window will open that shows all versions of the document that have been added to RAMS-IRB. Click on any file name to download and view the document.

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Documents Complete

Protocol Progress:
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- **BACKGROUND, RATIONALE & GOALS**
- **RESEARCH PLAN**
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- **POPULATIONS WITH SPECIAL CONSIDERATIONS**
- **INSTITUTIONAL REQUIREMENTS**
- **DOCUMENTS**

End of Application

Click Continue below to exit and submit this project

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Participants with TBI

2. * **Select all that apply to this consent / assent group:**

	Name
☑	**Signed Consent by Participant**
☑	**Signed Parent/Guardian Permission or Legally Authorized Representative Consent**
☑	**Signed Assent by Child or Decisionally Impaired Adult**
☐	Verbal/Other Indication of Assent by Child or Decisionally Impaired Adult
☐	Short Form Consent (limited applicability)
☐	None of the Above (select waiver below)

3. * **Select all electronic signature platforms that apply to this consent / assent group:**
   - ☐ Not using electronic signature platforms
   - ☐ DocuSign Part 11 (FDA regulated studies)
   - ☐ DocuSign (standard platform for non-FDA regulated studies)
   - ☐ REDCap e-Consent
   - ☐ iMedConsent (Veterans Affairs studies)
   - ☐ Other electronic signature platform

4. **If Other is selected, explain:**

5. * **Select any waivers that apply to this consent / assent group:**

☑	**No Waivers Requested**
☐	Waiver of All Consent or Some Elements in Consent Form
☐	Waiver of Parental Permission or Legally Authorized Representative Consent
☐	Waiver of All Assent by Child or Decisionally Impaired Adult
☐	Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)
☐	Exception from Informed Consent (for emergency research only)

6. * **Select all study team role(s) that will obtain consent / assent from this group:**

☐	Principal Investigator
☐	Co/Sub-Investigator

- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [x] **Research Coordinator**
- [ ] Research Nurse
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [x] **Other**
- [ ] N/A: Requesting Waiver of Consent

7. **If Other is selected, explain:**
   Interventionist

8. * **Describe the consent procedures used for this group. Address each point below:**

   - When and where consent will occur
   - What will be covered during the consent discussion
   - How the consent discussion will occur (e.g. in-person, phone, video conference)
   - How you will reconfirm consent on an ongoing basis, if applicable

   Participants will consent in the facilities housing the Department of Physical Medicine and Rehabilitation, Division of Neuropsychology and Rehabilitation Psychology Research Offices, located in West Hospital on the 3rd floor.

9. * **Select the processes for minimizing any potential perception of undue influence to participate, particularly when there is a pre-existing relationship between the participant and the researcher (e.g. treatment provider/patient; instructor/student; supervisor/employee, etc.):**
   - [ ] Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion
   - [ ] Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion
   - [ ] Removing physical symbols of authority like white coats or police badges
   - [ ] Sitting down beside the participant instead of standing over them
   - [ ] If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)
   - [ ] Moving to a more neutral location like a conference room
   - [ ] Obtaining consent / assent after other services/interactions have been completed (e.g. after school or the clinic visit)
   - [ ] Having a mandatory wait period for the participant to go home and think before they sign consent /assent
   - [ ] Sharing the consent / assent discussion between two people (i.e. a clinician might be the best person to explain study procedures and risks, but then they could step out and let a research assistant finish the consent process)
   - [ ] Other protection(s) not listed here – describe below
   - [ ] N/A: Requesting Waiver of Consent

10. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
    Emphasis will be placed on the fact that participation is voluntary; that participants can refuse to answer any questions

that they choose not to answer; and that they can stop being in the study at any time. Research staff will also emphasize that refusal to participate will not change an individual’s medical care, rehabilitation care, or any other any other benefits received.

11. * **How much time will participants be given to make a decision:**
Individuals are afforded as much time as they wish to decide about participation, and they may schedule a follow-up appointment with the study team if they wish to take the consent form home to discuss with others prior to deciding.

12. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**
If the individual's cognitive status improves during the course of this study, then consent will be sought.

Personnel

1. * **Name:**
   Jeffrey Kreutzer

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**

3. * **Roles:**

- ☐ Principal Investigator
- ☐ Co/Sub-Investigator
- ☐ Medical or Psychological Responsible Investigator
- ☐ Lead Student/Trainee Investigator (leading their own project)
- ☐ Research Coordinator
- ☐ Research Nurse
- ☑ **Consultant**
- ☐ Research Assistant
- ☐ Pharmacist
- ☐ Statistician
- ☐ Regulatory Coordinator
- ☐ Trainee/Student(working on project)
- ☐ Other

4. * **Study related responsibilities:**

- ☑ **Study Design**
- ☐ Data Collection - Lab
- ☐ Data Collection - Clinical
- ☐ Data Collection - Interviews/Surveys

- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [x] **Data Analysis**
- [ ] Project Coordination
- [ ] Participant Identification
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Ana Mills

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**

3. * **Roles:**

- ☐ Principal Investigator
- ☐ Co/Sub-Investigator
- ☐ Medical or Psychological Responsible Investigator
- ☐ Lead Student/Trainee Investigator (leading their own project)
- ☐ Research Coordinator
- ☐ Research Nurse
- ☐ Consultant
- ☐ Research Assistant
- ☐ Pharmacist
- ☐ Statistician
- ☐ Regulatory Coordinator
- ☐ Trainee/Student(working on project)
- ☑ **Other**

4. * **If other role is selected, explain:**
   Interventionist

5. * **Study related responsibilities:**

- ☐ Study Design
- ☐ Data Collection - Lab
- ☐ Data Collection - Clinical

- [x] **Data Collection - Interviews/Surveys**
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [x] **Intervention Services**
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
- [ ] Project Coordination
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

6. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Yes

7. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

8. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Nancy Hsu

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

   - [x] **Principal Investigator**
   - [ ] Co/Sub-Investigator
   - [ ] Medical or Psychological Responsible Investigator
   - [ ] Lead Student/Trainee Investigator (leading their own project)
   - [ ] Research Coordinator
   - [ ] Research Nurse
   - [ ] Consultant
   - [ ] Research Assistant
   - [ ] Pharmacist
   - [ ] Statistician
   - [ ] Regulatory Coordinator
   - [ ] Trainee/Student(working on project)
   - [x] **Other**

4. * **If other role is selected, explain:**
   Interventionist

5. * **Study related responsibilities:**

   - [x] **Study Design**
   - [ ] Data Collection - Lab
   - [ ] Data Collection - Clinical

- [x] **Data Collection - Interviews/Surveys**
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [x] **Intervention Services**
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [x] **Data Analysis**
- [ ] Project Coordination
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

6. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Yes

7. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

8. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Kristin Graham

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**

3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [x] **Other**

4. * **If other role is selected, explain:**
   Interventionist

5. * **Study related responsibilities:**

- [ ] Study Design
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical

- [x] **Data Collection - Interviews/Surveys**
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [x] **Intervention Services**
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
- [ ] Project Coordination
- [ ] Participant Identification
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

6. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Individual has no clinical responsibilities

7. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

8. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Laura Albert

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**

3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

4. * **Study related responsibilities:**

- [ ] Study Design
- [ ] Data Collection - Lab
- [x] **Data Collection - Clinical**
- [x] **Data Collection - Interviews/Surveys**

- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [x] **Data Entry**
- [x] **Data Coding**
- [ ] Data Management
- [ ] Data Analysis
- [ ] Project Coordination
- [ ] Participant Identification
- [ ] Participant Recruitment
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Ronald Seel

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**

3. * **Roles:**

- ☐ Principal Investigator
- ☑ **Co/Sub-Investigator**
- ☐ Medical or Psychological Responsible Investigator
- ☐ Lead Student/Trainee Investigator (leading their own project)
- ☐ Research Coordinator
- ☐ Research Nurse
- ☐ Consultant
- ☐ Research Assistant
- ☐ Pharmacist
- ☐ Statistician
- ☐ Regulatory Coordinator
- ☐ Trainee/Student(working on project)
- ☐ Other

4. * **Study related responsibilities:**

- ☐ Study Design
- ☐ Data Collection - Lab
- ☐ Data Collection - Clinical
- ☐ Data Collection - Interviews/Surveys

- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [x] **Data Analysis**
- [ ] Project Coordination
- [ ] Participant Identification
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Add Document

1. * **Document Name:**
   Consent Form
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   RAI+ consent_2021 05 25 clean.pdf(0.15)

Add Document

1. * **Document Name:**
   Assent Form
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   RAI+ assent_2021 05 25 clean.pdf(0.10)

Add Document

1. * **Document Name:**
   COVID Contingency Consent Script
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   COVID Contingency Consent Script RAI+ 2021 05 25 clean.pdf(0.10)

Add Document

1. * **Document Name:**
   COVID Contingency Consent Form
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   COVID Contingency Consent Info Sheet RAI+ 2021 05 25 clean.pdf(0.10)

Add Document

1. * **Document Name:**
   COVID Contingency Protocol
2. * **Type:**
   Research Protocol
3. * **File:**
   COVID Contingency Protocol v6 HM20011840 2021 05 25.docx(0.06)

Add Document

1. * **Document Name:**
   Flyer
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   RAI+ Study_Flyer 2021 05 25 clean.doc(0.03)

Add Document

1. * **Document Name:**
   Hsu PI Change Form
2. * **Type:**
   Other
3. * **File:**
   Hsu PI Change Form 2021 05 11.pdf(0.01)

Add Document

1. * **Document Name:**
   Hsu CV
2. * **Type:**
   CV/Biosketch
3. * **File:**
   Hsu CV 2020 Dec.pdf(0.01)

Add Document

1. * **Document Name:**
   Marwitz CV
2. * **Type:**
   CV/Biosketch
3. * **File:**
   Marwitz,Jennifer CV 2020 12 18.docx(0.01)

Add Document

1. * **Document Name:**
   Script for cases where follow-up done by phone
2. * **Type:**
   Research Measure
3. * **File:**
   Script follow-ups done by phone 2017 12 17.doc(0.01)

Add Document

1. * **Document Name:**
   Grant Proposal
2. * **Type:**
   Funding Proposal
3. * **File:**
   grantsApplication.pdf(0.01)

Add Document

1. * **Document Name:**
   Data Collection Forms
2. * **Type:**
   Research Measure
3. * **File:**
   RAI+ Measures.pdf(0.01)

Add Document

1. * **Document Name:**
   RAI+ Implementation Manual
2. * **Type:**
   Research Measure
3. * **File:**
   RAI+ Manual 2017 05 08.pdf(0.01)

Add Document

1. * **Document Name:**
   MacCAT-CR (Consent Evaluation)
2. * **Type:**
   Research Measure
3. * **File:**
   MacCAT-CR 2017 10.doc(0.01)

Add Document

1. * **Document Name:**
   CV/Biosketch-Kreutzer
2. * **Type:**
   CV/Biosketch
3. * **File:**
   JSK CV 2017 10 04.docx(0.01)