Study Identification

1. * **Select the Principal Investigator:**
   Paul Wehman

2. * **Study Title:**
   Effect of a 9-Month Internship Intervention for Military Dependents with ASD

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:**
   SOE Spec Ed and DP RRTC

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 **Previously submitted versions of this study (closed, withdrawn, auto-withdrawn studies)**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
McDonough	Jennifer	jltodd@vcu.edu	8048286984	
Schall	Carol	cmschall@vcu.edu	8048286979	
Whittenburg	Holly	whittenburhn@vcu.edu		

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. * Specify which component(s) of the DoD supports this research:

- ☑ **Army**
- ☑ **Navy/Marine Corp**
- ☑ **Air Force**
- ☐ National Security Agency
- ☐ National Geospatial Intelligence Agency

4. * 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**

HM20008778 - Paul Wehman
Effect of a 9-Month Internship Intervention for Military Dependents with ASD

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**

HM20008778 - Paul Wehman
Effect of a 9-Month Internship Intervention for Military Dependents with ASD

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. * **Would it be possible to convert in-person activities in your study to remote if there is an approved contingency protocol?**
   Yes, could convert to remote activities

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

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

6. * **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.
Possible or minimal direct benefit to the community
Scientific benefit

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.

7. 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.**

Individuals with Autism Spectrum Disorders (ASD) who graduate from high school seeking employment face significant challenges compared with those with other disabilities. Shattuck et al. (2011) noted that nearly 80% still live at home, almost half have no job or post-secondary training, 40% do not have contact with friends, 17% do not feel hopeful about their future, 21% do not engage in outside activities, and many experience a decrease in insurance coverage and access to therapy services. Additionally, individuals with ASD in adolescence and early adulthood have a higher incidence of anxiety disorders, including obsessive compulsive disorder, and depression than their peers without disabilities or other disabilities (Gotham, Brunwasser, & Lord, 2015). The lack of access to services and poor outcomes along with an apparent fragile mental health frequently may lead to social isolation, increasing the fragility of the individual (Bishop-Fitzpatrick, Mazefsky, Minshew, & Eack, 2015; Swain, Scarpa, White, & Laugeson, 2015). Thus, transition service providers, including educational and vocational rehabilitation service providers are struggling to meet their responsibility to prepare students with ASD for productive and independent lives after high school. At the same time, however, the blame for this condition does not rest entirely with teachers, job coaches, and vocational rehabilitation case managers. The research community bears significant responsibility for this dilemma by failing to include transition-aged high school students with ASD in meaningful research to determine practices that will reverse this trend. Military dependents with ASD in the 18-22 year old (transition) age ranges are further disadvantaged by a total lack of clinical research addressing their unique needs. Thus the proposed study fills an important clinical practice and research gap. Specifically, the proposed project will study the impact of a transition to employment model, Project SEARCH plus ASD Supports (PS+ASD), which has evidence of efficacy for increasing employment outcomes and independence in 18-22 year olds with ASD. The proposed project will extend previous work by exploring the impact of PS+ASD for military dependents with ASD while also measuring the impact of the intervention on social responsiveness, mental health, and quality of life.

In this project, we target 18-22 year old military dependents with ASD in their final year of high school as they transition to employment. The United States General Accountability Office noted that improved transition practices and outcomes for youth with disabilities is a major need (United States Government Accountability Office, July 2012). Young people with ASD present unique challenges related to post school employment outcomes. Community based employment rates for individuals with ASD, regardless of intellectual ability, reportedly range between 4.1 to 11.8% (Taylor & Seltzer, 2011). Across the ability spectrum, individuals with ASD have lower rates of participation in vocational or technical education, employment, and post-secondary education in 2 or 4-year programs than their peers with speech language impairments, learning disabilities or intellectual disabilities for as long as 7 years post high school. (Schall, Targett, & Wehman, 2013; Shattuck et al., 2012).
Additionally, adolescents and young adults with ASD largely have been orphaned from the research literature addressing transition from high school to employment. A review of the extant literature on interventions for individuals with ASD reveals a paucity of research regarding transition packages and models that would change this pattern of significant underperformance in the transition to adulthood and incorporate autism specific interventions (e.g., Schall, Carr, Targett, West, & Cifu, 2014; Schall, Targett, & Wehman, 2013; Shattuck, et al., 2012). Most of the existing literature has described the characteristics of transition-aged young adult population of individuals with ASD, the services or lack thereof that young adults with ASD access or the poor outcomes achieved by this group of individuals (e.g., Barker, et al., 2011; Cimera & Cowan, 2009; Henninger & Taylor, 2012; Schall & McDonough, 2010; Shattuck, et al., 2010; Shattuck, et al., 2012; Smith, Fleming, Wright, Losh, Humm, Olsen, & Bell, 2015). The findings from this literature indicate that, despite a slight lessening of the original symptoms, individuals with ASD continue to have significant challenges in all environments related to social interaction, communication, and independence into adolescence and adulthood.
Military dependents with ASD who are transitioning from school to employment experience greater disadvantages than their non-military peers with ASD. For example, relocation and deployment in service to our nation may unwittingly trigger many of the conditions associated with poor transition outcomes for youth with ASD. Specifically, life in the military may lead to increased stress, lower social skills, and increased maladaptive behavior for the individual with ASD. Additionally, due to frequent moves, the family may lack access to local resources to support the individual with ASD (Lincoln & Sweeten, 2011). Finally, there have been no research intervention studies to explore treatment models targeted to transition aged military dependents with ASD.
By subjecting PS+ASD to the rigor of a clinical trial with military dependents with ASD, we expect to expand the model to include essential elements to meet the needs of this population of individuals who may be dually disadvantaged by their disability and their status as military dependents. Such information may lead to the development of improved outcomes for these individuals and reduce stress for their families.

2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
There are three primary and three secondary endpoints under investigation in this study: (1) Employment status, (2) wage, (3) number of hours worked per week at 12 and 18-months post enrollment. In addition, the effect of the intervention on (5) social communication, (6) mental health, and (7) quality of life will be explored. Specifically, our hypotheses are:
Hypothesis 1: Young adults who participate in an employer-based employment training and placement program will demonstrate a higher rate of employment than those in the control condition.
Hypothesis 2: Young adults who participate in a work-based employment training and placement program will earn higher wages on average compared to those in the control condition.
Hypothesis 3: Young adults who participate in a work-based employment training and placement program will work more hours per week on average than those in the control condition.
Hypothesis 4: Young adults who participate in a work-based employment training and placement program will increase their social responsiveness skills compared to those in the control condition, as measured by the Social Responsive

Scale, 2nd Ed.
Hypothesis 5: Young adults who participate in a work based employment training and placement program will display lower anxiety and depression scores than those in the control condition as measured by the Behavior Assessment System for Children, 3rd Ed. Teacher Rating Scales – Adolescent version.
Hypothesis 6: Young adults who participate in a work based employment training and placement program will report higher quality of life scores than those in the control condition as measured by the Quality of Life Questionnaire.

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
The objective of this proposed project is to study the impact of Project SEARCH plus Autism Spectrum Disorders Supports (PS+ASD) on the social communication, behavioral, and employment outcomes of military dependents with ASD using a randomized clinical trial with a wait-list control group. We propose to implement an efficacious intervention, PS+ASD, for 18 – 22 year old military dependents with ASD, to measure the effect of this intervention on community-based competitive employment, social communication, mental health, and quality of life. The primary objective of this research is to determine if subjects who receive PS+ASD have greater improvement in three vocational domains (employment status, wage, number of hours worked per week) than subjects in a wait-list control group at 12 and 18 -months post-enrollment.
Secondary Objectives. To assess differences in three personal domains (social communication, mental health, and quality of life) for the treatment and wait-list control groups at baseline, 12 and 18-months post enrollment.
Exploratory Objectives. Exploratory objectives are to compare the three vocational domains and three personal domains at baseline, 12 and 18-months post enrollment in subjects receiving the treatment compared to those in the wait-list control group.
Aims. The aims of this project are to (1) Modify PS+ASD Model for Military Dependents, (2) implement the intervention based upon the PS+ASD manual with the addition of the modified elements and will measure fidelity of implementation, (3) measure the impact of the intervention on the employment outcomes social communication, mental health and quality of life of the military dependents who participate compared to an equal control group who do not receive the intervention.

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

Equally important, the successful conclusion of this research project will provide empirical validation of the most effective procedures for utilizing community-based instruction for youth with autism. Additionally, we expect to show the positive relationship between community experiences and competitive employment that occurs when a student's support needs and interests are identified prior to job placement. With the growing incidence of autism spectrum disorders, there is a corresponding need for instructional models that result in greater levels of financial independence, vocational competency, and long-term engagement in the workforce with supports. This project will contribute to the development of one such model. The single subject design used in this study provides preliminary evidence regarding the efficacy of the model that can be empirically validated with larger-scale replications. We feel that potential benefits far outweigh the minimal risk involved.

5. * **Describe any potential for direct benefits to participants in this study:**
We anticipate numerous positive outcomes from this project. At a minimum, 38 youth with autism will engage in community-based work experiences that lead to a competitive employment job while transitioning from school to adulthood. There is no guarantee of direct benefit to all individual participants.

The control group participants will benefit from participation in the assessments during the research. By completing the Supports Intensity Scale, they will gain a better understanding of their skill development needs with respect to future employment.

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:**
This study resulted in a significantly higher percentage of participants in the PS+ASD condition acquiring employment while participants who were initially assigned to the waitlist condition were unlikely to acquire employment. Further, the acquisition of employment was demonstrated to result in higher rates of independence and quality of life outcomes for participants who gained employment. This represents both an important research outcome and a critical outcome for military dependent and connected youth. This is also an important study for military families as they navigate the complexities of military life (frequent moves, wait lists for services, etc.) and supporting a youth with autism.

7. **Upload a supporting citation list if applicable:**

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Student Assent Version 2 11/1/2017	Student Assent Clean Version 2 11-1-2017.pdf	0.06	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Student Consent Version 10 11/22/2019	Student Consent 10 11-22-2019 clean version2.pdf	0.31	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	LAR Consent Version 10 11/22/2019	LAR Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Educator Consent Version 10 11/22/2019	Educator Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency	Student Assent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Assent Form Individual Assent						
View	COVID-19 Contingency Consent Form LAR Consent	LAR Consent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form Individual Consent	Individual Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form Educator Consent	Educator Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Protocol	COVID Contingency Protocol for CDMRP version 3.docx	0.03	6/8/2020 11:05 AM	Carol Schall	Other	Yes
View	York County Closure Form	relying_site_closure York.pdf	0.01	8/31/2019 1:45 PM	Carol Schall	Non-VCU site submission form	Yes
View	Williamsburg/ James City County Closure Form	relying_site_closure Williamsburg James City County-signed.pdf	0.01	8/31/2019 1:44 PM	Carol Schall	Non-VCU site submission form	Yes
View	Hampton City Public Schools Closure Form	relying_site_closure Hampton.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	New Horizons Closure Form	New Horizons Closure Report.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	Newport News Public Schools Closure Form	Nwport News Public Schools Signed Relying Site Closure Notice.pdf	0.01	8/31/2019 1:42 PM	Carol Schall	Non-VCU site submission form	Yes
View	Certificate of Confidentiality	Certificate of Confidentiality.pdf	0.03	11/28/2018 5:14 PM	Carol Schall	Other	Yes
View	Subject Eligibility Checklist	CDMRP subject_eligibility_screening checklist Version 2 Clean Line.doc	0.02	11/20/2018 4:52 PM	Carol Schall	Other	Yes
View	Student Screening Interview and Rubric	Student Selection Interview and Rubric 2019 Version 3 Clean.doc	0.05	11/20/2018 4:44 PM	Carol Schall	Other	Yes
View	Project SEARCH "Recommended" Curriculum Documents (Please note, these are not all used)	2003 PS HS Curriculum.doc	0.03	9/23/2018 4:19 PM	Carol Schall	Other	Yes
View	Draft Application for Participation	Draft Application for participation Version 3 Redline 10-26-2017.docx	0.06	10/26/2017 12:27 PM	Carol Schall	Recruitment/Advertising	Yes
View	HRPO IRB Approval	Virginia Commonwealth University Mail - A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Ancillary Committee Approval	Not Applicable
View	Fort Eustis Agreement to be the Location and Business Site for the Research	Virginia Commonwealth University Mail - Re_ [Non-DoD Source] Fwd_ A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	York County Public Schools Institutional Investigator Agreement	York VCU_ACE_YCSD Agreement.pdf	0.01	1/24/2017 1:56 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Williamsburg James City County Public Schools Institutional Investigator Agreement	WJCC VCU Project Search 2017 Agreement_W-JCC_Signed.pdf	0.01	1/24/2017 1:55 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	New Horizons Regional Education Center Institutional Investigator Agreement	New Horizons Invesitgator Agreement.pdf	0.01	1/24/2017 1:54 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Baseline Demographic Script Clean version 2 11-11-2016	Baseline Demographics Clean version 2 11-11-2016.docx	0.03	11/11/2016 12:55 PM	Carol Schall	Research Measure	Yes
View	OSP Proposal Review Documentation	OSP Approval_Project Search_Wehman.pdf	0.01	11/1/2016 2:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 13 Data sharing	NDAR.pdf	0.01	11/1/2016 1:25 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 12 Transition Plan	Transition.pdf	0.01	11/1/2016 1:24 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 10 Data Collection Instruments Description	1 Instruments Relationship to the Study Objectives.docx	0.01	11/1/2016 1:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 11 Impact Statement	Impact.pdf	0.01	11/1/2016 1:21 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Management Plan	3 Study Management Plan.docx	0.01	11/1/2016 1:19 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Description	2 Study Personnel Description.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Organizational Chart	1 Organizational Chart.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 8 Data Management	Data_Manage.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 7 Intervention	Intervention.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Grant Attachment 6 Human Subject Recruitment and Safety Procedures	HumSubProc.pdf	0.01	11/1/2016 1:16 PM	Carol Schall	Other	Yes
View	Grant Attachment 5 Statement of Work	SOW.pdf	0.01	11/1/2016 1:15 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 4 Lay Abstract	LayAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 3 Technical Abstract	TechAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Intellectual Property	7 Intellectual Property and Sharing of Data.docx	0.01	11/1/2016 1:13 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letters of Collaboration	3 Hampton City Public Schools.tif	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letters of Collaboration	2 Newport News.pdf	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letter of Organizational Support	5 Cifu Letter of Support.doc	0.01	11/1/2016 1:11 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 List of Relevant Publications	4 List of Relevant Publications.docx	0.01	11/1/2016 1:08 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Facilities	3 Facilities.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Abbreviations	2 List of Abbreviations.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 References	1 References.docx	0.01	11/1/2016 1:06 PM	Carol Schall	Other	Not Applicable
View	Grant Project Narrative	ProjectNarrative.pdf	0.01	11/1/2016 1:05 PM	Carol Schall	Other	Yes
View	VCU Response to peer and programmatic review	Response to Peer and Programatic Review Concerns.docx	0.01	11/1/2016 12:16 PM	Carol Schall	Other	Not Applicable
View	CDMRP Review Notes	CDMRP Review Notes.pdf	0.01	11/1/2016 12:15 PM	Carol Schall	Other	Not Applicable
View	Newport News Public Schools Institutional Investigator Agreement	Newport News Public Schools_Institutional Investigator Agreement.pdf	0.01	11/1/2016 12:14 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Hampton City Public Schools	Hampton City Public Schools IIA.pdf	0.01	10/3/2016 12:36 PM	Carol Schall	Non-VCU site submission form	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Institutional Investigator Agreement						
View	References Cited	References.docx	0.01	9/21/2016 9:16 PM	Carol Schall	Other	Not Applicable
View	Quality of Life Questionnaire Adult Version	8 qol question adults (1).doc	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Proxy Report	7 SRS2 Proxy Report.pdf	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Self Report	6 SRS 2 Self Report.pdf	0.01	9/21/2016 7:55 PM	Carol Schall	Research Measure	Yes
View	Behavior Assessment Scale in Children Adolescent Ages 12-21	5 30805_BASC3_TRS_A_RS_Form_FNL (1).pdf	0.01	9/21/2016 7:54 PM	Carol Schall	Research Measure	Yes
View	Support Intensity Scale	4 Support Intensity Scale.pdf	0.01	9/21/2016 7:53 PM	Carol Schall	Research Measure	Yes
View	12 and 18 Month Script Version 1 9-21-2016	3 Twelve and Eighteen Months Data script.docx	0.01	9/21/2016 7:52 PM	Carol Schall	Research Measure	Yes
View	Draft Teacher Recruitment Letter	Letter to teachers recruitment 2016 version 1 9-21-2016.docx	0.01	9/21/2016 7:39 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Treatment Acceptance Letter	Draft Treatment Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Parent/Student Recruitment Letter	Draft Parent Recruitment letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Open House Flyer	Draft open house flyer version 1 9-21-2016.doc	0.01	9/21/2016 7:35 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Control Group Acceptance Letter	Draft Control Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:34 PM	Carol Schall	Recruitment/Advertising	Yes
View	Avellone Biosketch	Avellone Bio Sketch.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	McDonough Biosketch	biosketch McDonough.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Schall Biosketch	Schall biosketch (1).doc	0.01	9/20/2016 4:33 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Wehman Biosketch	Bio Sketch Wehman.docx	0.01	9/20/2016 4:32 PM	Carol Schall	CV/Biosketch	Yes

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.
   96

2. **If this is a multi-Center Project, what is the maximum anticipated number of subjects across all sites?**
   This is not a multi Center project.

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:**
   The purpose of the statistical power analysis is to determine the sample size needed to credibly detect the treatment effects on the transition outcomes described above. For planning adequately powered experiments, the power analysis, using PASS (Hintze, 2011) was used with the six outcome variables including the primary outcome measure, employment rate, to determine the estimated level of power for any given sample size in this RCT efficacy study. To be conservative, a two-sided test is carried out (larger sample size required) in the power analysis.
   Based on available data and past testimonies, the employment rate of students who received Project SEARCH program varies from 60% to 90% across different states and sites. Our pilot study of students with ASD in the Virginia site (Wehman, Schall, et al., in review) indicates that the employment rate upon completion of students with ASD in the intervention group is higher than those with ASD in the control group with 87% vs. 6.7% employed at completion. Given the sample size designated in this study, with 16 in the treatment group and 22 in the wait-list control group, the study will have greater than .80 power to detect a significant difference (at the two sided 5% level) between treatment and control groups when using Fischer's Exact Test. For the six continuous outcome variables (i.e., hourly wages, hours/week, Social Responsiveness Scale total score, Behavior Assessment System for Children t-score, and Quality of Life Questionnaire percentile score), the effect sizes from the pilot study were used to determine that 16 subjects in the treatment and control groups were sufficient. The smallest relevant between group effect size (d) was 1.37 and smallest within group effect size (d) was 0.63 (Schall, Under Review). These moderate to large effect sizes were reduced to determine a minimum power of estimate of 80% for a sample size of 16 (N=32). The power analysis indicated that a between group effect size (d) of 1.10 with a sample size 16 (N=32) had 0.85 power (95%CL = 0.81 to 0.88) and a within group effect size (d) of 0.25 had 0.90 power (95%CL = 0.87 to 0.92) with alpha set at 0.05 when using a mixed model with SAS® PROC MIXED with three time points and two levels (SAS® v9.4, 2013). In this balanced design, power greater than or equal to .80 is often assumed to be adequate and acceptable to detect the difference of a given magnitude in the mean outcome for the two groups, holding the significance level (a = .05) constant.

   We anticipate that the individuals providing information will include:

   38 Individuals with ASD
   38 Parents of individuals with ASD
   20 Teachers of individuals with ASD
   Total = 96

4. * **List the study inclusion criteria:**
   In order to be selected for inclusion in the sample pool, participants must meet the following criteria: (1) A diagnosis of Autism Spectrum Disorder; (2) between 18 - 22 years of age; (3) entering final year of school participation and is on track to receive a diploma or a certificate; (4) meets eligibility requirements for vocational rehabilitation; (5) possesses independent personal hygiene, eating and grooming skills; (5) able to pass drug screen and felony check and have immunizations up to date (These items will be seen by the community business only as required by them for interns to be present at their work site); and (6) desires and plans to work competitively in the community at the conclusion of the 9-month program, (7) Be a military dependent or military connected youth.

5. * **List the study exclusion criteria:**
   Individuals who do not meet the inclusion criteria will be excluded from the study. Additionally, Students who will be excluded are those who cannot consent or assent to the research due to age or mental incapacity. In some cases, students will be of legal age but will be under the guardianship of their parent(s) or other legally authorized representative (LAR).

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.**
   Only those who are not able to consent or assent will be excluded from this research. We are targeting military dependents due to their double disadvantage as youth with ASD and military dependents. Specifically, Military dependents with ASD who are transitioning from school to employment experience greater disadvantages than their non-military peers with ASD. For example, relocation and deployment in service to our nation may unwittingly trigger many of the conditions associated with poor transition outcomes for youth with ASD. Specifically, life in the military may lead to increased stress, lower social skills, and increased maladaptive behavior for the individual with ASD. Additionally, due to frequent moves, the family may lack access to local resources to support the individual with ASD (Lincoln & Sweeten, 2011). Finally, there have been no research intervention studies to explore treatment models targeted to transition aged military dependents with ASD.

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.**
There are three primary and three secondary endpoints under investigation in this study: (1) Employment status, (2) wage, (3) number of hours worked per week at 12 and 18-months post enrollment. In addition, the effect of the intervention on (5) social communication, (6) mental health, and (7) quality of life will be explored. Specifically, our hypotheses are:
Hypothesis 1: Young adults who participate in an employer-based employment training and placement program will demonstrate a higher rate of employment than those in the control condition.
Hypothesis 2: Young adults who participate in a work-based employment training and placement program will earn higher wages on average compared to those in the control condition.
Hypothesis 3: Young adults who participate in a work-based employment training and placement program will work more hours per week on average than those in the control condition.
Hypothesis 4: Young adults who participate in a work-based employment training and placement program will increase their social responsiveness skills compared to those in the control condition, as measured by the Social Responsive Scale, 2nd Ed.
Hypothesis 5: Young adults who participate in a work based employment training and placement program will display lower anxiety and depression scores than those in the control condition as measured by the Behavior Assessment System for Children, 3rd Ed. Teacher Rating Scales – Adolescent version.
Hypothesis 6: Young adults who participate in a work based employment training and placement program will report higher quality of life scores than those in the control condition as measured by the Quality of Life Questionnaire.

2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
The objective of this proposed project is to study the impact of Project SEARCH plus Autism Spectrum Disorders Supports (PS+ASD) on the social communication, behavioral, and employment outcomes of military dependents with ASD using a randomized clinical trial with a wait-list control group. We propose to implement an efficacious intervention, PS+ASD, for 18 – 22 year old military dependents with ASD, to measure the effect of this intervention on community-based competitive employment, social communication, mental health, and quality of life. The primary objective of this research is to determine if subjects who receive PS+ASD have greater improvement in three vocational domains (employment status, wage, number of hours worked per week) than subjects in a wait-list control group at 12 and 18 -months post-enrollment.
Secondary Objectives. To assess differences in three personal domains (social communication, mental health, and quality of life) for the treatment and wait-list control groups at baseline, 12 and 18-months post enrollment.
Exploratory Objectives. Exploratory objectives are to compare the three vocational domains and three personal domains at baseline, 12 and 18-months post enrollment in subjects receiving the treatment compared to those in the wait-list control group.
Aims. The aims of this project are to (1) Modify PS+ASD Model for Military Dependents, (2) implement the intervention based upon the PS+ASD manual with the addition of the modified elements and will measure fidelity of implementation, (3) measure the impact of the intervention on the employment outcomes social communication, mental health and quality of life of the military dependents who participate compared to an equal control group who do not receive the intervention.

3. * **Choose all types of recruitment materials that may be used and upload them below:**
- [ ] 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
- [ ] 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.
Students will be recruited through their schools through (a) a flyer advertising an informational meeting for students and parents with information about the study; (b) a letter to students and parents sent by the school, and (c) regularly scheduled Individualized Education Plan (IEP) meetings at which parents and students attend. Information about the study will be provided to students and to their families.

Potential participants will submit an application that contains their contact information. (See Application for Participation located in the recruitment materials sections).

Recruitment activities will be held from January through May of years 1 and 2. Recruitment may occur in year 3 if there is significant attrition of participants. Once all participants are enrolled and identified, we will assign a number to each enrolled participant and complete randomization using a random numbers generator on a computer. The individual completing randomization will not know the identity or group to which individuals are assigned.

Recruitment procedures will be completed as follows:

1. Each school district representative who participates on the coordinating team will schedule an informational meeting in their school division for potential participants from their schools.

2. Applications and flyers announcing informational meetings will be sent to all school district representatives to share with potential participants in January of years 1, 2, and potentially 3.

3. Informational meetings will be held at the times and in the locations identified by the school district representatives.

4. If potential participants or their family members are unable to attend the informational meetings, VCU staff will meet with them at a time and location of their choosing.

5. At each informational meeting, potential participants and their family members will receive an application with instructions on how to apply, when and where to deliver completed applications.

6. VCU staff will answer any questions from potential participants regarding the research.

7. Upon receipt of the application, VCU staff will coordinate with the screening team to schedule screening interviews in a private location that is convenient to the potential participant and their family members.

Screening Procedures:

There will be two screening meetings held for all potential participants. The first meeting, the research screening meeting, will be for the purposes of completing consent and assent documentation, completing the subject eligibility checklist and reviewing research procedures with potential participants and their family members. This first research screening meeting will include the researcher or their designee, the potential participant, and their family members or guardians only. It will be held at a location of the participant and their family's choosing that is private with a door that is able to be closed to further maintain privacy. If the potential participant and their guardians agree to participate by signing the consent and assent documents, a second "Project SEARCH Screening meeting will be scheduled.

The Project SEARCH Screening meeting will be held in private locations convenient to the potential participant and their family members. These are most often held at the potential participant's school in a closed room, such as a guidance counselor's meeting room. The following people from the Project SEARCH team participate:
1. A VCU representative trained in the research protocol and completing consent/assent discussions
2. A Project SEARCH teacher or job coach
3. A Department of Aging and Rehabilitative Services Counselor
4. The Coordinating team member from the school division where the potential participant receives their education.
4. The potential participant
5. The potential participant's family members
6. The potential participant's current teacher (if acceptable to the potential participant)

During this meeting, the team mentioned above will complete the Student Screening and Interview Rubric.

In some cases, the potential participant is unable to verbally participate or has difficulty answering questions in the screening interview. When that is the case, the student will be asked if the VCU Representative and/or the Project SEARCH teacher or job coach can observe the potential participant in their classroom at their home school. The purpose of this observation is to be able to answer questions through observation that the person or their team could not answer in the interview.

(See the attached Student Screening Interview and Rubric in the Supporting Documents)

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
   This is a randomized, wait-list controlled study of the efficacy of the Project Search plus ASD Supports Model (PS+ASD) in 32 adolescents and young adults aged 18 to 22 with ASD. Approximately 32 subjects will be enrolled and randomized in a 1:1 ratio to treatment or wait-list control. A sufficient number of potential subjects will be screened to achieve this number of enrolled subjects.

   The six dependent variables in question are the primary endpoint employment rate (upon completion and at 12 months and 18 months post-enrollment) and the secondary endpoints hourly wages, hours/week, Social Responsiveness Scale total score, Behavior Assessment System for Children 3rd Ed. Anxiety and Depression t-score and the Quality of Life Questionnaire percentile score at baseline (Baseline), 12 months post enrollment (12 months), and 18 months post-enrollment (18 months). The efficacy of the intervention will be analyzed by comparing the differences in these six variables between the treatment group and the control group.
   The study will take place at Fort Eustis in collaboration with the local school division, Newport News, Hampton City, York County, Williamsburg James City County Public Schools, and the New Horizons Regional Education Center where most military dependents receive their education. The participating public schools will identify a teacher consultant and instructional assistant to staff the project. Additionally, we will collaborate with a variety of department at Fort Eustis Military base where the project will be housed. We will also collaborate with the Virginia Department of Aging and Vocational Rehabilitation Services (DARS) as well as Business Connections, VCU's Community Rehabilitation Provider for job coaching services. At baseline, we will collect demographic and descriptive data to assist us in identifying and describing the prior experiences and current situation for the participants in the study. The demographic variables collected will be age, gender, and race. We will also collect information regarding the military dependent with ASD's parents' military status including identification of the currently serving military parent(s), living situation, school division where served, and the current location of assignment of first and/or second military parent. In addition, we will collect total household income in ranges to assess the variability of employment outcomes based upon yearly total household income. We will collect diagnostic information regarding the participant including medical diagnosis, primary educational disability category, secondary educational disability category and intelligence quotient. Finally, we will collect information regarding the participant's work, internship, and educational experience. In addition to these variables, we will also complete the Support Intensity Scale (SIS).43 The SIS is an interview based assessment tool that identifies the type, amount, and frequency of support required by individuals with significant disabilities, including persons with autism, to perform 57 life activities. An additional 28 items address behavioral and medical areas. The assessment is completed through an interview with the individual, as well as family, school, and community members with in-depth knowledge of the individual. The assessment generates a composite scale score and individual scale scores in the areas of home living, community living, lifelong learning, employment, health and safety, and social areas. Completion of the SIS will allow us to describe the impact that the military dependents experiences as a result of their ASD. It is also a clinical tool that will allow us to ensure that all participants get the appropriate level of support to achieve their desired outcome. All collected paper data will be stored in locked file cabinets. All electronic data will be de-identified and stored in encrypted files on encrypted, password protected computers. All data collectors will be trained to complete all data collection to protect the confidentiality of the participants. In some cases where participants are not able to answer questions on the measures, parents or guardians may be asked to answer these questions. Because this will be determined on a case by case basis, parents and guardians will also be considered research participants for the purposes of consent.

   Project SEARCH is an intensive 9-month job training program where youth with developmental disabilities in their last year of high school are embedded in a large community business such as a hospital, government complex, or banking center where they rotate through three 10-12 week internships within the business. Subjects will log approximately 720 hours of internship time learning marketable skills and 180 hours of business site classroom time learning social communication and adaptive behavior for a total of approximately 900 hours embedded in the business setting. In order to meet the unique needs of youth with ASD, Wehman, et al. enhanced the Project SEARCH model by adding autism supports to the original model. Those added supports were: 1) on-site, intensive, systematic instruction using the principles of applied behavior analysis, 2) on-site support and consultation from a behavior/autism specialist, and 3) intensive staff training in ASD and the Project SEARCH Model. This resulted in PS+ASD. It is the impact of this intervention for military dependents with ASD we will assess through this project.

   As a part of this study, we will collect the following educational records:

   1. The Individualized Education Plan for each student.
   2. The student's attendance record to assess the student's fitness to participate in the study
   3. The student's transcript to insure eligibility for the study
   4. The student's prior work/study history for demographic information

5. Any prior career assessment information to assist in understanding the student's job training desires and needs.

Participation in this study will not be considered a part of the credits a student needs to complete graduation requirements.

We have submitted and received approval for our research protocol from the Human Research Protection Office of the DoD.

Prior to enrollment, each potential participant will complete an application for participation and will also complete a screening interview. Neither the application nor the screening interview will be used to collect data for research purposes. Instead, these activities are standard parts of the Project SEARCH program. The screening interview serves three purposes. First, it allows the team to describe Project SEARCH to the potential participant and ask any questions they may have. Second, it allows the research team to review the consent and assent documents and give participants an opportunity to ask questions about the research procedures. Third, it gives the Project SEARCH team the opportunity to interview the potential participant to learn more about their future career goals and to confirm their support needs. All screening meetings are held in private locations convenient to the potential participant and their family members. These are most often held at the potential participant's school in a closed room, such as a guidance counselor's meeting room. The following people from the Project SEARCH team participate:
1. A VCU representative trained in the research protocol and completing consent/assent discussions
2. A Project SEARCH teacher or job coach
3. A Department of Aging and Rehabilitative Services Counselor
4. The Coordinating team member from the school division where the potential participant receives their education.
4. The potential participant
5. The potential participant's family members
6. The potential participant's current teacher (if acceptable to the potential participant)

In some cases, the potential participant is unable to verbally participate or has difficulty answering questions in the screening interview. When that is the case, the student will be asked if the VCU Representative and/or the Project SEARCH teacher or job coach can observe the potential participant in their classroom at their home school. The purpose of this observation is to be able to answer questions through observation that the person or their team could not answer in the interview.

(See the attached Student Screening Interview and Rubric in the Supporting Documents)

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

The following procedures will be implemented for research purposes:

Screening
Consent
Randomization
Assessment using:
the Support Intensity Scale
Interview using the baseline and 12 and 18 month follow-up interview
Social Responsiveness Scale
Behavior Assessment Scale for Children
Quality of Life Questionnaire
Collection of documents including the IEP, and Transition Plan.

The following procedures would take place in the same manner regardless of the research:
Potential Participant Application
Project Search Team Interview Process
9-month Project SEARCH Intervention
Involvement by the Department of Aging and Rehabilitative Services
Services provided by a job coach

COVID-19 Contingency Plans

During the COVID-19 Crisis, we will meet with families and teams via phone or video conference. We will not hold any face to face or in-person contacts. When ever we hold such a meeting, at least two research staff will participate on the phone or video conference. Also, our research staff, who may be working from home, will ensure that they are in a private room in their homes where other's cannot hear their conversations.

8. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:**
The only alternative to participation in this study is not to participate.

If a student decides not to take part in the study, but is interested in work experiences like Project SEARCH, we will refer them to other similar programs if there are any in their locality.

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	Student Assent Version 2 11/1/2017	Student Assent Clean Version 2 11-1-2017.pdf	0.06	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Student Consent Version 10 11/22/2019	Student Consent 10 11-22-2019 clean version2.pdf	0.31	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	LAR Consent Version 10 11/22/2019	LAR Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Educator Consent Version 10 11/22/2019	Educator Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Assent Form Individual Assent	Student Assent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form LAR Consent	LAR Consent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form Individual Consent	Individual Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form Educator Consent	Educator Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Protocol	COVID Contingency Protocol for CDMRP version 3.docx	0.03	6/8/2020 11:05 AM	Carol Schall	Other	Yes
View	York County Closure Form	relying_site_closure York.pdf	0.01	8/31/2019 1:45 PM	Carol Schall	Non-VCU site submission form	Yes
View	Williamsburg/ James City County Closure Form	relying_site_closure Williamsburg James City County-signed.pdf	0.01	8/31/2019 1:44 PM	Carol Schall	Non-VCU site submission form	Yes
View	Hampton City Public Schools Closure Form	relying_site_closure Hampton.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	New Horizons Closure Form	New Horizons Closure Report.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	Newport News Public Schools Closure Form	Nwport News Public Schools Signed Relying Site Closure Notice.pdf	0.01	8/31/2019 1:42 PM	Carol Schall	Non-VCU site submission form	Yes
View	Certificate of Confidentiality	Certificate of Confidentiality.pdf	0.03	11/28/2018 5:14 PM	Carol Schall	Other	Yes
View	Subject Eligibility	CDMRP subject_eligibility_screening checklist Version 2 Clean Line.doc	0.02	11/20/2018 4:52 PM	Carol Schall	Other	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Checklist						
View	Student Screening Interview and Rubric	Student Selection Interview and Rubric 2019 Version 3 Clean.doc	0.05	11/20/2018 4:44 PM	Carol Schall	Other	Yes
View	Project SEARCH "Recommended" Curriculum Documents (Please note, these are not all used)	2003 PS HS Curriculum.doc	0.03	9/23/2018 4:19 PM	Carol Schall	Other	Yes
View	Draft Application for Participation	Draft Application for participation Version 3 Redline 10-26-2017.docx	0.06	10/26/2017 12:27 PM	Carol Schall	Recruitment/Advertising	Yes
View	HRPO IRB Approval	Virginia Commonwealth University Mail - A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Ancillary Committee Approval	Not Applicable
View	Fort Eustis Agreement to be the Location and Business Site for the Research	Virginia Commonwealth University Mail - Re_ [Non-DoD Source] Fwd_ A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Other	Not Applicable
View	York County Public Schools Institutional Investigator Agreement	York VCU_ACE_YCSD Agreement.pdf	0.01	1/24/2017 1:56 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Williamsburg James City County Public Schools Institutional Investigator Agreement	WJCC VCU Project Search 2017 Agreement_W-JCC_Signed.pdf	0.01	1/24/2017 1:55 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	New Horizons Regional Education Center Institutional Investigator Agreement	New Horizons Invesitgator Agreement.pdf	0.01	1/24/2017 1:54 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Baseline Demographic Script Clean version 2 11-11-2016	Baseline Demographics Clean version 2 11-11-2016.docx	0.03	11/11/2016 12:55 PM	Carol Schall	Research Measure	Yes
View	OSP Proposal Review Documentation	OSP Approval_Project Search_Wehman.pdf	0.01	11/1/2016 2:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 13 Data sharing	NDAR.pdf	0.01	11/1/2016 1:25 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 12 Transition Plan	Transition.pdf	0.01	11/1/2016 1:24 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 10 Data Collection Instruments Description	1 Instruments Relationship to the Study Objectives.docx	0.01	11/1/2016 1:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 11	Impact.pdf	0.01	11/1/2016 1:21 PM	Carol Schall	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Impact Statement						
View	Grant Attachment 9 Study Management Plan	3 Study Management Plan.docx	0.01	11/1/2016 1:19 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Description	2 Study Personnel Description.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Organizational Chart	1 Organizational Chart.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 8 Data Management	Data_Manage.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 7 Intervention	Intervention.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Yes
View	Grant Attachment 6 Human Subject Recruitment and Safety Procedures	HumSubProc.pdf	0.01	11/1/2016 1:16 PM	Carol Schall	Other	Yes
View	Grant Attachment 5 Statement of Work	SOW.pdf	0.01	11/1/2016 1:15 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 4 Lay Abstract	LayAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 3 Technical Abstract	TechAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Intellectual Property	7 Intellectual Property and Sharing of Data.docx	0.01	11/1/2016 1:13 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letters of Collaboration	3 Hampton City Public Schools.tif	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letters of Collaboration	2 Newport News.pdf	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letter of Organizational Support	5 Cifu Letter of Support.doc	0.01	11/1/2016 1:11 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 List of Relevant Publications	4 List of Relevant Publications.docx	0.01	11/1/2016 1:08 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2	3 Facilities.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Facilities						
View	Grant Attachment 2 Abbreviations	2 List of Abbreviations.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 References	1 References.docx	0.01	11/1/2016 1:06 PM	Carol Schall	Other	Not Applicable
View	Grant Project Narrative	ProjectNarrative.pdf	0.01	11/1/2016 1:05 PM	Carol Schall	Other	Yes
View	VCU Response to peer and programmatic review	Response to Peer and Programatic Review Concerns.docx	0.01	11/1/2016 12:16 PM	Carol Schall	Other	Not Applicable
View	CDMRP Review Notes	CDMRP Review Notes.pdf	0.01	11/1/2016 12:15 PM	Carol Schall	Other	Not Applicable
View	Newport News Public Schools Institutional Investigator Agreement	Newport News Public Schools_Institutional Investigator Agreement.pdf	0.01	11/1/2016 12:14 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Hampton City Public Schools Institutional Investigator Agreement	Hampton City Public Schools IIA.pdf	0.01	10/3/2016 12:36 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	References Cited	References.docx	0.01	9/21/2016 9:16 PM	Carol Schall	Other	Not Applicable
View	Quality of Life Questionnaire Adult Version	8 qol question adults (1).doc	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Proxy Report	7 SRS2 Proxy Report.pdf	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Self Report	6 SRS 2 Self Report.pdf	0.01	9/21/2016 7:55 PM	Carol Schall	Research Measure	Yes
View	Behavior Assessment Scale in Children Adolescent Ages 12-21	5 30805_BASC3_TRS_A_RS_Form_FNL (1).pdf	0.01	9/21/2016 7:54 PM	Carol Schall	Research Measure	Yes
View	Support Intensity Scale	4 Support Intensity Scale.pdf	0.01	9/21/2016 7:53 PM	Carol Schall	Research Measure	Yes
View	12 and 18 Month Script Version 1 9-21-2016	3 Twelve and Eighteen Months Data script.docx	0.01	9/21/2016 7:52 PM	Carol Schall	Research Measure	Yes
View	Draft Teacher Recruitment Letter	Letter to teachers recruitment 2016 version 1 9-21-2016.docx	0.01	9/21/2016 7:39 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Treatment Acceptance Letter	Draft Treatment Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Parent/Student Recruitment Letter	Draft Parent Recruitment letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Draft Open House Flyer	Draft open house flyer version 1 9-21-2016.doc	0.01	9/21/2016 7:35 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Control Group Acceptance Letter	Draft Control Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:34 PM	Carol Schall	Recruitment/Advertising	Yes
View	Avellone Biosketch	Avellone Bio Sketch.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	McDonough Biosketch	biosketch McDonough.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Schall Biosketch	Schall biosketch (1).doc	0.01	9/20/2016 4:33 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Wehman Biosketch	Bio Sketch Wehman.docx	0.01	9/20/2016 4:32 PM	Carol Schall	CV/Biosketch	Yes

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
   - [x] **Educational Settings/Assessments/Procedures**
   - [ ] None of the Above

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

4. * **Describe the purpose of the recordings, who will be recorded and when such recordings will occur:**
   The purpose of the recordings is to demonstrate intervention procedures to professionals seeking to understand the intervention and the needs of the students involved in the study. We will collect both video and photographs to be used in presentations to illustrate how the Project SEARCH plus ASD Supports model is implemented.

   Both video and photographic data is collected to increase our ability to tell the story of these individuals' journey through the program. It is used in presentation and will not be used as a source for research data collection. It allows us to show people with disabilities in photographic form demonstrating competency. We also use the photos to show some of the specific supports people with ASD require at work. We use this data for the purposes of educating others regarding the Project SEARCH plus ASD model.

5. * **Describe the impact this study might have on students' opportunity to learn required educational content:**
This project will neither increase not decrease the participant's opportunity to learn required content as community based employment training is included in student with disabilities' curriculum.

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

- [ ] 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 Project SEARCH + ASD Supports intervention is a 9-month intervention.

2. * **Describe any potential harms or discomforts that participants could experience during the intervention activity:**
   The only potential harm or discomfort participants might experience is possible loss of confidentiality.

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):**
   The potential impact of the intervention is that participants may acquire employment upon completion of the intervention. The nature of that impact is desirable and the duration of employment may vary depending on the participant's needs and abilities.

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.**
   We do not believe the participants will find the intervention offensive or embarrassing. We have concluded this because we have tested this intervention in other locations and no participants have reported feeling embarrassed or offended by the intervention. We also work with participating intervention sites to educate them regarding the needs and abilities of youth and young adults with ASD. Finally, we provide on-going support to participants and the sites to ensure that participants receive support in their participation to avoid embarrassing or offensive situations.

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.
   Educational Records including Individualized Education Plans, School Transcript. Prior Work/Study Experiences, School Attendance Record

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.**
   The records mentioned above will contain the student's name, address, parents', and teachers' names. It will also contain the students' disability as well as a description of the educational supports and services they require. We will maintain the records in locked filing cabinets and they will be destroyed upon completion of the study.

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:**
   - [ ] 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
   - [x] **Other**

2. * **If Other, explain:**
   The cost for taking part in the high school job training program includes any high school fees you would normally pay to the school.

3. * **Provide details of all financial costs to the participant, other than time and transportation. Additional details regarding standard of care costs will be requested on another screen, if applicable.**
   The cost for taking part in the community based job training program include:
   1. Buying appropriate clothing (which may include buying uniforms)
   2. Buying lunch if you are not able to bring a lunch from home

4. * **Describe any procedures, therapy, lab work, x-rays, drugs, or devices, etc that are considered standard of care and will be charged to the participant or their insurance.**
   There are no "standard of care" procedures associated with this study. There is no charge for services to the individual or their insurance.

5. * **Describe the process to determine whether participants' insurance will cover the expenses.**
   NA

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.)**

   A $300 research Incentive will be given to all participants across the study.

2. **If compensation will be pro-rated, explain the payment schedule.**
   Data collection baseline = $75.00, Data collection 12 months = $75.00, Data collection 18 months = $75.00, As an incentive for completion of all data collection points, all participants who participate in all three data collection points will receive an additional $75.00 bonus at the 18 month data collection point. Total potential compensation across the 18 months of the study is $300.00 per participant.

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

Click Continue below to go to the next section

Consent Process

1. * **List all consent groups:**

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
View	Participant Consent	Signed Consent by Participant	No Waivers Requested Exception from Informed Consent (for emergency research only)	Principal Investigator Co/Sub-Investigator Research Coordinator Research Assistant		Not using electronic signature platforms	Because this study involves special education students with ASD, consent meetings will be held concurrently with each potential participant's Individualized Education Plan (IEP) meeting at which students and parents/guardians are in attendance, or during an individual parent/teacher/student conference at the student's school. At least one member of the research team will also be available at the meeting to provide information about the study, answer questions, and obtain informed consent/assent. In the event that a non-English speaking individual participates, we will seek an interpreter so that the individual can receive the consent information and have their questions answered in their native language. COVID-19 Contingency Plan: We will meet with participants via phone or video conferencing only. We will have no in-person interactions. During this time, we will have two research staff on the phone or video conference. We will mark the form based upon the verbal consent of the participant. The participant will have up to 2 weeks to make their decision.	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 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) 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)	Students and/or parents who want additional time to consider participation may take the informed consent documents with them and will have up to two weeks to consider their decision.	For students who are legally emancipated, we will use a standard consent document; for those who are under the guardianship of an LAR, we will obtain consent from the LAR and assent from the student. participants will be made aware of consent form changes pertaining to the certificate of confidentiality and future use of data, and will have an opportunity to sign the updated consent form when they meet with the researchers.
View	Educators	Signed Consent by Participant	No Waivers Requested Exception from Informed Consent	Principal Investigator Co/Sub-Investigator Research Coordinator		Not using electronic signature platforms	Consent will be obtained when first meeting with the educator to review data collection measures. COVID-19	Removing physical symbols of authority like white coats or police badges Sitting down beside the participant instead of standing over them	We will offer educators 2 weeks to make a decision regarding	NA. All Educators are assumed to be competent by virtue of their position as certified

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
			(for emergency research only)	Research Assistant			Contingency Plan: We will meet with participants via phone or video conferencing only. We will have no in-person interactions. During this time, we will have two research staff on the phone or video conference. We will mark the form based upon the verbal consent of the participant. The participant will have up to 2 weeks to make their decision.	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)	their participation	educators. participants will be made aware of consent form changes pertaining to the certificate of confidentiality and future use of data, and will have an opportunity to sign the updated consent form when they meet with the researchers.
View	Student Assent	Signed Assent by Child or Decisionally Impaired Adult	No Waivers Requested Exception from Informed Consent (for emergency research only)	Principal Investigator Co/Sub-Investigator Research Coordinator Research Assistant		Not using electronic signature platforms	Because this study involves special education students with ASD, consent meetings will be held concurrently with each potential participant's Individualized Education Plan (IEP) meeting at which students and parents/guardians are in attendance, or during an individual parent/teacher/student conference at the student's school. At least one member of the research team will also be available at the meeting to provide information about the study, answer questions, and obtain informed consent/assent. In the event that a non-English speaking individual participates, we will seek an interpreter so that the individual can receive the consent information and have their questions answered in their native language. COVID-19 Contingency Plan: We will meet with participants via phone or video conferencing only. We will have no in-person interactions. During this time, we will have two research staff on the phone or video conference. We will mark the form based upon the verbal consent of the participant. The participant will have	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)	Students and/or parents who want additional time to consider participation may take the informed consent documents with them and will have up to two weeks to consider their decision.	For students who are legally emancipated, we will use a standard consent document; for those who are under the guardianship of an LAR, we will obtain consent from the LAR and assent from the student. participants will be made aware of consent form changes pertaining to the certificate of confidentiality and future use of data, and will have an opportunity to sign the updated consent form when they meet with the researchers.

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
							up to 2 weeks to make their decision.			
View	LAR Consent	Signed Parent/Guardian Permission or Legally Authorized Representative Consent	No Waivers Requested Exception from Informed Consent (for emergency research only)	Principal Investigator Co/Sub-Investigator Research Coordinator Research Assistant		Not using electronic signature platforms	Because this study involves special education students with ASD, consent meetings will be held concurrently with each potential participant's Individualized Education Plan (IEP) meeting at which students and parents/guardians are in attendance, or during an individual parent/teacher/student conference at the student's school. At least one member of the research team will also be available at the meeting to provide information about the study, answer questions, and obtain informed consent/assent. In the event that a non-English speaking individual participates, we will seek an interpreter so that the individual can receive the consent information and have their questions answered in their native language. COVID-19 Contingency Plan: We will meet with participants via phone or video conferencing only. We will have no in-person interactions. During this time, we will have two research staff on the phone or video conference. We will mark the form based upon the verbal consent of the participant. The participant will have up to 2 weeks to make their decision.	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)	Students and/or parents who want additional time to consider participation may take the informed consent documents with them and will have up to two weeks to consider their decision.	For students who are legally emancipated, we will use a standard consent document; for those who are under the guardianship of an LAR, we will obtain consent from the LAR and assent from the student. participants will be made aware of consent form changes pertaining to the certificate of confidentiality and future use of data, and will have an opportunity to sign the updated consent form when they meet with the researchers.

2. Upload any consent / assent documents:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Student Assent Version 2 11/1/2017	Student Assent Clean Version 2 11-1-2017.pdf	0.06	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Student Consent Version 10 11/22/2019	Student Consent 10 11-22-2019 clean version2.pdf	0.31	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	LAR Consent Version 10	LAR Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	11/22/2019						
View	Educator Consent Version 10 11/22/2019	Educator Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Assent Form Individual Assent	Student Assent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form LAR Consent	LAR Consent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form Individual Consent	Individual Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form Educator Consent	Educator Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Protocol	COVID Contingency Protocol for CDMRP version 3.docx	0.03	6/8/2020 11:05 AM	Carol Schall	Other	Yes
View	York County Closure Form	relying_site_closure York.pdf	0.01	8/31/2019 1:45 PM	Carol Schall	Non-VCU site submission form	Yes
View	Williamsburg/ James City County Closure Form	relying_site_closure Williamsburg James City County-signed.pdf	0.01	8/31/2019 1:44 PM	Carol Schall	Non-VCU site submission form	Yes
View	Hampton City Public Schools Closure Form	relying_site_closure Hampton.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	New Horizons Closure Form	New Horizons Closure Report.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	Newport News Public Schools Closure Form	Nwport News Public Schools Signed Relying Site Closure Notice.pdf	0.01	8/31/2019 1:42 PM	Carol Schall	Non-VCU site submission form	Yes
View	Certificate of Confidentiality	Certificate of Confidentiality.pdf	0.03	11/28/2018 5:14 PM	Carol Schall	Other	Yes
View	Subject Eligibility Checklist	CDMRP subject_eligibility_screening checklist Version 2 Clean Line.doc	0.02	11/20/2018 4:52 PM	Carol Schall	Other	Yes
View	Student Screening Interview and Rubric	Student Selection Interview and Rubric 2019 Version 3 Clean.doc	0.05	11/20/2018 4:44 PM	Carol Schall	Other	Yes
View	Project SEARCH "Recommended" Curriculum Documents (Please note, these are not all used)	2003 PS HS Curriculum.doc	0.03	9/23/2018 4:19 PM	Carol Schall	Other	Yes
View	Draft Application for Participation	Draft Application for participation Version 3 Redline 10-26-2017.docx	0.06	10/26/2017 12:27 PM	Carol Schall	Recruitment/Advertising	Yes
View	HRPO IRB Approval	Virginia Commonwealth University Mail - A-19693.a, A-19693.b, A-19693.c, and	0.01	1/24/2017 1:59 PM	Carol Schall	Ancillary Committee Approval	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
		A-19693.pdf					
View	Fort Eustis Agreement to be the Location and Business Site for the Research	Virginia Commonwealth University Mail - Re_ [Non-DoD Source] Fwd_ A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Other	Not Applicable
View	York County Public Schools Institutional Investigator Agreement	York VCU_ACE_YCSD Agreement.pdf	0.01	1/24/2017 1:56 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Williamsburg James City County Public Schools Institutional Investigator Agreement	WJCC VCU Project Search 2017 Agreement_W-JCC_Signed.pdf	0.01	1/24/2017 1:55 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	New Horizons Regional Education Center Institutional Investigator Agreement	New Horizons Invesitgator Agreement.pdf	0.01	1/24/2017 1:54 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Baseline Demographic Script Clean version 2 11-11-2016	Baseline Demographics Clean version 2 11-11-2016.docx	0.03	11/11/2016 12:55 PM	Carol Schall	Research Measure	Yes
View	OSP Proposal Review Documentation	OSP Approval_Project Search_Wehman.pdf	0.01	11/1/2016 2:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 13 Data sharing	NDAR.pdf	0.01	11/1/2016 1:25 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 12 Transition Plan	Transition.pdf	0.01	11/1/2016 1:24 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 10 Data Collection Instruments Description	1 Instruments Relationship to the Study Objectives.docx	0.01	11/1/2016 1:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 11 Impact Statement	Impact.pdf	0.01	11/1/2016 1:21 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Management Plan	3 Study Management Plan.docx	0.01	11/1/2016 1:19 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Description	2 Study Personnel Description.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Organizational Chart	1 Organizational Chart.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 8	Data_Manage.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Data Management						
View	Grant Attachment 7 Intervention	Intervention.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Yes
View	Grant Attachment 6 Human Subject Recruitment and Safety Procedures	HumSubProc.pdf	0.01	11/1/2016 1:16 PM	Carol Schall	Other	Yes
View	Grant Attachment 5 Statement of Work	SOW.pdf	0.01	11/1/2016 1:15 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 4 Lay Abstract	LayAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 3 Technical Abstract	TechAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Intellectual Property	7 Intellectual Property and Sharing of Data.docx	0.01	11/1/2016 1:13 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letters of Collaboration	3 Hampton City Public Schools.tif	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letters of Collaboration	2 Newport News.pdf	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letter of Organizational Support	5 Cifu Letter of Support.doc	0.01	11/1/2016 1:11 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 List of Relevant Publications	4 List of Relevant Publications.docx	0.01	11/1/2016 1:08 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Facilities	3 Facilities.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Abbreviations	2 List of Abbreviations.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 References	1 References.docx	0.01	11/1/2016 1:06 PM	Carol Schall	Other	Not Applicable
View	Grant Project Narrative	ProjectNarrative.pdf	0.01	11/1/2016 1:05 PM	Carol Schall	Other	Yes
View	VCU Response to peer and programmatic review	Response to Peer and Programatic Review Concerns.docx	0.01	11/1/2016 12:16 PM	Carol Schall	Other	Not Applicable
View	CDMRP Review Notes	CDMRP Review Notes.pdf	0.01	11/1/2016 12:15 PM	Carol Schall	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Newport News Public Schools Institutional Investigator Agreement	Newport News Public Schools_Institutional Investigator Agreement.pdf	0.01	11/1/2016 12:14 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Hampton City Public Schools Institutional Investigator Agreement	Hampton City Public Schools IIA.pdf	0.01	10/3/2016 12:36 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	References Cited	References.docx	0.01	9/21/2016 9:16 PM	Carol Schall	Other	Not Applicable
View	Quality of Life Questionnaire Adult Version	8 qol question adults (1).doc	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Proxy Report	7 SRS2 Proxy Report.pdf	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Self Report	6 SRS 2 Self Report.pdf	0.01	9/21/2016 7:55 PM	Carol Schall	Research Measure	Yes
View	Behavior Assessment Scale in Children Adolescent Ages 12-21	5 30805_BASC3_TRS_A_RS_Form_FNL (1).pdf	0.01	9/21/2016 7:54 PM	Carol Schall	Research Measure	Yes
View	Support Intensity Scale	4 Support Intensity Scale.pdf	0.01	9/21/2016 7:53 PM	Carol Schall	Research Measure	Yes
View	12 and 18 Month Script Version 1 9-21-2016	3 Twelve and Eighteen Months Data script.docx	0.01	9/21/2016 7:52 PM	Carol Schall	Research Measure	Yes
View	Draft Teacher Recruitment Letter	Letter to teachers recruitment 2016 version 1 9-21-2016.docx	0.01	9/21/2016 7:39 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Treatment Acceptance Letter	Draft Treatment Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Parent/Student Recruitment Letter	Draft Parent Recruitment letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Open House Flyer	Draft open house flyer version 1 9-21-2016.doc	0.01	9/21/2016 7:35 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Control Group Acceptance Letter	Draft Control Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:34 PM	Carol Schall	Recruitment/Advertising	Yes
View	Avellone Biosketch	Avellone Bio Sketch.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	McDonough Biosketch	biosketch McDonough.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Schall Biosketch	Schall biosketch (1).doc	0.01	9/20/2016 4:33 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Wehman Biosketch	Bio Sketch Wehman.docx	0.01	9/20/2016 4:32 PM	Carol Schall	CV/Biosketch	Yes

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.

   The potential physical or psychological risks to participants are minimal and do not exceed those that would be incurred by students who do not participate. The potential participants in this study currently receive community-based education and training as planned in this proposal. The only additional risks to participants would be loss of confidentiality or possible exposure to negative comments about their disabilities from employees or customers of the employment training sites.

   In addition, students and parents may find some of the questions we ask during discomforting or distressing. If that is the case, students or their parents may skip that question, ask us to stop that line of questioning, or ask us to stop the interview at any time.

2. * **Describe how each of the risks/harms/discomforts identified above will be minimized:**
   Study records will be maintained in locked storage areas with access only to individuals engaged in the research. No information about the study will include information that can be used to directly or indirectly identify participants. This statement refers to both reporting and storage of study data. One person on the research team will have a unique identifier code list all protocols and electronic data will be coded with that unique identifier. The list will be encrypted on a password protected computer and will be maintained in paper copy in a locked filing cabinet. Thus, stored electronic and paper data will be separated from the unique identifier code. No individual will be referenced in any reporting of data.

   Support personnel will be available to provide education and counseling to
   participants. In the event that a participant required professional services from a psychologist or behavioral counselor, support personnel will refer that individual to properly licensed services. Participants will access these services at their own cost through their own resources including insurance or other funding.

   We can guarantee that all locations where the Project SEARCH research intervention occurs will be EEOC compliant, however, we cannot guarantee that, once a participant leaves the intervention, their future job will be at an EEOC compliant location.

   During the COVID-19 crisis, we will not be holding any face-to-face or in person interactions. We will hold all meetings via phone or video conference. We will have at least two research staff on the phone or video conference. We will also email all forms to participants. Finally, we will have research staff ensure that they are in a private space in their homes away from others overhearing the conversation. We will ask participants to do the same if they wish.

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):**
   There are no potential risks or harms to a community or specific population based on the study findings known.

4. **Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects:**
   There are no plans to provide medical, professional, or psychological intervention to participants in the study. If such services are needed by participants, we will refer them to their own medical doctors or another community doctor psychologist or psychiatrists. Participants will bear financial responsibility for that care. The types of events that may result in referral to a student's home doctor includes minor first aid emergencies, illness, or visible signs of emotional distress, such that the student cannot continue with there daily activities. There is no person individually responsible for making such determinations. Rather the site coordinator on-site will be trained in first aid and will address any minor emergencies as they occur. We will notify ORSP and HRPO of any reportable events immediately upon becoming aware of the event. We will comply with all audits and reviews of our research procedures and protocols. Additionally, We will notify ORSP and HRPO of any additional risks discovered in the conduct of this research.

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.:**
As noted previously, participants who are placed in the community based employment training program will not go to their home high school. Instead, they will receive their education in the employment training program. In the event that a participant can no longer participate in the study due to emotional distress or inability to comply with the study protocol, we will contact the participant or their LAR, and the placing home school division to ensure a smooth transition from the study back to their home high school.

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:**
In the event that the study site becomes unsafe, or the findings indicate significant risk to participants, we will stop the study. In doing so, we will contact the participant or their LAR, and the placing home school division to ensure a smooth transition from the study back to their home high school. We will review all potential sites to ensure their compliance with safety procedures prior to initiating any off site employment training. This review will include ensuring that the community employment training site in question meets all VCU emergency procedures including fire, OSHA, and inclement weather safety protocols.

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

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:**
   - [x] **Conducting study activities in locations that maximize privacy (limited people passing by, closing doors, monitoring voice volume, etc.)**
   - [x] **Moving to a more private area to answer questions or to discuss concerns**
   - [x] **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
   - [x] **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
   - [x] **Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing instead of speaking)**
   - [x] **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
- [ ] 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**
- [ ] 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
- [ ] 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**
- [ ] 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)**
- [ ] 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**
- [x] **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)**
- [x] **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
- [x] **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*.

All meetings, including identification, recruitment, screening, consent, and data collection interviews specific to the research where students may be identified as receiving special education services will be conducted in a private room that is convenient to the student and their caretakers/parents. Additionally, when completing data collection

procedures, we will meet with participants individually at a private location of their choosing. Finally, data disseminated from the study will be aggregated. No individual participant data will be disseminated from the study.

Students will have the opportunity to select the location for meetings and ensure the privacy of that location prior to participation. Finally, students may, but are not required to attend the informational meeting regarding the research. If a student prefers to have the information at the informational meeting shared with them privately, we will make arrangements to do so.

During the COVID-19 crisis, all video calls will be completed using VCU approved video conferencing software. We will send all documents via email using the secure email function provided by VCU.

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**
   - [x] **Promptly transcribing, scanning, or abstracting data from paper into electronic platforms with destruction of the paper copy**
   - [x] **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)**
   - [x] **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)**
   - [x] **When analyzing particularly sensitive information, using computers that are unconnected from the internet.**
   - [x] **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.):**

- [x] **Transferring data promptly from the device/app given to the participant to a VCU storage location**
- [x] **Setting strong passwords on computers and research devices (when applicable) that leave VCU with participants**
- [x] **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
- [ ] 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.
Study records will be maintained in locked storage areas with access only to individuals engaged in the research. We will create an unique identifier for each individual for all electronic records and databases for data analysis. Only one person will have access to the code key so that others reviewing data will not be able to track individual data back to specific participants. No information about the study will include information that can be used to directly or indirectly identify participants. Electronic information will be stored on a encrypted computers and encrypted flash drives. All paper and electronic records will be stored within the Rehabilitation Research and Training Center, a center within the School of Education. No data will be stored in the School of Medicine.

All meetings and interviews specific to the research where students may be identified as receiving special education services will be conducted in a private room. Additionally, when completing data collection procedures, we will meet with participants individually at a private location of their choosing.

During the COVID-19 crisis, only the PI, Dr. Paul Wehman, Co-I, Dr. Carol Schall, Research Coordinators, Dr. Lauren Avellone, and Ms. Jennifer McDonough, and the Research Assistant, Ms. Hannah Seward will be allowed to have hard copies of study data in their homes. All study data maintained in the home during this crisis will be placed in a location in the person's home where others in the home will not have access to or be able to view the documents.

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 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**
- [ ] Social Security Numbers
- [x] **Dates (year alone is not an identifier)**
- [ ] Ages over 89 (age under 89 is not an identifier)
- [ ] Phone Numbers
- [ ] Facsimile Numbers
- [ ] E-mail Addresses
- [ ] 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.
Codes will be developed so that data will not be able to be connected with the participant in an electronic format. No private health information will be collected. Additionally, all data subject to analysis will be coded so that data analysts will not be able to identify individual participants. All study data will be stored in locked filing cabinets and in encrypted computers in encrypted files or on encrypted flash drives. All passwords for each level of encryption will be different from the previous passwords. Participants will be assigned individual numbers that are quasi-sequential. The code will consist of a number indicating the cohort in which they enrolled, the school division from which they applied, a number to indicate if they applied from the regional program added to their school division number, and a number indicating the order in which their application was received. Numbers will be assigned by the on-site coordinator when the application is received. Only the research coordinators and on-site coordinator will know the order of code and the meaning of each of the numbers in the code. No other person associated with the study will know the meaning of the code. If the participant elects to not enroll in the study or does not meet the inclusion criteria, their number will not be reassigned to another participant. Consequently, numbers will not be sequential. The key will be kept in an encrypted, password protected word document on an encrypted, password protected computer. Each of the passwords will be different. The key will be destroyed once the IRB is closed for the study.

For the purposes of NDAR data sharing, we will assign each participant who consented to share their data a random unique identifier developed from a random numbers table. We will not share their coded identifier, but will create a key to match the coded identifier with the random number identifier. This key will be maintained by the research assistant and data manager. It will be on an encrypted document maintained on an encrypted computer with different passwords for each level of encryption. Only the research assistant and data manager will have access to this key. It will be kept for the purposes of allowing participants to remove consent after having given consent initially. This key will be destroyed once the study has closed with the IRB.

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 will contact study staff and request to withdraw from the study. Study staff will contact the participants school division personnel and inform them of the participant's decision to withdraw. Study staff will work with school division staff to ensure a smooth transition back to the home school division.

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:**
   Recordings and photographs will be deleted from any portable camera or memory card and saved to encrypted, password protected computers. No recording will be made unless the participant gives permission via the consent process. Participants will have the right to remove permission to record them at any point. The consent document clarifies this by informing subjects that they can request to stop pictures or video recording at any point and may request to have the existing pictures and video recordings of them deleted. We will maintain pictures and video recordings where we have permission until they are no longer of use for the purposes of training. Once those pictures and video recordings are no longer of use, we will destroy all copies. Finally, we only share videos with project staff and do not post them on open web based video platforms, such as "YouTube".

7. **If no, explain why the recordings need to be maintained:**
   Recordings and photographs used for training purposes will be maintained to continue to provide training once the study is complete.

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. * **Since you responded in a question above that you may use or share anonymous, individual level data, indicate why the proposed use or sharing of anonymous data/specimens is not inconsistent with what participants would have reasonably understood from the consent document about the uses of their information. (Select all that apply.)**

- [x] **The consent form states that after identifiers are removed, information or specimens could be used for future research studies without additional informed consent from the subject (this is a new element of consent included in consent templates as of May 2018)**
- [ ] The consent form or exempt information sheet is silent about whether/how information or specimens could be used for future research studies.
- [ ] The information or specimens were/will be obtained under a waiver of informed consent, waiver of HIPAA authorization, or an exempt study that did not use an information sheet.
- [ ] Other reason why anonymous use/sharing is not inconsistent with the consent document

7. * The Principal Investigator certifies that prior to releasing an anonymized dataset or anonymized specimens the following conditions will all be met:

- all 18 HIPAA identifiers (including all dates) will be removed;
- all indirectly identifiable data elements (unusual, rare, uncommon data) will be removed, grouped, suppressed, or otherwise transformed to no longer be readily identifiable;
- a different subject ID will be assigned than the one used for the main study and a linkage key will not be kept; and
- the PI will review the dataset/specimens to confirm that the remaining information could not be used alone or in combination with any other information to re-identify the participants represented in the data.

***See help text for more information*.**

- (●) **Yes**
- ( ) No

8. * 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

9. If the Certificate of Confidentiality has been obtained by the PI, upload it here:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Student Assent Version 2 11/1/2017	Student Assent Clean Version 2 11-1-2017.pdf	0.06	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Student Consent Version 10 11/22/2019	Student Consent 10 11-22-2019 clean version2.pdf	0.31	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	LAR Consent Version 10 11/22/2019	LAR Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Educator Consent Version 10 11/22/2019	Educator Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Assent Form Individual Assent	Student Assent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form LAR Consent	LAR Consent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency	Individual Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Consent Form Individual Consent						
View	COVID-19 Contingency Consent Form Educator Consent	Educator Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Protocol	COVID Contingency Protocol for CDMRP version 3.docx	0.03	6/8/2020 11:05 AM	Carol Schall	Other	Yes
View	York County Closure Form	relying_site_closure York.pdf	0.01	8/31/2019 1:45 PM	Carol Schall	Non-VCU site submission form	Yes
View	Williamsburg/ James City County Closure Form	relying_site_closure Williamsburg James City County-signed.pdf	0.01	8/31/2019 1:44 PM	Carol Schall	Non-VCU site submission form	Yes
View	Hampton City Public Schools Closure Form	relying_site_closure Hampton.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	New Horizons Closure Form	New Horizons Closure Report.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	Newport News Public Schools Closure Form	Nwport News Public Schools Signed Relying Site Closure Notice.pdf	0.01	8/31/2019 1:42 PM	Carol Schall	Non-VCU site submission form	Yes
View	Certificate of Confidentiality	Certificate of Confidentiality.pdf	0.03	11/28/2018 5:14 PM	Carol Schall	Other	Yes
View	Subject Eligibility Checklist	CDMRP subject_eligibility_screening checklist Version 2 Clean Line.doc	0.02	11/20/2018 4:52 PM	Carol Schall	Other	Yes
View	Student Screening Interview and Rubric	Student Selection Interview and Rubric 2019 Version 3 Clean.doc	0.05	11/20/2018 4:44 PM	Carol Schall	Other	Yes
View	Project SEARCH "Recommended" Curriculum Documents (Please note, these are not all used)	2003 PS HS Curriculum.doc	0.03	9/23/2018 4:19 PM	Carol Schall	Other	Yes
View	Draft Application for Participation	Draft Application for participation Version 3 Redline 10-26-2017.docx	0.06	10/26/2017 12:27 PM	Carol Schall	Recruitment/Advertising	Yes
View	HRPO IRB Approval	Virginia Commonwealth University Mail - A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Ancillary Committee Approval	Not Applicable
View	Fort Eustis Agreement to be the Location and Business Site for the Research	Virginia Commonwealth University Mail - Re_ [Non-DoD Source] Fwd_ A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Other	Not Applicable
View	York County Public Schools Institutional Investigator Agreement	York VCU_ACE_YCSD Agreement.pdf	0.01	1/24/2017 1:56 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Williamsburg James City County Public Schools Institutional	WJCC VCU Project Search 2017 Agreement_W-JCC_Signed.pdf	0.01	1/24/2017 1:55 PM	Carol Schall	Non-VCU site submission form	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Investigator Agreement						
View	New Horizons Regional Education Center Institutional Investigator Agreement	New Horizons Invesitgator Agreement.pdf	0.01	1/24/2017 1:54 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Baseline Demographic Script Clean version 2 11-11-2016	Baseline Demographics Clean version 2 11-11-2016.docx	0.03	11/11/2016 12:55 PM	Carol Schall	Research Measure	Yes
View	OSP Proposal Review Documentation	OSP Approval_Project Search_Wehman.pdf	0.01	11/1/2016 2:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 13 Data sharing	NDAR.pdf	0.01	11/1/2016 1:25 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 12 Transition Plan	Transition.pdf	0.01	11/1/2016 1:24 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 10 Data Collection Instruments Description	1 Instruments Relationship to the Study Objectives.docx	0.01	11/1/2016 1:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 11 Impact Statement	Impact.pdf	0.01	11/1/2016 1:21 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Management Plan	3 Study Management Plan.docx	0.01	11/1/2016 1:19 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Description	2 Study Personnel Description.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Organizational Chart	1 Organizational Chart.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 8 Data Management	Data_Manage.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 7 Intervention	Intervention.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Yes
View	Grant Attachment 6 Human Subject Recruitment and Safety Procedures	HumSubProc.pdf	0.01	11/1/2016 1:16 PM	Carol Schall	Other	Yes
View	Grant Attachment 5 Statement of Work	SOW.pdf	0.01	11/1/2016 1:15 PM	Carol Schall	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Grant Attachment 4 Lay Abstract	LayAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 3 Technical Abstract	TechAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Intellectual Property	7 Intellectual Property and Sharing of Data.docx	0.01	11/1/2016 1:13 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letters of Collaboration	3 Hampton City Public Schools.tif	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letters of Collaboration	2 Newport News.pdf	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letter of Organizational Support	5 Cifu Letter of Support.doc	0.01	11/1/2016 1:11 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 List of Relevant Publications	4 List of Relevant Publications.docx	0.01	11/1/2016 1:08 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Facilities	3 Facilities.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Abbreviations	2 List of Abbreviations.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 References	1 References.docx	0.01	11/1/2016 1:06 PM	Carol Schall	Other	Not Applicable
View	Grant Project Narrative	ProjectNarrative.pdf	0.01	11/1/2016 1:05 PM	Carol Schall	Other	Yes
View	VCU Response to peer and programmatic review	Response to Peer and Programatic Review Concerns.docx	0.01	11/1/2016 12:16 PM	Carol Schall	Other	Not Applicable
View	CDMRP Review Notes	CDMRP Review Notes.pdf	0.01	11/1/2016 12:15 PM	Carol Schall	Other	Not Applicable
View	Newport News Public Schools Institutional Investigator Agreement	Newport News Public Schools_Institutional Investigator Agreement.pdf	0.01	11/1/2016 12:14 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Hampton City Public Schools Institutional Investigator Agreement	Hampton City Public Schools IIA.pdf	0.01	10/3/2016 12:36 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	References Cited	References.docx	0.01	9/21/2016 9:16 PM	Carol Schall	Other	Not Applicable
View	Quality of Life Questionnaire Adult Version	8 qol question adults (1).doc	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Social Responsiveness Scale 2 - Proxy Report	7 SRS2 Proxy Report.pdf	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Self Report	6 SRS 2 Self Report.pdf	0.01	9/21/2016 7:55 PM	Carol Schall	Research Measure	Yes
View	Behavior Assessment Scale in Children Adolescent Ages 12-21	5 30805_BASC3_TRS_A_RS_Form_FNL (1).pdf	0.01	9/21/2016 7:54 PM	Carol Schall	Research Measure	Yes
View	Support Intensity Scale	4 Support Intensity Scale.pdf	0.01	9/21/2016 7:53 PM	Carol Schall	Research Measure	Yes
View	12 and 18 Month Script Version 1 9-21-2016	3 Twelve and Eighteen Months Data script.docx	0.01	9/21/2016 7:52 PM	Carol Schall	Research Measure	Yes
View	Draft Teacher Recruitment Letter	Letter to teachers recruitment 2016 version 1 9-21-2016.docx	0.01	9/21/2016 7:39 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Treatment Acceptance Letter	Draft Treatment Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Parent/Student Recruitment Letter	Draft Parent Recruitment letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Open House Flyer	Draft open house flyer version 1 9-21-2016.doc	0.01	9/21/2016 7:35 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Control Group Acceptance Letter	Draft Control Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:34 PM	Carol Schall	Recruitment/Advertising	Yes
View	Avellone Biosketch	Avellone Bio Sketch.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	McDonough Biosketch	biosketch McDonough.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Schall Biosketch	Schall biosketch (1).doc	0.01	9/20/2016 4:33 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Wehman Biosketch	Bio Sketch Wehman.docx	0.01	9/20/2016 4:32 PM	Carol Schall	CV/Biosketch	Yes

Existing Registry/Repository Details

1. **Provide name(s) of the registry/repository, if applicable.**
   National Database for Autism Research (NDAR)

2. * **Site having overall responsibility for the management of this registry/repository**
   ○ VCU
   ● **Non-VCU**

3. **If registry is located at VCU, provide IRB number(s) for the registry/repository:**
   N/A

4. **If VCU is not responsible for the management of this registry/repository describe the organization and/or individual who is responsible:**
   The National Institutes of Health is responsible for this registry.

5. * **Describe the research materials (data elements, specimens, recordings, etc.) that this study will contribute to the registry/repository:**
   The following materials will be shared with NDAR:

   Subject random number identifier
   Subject random condition participation identifier
   Subject coded and scored interview and assessment information

6. * **List and describe any identifiers (including linkable codes) that will accompany data or samples to the registry/repository.**
   Our unique ID will not be sent to the database, however, we will use a double coding process. Specifically, we will assign each participant who consents to share their data a unique identifier that is not coded, but random. The reason for the additional random code is to ensure that we can guarantee data removal for participants who choose to do so after first consenting. The key will be kept by research assistant and data manager who will be the only person to have this unique double coded key.

   We will not share any recordings or other identifiable material or information.

7. **If the participant gives specific permission for future use of this data/specimens in the informed consent, address 1) what are the stipulations/conditions, if any (e.g., research only on diabetes) and 2) describe how the registry/repository has a mechanism to capture, utilize, and respect these conditions?**
   The only stipulations on future use of the data is ensuring that participants who withdrew consent were removed from the database prior to closure of the study on or around 9/30/2020. If participants withdraw consent for their data to be used the research assistant and data manager will remove that individual's data from the database.

8. **If there is not a mechanism to capture the participants data use stipulations, explain why this is not necessary.**
   N/A

9. * **If participants will be able to access their data and/or samples from the registry/repository for personal use, explain how this will occur.**
   N/A

10. * **Explain how participants are allowed to request the data/samples be destroyed/removed from the registry/repository or why it is not allowed:**
    Participants will notify the any study staff member to request removal of their data from the data repository. At that point, the staff member will notify the research assistant and data manager to remove their data from NDAR.

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.**
   There are no known possible pertinent or incidental findings stemming from research-only procedures that may be of importance to the subject's health or well-being or which may related to illegal or reportable activities. Should we inadvertently discover suspected abuse or participation in illegal activity, we will immediately inform the relevant public agencies including Adult Protective Services, counseling services, family members and support providers (as long as they are not implicated in the suspected illegal activity), and other such authorities as the situation will require.

3. * **Explain what actions or procedures research personnel should take to inform the PI of such a discovery :**
   We do not expect to discover such information. Should we inadvertently discover suspected abuse or participation in illegal activity, we will immediately inform the relevant public agencies including Adult Protective Services, counseling services, family members and support providers (as long as they are not implicated in the suspected illegal activity), and other such authorities as the situation will require. The study team will not be involved in the collection of the data regarding drug testing or background checks. Instead, we are assuring that the employer will complete these checks.

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

5. * **Describe a communication plan addressing:**
   1. What criteria will be used to determine which pertinent and/or incidental findings will be communicated, including the following for health related findings:
   --- The reliability of the tests/images, such as being done in a CLIA-certified lab,
   --- Whether the meaning and significance of the findings are known,
   --- Whether the findings reveal a significant risk of a serious health condition,
   --- Whether there is an accepted treatment for the health condition revealed by the findings, and
   --- The risks both of knowing and not knowing the findings, including risks to family members from genetic testing results.
   2. What information will be provided during the consent process about the plans for communicating pertinent and/or incidental findings;
   3. Whether the participants will be given the option of refusing communication of some or all types of pertinent and/or incidental findings to themselves, their family members, and/or any other individuals or groups; and
   4. To whom and by whom the findings will be communicated, when, and how.
   1. The only criteria under which findings will be disclosed to participants and/or any other person/group outside the study team will be if the findings reveal a significant risk of a serious health condition such as suspected abuse or neglect by another person.

   2. We share the following information with all participants and/or their legally authorized guardians during the consent process:

   The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily,
   without your consent, information that would identify you as a participant in the research project
   under the following circumstances:
   If you or your students tells us you intend to hurt yourself or others, or if we learn about real or
   suspected abuse.

   3. Participants will not be given the option of refusing communication regarding the situation described above.

   4. Findings related to threats of self harm or harm to others will be shared with the participant's parents or legally authorized guardians, and, if necessary, legal authorities. Findings related to potential abuse or neglect will be share with adult protective services.

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
- [ ] Pregnant women or fetuses
- [ ] Neonates or Post-delivery Materials
- [ ] Prisoners
- [x] **Decisionally Impaired Adults**
- [ ] VCU / VCUHS students or trainees
- [ ] 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

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.**
   ASD is commonly associated with cognitive and language difficulties.

3. * **Describe methods for determining whether participants are capable of providing consent or assent.**
   All prospective participants will be known to the staff of their respective schools, and school staff will be aware of which students are capable or incapable of understanding the study or their involvement, and thus for providing informed consent or assent to participate.

   In addition, prior to initiating any study procedures, study staff will meet with each participant and their caretakers/parents in a private location identified by the potential participant. During this screening meeting, the study staff will review the consent/assent information, ask the participant or their LAR if they are willing to consent to participate, and collect signatures and check marks on the consent/assent forms if the participant decides to participate.

   Once the potential participant and/or their LAR have consented to participate, research staff will conduct an informal interview to assess the subject's eligibility based upon the inclusion criteria. They will record their findings on the Subject Eligibility Checklist (attached in the documents section of this protocol).

   In addition, the Project SEARCH program also requires a group interview with all participating agencies. This group interview will be conducted at a time separate from the consent and screening meeting. This interview will take place in a private location selected by the participant and their caretakers/parents and will be large enough to accommodate the group interview. The group interview can include the following people:

   1. The participant
   2. Their caretakers/parents
   3. The Project SEARCH teacher, job coach, or other Project SEARCH direct services staff
   4. The student's teacher in their current school placement
   5. An administrator from the student's school district
   6. The Department of Aging and Rehabilitative Services staff member
   7. In some cases, the case manager of the individual's community services board
   8. Other individual identified by the participant.

   The purpose of this group interview is to complete the Student Selection Interview and Rubric as used in the Project SEARCH program.

4. * **If a participant is capable of exercising some judgment concerning the nature of the study, describe how assent will be obtained.**
   During the consent meetings, the research staff member will ask questions of the students in order to verify comprehension of the study and their involvement. We do not have specific questions to measure comprehension. Instead, we will ask the student to describe in their own words or method their understanding of the study and what will happen to them if they decide to become involved in the study. We will also ask them, in their own words or method of communication (sign language, etc.) to indicate if they would like to participate 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.**
   Through out the study, study staff will have on-going daily interaction with students and will continue to assess the student's ability to consent or assent to participation in the study. In addition, all data collectors will ask each participant if they are willing to continue in the research at each data collection point.

6. * **Describe how and when consent will be obtained from participants' legally authorized representative (LAR).**
   For those students who have a guardian or LAR, consent will be obtained from the guardian/LAR with assent from the student. Students who are under guardianship will not be involved in the study in any manner without obtaining consent of the guardian and assent of the student.

Populations with Special Considerations Section Complete

Protocol Progress:
● **INITIAL SETUP**
● **BACKGROUND, RATIONALE & GOALS**
● **RESEARCH PLAN**
● **CONSENT PLAN**
● **RISKS, PRIVACY & CONFIDENTIALITY**
● **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:

- [x] **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
FP00000902	Department of Defense	Paul Wehman	Effect of a 9-Month Internship for the Transition-Aged Military dependents with ASD	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
Condition 2 is not met.

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	Student Assent Version 2 11/1/2017	Student Assent Clean Version 2 11-1-2017.pdf	0.06	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Student Consent Version 10 11/22/2019	Student Consent 10 11-22-2019 clean version2.pdf	0.31	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	LAR Consent Version 10 11/22/2019	LAR Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Educator Consent Version 10 11/22/2019	Educator Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Assent Form Individual Assent	Student Assent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form LAR Consent	LAR Consent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form Individual Consent	Individual Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form Educator Consent	Educator Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Protocol	COVID Contingency Protocol for CDMRP version 3.docx	0.03	6/8/2020 11:05 AM	Carol Schall	Other	Yes
View	York County Closure Form	relying_site_closure York.pdf	0.01	8/31/2019 1:45 PM	Carol Schall	Non-VCU site submission form	Yes
View	Williamsburg/ James City County Closure Form	relying_site_closure Williamsburg James City County-signed.pdf	0.01	8/31/2019 1:44 PM	Carol Schall	Non-VCU site submission form	Yes
View	Hampton City Public Schools Closure Form	relying_site_closure Hampton.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	New Horizons Closure Form	New Horizons Closure Report.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	Newport News Public Schools Closure Form	Nwport News Public Schools Signed Relying Site Closure Notice.pdf	0.01	8/31/2019 1:42 PM	Carol Schall	Non-VCU site submission form	Yes
View	Certificate of Confidentiality	Certificate of Confidentiality.pdf	0.03	11/28/2018 5:14 PM	Carol Schall	Other	Yes
View	Subject Eligibility Checklist	CDMRP subject_eligibility_screening checklist Version 2 Clean Line.doc	0.02	11/20/2018 4:52 PM	Carol Schall	Other	Yes
View	Student Screening Interview and Rubric	Student Selection Interview and Rubric 2019 Version 3 Clean.doc	0.05	11/20/2018 4:44 PM	Carol Schall	Other	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Project SEARCH "Recommended" Curriculum Documents (Please note, these are not all used)	2003 PS HS Curriculum.doc	0.03	9/23/2018 4:19 PM	Carol Schall	Other	Yes
View	Draft Application for Participation	Draft Application for participation Version 3 Redline 10-26-2017.docx	0.06	10/26/2017 12:27 PM	Carol Schall	Recruitment/Advertising	Yes
View	HRPO IRB Approval	Virginia Commonwealth University Mail - A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Ancillary Committee Approval	Not Applicable
View	Fort Eustis Agreement to be the Location and Business Site for the Research	Virginia Commonwealth University Mail - Re_ [Non-DoD Source] Fwd_ A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Other	Not Applicable
View	York County Public Schools Institutional Investigator Agreement	York VCU_ACE_YCSD Agreement.pdf	0.01	1/24/2017 1:56 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Williamsburg James City County Public Schools Institutional Investigator Agreement	WJCC VCU Project Search 2017 Agreement_W-JCC_Signed.pdf	0.01	1/24/2017 1:55 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	New Horizons Regional Education Center Institutional Investigator Agreement	New Horizons Invesitgator Agreement.pdf	0.01	1/24/2017 1:54 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Baseline Demographic Script Clean version 2 11-11-2016	Baseline Demographics Clean version 2 11-11-2016.docx	0.03	11/11/2016 12:55 PM	Carol Schall	Research Measure	Yes
View	OSP Proposal Review Documentation	OSP Approval_Project Search_Wehman.pdf	0.01	11/1/2016 2:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 13 Data sharing	NDAR.pdf	0.01	11/1/2016 1:25 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 12 Transition Plan	Transition.pdf	0.01	11/1/2016 1:24 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 10 Data Collection Instruments Description	1 Instruments Relationship to the Study Objectives.docx	0.01	11/1/2016 1:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 11 Impact Statement	Impact.pdf	0.01	11/1/2016 1:21 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Management Plan	3 Study Management Plan.docx	0.01	11/1/2016 1:19 PM	Carol Schall	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Grant Attachment 9 Study Personnel Description	2 Study Personnel Description.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Organizational Chart	1 Organizational Chart.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 8 Data Management	Data_Manage.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 7 Intervention	Intervention.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Yes
View	Grant Attachment 6 Human Subject Recruitment and Safety Procedures	HumSubProc.pdf	0.01	11/1/2016 1:16 PM	Carol Schall	Other	Yes
View	Grant Attachment 5 Statement of Work	SOW.pdf	0.01	11/1/2016 1:15 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 4 Lay Abstract	LayAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 3 Technical Abstract	TechAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Intellectual Property	7 Intellectual Property and Sharing of Data.docx	0.01	11/1/2016 1:13 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letters of Collaboration	3 Hampton City Public Schools.tif	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letters of Collaboration	2 Newport News.pdf	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letter of Organizational Support	5 Cifu Letter of Support.doc	0.01	11/1/2016 1:11 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 List of Relevant Publications	4 List of Relevant Publications.docx	0.01	11/1/2016 1:08 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Facilities	3 Facilities.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Abbreviations	2 List of Abbreviations.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 References	1 References.docx	0.01	11/1/2016 1:06 PM	Carol Schall	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Grant Project Narrative	ProjectNarrative.pdf	0.01	11/1/2016 1:05 PM	Carol Schall	Other	Yes
View	VCU Response to peer and programmatic review	Response to Peer and Programatic Review Concerns.docx	0.01	11/1/2016 12:16 PM	Carol Schall	Other	Not Applicable
View	CDMRP Review Notes	CDMRP Review Notes.pdf	0.01	11/1/2016 12:15 PM	Carol Schall	Other	Not Applicable
View	Newport News Public Schools Institutional Investigator Agreement	Newport News Public Schools_Institutional Investigator Agreement.pdf	0.01	11/1/2016 12:14 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Hampton City Public Schools Institutional Investigator Agreement	Hampton City Public Schools IIA.pdf	0.01	10/3/2016 12:36 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	References Cited	References.docx	0.01	9/21/2016 9:16 PM	Carol Schall	Other	Not Applicable
View	Quality of Life Questionnaire Adult Version	8 qol question adults (1).doc	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Proxy Report	7 SRS2 Proxy Report.pdf	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Self Report	6 SRS 2 Self Report.pdf	0.01	9/21/2016 7:55 PM	Carol Schall	Research Measure	Yes
View	Behavior Assessment Scale in Children Adolescent Ages 12-21	5 30805_BASC3_TRS_A_RS_Form_FNL (1).pdf	0.01	9/21/2016 7:54 PM	Carol Schall	Research Measure	Yes
View	Support Intensity Scale	4 Support Intensity Scale.pdf	0.01	9/21/2016 7:53 PM	Carol Schall	Research Measure	Yes
View	12 and 18 Month Script Version 1 9-21-2016	3 Twelve and Eighteen Months Data script.docx	0.01	9/21/2016 7:52 PM	Carol Schall	Research Measure	Yes
View	Draft Teacher Recruitment Letter	Letter to teachers recruitment 2016 version 1 9-21-2016.docx	0.01	9/21/2016 7:39 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Treatment Acceptance Letter	Draft Treatment Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Parent/Student Recruitment Letter	Draft Parent Recruitment letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Open House Flyer	Draft open house flyer version 1 9-21-2016.doc	0.01	9/21/2016 7:35 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Control Group Acceptance Letter	Draft Control Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:34 PM	Carol Schall	Recruitment/Advertising	Yes
View	Avellone Biosketch	Avellone Bio Sketch.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	McDonough Biosketch	biosketch McDonough.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Schall Biosketch	Schall biosketch (1).doc	0.01	9/20/2016 4:33 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Wehman Biosketch	Bio Sketch Wehman.docx	0.01	9/20/2016 4:32 PM	Carol Schall	CV/Biosketch	Yes

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. * **List all Non-VCU sites and locations:**

Provide information only for sites that have agreed to participate or given permission for study activities to occur. For Single IRB studies where VCU will be the IRB of record, list all anticipated sites that will rely on VCU IRB, and in their Role indicate that site-specific materials and agreements will be submitted in amendments.

	Name	Role	Adequacy	IRB	FWA	Consultant(s)
View	Williamsburg James City County Public Schools	Williamsburg James City County Public Schools will participate in the following ways: (1) Assist with recruitment of student participants, study group assignments, and communications with parents; (2) include project activities in student IEPs; (3) provide support for transportation to job training sites; and (4) provide staffing support (i.e., teachers and aides) to deliver project interventions to students and collect study data. Please note: A closure form for	Williamsburg James City County Public Schools has Quality Assurance Offices that will provide oversight of their staff activities related to human subjects protections. Please note: A closure form for this site was submitted on 8/26/2019.	Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.	No	

	Name	Role	Adequacy	IRB	FWA	Consultant(s)
		this site was submitted on 8/26/2019.				
View	Fort Eustis	Fort Eustis will provide space on the base to house the treatment intervention, Project SEARCH plus ASD Supports. They will also identify a liaison who will be the main point of contact with the research team. They will also ask their department managers and staff to host internship sites in collaboration with VCU.	Fort Eustis, as a part of the Department of Defense, is under the supervision of the Human Rights Protection Office (HRPO). HRPO has reviewed our research protocol and approved our submission.	Site Not Engaged -- IRB Review Not Required	No IRB review is necessary.	
View	New Horizons Regional Education Center	New Horizons Regional Education Center will participate in the following ways: (1) Assist with recruitment of student participants, study group assignments, and communications with parents; (2) include project activities in student IEPs; (3) provide support for transportation to job training sites; and (4) provide staffing support (i.e., teachers and aides) to deliver project interventions to students and collect study data. Please note: A closure form for this site was submitted on 8/26/2019. Please note: A closure form for this site was submitted on 8/26/2019.	New Horizons Regional Education Center has Quality Assurance Offices that will provide oversight of their staff activities related to human subjects protections. Please note: A closure form for this site was submitted on 8/26/2019.	Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.	No	
View	York County Public Schools	York County Public Schools will participate in the following ways: (1) Assist with recruitment of student participants, study group assignments, and communications with parents; (2) include project activities in student IEPs; (3) provide support for transportation to job training sites; and (4) provide staffing support (i.e., teachers and aides) to deliver project interventions to students and collect study data. Please note: A closure form for this site was submitted on 8/26/2019.	York County Public Schools has Quality Assurance Offices that will provide oversight of their staff activities related to human subjects protections. Please note: A closure form for this site was submitted on 8/26/2019.	Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.	No	
View	Hampton City Public Schools	Hampton City Public Schools will participate in the following ways: (1) Assist with recruitment of student participants, study group assignments, and communications with parents; (2) include project activities in student IEPs; (3) provide support for transportation to job training sites; and (4) provide staffing support (i.e., teachers and aides) to deliver project interventions to students and collect study data. Please note: A closure form for this site was submitted on 8/26/2019.	Hampton City Public Schools has an institutional review boards or Quality Assurance Offices that will provide oversight of their staff activities related to human subjects protections. Please note: A closure form for this site was submitted on 8/26/2019.	Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.		
View	Newport News Public Schools	Newport News Public Schools will participate in the following ways: (1) Assist with recruitment of	Newport News Public Schools has Quality Assurance	Site Engaged -- Does not		

	Name	Role	Adequacy	IRB	FWA	Consultant(s)
		student participants, study group assignments, and communications with parents; (2) include project activities in student IEPs; (3) provide support for transportation to job training sites; and (4) provide staffing support (i.e., teachers and aides) to deliver project interventions to students and collect study data. Please note: A closure form for this site was submitted on 8/26/2019.	Offices that will provide oversight of their staff activities related to human subjects protections. Please note: A closure form for this site was submitted on 8/26/2019.	regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.		
View	Virginia Department of Aging and Rehabilitation Services (DARS)	he Virginia DARS will (1) assign a Vocational Rehabilitation Counselors to student participants and complete eligibility services; (2) with the student, family, and project staff, develop student individualized plans for employment; and (3) provide ongoing monitoring of student progress toward employment goals and terminal job placement opportunities. Oversight of the activities of these non-VCU staff will be provided by the PI and Study Coordinator, who will routinely observe training and data collection activities for quality assurance and human subjects' protection.	Virginia DARS has an institutional review board that will provide oversight of their staff activities related to human subjects protections.	Site Engaged -- Has FWA and Will Obtain Own IRB Review	FWA# 00008936	

5. * **How will communication occur between sites for discussion of study conduct, unexpected problems, project modifications, and interim results:**
Consider the following in your response:
- how frequently communication will occur between sites
- how are sites instructed to report unanticipated problems, adverse events, or noncompliance
- how sites can communicate needed revisions to study procedures
- who will disseminate IRB decisions
- who will notify the IRB of potential problems and changes to the protocol
Non VCU site staff will meet with VCU staff on a quarterly basis at minimum to discuss the implementation of the research.

6. **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:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Student Assent Version 2 11/1/2017	Student Assent Clean Version 2 11-1-2017.pdf	0.06	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Student Consent Version 10 11/22/2019	Student Consent 10 11-22-2019 clean version2.pdf	0.31	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	LAR Consent Version 10 11/22/2019	LAR Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Educator Consent Version 10 11/22/2019	Educator Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency	Student Assent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Assent Form Individual Assent						
View	COVID-19 Contingency Consent Form LAR Consent	LAR Consent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form Individual Consent	Individual Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form Educator Consent	Educator Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Protocol	COVID Contingency Protocol for CDMRP version 3.docx	0.03	6/8/2020 11:05 AM	Carol Schall	Other	Yes
View	York County Closure Form	relying_site_closure York.pdf	0.01	8/31/2019 1:45 PM	Carol Schall	Non-VCU site submission form	Yes
View	Williamsburg/ James City County Closure Form	relying_site_closure Williamsburg James City County-signed.pdf	0.01	8/31/2019 1:44 PM	Carol Schall	Non-VCU site submission form	Yes
View	Hampton City Public Schools Closure Form	relying_site_closure Hampton.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	New Horizons Closure Form	New Horizons Closure Report.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	Newport News Public Schools Closure Form	Nwport News Public Schools Signed Relying Site Closure Notice.pdf	0.01	8/31/2019 1:42 PM	Carol Schall	Non-VCU site submission form	Yes
View	Certificate of Confidentiality	Certificate of Confidentiality.pdf	0.03	11/28/2018 5:14 PM	Carol Schall	Other	Yes
View	Subject Eligibility Checklist	CDMRP subject_eligibility_screening checklist Version 2 Clean Line.doc	0.02	11/20/2018 4:52 PM	Carol Schall	Other	Yes
View	Student Screening Interview and Rubric	Student Selection Interview and Rubric 2019 Version 3 Clean.doc	0.05	11/20/2018 4:44 PM	Carol Schall	Other	Yes
View	Project SEARCH "Recommended" Curriculum Documents (Please note, these are not all used)	2003 PS HS Curriculum.doc	0.03	9/23/2018 4:19 PM	Carol Schall	Other	Yes
View	Draft Application for Participation	Draft Application for participation Version 3 Redline 10-26-2017.docx	0.06	10/26/2017 12:27 PM	Carol Schall	Recruitment/Advertising	Yes
View	HRPO IRB Approval	Virginia Commonwealth University Mail - A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Ancillary Committee Approval	Not Applicable
View	Fort Eustis Agreement to be the Location and Business Site for the Research	Virginia Commonwealth University Mail - Re_ [Non-DoD Source] Fwd_ A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	York County Public Schools Institutional Investigator Agreement	York VCU_ACE_YCSD Agreement.pdf	0.01	1/24/2017 1:56 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Williamsburg James City County Public Schools Institutional Investigator Agreement	WJCC VCU Project Search 2017 Agreement_W-JCC_Signed.pdf	0.01	1/24/2017 1:55 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	New Horizons Regional Education Center Institutional Investigator Agreement	New Horizons Invesitgator Agreement.pdf	0.01	1/24/2017 1:54 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Baseline Demographic Script Clean version 2 11-11-2016	Baseline Demographics Clean version 2 11-11-2016.docx	0.03	11/11/2016 12:55 PM	Carol Schall	Research Measure	Yes
View	OSP Proposal Review Documentation	OSP Approval_Project Search_Wehman.pdf	0.01	11/1/2016 2:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 13 Data sharing	NDAR.pdf	0.01	11/1/2016 1:25 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 12 Transition Plan	Transition.pdf	0.01	11/1/2016 1:24 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 10 Data Collection Instruments Description	1 Instruments Relationship to the Study Objectives.docx	0.01	11/1/2016 1:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 11 Impact Statement	Impact.pdf	0.01	11/1/2016 1:21 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Management Plan	3 Study Management Plan.docx	0.01	11/1/2016 1:19 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Description	2 Study Personnel Description.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Organizational Chart	1 Organizational Chart.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 8 Data Management	Data_Manage.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 7 Intervention	Intervention.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Grant Attachment 6 Human Subject Recruitment and Safety Procedures	HumSubProc.pdf	0.01	11/1/2016 1:16 PM	Carol Schall	Other	Yes
View	Grant Attachment 5 Statement of Work	SOW.pdf	0.01	11/1/2016 1:15 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 4 Lay Abstract	LayAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 3 Technical Abstract	TechAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Intellectual Property	7 Intellectual Property and Sharing of Data.docx	0.01	11/1/2016 1:13 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letters of Collaboration	3 Hampton City Public Schools.tif	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letters of Collaboration	2 Newport News.pdf	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letter of Organizational Support	5 Cifu Letter of Support.doc	0.01	11/1/2016 1:11 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 List of Relevant Publications	4 List of Relevant Publications.docx	0.01	11/1/2016 1:08 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Facilities	3 Facilities.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Abbreviations	2 List of Abbreviations.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 References	1 References.docx	0.01	11/1/2016 1:06 PM	Carol Schall	Other	Not Applicable
View	Grant Project Narrative	ProjectNarrative.pdf	0.01	11/1/2016 1:05 PM	Carol Schall	Other	Yes
View	VCU Response to peer and programmatic review	Response to Peer and Programatic Review Concerns.docx	0.01	11/1/2016 12:16 PM	Carol Schall	Other	Not Applicable
View	CDMRP Review Notes	CDMRP Review Notes.pdf	0.01	11/1/2016 12:15 PM	Carol Schall	Other	Not Applicable
View	Newport News Public Schools Institutional Investigator Agreement	Newport News Public Schools_Institutional Investigator Agreement.pdf	0.01	11/1/2016 12:14 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Hampton City Public Schools	Hampton City Public Schools IIA.pdf	0.01	10/3/2016 12:36 PM	Carol Schall	Non-VCU site submission form	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Institutional Investigator Agreement						
View	References Cited	References.docx	0.01	9/21/2016 9:16 PM	Carol Schall	Other	Not Applicable
View	Quality of Life Questionnaire Adult Version	8 qol question adults (1).doc	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Proxy Report	7 SRS2 Proxy Report.pdf	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Self Report	6 SRS 2 Self Report.pdf	0.01	9/21/2016 7:55 PM	Carol Schall	Research Measure	Yes
View	Behavior Assessment Scale in Children Adolescent Ages 12-21	5 30805_BASC3_TRS_A_RS_Form_FNL (1).pdf	0.01	9/21/2016 7:54 PM	Carol Schall	Research Measure	Yes
View	Support Intensity Scale	4 Support Intensity Scale.pdf	0.01	9/21/2016 7:53 PM	Carol Schall	Research Measure	Yes
View	12 and 18 Month Script Version 1 9-21-2016	3 Twelve and Eighteen Months Data script.docx	0.01	9/21/2016 7:52 PM	Carol Schall	Research Measure	Yes
View	Draft Teacher Recruitment Letter	Letter to teachers recruitment 2016 version 1 9-21-2016.docx	0.01	9/21/2016 7:39 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Treatment Acceptance Letter	Draft Treatment Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Parent/Student Recruitment Letter	Draft Parent Recruitment letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Open House Flyer	Draft open house flyer version 1 9-21-2016.doc	0.01	9/21/2016 7:35 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Control Group Acceptance Letter	Draft Control Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:34 PM	Carol Schall	Recruitment/Advertising	Yes
View	Avellone Biosketch	Avellone Bio Sketch.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	McDonough Biosketch	biosketch McDonough.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Schall Biosketch	Schall biosketch (1).doc	0.01	9/20/2016 4:33 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Wehman Biosketch	Bio Sketch Wehman.docx	0.01	9/20/2016 4:32 PM	Carol Schall	CV/Biosketch	Yes

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	Paul Wehman	Principal Investigator		Study Design		Experience - Research Experience - Related Skills Experience - Clinical Education and/or Professional Preparation		yes
View	Carol Schall	Co/Sub-Investigator Research Coordinator		Data Analysis Project Coordination Data Collection - Direct Observation Participant Consent Data Management Participant Identification Data Entry Study Design Data Coding Participant Recruitment Intervention Services Data Collection - Interviews/Surveys		Experience - Research Experience - Related Skills Experience - Clinical Education and/or Professional Preparation		yes
View	Jennifer McDonough	Research Coordinator		Data Analysis Project Coordination Data Collection - Direct Observation Participant Consent Data Collection - Lab		Experience - Related Skills Experience - Clinical Education and/or Professional Preparation		yes

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
				Regulatory Management Data Management Data Collection - Clinical Participant Identification Data Entry Data Coding Participant Recruitment Intervention Services Data Collection - Interviews/Surveys				
View	Holly Whittenburg	Other	On-Site Coordinator	Project Coordination Data Collection - Direct Observation Participant Identification Participant Recruitment Intervention Services Clinical Services Data Collection - Interviews/Surveys		Experience - Research Experience - Related Skills Experience - Clinical Education and/or Professional Preparation		no
View	Lauren Avellone	Research Coordinator		Data Analysis Data Collection - Direct Observation Data Management Data Collection - Clinical Data Entry Data Coding Intervention Services Clinical Services Data Collection - Interviews/Surveys		Experience - Research Experience - Related Skills Experience - Clinical Education and/or Professional Preparation		yes
View	Hannah Seward	Research Assistant		Data Collection - Direct Observation Data Collection - Clinical Data Entry Data Coding Data Collection - Interviews/Surveys		Experience - Research Experience - Related Skills Experience - Clinical Education and/or Professional Preparation		no
View	Thomas Dubois	Other	Job Coach	Data Collection - Direct Observation Intervention Services	Provide direct job coaching to participants in the treatment condition. Participate in interviews regarding the participants' response to intervention and outcomes from	Experience - Clinical Education and/or Professional Preparation		no

Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
				intervention. Collect regular behavioral data during job coaching.			

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 persons on the roster will meet at the beginning of the project and maintain quarterly or more contact to discuss research implementation as needed. All periodic meetings will occur in person or via electronic means and may include training. All staff will be instructed to contact the PI in the event of an adverse event in multiple means including email, phone call, and in person meeting as soon as the adverse event is discovered. This study will be carried out at a community business. The team who delivers the intervention will meet at least weekly to discuss subject success, strengths, and needs. Agency coordinators or their designees will meet at least monthly. Research data collectors will meet as needed.

In order to maintain communication between all partners and agencies outside VCU the following team meetings will occur.

On-site Staff Meetings: The intervention is delivered by a teacher and instructional assistant from Newport News Public Schools, and by Holly Whittenburg, On-site Coordinator and Thomas Dubois, Job Coach. These individuals meet daily to discuss on-going implementation issues and plan for the days activities. Issues related to the research participants and their needs are discussed at this meeting. If there is need for additional support, individual meetings are set up with the participant and/or their family members.

Coordinating Staff Meetings: Each site engaged in research will designate a person to represent their agency on the coordinating team. This team is composed of the following individuals:
VCU Site Coordinator
Fort Eustis Business Liaison (Not engaged in research)
Newport News Public Schools Teacher and Transition Coordinator
Hampton City Public Schools Transition Coordinator
York County Public Schools Transition Coordinator
Williamsburg/James City County Transition Coordinator
Department of Aging and Rehabilitative Services Representative
This meeting is held monthly on a regular basis. In addition to updating partners on research protocol, this meeting also allows for future planning and problem solving. We maintain a file of agendas, notes, and discussion during this meeting.

Due to the nature of the incident report dated 9/18/2018, we will convene a training meeting within 2 weeks of approval of this amendment to train all staff in the revised consent and screening procedures.

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.**

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Student Assent Version 2 11/1/2017	Student Assent Clean Version 2 11-1-2017.pdf	0.06	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Student Consent Version 10 11/22/2019	Student Consent 10 11-22-2019 clean version2.pdf	0.31	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	LAR Consent Version 10 11/22/2019	LAR Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Educator Consent Version 10 11/22/2019	Educator Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Assent Form Individual Assent	Student Assent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	COVID-19 Contingency Consent Form LAR Consent	LAR Consent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form Individual Consent	Individual Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form Educator Consent	Educator Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Protocol	COVID Contingency Protocol for CDMRP version 3.docx	0.03	6/8/2020 11:05 AM	Carol Schall	Other	Yes
View	York County Closure Form	relying_site_closure York.pdf	0.01	8/31/2019 1:45 PM	Carol Schall	Non-VCU site submission form	Yes
View	Williamsburg/ James City County Closure Form	relying_site_closure Williamsburg James City County-signed.pdf	0.01	8/31/2019 1:44 PM	Carol Schall	Non-VCU site submission form	Yes
View	Hampton City Public Schools Closure Form	relying_site_closure Hampton.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	New Horizons Closure Form	New Horizons Closure Report.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	Newport News Public Schools Closure Form	Nwport News Public Schools Signed Relying Site Closure Notice.pdf	0.01	8/31/2019 1:42 PM	Carol Schall	Non-VCU site submission form	Yes
View	Certificate of Confidentiality	Certificate of Confidentiality.pdf	0.03	11/28/2018 5:14 PM	Carol Schall	Other	Yes
View	Subject Eligibility Checklist	CDMRP subject_eligibility_screening checklist Version 2 Clean Line.doc	0.02	11/20/2018 4:52 PM	Carol Schall	Other	Yes
View	Student Screening Interview and Rubric	Student Selection Interview and Rubric 2019 Version 3 Clean.doc	0.05	11/20/2018 4:44 PM	Carol Schall	Other	Yes
View	Project SEARCH "Recommended" Curriculum Documents (Please note, these are not all used)	2003 PS HS Curriculum.doc	0.03	9/23/2018 4:19 PM	Carol Schall	Other	Yes
View	Draft Application for Participation	Draft Application for participation Version 3 Redline 10-26-2017.docx	0.06	10/26/2017 12:27 PM	Carol Schall	Recruitment/Advertising	Yes
View	HRPO IRB Approval	Virginia Commonwealth University Mail - A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Ancillary Committee Approval	Not Applicable
View	Fort Eustis Agreement to be the Location and Business Site for the Research	Virginia Commonwealth University Mail - Re_ [Non-DoD Source] Fwd_ A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Other	Not Applicable
View	York County Public Schools Institutional	York VCU_ACE_YCSD Agreement.pdf	0.01	1/24/2017 1:56 PM	Carol Schall	Non-VCU site submission form	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Investigator Agreement						
View	Williamsburg James City County Public Schools Institutional Investigator Agreement	WJCC VCU Project Search 2017 Agreement_W-JCC_Signed.pdf	0.01	1/24/2017 1:55 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	New Horizons Regional Education Center Institutional Investigator Agreement	New Horizons Invesitgator Agreement.pdf	0.01	1/24/2017 1:54 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Baseline Demographic Script Clean version 2 11-11-2016	Baseline Demographics Clean version 2 11-11-2016.docx	0.03	11/11/2016 12:55 PM	Carol Schall	Research Measure	Yes
View	OSP Proposal Review Documentation	OSP Approval_Project Search_Wehman.pdf	0.01	11/1/2016 2:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 13 Data sharing	NDAR.pdf	0.01	11/1/2016 1:25 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 12 Transition Plan	Transition.pdf	0.01	11/1/2016 1:24 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 10 Data Collection Instruments Description	1 Instruments Relationship to the Study Objectives.docx	0.01	11/1/2016 1:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 11 Impact Statement	Impact.pdf	0.01	11/1/2016 1:21 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Management Plan	3 Study Management Plan.docx	0.01	11/1/2016 1:19 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Description	2 Study Personnel Description.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Organizational Chart	1 Organizational Chart.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 8 Data Management	Data_Manage.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 7 Intervention	Intervention.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Yes
View	Grant Attachment 6 Human Subject Recruitment and	HumSubProc.pdf	0.01	11/1/2016 1:16 PM	Carol Schall	Other	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Safety Procedures						
View	Grant Attachment 5 Statement of Work	SOW.pdf	0.01	11/1/2016 1:15 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 4 Lay Abstract	LayAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 3 Technical Abstract	TechAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Intellectual Property	7 Intellectual Property and Sharing of Data.docx	0.01	11/1/2016 1:13 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letters of Collaboration	3 Hampton City Public Schools.tif	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letters of Collaboration	2 Newport News.pdf	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letter of Organizational Support	5 Cifu Letter of Support.doc	0.01	11/1/2016 1:11 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 List of Relevant Publications	4 List of Relevant Publications.docx	0.01	11/1/2016 1:08 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Facilities	3 Facilities.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Abbreviations	2 List of Abbreviations.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 References	1 References.docx	0.01	11/1/2016 1:06 PM	Carol Schall	Other	Not Applicable
View	Grant Project Narrative	ProjectNarrative.pdf	0.01	11/1/2016 1:05 PM	Carol Schall	Other	Yes
View	VCU Response to peer and programmatic review	Response to Peer and Programatic Review Concerns.docx	0.01	11/1/2016 12:16 PM	Carol Schall	Other	Not Applicable
View	CDMRP Review Notes	CDMRP Review Notes.pdf	0.01	11/1/2016 12:15 PM	Carol Schall	Other	Not Applicable
View	Newport News Public Schools Institutional Investigator Agreement	Newport News Public Schools_Institutional Investigator Agreement.pdf	0.01	11/1/2016 12:14 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Hampton City Public Schools Institutional Investigator Agreement	Hampton City Public Schools IIA.pdf	0.01	10/3/2016 12:36 PM	Carol Schall	Non-VCU site submission form	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	References Cited	References.docx	0.01	9/21/2016 9:16 PM	Carol Schall	Other	Not Applicable
View	Quality of Life Questionnaire Adult Version	8 qol question adults (1).doc	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Proxy Report	7 SRS2 Proxy Report.pdf	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Self Report	6 SRS 2 Self Report.pdf	0.01	9/21/2016 7:55 PM	Carol Schall	Research Measure	Yes
View	Behavior Assessment Scale in Children Adolescent Ages 12-21	5 30805_BASC3_TRS_A_RS_Form_FNL (1).pdf	0.01	9/21/2016 7:54 PM	Carol Schall	Research Measure	Yes
View	Support Intensity Scale	4 Support Intensity Scale.pdf	0.01	9/21/2016 7:53 PM	Carol Schall	Research Measure	Yes
View	12 and 18 Month Script Version 1 9-21-2016	3 Twelve and Eighteen Months Data script.docx	0.01	9/21/2016 7:52 PM	Carol Schall	Research Measure	Yes
View	Draft Teacher Recruitment Letter	Letter to teachers recruitment 2016 version 1 9-21-2016.docx	0.01	9/21/2016 7:39 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Treatment Acceptance Letter	Draft Treatment Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Parent/Student Recruitment Letter	Draft Parent Recruitment letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Open House Flyer	Draft open house flyer version 1 9-21-2016.doc	0.01	9/21/2016 7:35 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Control Group Acceptance Letter	Draft Control Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:34 PM	Carol Schall	Recruitment/Advertising	Yes
View	Avellone Biosketch	Avellone Bio Sketch.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	McDonough Biosketch	biosketch McDonough.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Schall Biosketch	Schall biosketch (1).doc	0.01	9/20/2016 4:33 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Wehman Biosketch	Bio Sketch Wehman.docx	0.01	9/20/2016 4:32 PM	Carol Schall	CV/Biosketch	Yes

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.
   There are no known institutional conflicts of interest.

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**

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	Student Assent Version 2 11/1/2017	Student Assent Clean Version 2 11-1-2017.pdf	0.06	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Student Consent Version 10 11/22/2019	Student Consent 10 11-22-2019 clean version2.pdf	0.31	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	LAR Consent Version 10 11/22/2019	LAR Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Educator Consent Version 10 11/22/2019	Educator Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Assent Form Individual Assent	Student Assent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form LAR Consent	LAR Consent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form Individual Consent	Individual Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form Educator Consent	Educator Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Protocol	COVID Contingency Protocol for CDMRP version 3.docx	0.03	6/8/2020 11:05 AM	Carol Schall	Other	Yes
View	York County Closure Form	relying_site_closure York.pdf	0.01	8/31/2019 1:45 PM	Carol Schall	Non-VCU site submission form	Yes
View	Williamsburg/ James City County Closure Form	relying_site_closure Williamsburg James City County-signed.pdf	0.01	8/31/2019 1:44 PM	Carol Schall	Non-VCU site submission form	Yes
View	Hampton City Public Schools Closure Form	relying_site_closure Hampton.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	New Horizons Closure Form	New Horizons Closure Report.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	Newport News Public Schools Closure Form	Nwport News Public Schools Signed Relying Site Closure Notice.pdf	0.01	8/31/2019 1:42 PM	Carol Schall	Non-VCU site submission form	Yes
View	Certificate of Confidentiality	Certificate of Confidentiality.pdf	0.03	11/28/2018 5:14 PM	Carol Schall	Other	Yes
View	Subject Eligibility Checklist	CDMRP subject_eligibility_screening checklist Version 2 Clean Line.doc	0.02	11/20/2018 4:52 PM	Carol Schall	Other	Yes
View	Student Screening Interview and Rubric	Student Selection Interview and Rubric 2019 Version 3 Clean.doc	0.05	11/20/2018 4:44 PM	Carol Schall	Other	Yes
View	Project SEARCH "Recommended" Curriculum Documents (Please note, these are not all used)	2003 PS HS Curriculum.doc	0.03	9/23/2018 4:19 PM	Carol Schall	Other	Yes
View	Draft Application for Participation	Draft Application for participation Version 3 Redline 10-26-2017.docx	0.06	10/26/2017 12:27 PM	Carol Schall	Recruitment/Advertising	Yes
View	HRPO IRB Approval	Virginia Commonwealth University Mail - A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Ancillary Committee Approval	Not Applicable
View	Fort Eustis Agreement to be the Location and Business Site for the Research	Virginia Commonwealth University Mail - Re_ [Non-DoD Source] Fwd_ A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Other	Not Applicable
View	York County Public Schools Institutional Investigator Agreement	York VCU_ACE_YCSD Agreement.pdf	0.01	1/24/2017 1:56 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Williamsburg James City County Public Schools Institutional Investigator Agreement	WJCC VCU Project Search 2017 Agreement_W-JCC_Signed.pdf	0.01	1/24/2017 1:55 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	New Horizons Regional Education Center Institutional Investigator Agreement	New Horizons Invesitgator Agreement.pdf	0.01	1/24/2017 1:54 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Baseline Demographic Script Clean version 2 11-11-2016	Baseline Demographics Clean version 2 11-11-2016.docx	0.03	11/11/2016 12:55 PM	Carol Schall	Research Measure	Yes
View	OSP Proposal Review Documentation	OSP Approval_Project Search_Wehman.pdf	0.01	11/1/2016 2:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 13 Data sharing	NDAR.pdf	0.01	11/1/2016 1:25 PM	Carol Schall	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Grant Attachment 12 Transition Plan	Transition.pdf	0.01	11/1/2016 1:24 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 10 Data Collection Instruments Description	1 Instruments Relationship to the Study Objectives.docx	0.01	11/1/2016 1:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 11 Impact Statement	Impact.pdf	0.01	11/1/2016 1:21 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Management Plan	3 Study Management Plan.docx	0.01	11/1/2016 1:19 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Description	2 Study Personnel Description.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Organizational Chart	1 Organizational Chart.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 8 Data Management	Data_Manage.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 7 Intervention	Intervention.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Yes
View	Grant Attachment 6 Human Subject Recruitment and Safety Procedures	HumSubProc.pdf	0.01	11/1/2016 1:16 PM	Carol Schall	Other	Yes
View	Grant Attachment 5 Statement of Work	SOW.pdf	0.01	11/1/2016 1:15 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 4 Lay Abstract	LayAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 3 Technical Abstract	TechAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Intellectual Property	7 Intellectual Property and Sharing of Data.docx	0.01	11/1/2016 1:13 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letters of Collaboration	3 Hampton City Public Schools.tif	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letters of Collaboration	2 Newport News.pdf	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Grant Attachment 2 Letter of Organizational Support	5 Cifu Letter of Support.doc	0.01	11/1/2016 1:11 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 List of Relevant Publications	4 List of Relevant Publications.docx	0.01	11/1/2016 1:08 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Facilities	3 Facilities.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Abbreviations	2 List of Abbreviations.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 References	1 References.docx	0.01	11/1/2016 1:06 PM	Carol Schall	Other	Not Applicable
View	Grant Project Narrative	ProjectNarrative.pdf	0.01	11/1/2016 1:05 PM	Carol Schall	Other	Yes
View	VCU Response to peer and programmatic review	Response to Peer and Programatic Review Concerns.docx	0.01	11/1/2016 12:16 PM	Carol Schall	Other	Not Applicable
View	CDMRP Review Notes	CDMRP Review Notes.pdf	0.01	11/1/2016 12:15 PM	Carol Schall	Other	Not Applicable
View	Newport News Public Schools Institutional Investigator Agreement	Newport News Public Schools_Institutional Investigator Agreement.pdf	0.01	11/1/2016 12:14 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Hampton City Public Schools Institutional Investigator Agreement	Hampton City Public Schools IIA.pdf	0.01	10/3/2016 12:36 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	References Cited	References.docx	0.01	9/21/2016 9:16 PM	Carol Schall	Other	Not Applicable
View	Quality of Life Questionnaire Adult Version	8 qol question adults (1).doc	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Proxy Report	7 SRS2 Proxy Report.pdf	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Self Report	6 SRS 2 Self Report.pdf	0.01	9/21/2016 7:55 PM	Carol Schall	Research Measure	Yes
View	Behavior Assessment Scale in Children Adolescent Ages 12-21	5 30805_BASC3_TRS_A_RS_Form_FNL (1).pdf	0.01	9/21/2016 7:54 PM	Carol Schall	Research Measure	Yes
View	Support Intensity Scale	4 Support Intensity Scale.pdf	0.01	9/21/2016 7:53 PM	Carol Schall	Research Measure	Yes
View	12 and 18 Month Script Version 1 9-21-2016	3 Twelve and Eighteen Months Data script.docx	0.01	9/21/2016 7:52 PM	Carol Schall	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Draft Teacher Recruitment Letter	Letter to teachers recruitment 2016 version 1 9-21-2016.docx	0.01	9/21/2016 7:39 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Treatment Acceptance Letter	Draft Treatment Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Parent/Student Recruitment Letter	Draft Parent Recruitment letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Open House Flyer	Draft open house flyer version 1 9-21-2016.doc	0.01	9/21/2016 7:35 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Control Group Acceptance Letter	Draft Control Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:34 PM	Carol Schall	Recruitment/Advertising	Yes
View	Avellone Biosketch	Avellone Bio Sketch.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	McDonough Biosketch	biosketch McDonough.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Schall Biosketch	Schall biosketch (1).doc	0.01	9/20/2016 4:33 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Wehman Biosketch	Bio Sketch Wehman.docx	0.01	9/20/2016 4:32 PM	Carol Schall	CV/Biosketch	Yes

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

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.

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Student Assent Version 2 11/1/2017	Student Assent Clean Version 2 11-1-2017.pdf	0.06	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Student Consent Version 10 11/22/2019	Student Consent 10 11-22-2019 clean version2.pdf	0.31	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	LAR Consent Version 10 11/22/2019	LAR Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	Educator Consent Version 10 11/22/2019	Educator Consent Version 10 clean version2.pdf	0.30	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Assent Form Individual Assent	Student Assent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form LAR Consent	LAR Consent.pdf	0.03	4/15/2023 11:40 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form Individual Consent	Individual Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Consent Form Educator Consent	Educator Consent.pdf	0.03	4/15/2023 11:39 AM	Carol Schall	Consent/Assent/Information Sheet	Not Applicable
View	COVID-19 Contingency Protocol	COVID Contingency Protocol for CDMRP version 3.docx	0.03	6/8/2020 11:05 AM	Carol Schall	Other	Yes
View	York County Closure Form	relying_site_closure York.pdf	0.01	8/31/2019 1:45 PM	Carol Schall	Non-VCU site submission form	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Williamsburg/ James City County Closure Form	relying_site_closure Williamsburg James City County-signed.pdf	0.01	8/31/2019 1:44 PM	Carol Schall	Non-VCU site submission form	Yes
View	Hampton City Public Schools Closure Form	relying_site_closure Hampton.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	New Horizons Closure Form	New Horizons Closure Report.pdf	0.01	8/31/2019 1:43 PM	Carol Schall	Non-VCU site submission form	Yes
View	Newport News Public Schools Closure Form	Nwport News Public Schools Signed Relying Site Closure Notice.pdf	0.01	8/31/2019 1:42 PM	Carol Schall	Non-VCU site submission form	Yes
View	Certificate of Confidentiality	Certificate of Confidentiality.pdf	0.03	11/28/2018 5:14 PM	Carol Schall	Other	Yes
View	Subject Eligibility Checklist	CDMRP subject_eligibility_screening checklist Version 2 Clean Line.doc	0.02	11/20/2018 4:52 PM	Carol Schall	Other	Yes
View	Student Screening Interview and Rubric	Student Selection Interview and Rubric 2019 Version 3 Clean.doc	0.05	11/20/2018 4:44 PM	Carol Schall	Other	Yes
View	Project SEARCH "Recommended" Curriculum Documents (Please note, these are not all used)	2003 PS HS Curriculum.doc	0.03	9/23/2018 4:19 PM	Carol Schall	Other	Yes
View	Draft Application for Participation	Draft Application for participation Version 3 Redline 10-26-2017.docx	0.06	10/26/2017 12:27 PM	Carol Schall	Recruitment/Advertising	Yes
View	HRPO IRB Approval	Virginia Commonwealth University Mail - A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Ancillary Committee Approval	Not Applicable
View	Fort Eustis Agreement to be the Location and Business Site for the Research	Virginia Commonwealth University Mail - Re_ [Non-DoD Source] Fwd_ A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf	0.01	1/24/2017 1:59 PM	Carol Schall	Other	Not Applicable
View	York County Public Schools Institutional Investigator Agreement	York VCU_ACE_YCSD Agreement.pdf	0.01	1/24/2017 1:56 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Williamsburg James City County Public Schools Institutional Investigator Agreement	WJCC VCU Project Search 2017 Agreement_W-JCC_Signed.pdf	0.01	1/24/2017 1:55 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	New Horizons Regional Education Center Institutional Investigator Agreement	New Horizons Invesitgator Agreement.pdf	0.01	1/24/2017 1:54 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Baseline Demographic Script Clean version 2 11-11-2016	Baseline Demographics Clean version 2 11-11-2016.docx	0.03	11/11/2016 12:55 PM	Carol Schall	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	OSP Proposal Review Documentation	OSP Approval_Project Search_Wehman.pdf	0.01	11/1/2016 2:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 13 Data sharing	NDAR.pdf	0.01	11/1/2016 1:25 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 12 Transition Plan	Transition.pdf	0.01	11/1/2016 1:24 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 10 Data Collection Instruments Description	1 Instruments Relationship to the Study Objectives.docx	0.01	11/1/2016 1:22 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 11 Impact Statement	Impact.pdf	0.01	11/1/2016 1:21 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Management Plan	3 Study Management Plan.docx	0.01	11/1/2016 1:19 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Description	2 Study Personnel Description.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 9 Study Personnel Organizational Chart	1 Organizational Chart.docx	0.01	11/1/2016 1:18 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 8 Data Management	Data_Manage.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 7 Intervention	Intervention.pdf	0.01	11/1/2016 1:17 PM	Carol Schall	Other	Yes
View	Grant Attachment 6 Human Subject Recruitment and Safety Procedures	HumSubProc.pdf	0.01	11/1/2016 1:16 PM	Carol Schall	Other	Yes
View	Grant Attachment 5 Statement of Work	SOW.pdf	0.01	11/1/2016 1:15 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 4 Lay Abstract	LayAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 3 Technical Abstract	TechAbs.pdf	0.01	11/1/2016 1:14 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Intellectual Property	7 Intellectual Property and Sharing of Data.docx	0.01	11/1/2016 1:13 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2	3 Hampton City Public Schools.tif	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Letters of Collaboration						
View	Grant Attachment 2 Letters of Collaboration	2 Newport News.pdf	0.01	11/1/2016 1:12 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Letter of Organizational Support	5 Cifu Letter of Support.doc	0.01	11/1/2016 1:11 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 List of Relevant Publications	4 List of Relevant Publications.docx	0.01	11/1/2016 1:08 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Facilities	3 Facilities.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 Abbreviations	2 List of Abbreviations.docx	0.01	11/1/2016 1:07 PM	Carol Schall	Other	Not Applicable
View	Grant Attachment 2 References	1 References.docx	0.01	11/1/2016 1:06 PM	Carol Schall	Other	Not Applicable
View	Grant Project Narrative	ProjectNarrative.pdf	0.01	11/1/2016 1:05 PM	Carol Schall	Other	Yes
View	VCU Response to peer and programmatic review	Response to Peer and Programatic Review Concerns.docx	0.01	11/1/2016 12:16 PM	Carol Schall	Other	Not Applicable
View	CDMRP Review Notes	CDMRP Review Notes.pdf	0.01	11/1/2016 12:15 PM	Carol Schall	Other	Not Applicable
View	Newport News Public Schools Institutional Investigator Agreement	Newport News Public Schools_Institutional Investigator Agreement.pdf	0.01	11/1/2016 12:14 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	Hampton City Public Schools Institutional Investigator Agreement	Hampton City Public Schools IIA.pdf	0.01	10/3/2016 12:36 PM	Carol Schall	Non-VCU site submission form	Not Applicable
View	References Cited	References.docx	0.01	9/21/2016 9:16 PM	Carol Schall	Other	Not Applicable
View	Quality of Life Questionnaire Adult Version	8 qol question adults (1).doc	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Proxy Report	7 SRS2 Proxy Report.pdf	0.01	9/21/2016 7:56 PM	Carol Schall	Research Measure	Yes
View	Social Responsiveness Scale 2 - Self Report	6 SRS 2 Self Report.pdf	0.01	9/21/2016 7:55 PM	Carol Schall	Research Measure	Yes
View	Behavior Assessment Scale in Children Adolescent Ages 12-21	5 30805_BASC3_TRS_A_RS_Form_FNL (1).pdf	0.01	9/21/2016 7:54 PM	Carol Schall	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Support Intensity Scale	4 Support Intensity Scale.pdf	0.01	9/21/2016 7:53 PM	Carol Schall	Research Measure	Yes
View	12 and 18 Month Script Version 1 9-21-2016	3 Twelve and Eighteen Months Data script.docx	0.01	9/21/2016 7:52 PM	Carol Schall	Research Measure	Yes
View	Draft Teacher Recruitment Letter	Letter to teachers recruitment 2016 version 1 9-21-2016.docx	0.01	9/21/2016 7:39 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Treatment Acceptance Letter	Draft Treatment Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Parent/Student Recruitment Letter	Draft Parent Recruitment letter version 1 9-21-2016.doc	0.01	9/21/2016 7:37 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Open House Flyer	Draft open house flyer version 1 9-21-2016.doc	0.01	9/21/2016 7:35 PM	Carol Schall	Recruitment/Advertising	Yes
View	Draft Control Group Acceptance Letter	Draft Control Acceptance Letter version 1 9-21-2016.doc	0.01	9/21/2016 7:34 PM	Carol Schall	Recruitment/Advertising	Yes
View	Avellone Biosketch	Avellone Bio Sketch.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	McDonough Biosketch	biosketch McDonough.doc	0.01	9/20/2016 4:34 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Schall Biosketch	Schall biosketch (1).doc	0.01	9/20/2016 4:33 PM	Carol Schall	CV/Biosketch	Not Applicable
View	Wehman Biosketch	Bio Sketch Wehman.docx	0.01	9/20/2016 4:32 PM	Carol Schall	CV/Biosketch	Yes

Documents Complete

Protocol Progress:

- **INITIAL SETUP**
- **BACKGROUND, RATIONALE & GOALS**
- **RESEARCH PLAN**
- **CONSENT PLAN**
- **RISKS, PRIVACY & CONFIDENTIALITY**
- **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:**
   Participant Consent

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)
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

7. * **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

   Because this study involves special education students with ASD, consent meetings will be held concurrently with each potential participant's Individualized Education Plan (IEP) meeting at which students and parents/guardians are in attendance, or during an individual parent/teacher/student conference at the student's school. At least one member of the research team will also be available at the meeting to provide information about the study, answer questions, and obtain informed consent/assent. In the event that a non-English speaking individual participates, we will seek an interpreter so that the individual can receive the consent information and have their questions answered in their native language.

   COVID-19 Contingency Plan: We will meet with participants via phone or video conferencing only. We will have no in-person interactions. During this time, we will have two research staff on the phone or video conference. We will mark the form based upon the verbal consent of the participant. The participant will have up to 2 weeks to make their decision.

8. * **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.):**
   - [x] **Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion**
   - [x] **Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion**
   - [x] **Removing physical symbols of authority like white coats or police badges**
   - [x] **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)
   - [x] **Moving to a more neutral location like a conference room**
   - [x] **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
   - [x] **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

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
   Students and/or parents who want additional time to consider participation may take the informed consent documents with them and will have up to two weeks to consider their decision.

10. * **How much time will participants be given to make a decision:**
Students and/or parents who want additional time to consider participation may take the informed consent documents with them and will have up to two weeks to consider their decision.

11. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**
For students who are legally emancipated, we will use a standard consent document; for those who are under the guardianship of an LAR, we will obtain consent from the LAR and assent from the student.

participants will be made aware of consent form changes pertaining to the certificate of confidentiality and future use of data, and will have an opportunity to sign the updated consent form when they meet with the researchers.

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Educators

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)
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

7. * **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

   Consent will be obtained when first meeting with the educator to review data collection measures.

   COVID-19 Contingency Plan: We will meet with participants via phone or video conferencing only. We will have no in-person interactions. During this time, we will have two research staff on the phone or video conference. We will mark the form based upon the verbal consent of the participant. The participant will have up to 2 weeks to make their decision.

8. * **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
   - [x] **Removing physical symbols of authority like white coats or police badges**
   - [x] **Sitting down beside the participant instead of standing over them**
   - [x] **If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)**
   - [x] **Moving to a more neutral location like a conference room**
   - [x] **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

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
   Study staff will review the consent document and respond to any questions by potential participants in person. Participants will be asked if they are comfortable signing the document once they have had all of their questions answered. In the event that participants are not comfortable signing, participants will be offered a copy of the consent document and allowed to consider whether or not they want to participate in the research. No data will be collected prior to participant educators signing the document.

10. * **How much time will participants be given to make a decision:**
    We will offer educators 2 weeks to make a decision regarding their participation

11. If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:

NA. All Educators are assumed to be competent by virtue of their position as certified educators.

participants will be made aware of consent form changes pertaining to the certificate of confidentiality and future use of data, and will have an opportunity to sign the updated consent form when they meet with the researchers.

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Student Assent

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)
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

7. * **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

   Because this study involves special education students with ASD, consent meetings will be held concurrently with each potential participant's Individualized Education Plan (IEP) meeting at which students and parents/guardians are in attendance, or during an individual parent/teacher/student conference at the student's school. At least one member of the research team will also be available at the meeting to provide information about the study, answer questions, and obtain informed consent/assent. In the event that a non-English speaking individual participates, we will seek an interpreter so that the individual can receive the consent information and have their questions answered in their native language.

   COVID-19 Contingency Plan: We will meet with participants via phone or video conferencing only. We will have no in-person interactions. During this time, we will have two research staff on the phone or video conference. We will mark the form based upon the verbal consent of the participant. The participant will have up to 2 weeks to make their decision.

8. * **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.):**
   - [x] **Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion**
   - [x] **Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion**
   - [x] **Removing physical symbols of authority like white coats or police badges**
   - [x] **Sitting down beside the participant instead of standing over them**
   - [x] **If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)**
   - [x] **Moving to a more neutral location like a conference room**
   - [x] **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

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
   Students and/or parents who want additional time to consider participation may take the informed consent documents with them and will have up to two weeks to consider their decision.

10. * **How much time will participants be given to make a decision:**
Students and/or parents who want additional time to consider participation may take the informed consent documents with them and will have up to two weeks to consider their decision.

11. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**
For students who are legally emancipated, we will use a standard consent document; for those who are under the guardianship of an LAR, we will obtain consent from the LAR and assent from the student.

participants will be made aware of consent form changes pertaining to the certificate of confidentiality and future use of data, and will have an opportunity to sign the updated consent form when they meet with the researchers.

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   LAR Consent

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)
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

7. * **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

   Because this study involves special education students with ASD, consent meetings will be held concurrently with each potential participant's Individualized Education Plan (IEP) meeting at which students and parents/guardians are in attendance, or during an individual parent/teacher/student conference at the student's school. At least one member of the research team will also be available at the meeting to provide information about the study, answer questions, and obtain informed consent/assent. In the event that a non-English speaking individual participates, we will seek an interpreter so that the individual can receive the consent information and have their questions answered in their native language.

   COVID-19 Contingency Plan: We will meet with participants via phone or video conferencing only. We will have no in-person interactions. During this time, we will have two research staff on the phone or video conference. We will mark the form based upon the verbal consent of the participant. The participant will have up to 2 weeks to make their decision.

8. * **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.):**
   - [x] **Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion**
   - [x] **Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion**
   - [x] **Removing physical symbols of authority like white coats or police badges**
   - [x] **Sitting down beside the participant instead of standing over them**
   - [x] **If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)**
   - [x] **Moving to a more neutral location like a conference room**
   - [x] **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

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
   Students and/or parents who want additional time to consider participation may take the informed consent documents with them and will have up to two weeks to consider their decision.

10. * **How much time will participants be given to make a decision:**
Students and/or parents who want additional time to consider participation may take the informed consent documents with them and will have up to two weeks to consider their decision.

11. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**
For students who are legally emancipated, we will use a standard consent document; for those who are under the guardianship of an LAR, we will obtain consent from the LAR and assent from the student.

participants will be made aware of consent form changes pertaining to the certificate of confidentiality and future use of data, and will have an opportunity to sign the updated consent form when they meet with the researchers.

Non-VCU Site Details

1. * **Name of institution or site:**
   Williamsburg James City County Public Schools

2. * **Provide a description of the institution's or site's role in the research and what study activities they will be performing. For example involvement in study design, carrying out research procedures, recruiting subjects, consenting, analyzing data and or specimens (regardless of identifiability), writing manuscripts or publications, solely being a location for VCU investigators to conduct activities, etc.:**
   Williamsburg James City County Public Schools will participate in the following ways: (1) Assist with recruitment of student participants, study group assignments, and communications with parents; (2) include project activities in student IEPs; (3) provide support for transportation to job training sites; and (4) provide staffing support (i.e., teachers and aides) to deliver project interventions to students and collect study data.

   Please note: A closure form for this site was submitted on 8/26/2019.

3. * **Describe the adequacy of the institution or site to ensure human participant safety, particularly in event of unanticipated emergency:**
   Williamsburg James City County Public Schools has Quality Assurance Offices that will provide oversight of their staff activities related to human subjects protections.

   Please note: A closure form for this site was submitted on 8/26/2019.

4. * **Select the IRB review path the Non-VCU institution or site will follow:**

   - ○ Exempt study submission
   - ○ Site Engaged -- Has FWA and Will Obtain Own IRB Review
   - ○ Site Engaged -- Requests to Rely on VCU IRB Review
   - ○ Site Not Engaged -- IRB Review Not Required
   - ● **Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.**

5. **If the institution or site is engaged and will either 1) obtain their own IRB review OR 2) rely on VCU IRB review, provide the FWA# of the site:**
   No

6. **If this is a foreign site or location, select which individuals and/or groups will be serving as the cultural consultant for the site to ensure that the research will be conducted according to local customs and procedures:**

   - ☐ This is not a foreign site/location
   - ☐ Foreign IRB or ethics committee (required for foreign sites engaged in expedited and full board research)
   - ☐ Foreign site principal investigator
   - ☐ Foreign site community advisory board
   - ☐ Foreign site community elders or similar governing body
   - ☐ Other cultural consultant (select if none of the above options apply; more information will be required about this individual)

Non-VCU Site Details

1. * **Name of institution or site:**
   Fort Eustis

2. * **Provide a description of the institution's or site's role in the research and what study activities they will be performing. For example involvement in study design, carrying out research procedures, recruiting subjects, consenting, analyzing data and or specimens (regardless of identifiability), writing manuscripts or publications, solely being a location for VCU investigators to conduct activities, etc.:**
   Fort Eustis will provide space on the base to house the treatment intervention, Project SEARCH plus ASD Supports. They will also identify a liaison who will be the main point of contact with the research team. They will also ask their department managers and staff to host internship sites in collaboration with VCU.

3. * **Describe the adequacy of the institution or site to ensure human participant safety, particularly in event of unanticipated emergency:**
   Fort Eustis, as a part of the Department of Defense, is under the supervision of the Human Rights Protection Office (HRPO). HRPO has reviewed our research protocol and approved our submission.

4. * **Select the IRB review path the Non-VCU institution or site will follow:**

   - ○ Exempt study submission
   - ○ Site Engaged -- Has FWA and Will Obtain Own IRB Review
   - ○ Site Engaged -- Requests to Rely on VCU IRB Review
   - ● **Site Not Engaged -- IRB Review Not Required**
   - ○ Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.

5. **If the institution or site is engaged and will either 1) obtain their own IRB review OR 2) rely on VCU IRB review, provide the FWA# of the site:**
   No IRB review is necessary.

6. **If this is a foreign site or location, select which individuals and/or groups will be serving as the cultural consultant for the site to ensure that the research will be conducted according to local customs and procedures:**
   - ☐ This is not a foreign site/location
   - ☐ Foreign IRB or ethics committee (required for foreign sites engaged in expedited and full board research)
   - ☐ Foreign site principal investigator
   - ☐ Foreign site community advisory board
   - ☐ Foreign site community elders or similar governing body
   - ☐ Other cultural consultant (select if none of the above options apply; more information will be required about this individual)

Non-VCU Site Details

1. * **Name of institution or site:**
   New Horizons Regional Education Center

2. * **Provide a description of the institution's or site's role in the research and what study activities they will be performing. For example involvement in study design, carrying out research procedures, recruiting subjects, consenting, analyzing data and or specimens (regardless of identifiability), writing manuscripts or publications, solely being a location for VCU investigators to conduct activities, etc.:**
   New Horizons Regional Education Center will participate in the following ways: (1) Assist with recruitment of student participants, study group assignments, and communications with parents; (2) include project activities in student IEPs; (3) provide support for transportation to job training sites; and (4) provide staffing support (i.e., teachers and aides) to deliver project interventions to students and collect study data.

   Please note: A closure form for this site was submitted on 8/26/2019.

   Please note: A closure form for this site was submitted on 8/26/2019.

3. * **Describe the adequacy of the institution or site to ensure human participant safety, particularly in event of unanticipated emergency:**
   New Horizons Regional Education Center has Quality Assurance Offices that will provide oversight of their staff activities related to human subjects protections.

   Please note: A closure form for this site was submitted on 8/26/2019.

4. * **Select the IRB review path the Non-VCU institution or site will follow:**

   - ○ Exempt study submission
   - ○ Site Engaged -- Has FWA and Will Obtain Own IRB Review
   - ○ Site Engaged -- Requests to Rely on VCU IRB Review
   - ○ Site Not Engaged -- IRB Review Not Required
   - ● **Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.**

5. **If the institution or site is engaged and will either 1) obtain their own IRB review OR 2) rely on VCU IRB review, provide the FWA# of the site:**
   No

6. **If this is a foreign site or location, select which individuals and/or groups will be serving as the cultural consultant for the site to ensure that the research will be conducted according to local customs and procedures:**
   - ☐ This is not a foreign site/location
   - ☐ Foreign IRB or ethics committee (required for foreign sites engaged in expedited and full board research)
   - ☐ Foreign site principal investigator
   - ☐ Foreign site community advisory board
   - ☐ Foreign site community elders or similar governing body
   - ☐ Other cultural consultant (select if none of the above options apply; more information will be required about this individual)

Non-VCU Site Details

1. * **Name of institution or site:**
   York County Public Schools

2. * **Provide a description of the institution's or site's role in the research and what study activities they will be performing. For example involvement in study design, carrying out research procedures, recruiting subjects, consenting, analyzing data and or specimens (regardless of identifiability), writing manuscripts or publications, solely being a location for VCU investigators to conduct activities, etc.:**
   York County Public Schools Public Schools will participate in the following ways: (1) Assist with recruitment of student participants, study group assignments, and communications with parents; (2) include project activities in student IEPs; (3) provide support for transportation to job training sites; and (4) provide staffing support (i.e., teachers and aides) to deliver project interventions to students and collect study data.

   Please note: A closure form for this site was submitted on 8/26/2019.

3. * **Describe the adequacy of the institution or site to ensure human participant safety, particularly in event of unanticipated emergency:**
   York County Public Schools has Quality Assurance Offices that will provide oversight of their staff activities related to human subjects protections.

   Please note: A closure form for this site was submitted on 8/26/2019.

4. * **Select the IRB review path the Non-VCU institution or site will follow:**

   - ○ Exempt study submission
   - ○ Site Engaged -- Has FWA and Will Obtain Own IRB Review
   - ○ Site Engaged -- Requests to Rely on VCU IRB Review
   - ○ Site Not Engaged -- IRB Review Not Required
   - ● **Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.**

5. **If the institution or site is engaged and will either 1) obtain their own IRB review OR 2) rely on VCU IRB review, provide the FWA# of the site:**
   No

6. **If this is a foreign site or location, select which individuals and/or groups will be serving as the cultural consultant for the site to ensure that the research will be conducted according to local customs and procedures:**
   - ☐ This is not a foreign site/location
   - ☐ Foreign IRB or ethics committee (required for foreign sites engaged in expedited and full board research)
   - ☐ Foreign site principal investigator
   - ☐ Foreign site community advisory board
   - ☐ Foreign site community elders or similar governing body
   - ☐ Other cultural consultant (select if none of the above options apply; more information will be required about this individual)

Non-VCU Site Details

1. * **Name of institution or site:**
   Hampton City Public Schools

2. * **Provide a description of the institution's or site's role in the research and what study activities they will be performing. For example involvement in study design, carrying out research procedures, recruiting subjects, consenting, analyzing data and or specimens (regardless of identifiability), writing manuscripts or publications, solely being a location for VCU investigators to conduct activities, etc.:**
   Hampton City Public Schools will participate in the following ways: (1) Assist with recruitment of student participants, study group assignments, and communications with parents; (2) include project activities in student IEPs; (3) provide support for transportation to job training sites; and (4) provide staffing support (i.e., teachers and aides) to deliver project interventions to students and collect study data.

   Please note: A closure form for this site was submitted on 8/26/2019.

3. * **Describe the adequacy of the institution or site to ensure human participant safety, particularly in event of unanticipated emergency:**
   Hampton City Public Schools has an institutional review boards or Quality Assurance Offices that will provide oversight of their staff activities related to human subjects protections.

   Please note: A closure form for this site was submitted on 8/26/2019.

4. * **Select the IRB review path the Non-VCU institution or site will follow:**

   - ○ Exempt study submission
   - ○ Site Engaged -- Has FWA and Will Obtain Own IRB Review
   - ○ Site Engaged -- Requests to Rely on VCU IRB Review
   - ○ Site Not Engaged -- IRB Review Not Required
   - ● **Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.**

5. **If the institution or site is engaged and will either 1) obtain their own IRB review OR 2) rely on VCU IRB review, provide the FWA# of the site:**

6. **If this is a foreign site or location, select which individuals and/or groups will be serving as the cultural consultant for the site to ensure that the research will be conducted according to local customs and procedures:**
   - ☐ This is not a foreign site/location
   - ☐ Foreign IRB or ethics committee (required for foreign sites engaged in expedited and full board research)
   - ☐ Foreign site principal investigator
   - ☐ Foreign site community advisory board
   - ☐ Foreign site community elders or similar governing body
   - ☐ Other cultural consultant (select if none of the above options apply; more information will be required about this individual)

Non-VCU Site Details

1. * **Name of institution or site:**
   Newport News Public Schools

2. * **Provide a description of the institution's or site's role in the research and what study activities they will be performing. For example involvement in study design, carrying out research procedures, recruiting subjects, consenting, analyzing data and or specimens (regardless of identifiability), writing manuscripts or publications, solely being a location for VCU investigators to conduct activities, etc.:**
   Newport News Public Schools will participate in the following ways: (1) Assist with recruitment of student participants, study group assignments, and communications with parents; (2) include project activities in student IEPs; (3) provide support for transportation to job training sites; and (4) provide staffing support (i.e., teachers and aides) to deliver project interventions to students and collect study data.

   Please note: A closure form for this site was submitted on 8/26/2019.

3. * **Describe the adequacy of the institution or site to ensure human participant safety, particularly in event of unanticipated emergency:**
   Newport News Public Schools has Quality Assurance Offices that will provide oversight of their staff activities related to human subjects protections.

   Please note: A closure form for this site was submitted on 8/26/2019.

4. * **Select the IRB review path the Non-VCU institution or site will follow:**

   - ○ Exempt study submission
   - ○ Site Engaged -- Has FWA and Will Obtain Own IRB Review
   - ○ Site Engaged -- Requests to Rely on VCU IRB Review
   - ○ Site Not Engaged -- IRB Review Not Required
   - ● **Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.**

5. **If the institution or site is engaged and will either 1) obtain their own IRB review OR 2) rely on VCU IRB review, provide the FWA# of the site:**

6. **If this is a foreign site or location, select which individuals and/or groups will be serving as the cultural consultant for the site to ensure that the research will be conducted according to local customs and procedures:**
   - ☐ This is not a foreign site/location
   - ☐ Foreign IRB or ethics committee (required for foreign sites engaged in expedited and full board research)
   - ☐ Foreign site principal investigator
   - ☐ Foreign site community advisory board
   - ☐ Foreign site community elders or similar governing body
   - ☐ Other cultural consultant (select if none of the above options apply; more information will be required about this individual)

Non-VCU Site Details

1. * **Name of institution or site:**
   Virginia Department of Aging and Rehabilitation Services (DARS)

2. * **Provide a description of the institution's or site's role in the research and what study activities they will be performing. For example involvement in study design, carrying out research procedures, recruiting subjects, consenting, analyzing data and or specimens (regardless of identifiability), writing manuscripts or publications, solely being a location for VCU investigators to conduct activities, etc.:**
   he Virginia DARS will (1) assign a Vocational Rehabilitation Counselors to student participants and complete eligibility services; (2) with the student, family, and project staff, develop student individualized plans for employment; and (3) provide ongoing monitoring of student progress toward employment goals and terminal job placement opportunities. Oversight of the activities of these non-VCU staff will be provided by the PI and Study Coordinator, who will routinely observe training and data collection activities for quality assurance and human subjects' protection.

3. * **Describe the adequacy of the institution or site to ensure human participant safety, particularly in event of unanticipated emergency:**
   Virginia DARS has an institutional review board that will provide oversight of their staff activities related to human subjects protections.

4. * **Select the IRB review path the Non-VCU institution or site will follow:**

- ○ Exempt study submission
- ● **Site Engaged -- Has FWA and Will Obtain Own IRB Review**
- ○ Site Engaged -- Requests to Rely on VCU IRB Review
- ○ Site Not Engaged -- IRB Review Not Required
- ○ Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.

5. **If the institution or site is engaged and will either 1) obtain their own IRB review OR 2) rely on VCU IRB review, provide the FWA# of the site:**
   FWA# 00008936

6. **If this is a foreign site or location, select which individuals and/or groups will be serving as the cultural consultant for the site to ensure that the research will be conducted according to local customs and procedures:**

- ☐ This is not a foreign site/location
- ☐ Foreign IRB or ethics committee (required for foreign sites engaged in expedited and full board research)
- ☐ Foreign site principal investigator
- ☐ Foreign site community advisory board
- ☐ Foreign site community elders or similar governing body
- ☐ Other cultural consultant (select if none of the above options apply; more information will be required about this individual)

Personnel

1. * **Name:**
   Paul Wehman

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)
   - [ ] Other

4. * **Study related responsibilities:**

   - [x] **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
- [ ] 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:**
Yes

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**
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**
804-828-1851

Personnel

1. * **Name:**
   Carol Schall

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
   - [x] **Co/Sub-Investigator**
   - [ ] Medical or Psychological Responsible Investigator
   - [ ] Lead Student/Trainee Investigator (leading their own project)
   - [x] **Research Coordinator**
   - [ ] Research Nurse
   - [ ] Consultant
   - [ ] Research Assistant
   - [ ] Pharmacist
   - [ ] Statistician
   - [ ] Regulatory Coordinator
   - [ ] Trainee/Student(working on project)
   - [ ] Other

4. * **Study related responsibilities:**

   - [x] **Study Design**
   - [ ] Data Collection - Lab
   - [ ] Data Collection - Clinical
   - [x] **Data Collection - Interviews/Surveys**
   - [x] **Data Collection - Direct Observation**

- [ ] Clinical Services
- [x] **Intervention Services**
- [x] **Data Entry**
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **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:**
   Yes

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**
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**
   804-828-6979

Personnel

1. * **Name:**
   Jennifer McDonough

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)
   - [x] **Research Coordinator**
   - [ ] Research Nurse
   - [ ] Consultant
   - [ ] Research Assistant
   - [ ] Pharmacist
   - [ ] Statistician
   - [ ] Regulatory Coordinator
   - [ ] Trainee/Student(working on project)
   - [ ] Other

4. * **Study related responsibilities:**

   - [ ] Study Design
   - [x] **Data Collection - Lab**
   - [x] **Data Collection - Clinical**
   - [x] **Data Collection - Interviews/Surveys**
   - [x] **Data Collection - Direct Observation**

- [ ] Clinical Services
- [x] **Intervention Services**
- [x] **Data Entry**
- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [x] **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:**
Yes

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [ ] Experience - Research
- [x] **Experience - Clinical**
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**
804-828-6984

Personnel

1. * **Name:**
   Holly Whittenburg

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:**
   On-Site Coordinator

5. * **Study related responsibilities:**

- ☐ Study Design
- ☐ Data Collection - Lab
- ☐ Data Collection - Clinical
- ☑ **Data Collection - Interviews/Surveys**

- [x] **Data Collection - Direct Observation**
- [x] **Clinical Services**
- [x] **Intervention Services**
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [ ] 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**
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

8. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Lauren Avellone

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)
   - [x] **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
   - [x] **Data Collection - Clinical**
   - [x] **Data Collection - Interviews/Surveys**
   - [x] **Data Collection - Direct Observation**

- [x] **Clinical Services**
- [x] **Intervention Services**
- [x] **Data Entry**
- [x] **Data Coding**
- [x] **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:**
Yes

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**
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Hannah Seward

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
- [x] **Data Entry**
- [x] **Data Coding**
- [ ] Data Management
- [ ] 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:**
Yes

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**
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Thomas Dubois

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:**
   Job Coach

5. * **Study related responsibilities:**

   - ☐ Study Design
   - ☐ Data Collection - Lab
   - ☐ Data Collection - Clinical
   - ☐ Data Collection - Interviews/Surveys

- [x] **Data Collection - Direct Observation**
- [ ] Clinical Services
- [x] **Intervention Services**
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
- [ ] Project Coordination
- [ ] Participant Identification
- [ ] Participant Recruitment
- [ ] 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**
- [ ] Experience - Research
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

8. **Additional or Emergency Phone:**

Add Document

1. * **Document Name:**
   Student Assent Version 2 11/1/2017
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Student Assent Clean Version 2 11-1-2017.pdf(0.06)

Add Document

1. * **Document Name:**
   Student Consent Version 10 11/22/2019
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Student Consent 10 11-22-2019 clean version2.pdf(0.31)

Add Document

1. * **Document Name:**
   LAR Consent Version 10 11/22/2019
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   LAR Consent Version 10 clean version2.pdf(0.30)

Add Document

1. * **Document Name:**
   Educator Consent Version 10 11/22/2019
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Educator Consent Version 10 clean version2.pdf(0.30)

Add Document

1. * **Document Name:**
   COVID-19 Contingency Assent Form Individual Assent
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Student Assent.pdf(0.03)

Add Document

1. * **Document Name:**
   COVID-19 Contingency Consent Form LAR Consent
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   LAR Consent.pdf(0.03)

Add Document

1. * **Document Name:**
   COVID-19 Contingency Consent Form Individual Consent
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Individual Consent.pdf(0.03)

Add Document

1. * **Document Name:**
   COVID-19 Contingency Consent Form Educator Consent
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   Educator Consent.pdf(0.03)

Add Document

1. * **Document Name:**
   COVID-19 Contingency Protocol
2. * **Type:**
   Other
3. * **File:**
   COVID Contingency Protocol for CDMRP version 3.docx(0.03)

Add Document

1. * **Document Name:**
   York County Closure Form
2. * **Type:**
   Non-VCU site submission form
3. * **File:**
   relying_site_closure York.pdf(0.01)

Add Document

1. * **Document Name:**
   Williamsburg/ James City County Closure Form
2. * **Type:**
   Non-VCU site submission form
3. * **File:**
   relying_site_closure Williamsburg James City County-signed.pdf(0.01)

Add Document

1. * **Document Name:**
   Hampton City Public Schools Closure Form
2. * **Type:**
   Non-VCU site submission form
3. * **File:**
   relying_site_closure Hampton.pdf(0.01)

Add Document

1. * **Document Name:**
   New Horizons Closure Form
2. * **Type:**
   Non-VCU site submission form
3. * **File:**
   New Horizons Closure Report.pdf(0.01)

Add Document

1. * **Document Name:**
   Newport News Public Schools Closure Form
2. * **Type:**
   Non-VCU site submission form
3. * **File:**
   Nwport News Public Schools Signed Relying Site Closure Notice.pdf(0.01)

Add Document

1. * **Document Name:**
   Certificate of Confidentiality
2. * **Type:**
   Other
3. * **File:**
   Certificate of Confidentiality.pdf(0.03)

Add Document

1. * **Document Name:**
   Subject Eligibility Checklist
2. * **Type:**
   Other
3. * **File:**
   CDMRP subject_eligibility_screening checklist Version 2 Clean Line.doc(0.02)

Add Document

1. * **Document Name:**
   Student Screening Interview and Rubric
2. * **Type:**
   Other
3. * **File:**
   Student Selection Interview and Rubric 2019 Version 3 Clean.doc(0.05)

Add Document

1. * **Document Name:**
   Project SEARCH "Recommended" Curriculum Documents (Please note, these are not all used)
2. * **Type:**
   Other
3. * **File:**
   2003 PS HS Curriculum.doc(0.03)

Add Document

1. * **Document Name:**
   Draft Application for Participation
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Draft Application for participation Version 3 Redline 10-26-2017.docx(0.06)

Add Document

1. * **Document Name:**
   HRPO IRB Approval
2. * **Type:**
   Ancillary Committee Approval
3. * **File:**
   Virginia Commonwealth University Mail - A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf(0.01)

Add Document

1. * **Document Name:**
   Fort Eustis Agreement to be the Location and Business Site for the Research

2. * **Type:**
   Other

3. * **File:**
   Virginia Commonwealth University Mail - Re_ [Non-DoD Source] Fwd_ A-19693.a, A-19693.b, A-19693.c, and A-19693.pdf(0.01)

Add Document

1. * **Document Name:**
   York County Public Schools Institutional Investigator Agreement
2. * **Type:**
   Non-VCU site submission form
3. * **File:**
   York VCU_ACE_YCSD Agreement.pdf(0.01)

Add Document

1. * **Document Name:**
   Williamsburg James City County Public Schools Institutional Investigator Agreement

2. * **Type:**
   Non-VCU site submission form

3. * **File:**
   WJCC VCU Project Search 2017 Agreement_W-JCC_Signed.pdf(0.01)

Add Document

1. * **Document Name:**
   New Horizons Regional Education Center Institutional Investigator Agreement

2. * **Type:**
   Non-VCU site submission form

3. * **File:**
   New Horizons Invesitgator Agreement.pdf(0.01)

Add Document

1. * **Document Name:**
   Baseline Demographic Script Clean version 2 11-11-2016
2. * **Type:**
   Research Measure
3. * **File:**
   Baseline Demographics Clean version 2 11-11-2016.docx(0.03)

Add Document

1. * **Document Name:**
   OSP Proposal Review Documentation
2. * **Type:**
   Other
3. * **File:**
   OSP Approval_Project Search_Wehman.pdf(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 13 Data sharing
2. * **Type:**
   Other
3. * **File:**
   NDAR.pdf(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 12 Transition Plan
2. * **Type:**
   Other
3. * **File:**
   Transition.pdf(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 10 Data Collection Instruments Description
2. * **Type:**
   Other
3. * **File:**
   1 Instruments Relationship to the Study Objectives.docx(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 11 Impact Statement
2. * **Type:**
   Other
3. * **File:**
   Impact.pdf(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 9 Study Management Plan
2. * **Type:**
   Other
3. * **File:**
   3 Study Management Plan.docx(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 9 Study Personnel Description
2. * **Type:**
   Other
3. * **File:**
   2 Study Personnel Description.docx(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 9 Study Personnel Organizational Chart
2. * **Type:**
   Other
3. * **File:**
   1 Organizational Chart.docx(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 8 Data Management
2. * **Type:**
   Other
3. * **File:**
   Data_Manage.pdf(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 7 Intervention
2. * **Type:**
   Other
3. * **File:**
   Intervention.pdf(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 6 Human Subject Recruitment and Safety Procedures
2. * **Type:**
   Other
3. * **File:**
   HumSubProc.pdf(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 5 Statement of Work
2. * **Type:**
   Other
3. * **File:**
   SOW.pdf(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 4 Lay Abstract
2. * **Type:**
   Other
3. * **File:**
   LayAbs.pdf(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 3 Technical Abstract
2. * **Type:**
   Other
3. * **File:**
   TechAbs.pdf(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 2 Intellectual Property
2. * **Type:**
   Other
3. * **File:**
   7 Intellectual Property and Sharing of Data.docx(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 2 Letters of Collaboration
2. * **Type:**
   Other
3. * **File:**
   3 Hampton City Public Schools.tif(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 2 Letters of Collaboration
2. * **Type:**
   Other
3. * **File:**
   2 Newport News.pdf(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 2 Letter of Organizational Support
2. * **Type:**
   Other
3. * **File:**
   5 Cifu Letter of Support.doc(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 2 List of Relevant Publications
2. * **Type:**
   Other
3. * **File:**
   4 List of Relevant Publications.docx(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 2 Facilities
2. * **Type:**
   Other
3. * **File:**
   3 Facilities.docx(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 2 Abbreviations
2. * **Type:**
   Other
3. * **File:**
   2 List of Abbreviations.docx(0.01)

Add Document

1. * **Document Name:**
   Grant Attachment 2 References
2. * **Type:**
   Other
3. * **File:**
   1 References.docx(0.01)

Add Document

1. * **Document Name:**
   Grant Project Narrative
2. * **Type:**
   Other
3. * **File:**
   ProjectNarrative.pdf(0.01)

Add Document

1. * **Document Name:**
   VCU Response to peer and programmatic review
2. * **Type:**
   Other
3. * **File:**
   Response to Peer and Programatic Review Concerns.docx(0.01)

Add Document

1. * **Document Name:**
   CDMRP Review Notes
2. * **Type:**
   Other
3. * **File:**
   CDMRP Review Notes.pdf(0.01)

Add Document

1. * **Document Name:**
   Newport News Public Schools Institutional Investigator Agreement
2. * **Type:**
   Non-VCU site submission form
3. * **File:**
   Newport News Public Schools_Institutional Investigator Agreement.pdf(0.01)

Add Document

1. * **Document Name:**
   Hampton City Public Schools Institutional Investigator Agreement
2. * **Type:**
   Non-VCU site submission form
3. * **File:**
   Hampton City Public Schools IIA.pdf(0.01)

Add Document

1. * **Document Name:**
   References Cited
2. * **Type:**
   Other
3. * **File:**
   References.docx(0.01)

Add Document

1. * **Document Name:**
   Quality of Life Questionnaire Adult Version
2. * **Type:**
   Research Measure
3. * **File:**
   8 qol question adults (1).doc(0.01)

Add Document

1. * **Document Name:**
   Social Responsiveness Scale 2 - Proxy Report
2. * **Type:**
   Research Measure
3. * **File:**
   7 SRS2 Proxy Report.pdf(0.01)

Add Document

1. * **Document Name:**
   Social Responsiveness Scale 2 - Self Report
2. * **Type:**
   Research Measure
3. * **File:**
   6 SRS 2 Self Report.pdf(0.01)

Add Document

1. * **Document Name:**
   Behavior Assessment Scale in Children Adolescent Ages 12-21
2. * **Type:**
   Research Measure
3. * **File:**
   5 30805_BASC3_TRS_A_RS_Form_FNL (1).pdf(0.01)

Add Document

1. * **Document Name:**
   Support Intensity Scale
2. * **Type:**
   Research Measure
3. * **File:**
   4 Support Intensity Scale.pdf(0.01)

Add Document

1. * **Document Name:**
   12 and 18 Month Script Version 1 9-21-2016
2. * **Type:**
   Research Measure
3. * **File:**
   3 Twelve and Eighteen Months Data script.docx(0.01)

Add Document

1. * **Document Name:**
   Draft Teacher Recruitment Letter
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Letter to teachers recruitment 2016 version 1 9-21-2016.docx(0.01)

Add Document

1. * **Document Name:**
   Draft Treatment Acceptance Letter
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Draft Treatment Acceptance Letter version 1 9-21-2016.doc(0.01)

Add Document

1. * **Document Name:**
   Draft Parent/Student Recruitment Letter
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Draft Parent Recruitment letter version 1 9-21-2016.doc(0.01)

Add Document

1. * **Document Name:**
   Draft Open House Flyer
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Draft open house flyer version 1 9-21-2016.doc(0.01)

Add Document

1. * **Document Name:**
   Draft Control Group Acceptance Letter
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Draft Control Acceptance Letter version 1 9-21-2016.doc(0.01)

Add Document

1. * **Document Name:**
   Avellone Biosketch
2. * **Type:**
   CV/Biosketch
3. * **File:**
   Avellone Bio Sketch.doc(0.01)

Add Document

1. * **Document Name:**
   McDonough Biosketch
2. * **Type:**
   CV/Biosketch
3. * **File:**
   biosketch McDonough.doc(0.01)

Add Document

1. * **Document Name:**
   Schall Biosketch
2. * **Type:**
   CV/Biosketch
3. * **File:**
   Schall biosketch (1).doc(0.01)

Add Document

1. * **Document Name:**
   Wehman Biosketch
2. * **Type:**
   CV/Biosketch
3. * **File:**
   Bio Sketch Wehman.docx(0.01)