Protocol

Title: Producing a Fully Asynchronous Online Savvy Program

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PROTOCOL TITLE: Producing a Fully Asynchronous Online Savvy Program

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REVISION HISTORY

Revision #	Version Date	Summary of Changes
3	5-14-2020	Updated and provided different options to obtaining consents

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1. Study Summary

Study Title	Producing a Fully Asynchronous Online Savvy Program
Study Design	Pilot/Feasibility Study
Primary Objective	We are seeking to develop and test a fully online, self-administered psychoeducation program to enhance the caregiving mastery of family and friends who provide unpaid care for persons living with Alzheimer's and similar dementia disorders (PLWD).
Secondary Objective(s)	n/a
Research Intervention(s)/Interactions	Fully asynchronous online caregiver education program
Study Population	Dementia caregivers
Sample Size	Aim 1 = 20; Aim 2 = 60
Study Duration for individual participants	Aim 1 participants-5 months Aim 2 participants-3 months
Study Specific Abbreviations/ Definitions	ADRD = Alzheimer's Disease and Related Dementias PLWD = person living with Alzheimer's and similar dementia disorders.
Funding Source (if any)	Pending funding from National Institute on Aging

2. Objectives

To make a program that appears to enhance caregiving mastery even more accessible and available to a growing number of dementia family caregivers, we seek to pursue two aims:

Aim 1. Develop a fully asynchronous online Savvy program that incorporates learning activities that promote both knowledge and skill acquisition and develop/enhance caregivers' felt-sense of caregiving mastery.

With input from clinicians, educators, Tele-Savvy facilitators, and caregiver advisors, and assisted by the Roybal Center's Design Studio, we will iteratively develop a storyboard and scripted curriculum for this online educational program. Then, in collaboration with our educational design consultant, we will modify/produce the text and video assets and place them on a continuing education platform that promotes active learning.

Aim 2. Establish the feasibility, acceptability and preliminary efficacy of the online program.

We will use a number of highly reliable channels to recruit 60 family caregivers to take part in a no-control trial of the program, gathering data – at baseline, immediately upon course completion and at 3 months post-baseline – on caregiver distress measures (depression, strain, burden, anxiety), caregiver competence/ mastery, and care recipient quality of life. We will administer investigator-developed evaluation surveys to assess feasibility and acceptability and ad lib improvement comments. We will also seek formative evaluation input through at least 15 semi-structured debriefing interviews, post completion.

3. Background

We are seeking to develop and test a fully online, self-administered psychoeducation program to enhance the caregiving mastery of family and friends who provide unpaid care for persons living with Alzheimer's and similar dementia disorders (PLWD). These caregivers are the bulwark of care for PLWD. The proposed work will build on, modify, and augment an existing program (Tele-Savvy; RO1AG054079). As the number of PLWD rises in the U.S. from the perhaps 7 million today to possibly 15 million in 2050, the healthcare system will rely on those caregivers even more. It is well established that family caregiving is taxing and stressful and that managing the day-to-day life of PLWD and handling the behavioral and psychological symptoms in dementia (BPSD) that they may exhibit are the main sources of stress. Group-based psychoeducational programs such as the Savvy Caregiver program (SCP) have demonstrated that the acquisition of skills, knowledge, and caregiving mastery can ameliorate caregiving stress – and enhance PLWD quality of life. Many factors, however, preclude caregivers' attendance in group-based programs and limit programs' scalability. To address the issue of access, we have developed and are nearly finished testing the Tele-Savvy program, an online version of SCP that brings groups of caregivers together in facilitator-led synchronous groups and provides substantive educational augmentation through asynchronous e-mail-delivered video lessons.

Three key preliminary findings from the online Tele-Savvy program drive and support this pilot project. The first finding is that Tele-Savvy seems to have worked. It appears to have demonstrated efficacy in reducing the distress associated with dementia family caregiving and to have increased caregivers' sense of mastery in carrying out the caregiving role. Preliminary results from the first 220 participants in the baseline to six month segment of this three arm trial (Tele-Savvy; Healthy Living attention control; and Usual Care) indicate that Tele-Savvy participants demonstrated statistically significant group-by-time reductions in depression and caregiver strain and statistically significant group-by-time increases in caregiver mastery, compared to those in the other two groups. The second finding is that participants were highly adherent to the asynchronous portion of Tele-Savvy (36 8-15 minute daily video lessons that are viewed whenever and as often as participants wish); they spent, on average, more than 8 hours watching the videos over the 43-day course of the program. The third finding is that the group nature of the synchronous portion of the program constitutes a barrier for participation and a threat to scalability. A substantial number of individuals who consented to be a part of the trial of the program were never able to participate because their schedules precluded incorporating them into online groups.

4. Study Endpoints

Primary endpoints that will be measured are depression (CES-D), burden (Zarit), anxiety (STAI), mastery (Pearlin), and care recipient behavior (RMBPC).

5. Study Intervention / Design

The proposed intervention for this study is a Fully Asynchronous Online Savvy program. This proposed research follows the NIH Stage model for intervention development. In Aim

1, we will be engaging in Stage 1A of the model. In Aim 2, we will be engaging in the Stage 1B of the NIH Stage Model.

6. Procedures Involved

The Aim 1 portion of this pilot will recruit approximately 20 individuals to take part in Design Studio activities aimed at developing the a Fully Asynchronous Online Savvy program. With advisory input from clinicians, educators, Tele-Savvy facilitators, and caregivers, and assisted by the Roybal Center's Design Studio, we will iteratively develop a storyboard and scripted curriculum for this online educational program. Aim 1 advisor inclusion criteria: master's/doctoral prepared, hold a professional license, or an informal caregiver; currently or formerly worked with or cared for individuals diagnosed with dementia; and have access to a computer or mobile device with internet. In Aim 2, we will be engaging in the Stage 1B of the NIH Stage Model. The clinical trial portion of this pilot (Aim 2; Stage 1b) will recruit 60 individuals to take part in a test of the Fully Asynchronous Online Savvy program. Aim 2 participant inclusion criteria: primary unpaid caregiver for a community-dwelling PWD; provide at least 10 hours of direct care per week; able to read and understand English; be able to access the course online; naïve to Savvy or Tele-Savvy. Participants will be asked to take part, individually, in a 43-day fully online self-guided learning course that uses instructional and psychoeducational methods to promote and enhance dementia caregiving mastery.

Sources of Materials

All Design Studio research materials will be gathered through audio-recorded participation in 3 group brainstorming activity aimed at developing the online caregiver mastery course. Design Studio data will include input from clinicians, educators, Tele-Savvy facilitators, and caregiver advisors' reflections on the mastery-development needs of dementia family caregivers and on the structure, content, and mode of delivery of the course proposed to address these needs.

All Aim 2 research materials will be gathered by a trained interviewer through distance means (by phone or videoconference). The data will be in the form of an interview consisting, principally, of well-established instruments focused on the participant's experience of caregiving and his/her observations about and reactions to the care recipient's behavior and well-being. Interviews will be collected at baseline, 2 months, and 3 months. The data for the study will be entered into a secured database using an electronic data capture program such Research Electronic Data Capture (REDCap). The database will be stored on a secure password-protected server and not on individual desktop computers. The code sheet will be password protected and the password will be updated annually. A semi-structured interview will be conducted with a subsample of Aim 2 participants. These interviews will focus on caregivers' experiences of providing care during the pandemic and on their experience of the course developed by this project.

7. Data and Specimen Banking

The proposed Aim 2 research will include data from a community-based sample of 60 informal caregivers of persons living with Alzheimer's disease or a similar neurocognitive illness. In addition to base demographics, the dataset will include four common measures of caregiver depression, anxiety, burden, and mastery. The final dataset also will include additional self-report

measures based on current literature on caregivers. The final dataset will be stored in the Roybal Center data repository. Data from this pilot study will be available to qualified researchers through a data sharing agreement that is fully consistent with NIH data sharing policies and applicable laws and regulations as well as official policies and practices established by the Roybal Center at Emory. Although these data will be de-identified prior to release for sharing, there remains a possibility of deductive disclosure of participants with unusual characteristics. Therefore, this data sharing agreement will require: 1) a commitment only to use the data for research purposes and not to identify any individual participant; 2) a commitment to securing the data using appropriate computer technology; and 3) a commitment to destroy or return the data after analyses are completed.

8. Sharing of Results with Participants

Study results will not be shared with participants or others (e.g., the subject's primary care physicians).

9. Study Timelines

The overall project has a timeline of 12 months. Participants taking part in Aim 1 for a total of 5 months. This is will represent Months 0-5 of the overall project. Participants taking part in Aim 2 for a total of 7 months. This is will represent Months 6-12 of the overall project.

10. Subject Population

Inclusion Criteria: Aim 1 advisor inclusion criteria: master's/doctoral prepared, hold a professional license, or an informal caregiver; currently or formerly worked with or cared for individuals diagnosed with dementia; and have access to a computer or mobile device with internet. In Aim 2, we will be engaging in the Stage 1B of the NIH Stage Model. The clinical trial portion of this pilot (Aim 2; Stage 1b) will recruit 60 individuals to take part in a test of the Fully Asynchronous Online Savvy program. Aim 2 participant inclusion criteria: primary unpaid caregiver for a community-dwelling PWD; provide at least 10 hours of direct care per week; able to read and understand English; be able to access the course online; naïve to Savvy or Tele-Savvy.

Exclusion Criteria: Those who cannot provide consent, are not yet adults (<18 years of age), prisoners, cognitively impaired adults, and who are not able to clearly understand English.

This study is proposed to benefit informal caregivers, and a proportion of the advisory board in Aim 1 will be included in the group activities for the design studio. Caregiver advisors will be involved in the development of the intervention.

11. Vulnerable Populations

N/A

12. Local Number of Participants

A total of 80 participants will be recruited locally.

13. Recruitment Methods

We will recruit the approximately 20 individuals (e.g., clinicians, educators, Tele-Savvy facilitators, and caregiver advisors) for Aim 1 activities from the investigative team's professional network. The proposed sample size of 20 for Phase 1 is justified by the proposed qualitative approach. For Aim 2, we will recruit the 60 subjects by reaching out to caregivers through a number of channels: Dr. Clevenger's IMCC has a current PWD enrollment of 625, most of whom are community dwelling; Dr. Epps's work with Atlanta area churches and African American families affected by dementia provides a large recruitment base; Dr. Hepburn's connections with Emory's Alzheimer's Disease Research Center (ADRC) and the statewide diagnostic and care planning Georgia Memory Net also offers a large base. In addition, Dr. Hepburn maintains contact with numerous organizations across the country that offer the Savvy Caregiver in-person program, and he will seek their assistance in recruitment. Existing collaborations with other ADRCs and organizations offering Savvy provides an even larger recruitment base. We will also recruit through various social media platforms. Recruitment material will provide information about the trial and phone and email contacts to indicate further interest. The proposed sample size of 60 subjects is modest, reasonable, and justified by through Browne's general rule of using a minimum of 30 participants to have the capacity to estimate a parameter for feasibility.

Verbal and email scripts (see attached) will be used by the investigative team to recruit through their professional networks for Aim1.

Flyers (see attached) will be used to recruit across all proposed platforms. For recruiting on social media, potential participants will see the flyer and will be directed to contact MPI for further information.

Potential participants will be screened via phone according to inclusion criteria. If eligibility criteria are met, participant will be consented by a member of the research team.

Participants will receive a $20 honorarium (gift card) for their completion of focus groups or timepoint interviews. Payments will be administered via mail to participants after their participation in each focus group and timepoint interview.

14. Withdrawal of Participants

We anticipate participants will be withdrawn from the study without consent when they do not respond to scheduling baseline and at least 1 follow up interview. When participants self-select to withdraw from the study, one of the PIs will follow up with the participant and confirm withdrawal. Participants can withdraw from the study at any time with no consequence. The team will then discuss if partial data can be included in analysis.

15. Risks to Participants

Protection against risks from participation in Design Studio activities. Participants in the sessions will be identified only by first names, and transcripts of the audio-recorded Design Studio sessions will be fully anonymized, so the threat to confidentiality will be virtually eliminated.

Risks from Research Interviews. There is virtual no risk to the confidentiality of the research data. All study subjects will be assigned ID numbers. The file linking the ID numbers to subjects' identities will be kept in a separate locked filing cabinet in MPI Epps' locked office. There is a minimal risk that participants might find that some elements of the research questionnaires provoke transient emotional responses. The research interviewer will be trained to be alert for such moments and will be able to provide reassurance, offer a break from the interview, and/or reschedule the remaining portion of the interview. In addition, a protocol from another study will be in place to identify participants whose scores on a set of three questionnaires exceed established limits; in such cases, one of the MPIs will contact the individual to check on his/her safety and well-being.

Risks from Participating in the Asynchronous Online Course. The course will engage participants in a series of self-guided reflections on the condition of the person for whom they are providing care, and it will present material that makes it clear that dementing illnesses are, by their nature, progressive and irreversible. Such reflection and information might cause transient emotional distress for the participant. The course will be framed in a manner that alerts participants to this risk. It will also contain content and exercises meant to assist participants to acknowledge and deal with these and other feelings of distress they might experience in their caregiving. As part of the course, participants will be asked to complete a variety of exercises before they can move to next segments of the course; among these will be exercises asking participants to gauge their own well-being and identify any troubling thoughts they might be experiencing. We will be monitoring these exercises, and if we observe any responses that suggest the possibility that an individual is considering harm to him/herself or to the care recipient, we will contact the person to discuss the situation and provide advice about help-seeking.

The participants to be recruited for this study are dementia caregivers. As such, the target sample, in itself, is not considered among vulnerable populations although we are sensitive to the fact that they may be highly distressed. It is possible that the participants may be pregnant women. We will not exclude women due to pregnancy, however, since their participation in the study is voluntary, they are able to withdraw at any time.

16. Potential Benefits to Participants

We will not assert to participants that taking part in the course will be beneficial to their caregiving, although we are hopeful it will. We will acknowledge that their participation may contribute eventually to the well-being of other caregivers, and this may prove rewarding for them.

17. Data Analysis, Management and Confidentiality

All data entry screens are set up in Research Electronic Data Capture (REDCap) and, where possible, include data delimiters (i.e., skip patterns, valid range limits) to ensure correctness and minimize missing data. Data will be exported into SPSS monthly and syntax run for cleaning, further data verification and file concatenation. Descriptive statistics will be computed through SPSS v 24 to examine participant characteristics. In

preliminary analyses, descriptive statistics and frequency distributions will be examined to identify outliers and ensure integrity of merged files. Analysis of variance (ANOVA) with repeated measures, non-parametric Kruskal–Wallis ANOVA, and Chi-Square tests will be used to assess preliminary efficacy and establish effect size for a larger study. Internal consistency will be examined using Cronbach's alpha and associated statistics (e.g., item-total correlations, alpha if item deleted). Formal test-retest/inter-rater reliability coefficients will be computed as data are concatenated. NVivo will be used to analyze qualitative data such as focus groups for Aim 1 and interviews for Aim 2. All audio recordings will be transcribed verbatim. The databases will be stored on a secure password-protected server and not on individual desktop computers. The code sheet will be password protected and the password will be updated annually.

The study team for this study will be comprised of the Principal Investigators (Drs. Epps and Clevenger), and Co-Investigator (Dr. Kenneth Hepburn). The MPIs will responsible for the day to day operations of the study including recruitment and data collection management and analysis. The administrative site will be at Emory University, Nell Hodgson Woodruff School of Nursing. All team members have completed CITI training. Study-specific training for staff who will be obtaining data by interview.

Dr. Epps is the primary individual charged with identification and reporting of all adverse events (AE) and serious adverse events (SAE). Dr. Epps will provide systematic routine monitoring for the following central elements: protocol eligibility (direct source documentation of eligibility as defined in the protocol), appropriateness of consent documentation, and timeliness and accuracy of data. Monitoring reports will be conducted on a bi-weekly basis and as needed, and will be reviewed at the weekly core team meeting of the investigator team.

All caregiver survey assessment data will be audited upon completion of the study. Each audit will consist of review and evaluation of: 1) conformance with informed consent requirements; and 2) individual subject case review to detect low data quality (e.g., inconsistent responses on a data element that should be the same throughout the study period, such as age within 1 year). All data that impact on the interpretation of primary study endpoints will be verified with source documents. Investigator compliance with the protocol also will be evaluated. We will encourage a culture of transparency to encourage self-report of protocol breaches.

18. Provisions to Monitor the Data to Ensure the Safety of Participants

The project MPI (Epps) will be responsible for ensuring participants' safety in this minimal risk, single-site Stage 1 intervention development study. Because this study is being conducted at a single site, involves fewer than 200 subjects, and is not a phase III clinical trial it does not require a Data Safety and Monitoring Board. Instead, the Assistant Dean for Research Operations and Training at the Nell Hodgson Woodruff School of Nursing (Dr. Drenna Waldrop-Valverde) has agreed to serve as the Safety Officer for the project.

Frequency of Data and Safety Monitoring

MPI Epps will be informed of any deaths as soon as they occur and will notify the NIA Program Officer and the Safety Officer (SO) within 24 hours of notification; the PI will also inform the Emory IRB of any such events within the time frame specified by the IRB. Beginning with the initiation of study phase 2 activities, MPI (Epps) will be responsible for providing quarterly summary reports of SAEs to the NIA Program Officer and the SO. Beginning with the initiation of phase 2 activities, safety reports will be sent to the SO twice a year and will include a detailed analysis of study progress, data and safety issues. Such reports will be developed by the co-PIs but reviewed by key study personnel and, as appropriate, study consultants and advisors.

Content of Data and Safety Monitoring Report

The study MPI (Epps) will provide semi-annual data safety and monitoring reports to the NIA Program Officer and the SO. Each report will update the previous report. Each report will summarize:

- Overall study status
- Study participant characteristics
- Study recruitment and retention statistics
- Data completeness
- Summary statistics on caregiver and care recipient outcome measures
- Deployment of the risk protocol based on observations or scale scores
- Unanticipated Serious Adverse Events, including Deaths.

Monitoring plan: This Data and Safety Monitoring Plan is intended to ensure the safety of participants and the validity and integrity of the data and reporting. The Clinical Research is to be performed in compliance within the guidelines of the National Institutes of Health (NIH) and the Emory University IRB. The MPI of the study are Fayron Epps, RN, PhD and Carolyn Clevenger, RN, DNP.

19. Provisions to Protect the Privacy Interests of Participants and Confidentiality of Participants' identifiable data

Under the direction of Drs. Epps and Clevenger, all data will be managed in a secure fashion. All of the data will be kept on a secure server. In all of the data files, data will be coded by identification number only. Participants' names will be separated from the data and kept on a secure server or in a locked file cabinet. Access to the secure server and the file cabinet will be strictly controlled by the MPI Epps at Emory University. Audio recordings of qualitative interviews will be destroyed after the completion of the study and transcripts are confirmed.

Participants will be informed that their personal information we only be shared with the members of the research team as they will used this data to contact them during business hours to schedule interviews.

We will allow participants to break up interviews to make them feel at ease with research interviews. The research interviewer will be trained to be alert for such moments where the participants may feel uncomfortable and will be able to provide reassurance, offer a break from the interview, and/or reschedule the remaining portion of the interview.

Results will not be placed in any of participants' medical records.

20. Economic Burden to Participants

Participant will be responsible for any cost associated with internet services during their time in this study.

21. Consent Process

Interested individuals will be contacted by the PI or member of the research team to screen for eligibility using inclusion criteria and to schedule a time to consent prior to data collection. If eligibility criteria are met, individuals will be scheduled to be consented by the study coordinator or investigator on the research team.

We will have 2 options to obtain consents. **Option 1.** We will email the consent document in an encrypted email to participants, discuss the informed consent over the phone or using Emory Zoom videoconference (using log in password), and have the participant email the signed consent back encouraging them to reply to the encrypted message. **Option 2.** We will email a link to the consent via REDCap (Part 11 validation) to the participant, discuss the informed consent over the phone or using Emory Zoom videoconference (using log in password), and have the participant provide an digital signature via REDCap. The uploaded consent to the IRB application will be used and uploaded to REDCap to obtain digital signature.

Consents will be obtained prior to data collection and investigators and the study coordinator will be responsible for obtaining consent.

The following measures will be implemented to minimize the possibility of coercion or undue influence: explaining the (a) voluntary nature of participation; (b) any alternatives to participating; (c) ability to withdraw at any time; and (d) fact that the decision whether or not to participate will have no impact on the availability of care through Emory Healthcare System.

All aspects of the study will be communicated to the participant. We will make it clear that this is a feasibility/pilot study. We will also make it clear that individuals will have opportunity to pose questions about the project. Consent will be sought and documented when provided. Consent discussion will take approximately 25 minutes.

In compliance with Emory University policy, the Fully Asynchronous Online Savvy program pilot/feasibility project will be registered with and information submitted to ClinicalTrials.gov in a timely manner. The informed consent procedure and its documentation will note the registration of the trials in ClinicalTrials.gov.

Non-English-Speaking Participants

- N/A

- As part of inclusion criteria, participants will be required to read and understand English. The reason for this exclusion of subjects with limited English proficiency is because the education program will only be provided in English.

22. Setting

The intervention will be delivered online and the research procedures for the study will be conducted by Emory University, School of Nursing. The research team will identify potential participants from the investigative team's professional network. In addition, Dr. Clevenger's IMCC has a current PWD enrollment of 625, most of whom are community dwelling; Dr. Epps's work with Atlanta area churches and African American families affected by dementia provides a large recruitment base; Dr. Hepburn's connections with Emory's Alzheimer's Disease Research Center (ADRC) and the statewide diagnostic and care planning Georgia Memory Net also offers a large base. In addition, Dr. Hepburn maintains contact with numerous organizations across the country that offer the Savvy Caregiver in-person program, and he will seek their assistance in recruitment. Existing collaborations with other ADRCs and organizations offering Savvy provides an even larger recruitment base. We will also recruit through various social media platforms.

23. Resources Available

We will recruit the approximately 20 individuals (e.g., clinicians, educators, Tele-Savvy facilitators, and caregiver advisors) for Aim 1 activities from the investigative team's professional network in the 1st month of the study. The proposed sample size of 20 for Phase 1 is justified by the proposed qualitative approach.

For Aim 2, we will recruit the 60 subjects by reaching out to caregivers through a number of channels: Dr. Clevenger's IMCC has a current PWD enrollment of 625, most of whom are community dwelling; Dr. Epps's work with Atlanta area churches and African American families affected by dementia provides a large recruitment base; Dr. Hepburn's connections with Emory's Alzheimer's Disease Research Center (ADRC) and the statewide diagnostic and care planning Georgia Memory Net also offers a large base. In addition, Dr. Hepburn maintains contact with numerous organizations across the country that offer the Savvy Caregiver in-person program, and he will seek their assistance in recruitment. Existing collaborations with other ADRCs and organizations offering Savvy provides an even larger recruitment base. We will also recruit through various social media platforms. The proposed sample size of 60 subjects is modest, reasonable, and justified by through Browne's general rule of using a minimum of 30 participants to have the capacity to estimate a parameter for feasibility. Participants for Aim 2 will be recruited over 5 months, with a target of recruiting 12 participants per month.

The study team for this study will be comprised of the Principal Investigators (Drs. Epps and Clevenger), and Co-Investigator (Dr. Kenneth Hepburn). The MPIs will responsible for the day to day operations of the study including recruitment and data collection

management and analysis. Each investigator on the study will devote up to 5% effort to conducting the study.

Emory School of Nursing has 95 faculty as well as 114 instructors, and students can learn from adjunct faculty at more than 500 clinical sites, including an alternative winter/spring break in four countries and a multi-university, multidisciplinary summer program with Georgia migrant farmworkers. The school has 8,268 alumni. The Nell Hodgson Woodruff School of Nursing Biobehavioral Research Laboratory includes 400 sq. ft. of dedicated space that serves as a resource for use by School of Nursing and affiliated researchers. This laboratory is equipped for processing and analyzing samples and is outfitted with a Beckman-Coulter refrigerated centrifuge, a 4-degree refrigerator, one -20 and three -80 freezers for long-term storage of clinical samples. Additionally, the lab is equipped with a biotech plate reader, ultra-pure water maker, pipettes, blood drawing supplies, processing tubes and other equipment and supplies needed to advance the range of biobehavioral research conducted in the School of Nursing.

Technology: Emory's information systems are critical resources and play an integral part in the fulfillment of the university's objectives of teaching, research and extension of knowledge to the public. All of the information technology offered through GSU to students, staff and faculty is fully supported by a large technology staff. In addition, in-person and online workshops and tutorials are available as requested for use of a wide range of computer technologies for individual use and classroom use. Emory's information technology (IT) services include access to software for use in the work and classroom environment with all the necessary security to ensure the integrity, confidentiality and availability of vital information technology resources. A fully staffed IT Help Center provides assistance for campus computing in-person, online, and by telephone. Emory provides high performance computing cycles for researchers including a large-scale computer system (IBM System p575, AIX operating system with high speed interconnect), centrally managed resource for use by campus researchers. One computer with media, software, internet, video-based conferencing and secure data base housing will be available for the duration of the project along with dedicated supplies and technology maintenance. An HP office jet printer with interface to the dedicated computer above will be available. Technical assistance will also be made available to the investigator to program tablets.

Office and Laboratory: The investigators have private offices in the School of Nursing. The offices are spacious, 230 square feet, with a telephone with voicemail, desktop computer, printer and file cabinets for data storage. Another private office located in the School of Nursing will serve as the investigator's lab for research team members to use to assist in the implementation and analyses of the proposed project.

A protocol from another study will be in place to identify participants whose scores on a set of three questionnaires exceed established limits; in such cases, one of the MPIs will contact the individual to check on his/her safety and well-being.

Weekly research team meetings will be held to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

24. Multi-Site Research when Emory is the Lead Site

N/A

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