Enhancing Social Functioning in Schizophrenia Through Scalable Mobile Technology
NCT03404219
Unique Protocol ID: 1 R21 MH111501-01
Version date 4.8.2020

IRB Office use only Date submitted_____ FB_____ Exp. ____

BU Charles River IRB
Application Form (Full Board and Expedited Review)

SECTION A: PROTOCOL AND CONTACT INFORMATION

Protocol Number (To be assigned by IRB Office):	4921
Protocol Title:	Motivation and Skills Support (MASS)
Principal Investigator (Name, degrees, licenses, etc.): ☒ Mr. ☐ Ms.	Daniel Fulford, PhD
Department/School:	Occupational Therapy, Sargent College
BU Mailing Address:	635 Commonwealth Ave, SAR-512
Email:	dfulford@bu.edu
Telephone:	617-358-2614
Additional Contact Person:	Lab coordinator
Email:	buamplab@gmail.com
Telephone:	

☒ YES **(REQUIRED)**	I confirm that I qualify to serve as the Principal Investigator of this study and am in compliance with the following policies: • http://www.bu.edu/researchsupport/compliance/human-subjects/

SECTION B: FUNDING

Provide information regarding **ALL** funding sources in this section. This includes **ANY EXISTING FUNDING, PENDING FUNDING, OR FUNDING THAT HAS BEEN APPLIED FOR TO SUPPORT THIS RESEARCH**.

Please check all that apply:	
☒	This research is funded Have you received Just In Time (JIT) Notification? ☒ Yes ☐ No
☐	Funding has been requested Have you received Just In Time (JIT) Notification? ☐ Yes ☐ No

	NOTE: Once the funding has been awarded, submit an amendment to the IRB to add the funding source
☐	Research is not funded

If the research is funded or funding has been requested, it is REQUIRED that you complete the box below. The Sponsor Award # must be included in the box below. If you don't have an award #, please state that in the box below. If you have multiple funding sources, add additional boxes as necessary.

Sponsor Name			National Institute of Mental Health (NIMH)
Title of Grant/Proposal			Enhancing Social Functioning in Schizophrenia through Scalable Mobile Technology
Sponsor Award # **(REQUIRED)*** ***If Award # is pending, put pending. Once the funding has been awarded, submit an amendment to the IRB to add the funding source**			R21MH111501-01
YES	**NO**		
☒	☐		Is Boston University the Prime Awardee of the grant?
☐	☒		Is Boston University receiving a sub-award? Name of Prime Recipient:

***NOTE:** Provide a copy of the grant application, funding proposal, scope of work, or sub-award agreement. The University is required to verify that all funding proposals and grants have been reviewed by the IRB before funds are awarded.

If this research study is for your dissertation, provide a copy of your prospectus (if available).

SECTION C: CONFLICT OF INTEREST

☒ YES **(REQUIRED)**	I confirm that **ALL** those responsible for the design, conduct, or reporting of the proposed program, including at minimum, all Senior/key personnel in the grant application, have completed the financial interest disclosure forms, submitted them to the COI office, and completed training as dictated at: http://www.bu.edu/researchsupport/compliance/conflicts-of-interest/, and as provided under *the Boston University Investigator Conflicts of Interest Policy for Research.* **NOTE: You must attach a copy of the PI's COI submission confirmation email. COI submission confirmation emails for all other study staff should be maintained at the research site.**
Of the financial interest disclosure forms submitted, did you check "yes" to any of the questions on either the FIND1 or NONFIND1 form? ☐ Yes* ☒ No	

***If you checked "yes" to any of the questions on either the FIND1 or NONFIND1 form, the IRB Director will contact the COI office to obtain the disclosure information.**

SECTION D: TYPE OF REVIEW

For Guidance regarding Type of Review please refer to the following website:
http://www.bu.edu/researchsupport/compliance/human-subjects/submitting-an-irb-protocol/

I. **FULL BOARD** ☒

Please refer to the IRB website for Full Board submission deadlines and meeting dates:
http://www.bu.edu/researchsupport/compliance/human-subjects/dates-and-timing-of-the-irb-committee/

II. **EXPEDITED** ☐

In order to qualify for expedited review, the study must be no more than minimal risk* **AND** must fall into one of the categories below. Check all that apply:

1. ☐ Clinical studies of drugs and medical devices only when an investigational new drug application (IND) or investigational device exemption application (IDE) is not required

2. ☐ Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. ☐ Prospective collection of biological specimens for research purposes by noninvasive means. Examples include hair and nail clippings, saliva or cheek swabs, sweat, etc.

4. ☐ Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.

   Examples:
   1. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy
   2. Weighing or testing sensory acuity
   3. Magnetic resonance imaging
   4. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
   5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

5. ☐ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)

6. ☐ Collection of data from voice, video, digital, or image recordings made for research purposes.

7. ☐ Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Note: The IRB will make the final determination on the Type of Review

***Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

SECTION E: STUDY STAFF AND HUMAN SUBJECTS TRAINING

List **ALL** current members of the research team in the table below. Add more rows as necessary.

STUDENT RESEARCH:
T**he Faculty Advisor must be listed as a co-investigator in this section and must complete the Human Subjects training requirements. Faculty Advisors are responsible for reviewing the IRB application, agreeing to serve as the Co-PI for this study with the student and are responsible for the ethical conduct of this student's human subjects research. Faculty Advisors must sign this Application prior to it being submitted to the IRB.**

BU CHARLES RIVER CAMPUS (CRC) INVESTIGATORS/STUDY STAFF

Note: Boston University Medical Campus (BUMC) investigators/study staff should be listed in the NON-BU INVESTIGATOR/STUDY STAFF section

Name, Degree, & Department/School	Study Role (e.g. co-investigator, research coordinator, research assistant, project manager, lab manager)	Human Subjects Training*
Daniel Fulford, PhD, Occupational Therapy/Sargent	PI	☒ CITI ☐ Other**:_____ Most Recent Date Completed: 2019
Kim Mueser, PhD, Occupational Therapy/Sargent	Co-Investigator	☒ CITI ☐ Other**:_____ Most Recent Date Completed: 2019
Samuel Abplanalp, B.A., Department of Occupational Therapy, College of Health & Rehabilitation Sciences: Sargent College	Graduate assistant	☒ CITI ☐ Other**:_____ Most Recent Date Completed: _2019
Kathryn Gill, BA, Department of Occupational Therapy, College of Health & Rehabilitation Sciences: Sargent College	Research Coordinator	☒ CITI ☐ Other**:_____ Most Recent Date Completed: 2018

Arti Gandhi, Department of Occupational Therapy, College of Health & Rehabilitation Sciences: Sargent College	Research assistant	☒ CITI ☐ Other**:_____ Most Recent Date Completed: _2017
Christina Colon-Semenza, PT, MPT, NCS, Department of Physical Therapy & Athletic Training, College of Health & Rehabilitation Sciences: Sargent College	Graduate assistant	☒ CITI ☐ Other**:_____ Most Recent Date Completed: _2017
Anup Dupaguntla, Department of Occupational Therapy, College of Health & Rehabilitation Sciences: Sargent College	Research assistant	☒ CITI ☐ Other**: Most Recent Date Completed: 2018
Alisa Gold, Department of Occupational Therapy, College of Health & Rehabilitation Sciences: Sargent College	Research assistant	☒ CITI ☐ Other**: Most Recent Date Completed: 2018
Emma Weizenbaum, MA, Department of Psychological and Brain Sciences/ CAS	Graduate Assistant	☒ CITI ☐ Other**:_____ Most Recent Date Completed: 2018
Jessica Mow, Department of Occupational Therapy, College of Health & Rehabilitation Sciences: Sargent College	Graduate Assistant	☒ CITI ☐ Other**:_____ Most Recent Date Completed: 2018

Jasmine Mote, PhD, Department of Occupational Therapy, Sargent College	Post-doctoral research associate	☒ CITI ☐ Other**: Most Recent Date Completed: 2018
Kathy Vong, Department of Occupational Therapy, College of Health & Rehabilitation Sciences: Sargent College	Research assistant	☒ CITI ☐ Other**:_____ Most Recent Date Completed: _2018__
Sophia Aburida, Department of Occupational Therapy, College of Health & Rehabilitation Sciences: Sargent College	Research assistant	☒ CITI ☐ Other**: Most Recent Date Completed: 2019
Liam Quidore, Department of Occupational Therapy, College of Health & Rehabilitation Sciences: Sargent College	Research assistant	☒ CITI ☐ Other**: Most Recent Date Completed: 2019
Tairmae Kanarloo, Department of Occupational Therapy, College of Health & Rehabilitation Sciences: Sargent College	Graduate assistant	☒ CITI ☐ Other**: Most Recent Date Completed: 2019

Shari Gordon, Department of Occupational Therapy, College of Health & Rehabilitation Sciences: Sargent College	Graduate assistant	☒ CITI ☐ Other**: Most Recent Date Completed: 2019
Riley Mcdonald, Department of Occupational Therapy, College of Health & Rehabilitation Sciences: Sargent College	Research Assistant	☒ CITI ☐ Other**: Most Recent Date Completed: 2020

*For more information regarding the Human Subjects Training Policy, refer to the 'Training' section of the Policies & Guidance section IRB website: http://www.bu.edu/researchsupport/training-how-to/human-subjects-training/. This site includes a Study Personnel Training List. You can search this list by name to obtain the completion and expiration dates of training for investigators and study staff.

**If the investigator/study staff did not complete CITI, you must submit a copy of his/her training certificate.

NON-BU INVESTIGATORS/STUDY STAFF* ☐ **N/A**

Note: BUMC and BMC staff are considered to be non-BU staff and should be listed in this section. Add more rows as necessary. All the columns in the box below must be completed. In addition, you must complete the box that follows with a description of the activities for each staff member.

Name, Degree, & Affiliate Institution	Study Role	Staff Information	Will IRB Approval be Obtained from Affiliate?
David Gard, PhD San Francisco State University	Co-Investigator	1. Will this staff interact with subjects? ☒ Yes ☐ No 2.Will this staff have access to identifiable information? ☒ Yes ☐ No 3.Is the work that the staff will complete related to his/her role or coursework at his/her affiliate institution.? ☒ Yes ☐ No	☒ Yes: Provide copy of IRB approval letter when available: ☐ No (provide reason): _____
Lawrence Leung, San Francisco State University	Research assistant	1. Will this staff interact with subjects? ☒ Yes ☐ No 2.Will this staff have access to identifiable information? ☒ Yes ☐ No 3.Is the work that the staff will complete related to his/her role or coursework at his/her affiliate institution.? ☒ Yes ☐ No	☒ Yes: Provide copy of IRB approval letter when available: ☐ No (provide reason): _____
Jake Gibson, San Francisco State University	Research assistant	1. Will this staff interact with subjects? ☒ Yes ☐ No 2.Will this staff have access to identifiable information?	☒ Yes: Provide copy of IRB approval letter when available: ☐ No (provide reason): _____

		☒ Yes ☐ No 3.Is the work that the staff will complete related to his/her role or coursework at his/her affiliate institution.? ☒ Yes ☐ No	
James Geri, San Francisco State University	Research assistant	1. Will this staff interact with subjects? ☒ Yes ☐ No 2.Will this staff have access to identifiable information? ☒ Yes ☐ No 3.Is the work that the staff will complete related to his/her role or coursework at his/her affiliate institution.? ☒ Yes ☐ No	☒ Yes: Provide copy of IRB approval letter when available: ☐ No (provide reason): _____
Julia Catalano, San Francisco State University	Research assistant	1. Will this staff interact with subjects? ☒ Yes ☐ No 2.Will this staff have access to identifiable information? ☒ Yes ☐ No 3.Is the work that the staff will complete related to his/her role or coursework at his/her affiliate institution.? ☒ Yes ☐ No	☒ Yes: Provide copy of IRB approval letter when available: ☐ No (provide reason): _____

Valerie La, San Francisco State University	Research assistant	1. Will this staff interact with subjects? ☒ Yes ☐ No 2.Will this staff have access to identifiable information? ☒ Yes ☐ No 3.Is the work that the staff will complete related to his/her role or coursework at his/her affiliate institution.? ☒ Yes ☐ No	☒ Yes: Provide copy of IRB approval letter when available: ☐ No (provide reason): _____
Jocelyn Barete, San Francisco State University	Research assistant	1. Will this staff interact with subjects? ☒ Yes ☐ No 2.Will this staff have access to identifiable information? ☒ Yes ☐ No 3.Is the work that the staff will complete related to his/her role or coursework at his/her affiliate institution.? ☒ Yes ☐ No	☒ Yes: Provide copy of IRB approval letter when available: ☐ No (provide reason): _____
Ana Nieto, San Francisco State University	Research assistant	1. Will this staff interact with subjects? ☒ Yes ☐ No 2.Will this staff have access to identifiable information? ☒ Yes ☐ No 3.Is the work that the staff will complete	☒ Yes: Provide copy of IRB approval letter when available: ☐ No (provide reason): _____

		related to his/her role or coursework at his/her affiliate institution.? ☒ Yes ☐ No	
Luna Rivera	Research assistant	1. Will this staff interact with subjects? ☒ Yes ☐ No 2.Will this staff have access to identifiable information? ☒ Yes ☐ No 3.Is the work that the staff will complete related to his/her role or coursework at his/her affiliate institution.? ☒ Yes ☐ No	☒ Yes: Provide copy of IRB approval letter when available: ☐ No (provide reason): _____

*If IRB approval will be obtained from the affiliate site, only list the lead investigator from the affiliate on this form.

The box below must be completed. Include a summary for each staff listed in the above box. If any of the investigators listed on this form are not affiliated with BU, provide a summary of the study activities that he/she will conduct. If IRB approval is not being obtained at the 2affiliate institution, provide an explanation. **NOTE: Non-BU staff may be required to complete an Individual Investigator Agreement (IIA). The IRB will notify you if this form is required.**

Dr. Gard is a Co-Investigator on this grant. He will be involved with planning of the research activities and data analysis.

Lawrence Leung, Jake Gibson, James Geri, Julia Catalano, Valerie La, Jocelyn Barete, Ana Nieto, and Luna Rivera are all research assistants who will be responsible for assisting with research activities; including participant recruitment, data collection, and analysis.

REQUIRED GOOD CLINICAL PRACTICE TRAINING FOR NIH-FUNDED CLINICAL TRIALS

YES*	NO	NIH-FUNDED CLINICAL TRIALS
☒	☐	Is your study NIH-Funded AND meet the definition of a clinical trial as defined below: **Clinical Trial**: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those intervention on health-related biomedical or behavioral outcomes. This definition encompasses phase 1 trials of FDA-regulated drug and biological products, small feasibility studies of FDA-regulated device products, and studies of any intervention not regulated by the FDA, e.g. behavioral interventions. Of note, this requirement for GCP training applies to both biomedical and behavioral clinical trials funded by the NIH. On January 1, 2017, a new policy of the National Institutes of Health (NIH) goes into effect that requires all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP). The policy applies to all active grants and contracts, no matter what point they are in the life cycle of the trial. Currently, there is a GCP course available in our CITI training program (https://www.citiprogram.org/). This current course does have a focus on FDA-regulated research. Please note that online social-behavioral GCP courses are under development and we expect to have a social-behavioral focused GCP course available in the near future. If this study meets the definition, all staff must complete GCP training. For more information on this policy please refer to: • NIH definition of a Clinical Trial: http://osp.od.nih.gov/sites/default/files/NIH%20Definition%20of%20Clinical%20Trial%2010-23-2014-UPDATED_0.pdf • Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html

		• Frequently Asked Questions: http://osp.od.nih.gov/sites/default/files/FAQs_on_NIH_GCP_Policy.pdf

SECTION F: LOCATION OF THE RESEARCH

YES*	NO	
☒	☐	Will this research take place at sites/locations other than Boston University? Note: If the research will take place at Boston University, state the location (Building and Room number):

*If **YES,** please complete the boxes below

NOTE: You are responsible for obtaining permission/letters of support for research conducted off-site. This may include locations such as schools, workplaces, community organizations, etc. You must submit the letters/documentation of support with this application.

Institution Name and Address (if known)	**Describe Involvement (recruiting, consenting, data analysis, etc.) of the site. If the site or the site staff is not involved (engaged)[1] in research procedures, state NONE.**	**IRB/Ethics Approval/Site Permission Attached? If no[2], explain the plan to obtain this approval. If the site is not engaged in the research, you do not need to complete the box.**
San Francisco State University, 1600 Holloway Ave, San Francisco, CA 94132	Researcher at SFSU will be involved with recruiting, consenting, and collecting data.	No (A cede review form as been submitted to indicate that BU will be the IRB of record.)

[1]Guidance on Engagement of Institutions in Human Subjects Research: http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

[2]If IRB approval will not be obtained at the site, describe the IRB oversight arrangements here:

YES*	NO	
☒	☐	Is the off-site location requesting that the Boston University IRB review the protocol in place of local IRB review?

		*If **YES**, complete the Single IRB Review Form "Boston University is Institution A": http://www.bu.edu/researchsupport/compliance/human-subjects/.

YES*	NO	
☒	☐	Is the BU PI the lead investigator **OR** is BU the lead site for this research? **Note: This box only needs to be completed if the off-site location is engaged in the research.**

*If **YES**, provide the following information in this box:

- The plan for collection and management of data from all the sites:

After consent, data from pilot testing will be collected and recorded at both locations. This data will be de-identified before being shared between locations. Procedures for ensuring confidentiality at both sites include training of all study staff and regular meetings among Investigative team, including regular review of procedures. Steps to ensure confidentiality include: confidentiality training for all new employees and refresher seminars annually for all clinical referrers; identifying subjects by an arbitrary number; filing ID number key lists separately from data; removing or obscuring participant names from any forms; using an acronym in return addresses on any correspondence to participants; sorting all data in locked file cabinets; securing all computers that store data; and destroying audio files used for interviewer reliability checks and fidelity ratings at the end of the project. All research staff will fulfill the educational requirements set forth by NIMH and the Office for Human Research Protections.

- The plan for reporting and evaluating:
  - Unanticipated problems
  - Serious and/or continuing non-compliance
  - Suspensions and terminations of research
  - Interim results
  - Protocol modifications

Any of the above occurrences will be immediately reported to the PI and proper steps will be taken for evaluation.

- The name of the Principal Investigator from each site

Daniel Fulford (BU), David Gard (SFSU)

- If IRB approval will be obtained at the site, confirmation that you have a copy (or will obtain a copy) of the IRB approval letters and the IRB-approved protocols from each site
- If IRB approval will be obtained at the site, confirmation that the site IRB has a federalwide assurance (FWA)

YES*	NO	
☐	☒	Will this research be conducted outside of the United States?*

*If **YES**, complete the International Research Form at
http://www.bu.edu/researchsupport/compliance/human-subjects/

SECTION G: STUDY SUMMARY

Summarize the study in lay language (do not copy from the grant/scope of work/proposal, etc.). This summary should include the research design, purpose, objectives, research question, hypothesis, and any relevant background information.

Note: Do not include a list of citations in this section. Please limit this section to no more than 300 words.

Schizophrenia is a severe mental illness that affects millions of people worldwide. The illness is often associated with social impairments, including limitations in verbal and non-verbal behavior, initiating conversations, and social motivation. People with schizophrenia often report a desire to socialize but expend less effort in the actual behavior and set fewer socially-related goals than others. While diminished social motivation is not fully understood, past research suggests a reduced ability to connect past, pleasurable experiences with current states, resulting in reduced effort for social connection in people with schizophrenia. Because this reduced effort for social connection may cause people with schizophrenia to have difficulty obtaining relationships they desire, it is important to focus on factors that are modifiable, such as social skills and motivational deficits. Interventions that target these impairments usually take place at mental health clinics, but there is a growing recognition that people with schizophrenia need assistance with these skills outside of a clinical setting.

Findings from an ongoing study (i.e., Aims 1 and 2 of the larger grant; (NIMH# R21MH111501-01, IRB protocol #4394) will inform development of a pilot intervention study examining the impact of this mobile application on social functioning over time. We will employ a two-site study to test the application in a group of 30 persons with schizophrenia over a 60-day period. We will measure social functioning at baseline, intervention termination, and 90-day follow-up using clinician administered interviews and self-report questionnaires. We hypothesize that levels of social functioning will increase significantly from baseline to post-intervention and follow-up, and that these increases will be accompanied by increased self-reported social motivation using periodic measures incorporated into the mobile application.

SECTION H: RESEARCH METHODS AND ACTIVITIES (Check all that apply)

☒	Collection of audio, video, digital, or image recordings
☐	Biological samples → **Complete Biological Samples Form:** http://www.bu.edu/researchsupport/compliance/human-subjects/ Examples: blood, hair, cheek swab, urine, tears, saliva, etc.
☐	Collection of data that may be sensitive and if disclosed could put subjects at risk for legal or social harms. Examples: Illegal behaviors, HIV status, psychiatric illness, information related to sexual behaviors, etc.
☐	Coordinating Center/Lead Site
☐	Deception
☐	Devices → **Complete Devices Form:** http://www.bu.edu/researchsupport/compliance/human-subjects/
☐	Drugs → **Complete Drugs Form:** http://www.bu.edu/researchsupport/compliance/human-subjects/
☐	Ethnographic: The study of people in their own environment through the use of methods such as participant observation and face-to-face interviewing
☐	Focus Groups
☐	Genetics Testing → **Complete Genetics Form:** http://www.bu.edu/researchsupport/compliance/human-subjects/
☐	MRI
☐	Placebo
☐	Pregnancy Testing
☐	Randomization
☒	Surveys, interviews, questionnaires
☐	Secondary Data Analysis
☒	Other (please describe): Behavioral task (Stop Distance Paradigm)

SECTION I: SUBJECT POPULATION

Number of Subjects to be Enrolled: If you have sub-groups or more than one arm, please separate out these enrollment numbers. **Note: Please account for subjects who may drop out or be withdrawn from the study. Any subject who signs a consent form is considered to be enrolled regardless of whether they complete any study procedures**	50 people with schizophrenia or schizoaffective disorder

Check all categories that apply to your target population:	
☒	Adults
☐	Children (< 18 years of age)
☐	Cognitively-Impaired Adults
☐	Non-English Speaking
☐	Prisoners
☐	BU Employees
☐	BU Students
☐	Wards of the state
☐	Other (please describe):

If Categories other than 'Adult' are checked, describe the additional safeguards that have been put in place to protect that subject population. For Cognitively-Impaired Subjects, provide the rationale for including this population in this research study.

Eligibility Criteria
Inclusion Criteria: All participants with schizophrenia or schizoaffective disorder (identified either by chart diagnosis or by using the Structured Clinical Interview for DSM-5 [SCID-5]), between 18 and 65 years old (as to not confound developmental issues with our focus), and fluent in English.
Exclusion Criteria (exclusion criteria are the specific criteria which would disqualify an individual from participating in the study not simply the opposite of the inclusion criteria): We will exclude participants with a current (past 6 months) substance use disorder, which will be determined by administration of the SCID-5, self-reported current suicidal ideation with intent and/or a plan (assessed using attached instrument; i.e., "High" risk), or self-reported diagnosis of a current/ongoing neurological disorder (i.e. not managed with medication). We will exclude participants who have been hospitalized in the past month for mental health reasons or for life threatening physical conditions (such as stroke or heart attack). Potential participants who have a guardian and cannot sign consent independently will be excluded.

SECTION J: RECRUITMENT

Provide a summary of the recruitment process, including who will recruit, when and where recruitment will occur, and how subjects will be identified **Note: Submit any recruitment materials such as advertisements, brochures, flyers, letters/e-mails, scripts, etc. Please submit these materials as separate documents in either Word or PDF format.**
Participants with schizophrenia or schizoaffective disorder will be outpatients recruited from clinics within the Boston and San Francisco community, including the BU Center for Psychiatric Rehabilitation (CPR). Flyers will be posted throughout the CPR and around the community as well. The investigators have extensive contacts in this community. Potentially eligible consumers will also be identified through informing clinicians and recovery center instructors at each site about the study and eligibility criteria for participation. We will provide clinicians with study flyers. We will also verbally brief all partnering clinicians on the overall study aims and goals. They will have access to the consent form for review Referrals to the study will be made by either consumers' providers or by recovery center instructors (at CPR). When a referral is made, the consumer's provider/instructor will meet with the consumer to briefly explain the project. If the consumer is potentially interested in participating in the project, the referrer will arrange for the consumer to contact the Project Coordinator by phone or in person, who will ask the screening questions (see attached phone screen form). Eligible consumers who express interest in participating in the study and are able to correctly answer questions about the project (demonstrating their comprehension) will attend an in-person

meting to provide signed informed consent. For those participants recruited from CPR, diagnostic information will be obtained by self-report, and substance use disorder will be assessed by SCID-5. For participants from outside the CPR interested in the study, we will confirm diagnosis and substance use disorder using the SCID-5. Consumers who complete the SCID-5 will be paid $10, regardless of whether they meet additional eligibility criteria (i.e., diagnosis). The SCID-5 will be administered by trained research staff. Consumers who do not meet eligibility criteria will be informed of this.

SECTION K: CONSENT AND ASSENT

NOTE: Please refer to the consent and assent form templates on the IRB website when creating your consent/assent documents. The templates include the required elements of consent and will help to ensure that your consent/assent form meets the requirements of the federal regulations and the BU CRC IRB. The consent templates can be located at: http://www.bu.edu/researchsupport/compliance/human-subjects/.

Note: STUDENT RESEARCHERS must: 1) indicate in the consent form/information sheet/script that he/she is a student and 2) list the Faculty Advisor as a contact in the form/sheet/script.

Provide a summary of the consent process, including who will consent, and when and where consent will occur. The summary should include, as appropriate, any waiting period between informing the prospective participant and obtaining consent, that the prospective participant or the legally authorized representative has sufficient opportunity to consider whether to participate, and steps taken to minimize coercion or undue influence.

Note: Submit copies of all consent forms and scripts. Please submit these materials as separate documents in Word format.

Written consent will be obtained for all study procedures. Those with a guardian who cannot independently consent will be excluded from the study. All consent forms will be provided by trained researchers. Written consent will be provided prior to participation in the study, and participants will have as much time as they would like to consider whether they will participate. There is no time limit for making a decision about whether to participate. Consenting will take place in private areas at Boston University's Center for Psychiatric Rehabilitation or the PIs' laboratories.

Prior to the study the researcher/interviewer will ask the person if they could explain what their understanding is of the study they are being asked to be involved in. In addition to allowing time for participants to read the consent form, the specific contents of the consent form will be discussed with each participant, and any questions will be answered. Participants

must be fluent in English to participate in this study. The participants will receive a copy of the informed consent form with the primary researcher's contact information. All consent forms are attached to this application.

Indicate the consent and/or assent process and document(s) to be used in this study. Check all that apply

Consent: Adults (≥18 years of age) N/A ☐ **One of the following MUST apply**	
☒	Consent Form/Information Sheet
☐	Verbal Consent (Script) **Note: If written consent will not be obtained, complete the 'Waiver of Written Documentation Consent' box (Box 1) located further down in this section**
☐	Consent will not be obtained **Note: If consent will not be obtained, complete the 'Waiver or Alteration of Consent' box (Box 2) located further down in this section**

Assent of Children (≤ 18 years of age) N/A ☒ **One of the following MUST apply**	
☐	Assent Form OR Parent Consent Form/Information Sheet (older children may sign the parent consent form along with their parents as long as the consent form is written at the grade level of the subjects)
☐	Verbal Assent (Script)
☐	Assent will not be obtained **If assent will not be obtained, one of the following conditions must exist:** 1. ☐ The capability of some or all of the children is so limited that they cannot reasonably be consulted 2. ☐ The children are too young to provide assent

	3. ☐ The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research 4. ☐ The research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at 45 CFR 46.116(d)*. **(Complete the 'Waiver or Alteration of Consent' box (Box 2) located further down in this section)** ***45 CFR 46.116(d):** **http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html**
Guidance on age requirements for obtaining assent: • **Parental Permission for minors under 6 years of age** • **Verbal assent for minors 6-11 years of age** • **Written assent from minors ages 12-17 (unless verbal consent is approved for the parents/adult subjects**	
Parental Permission **N/A ☒** **One of the following MUST apply**	
☐	Parental Consent Form
☐	Parental Verbal Consent (Script) **Note: If written consent will not be obtained, complete the 'Waiver of Written Documentation of Consent' box (Box 1) located further down in this section**
☐	Parental permission will not be obtained **If parental permission will not be obtained, one of the following conditions must exist:** 1. ☐ The research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children).

	2. ☐ The research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at 45 CFR 46.116(d)*. **(Complete the 'Waiver or Alteration of Consent' box (Box 2) located further down in this section)** ***45 CFR 46.116(d):** **http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html**

Consent: Cognitively Impaired Adults (≥18 years of age) **N/A ☒** **Describe the process for the consent and/or assent process for enrolling cognitively impaired adult subjects including how capacity to consent is determined and if there is continual assessment of capacity**	
Assent will be obtained from: ☐ All Subjects ☐ Some Subjects, specify: ☐ No Subjects	
☐	Consent will be obtained from the subject's Legally Authorized Representative **(REQUIRED)**

CONSENT OF NON-ENGLISH SPEAKING SUBJECTS **N/A ☒** **Describe the process for obtaining consent from non-English speaking subjects. List the individual who will serve as the interpreter and his/her qualifications.** **NOTE: A copy of the translated consent along with the Attestation Form for Translation of Consent must be submitted. The Attestation Form can be located at:** http://www.bu.edu/researchsupport/compliance/human-subjects/.

BOX 1—WAIVER OF WRITTEN DOCUMENTATION OF CONSENT

WAIVER OF WRITTEN DOCUMENTATION OF CONSENT N/A ☒ **Either Criteria 1 or 2 must be met in order to qualify**	**Yes**	**No**
☐ **Criteria 1**		
The research is **NOT** FDA Regulated	☐	☐
The only record linking the subject and the research would be the consent document	☐	☐
The principal risk would be potential harm resulting from a breach of confidentiality	☐	☐
Each subject will be asked whether the subject wants documentation linking the subject to the research and the subject's wishes will govern	☐	☐
A written statement/information sheet will be provided to subjects. If **NO**, provide rationale for not providing this information	☐	☐
☐ **Criteria 2**		
The research is **NOT** FDA Regulated	☐	☐
The research presents no more than minimal risk of harm to subjects	☐	☐
The research involves no procedures for which written consent is normally required outside of the research context	☐	☐
A written statement/information sheet will be provided to subjects. If **NO**, provide rationale for not providing this information	☐	☐

BOX 2—WAIVE OR ALTERATION OF CONSENT

WAIVER OR ALTERATION OF CONSENT N/A ☒ **All of the criteria below must be met in order to qualify**	**Yes**	**No**
The research is **NOT** FDA Regulated	☐	☐
The research involves no more than minimal risk to the subjects	☐	☐
The waiver or alteration will not adversely affect the rights and welfare of the subjects	☐	☐
The research could not practicably be carried out without the waiver or alteration	☐	☐
Whenever appropriate, the subjects will be provided with additional pertinent information after participation. If **NO**, provide rationale for not providing this information:	☐	☐

Provide the justification/rationale for why this study meets the above criteria for waiving or altering consent (REQUIRED):

SECTION L: STUDY PROCEDURES

In the box below provide a detailed description of the study procedures to be performed (preferably in sequential order). Be sure to specify which procedures are for research purposes versus which procedures are part of standard of care, if applicable. Be sure to include the following information:

- **Methods of data collection**
- **Details regarding research activities/procedures/interventions**
- **Number, frequency, duration and types of subject contacts (visits, phone calls, internet surveys, mailings, etc.)**
- **Time required from each subject**
- **Use of equipment (eye-tracker, treadmill, sensors, etc.). Provide a brief description of equipment that will be used in the study.***

***Note: The IRB may request more information about the equipment (including equipment manuals) and/or request that you submit Appendix C: Device Form.**

Submit copies of all surveys, interview questions, assessments, screening scripts, etc. that will be used during the conduct of this study. Please submit these materials as separate documents in either Word or PDF format.

Note: If subjects will have standard of care procedures in addition to research procedures, clearly state which procedures are standard of care and which are for research purposes only.

Note: The procedures below include only Phase II of this research study. This will include a pilot intervention trial of the mobile support tool developed in Phase 1: the Motivation and Skills Support (MASS) application (IRB Protocol #4394).

The MASS Application

The MASS application includes 1) the identification of a social goal from a list of prototypes (e.g., develop a friendship with someone at school), 2) twice daily reminders of the selected social goal and associated steps/subgoals, 3) assessment of progress on the selected social goal and associated affect, and 4) social skills training video displays. All of these features are delivered via notifications from the app. In addition, the app gathers geo-location (i.e., GPS) data that is triangulated with self-reported activity as a proxy for goal-striving. In Phase 1, we ran focus groups with consumers and individual interviews with expert clinicians with the aim of

identifying meaningful social goals and use of mobile phones in this population. Qualitative feedback informed app development. We are currently conducting usability testing in a small group of consumers over 2-week periods of use of our MASS application. Consumers provide feedback in individual interviews following app use to help improve app features. All procedures in the current study are for research purposes, and not related to standard of care.

Phase II: Pilot Testing of the MASS Application

Following our current usability testing (anticipated completion: August 2018), we will employ a two-site study to test the MASS application in a total of 30 persons (we will recruit up to 50 people to account for attrition, ending up with complete data on 15 persons per site) with schizophrenia or schizoaffective disorder over a 60-day period. We will measure social functioning at baseline, intervention termination, and 90-day post-intervention follow-up using the Social Functioning Scale (SFS) and the Quality of Life Scale (QLS). Social cognition and preference for personal space will be measured with the Stop Distance Paradigm. We will also measure symptoms and cognitive function with the Brief Psychiatric Rating Scale (BPRS) or the Wide Range Achievement Test (WRAT), the Clinical Assessment Interview for Negative Symptoms (CAINS), Penn Emotion Recognition Task (ER-40) and the Brief Assessment of Cognition Schizophrenia (BACS). Self-report measures to assess theory of motivation and social skills will also be administered. Self-report measures and the ER-40 will be administered through Qualtrics. Demographic information will be collected through a custom questionnaire and the Structured Clinical Interview for DSM-5 [SCID-5]). Participant satisfaction questionnaire will also be administered at termination and a subset of the satisfaction questions will be administered at follow up.

Procedures

Baseline Assessment. After providing informed consent, participants will complete diagnostic and clinical evaluations at the Center for Psychiatric Rehabilitation or in the Fulford or Gard laboratories. The assessment procedures will involve a total of 4 hours for the completion of clinical interviews, demographics questionnaires, cognitive/behavioral tests, and community functioning measures, conducted over 1-2 days as needed by participants. At the conclusion of the assessment, the participant will be issued a mobile phone and trained on its use. They will identify a social goal and work with study staff to lay out sub-goals and steps necessary to achieve them—this goal will be programmed into the mobile app based on a pre-defined set of available goal prototypes. Participants will be oriented to all application components during this visit. They will also be given instructions to watch the social skill video clips within the app.

*Mobile Intervention***.** Research assistants will call participants the day after the initial meeting and will provide instruction on watching 4 brief summaries of the social skills training video clips (each video summary is approximately 10 minutes in length). They will then be called 1-2 days later to check in on video watching and will be instructed to watch the second video summary. 1-2 days later they will receive another call to again check in and will be instructed to watch the final summary. Call frequency will be based on participant preference. We will also provide follow up calls based on adherence to EMA reports (ascertained by logging onto the mobile app's researcher portal online) throughout the course of the 60-day intervention trial.

Participants will always have the option of calling our laboratory to discuss any issues with the phone or mobile intervention.

Use of the MASS application over the 2-month intervention period will involve interaction with social goal-related content based on pre-programmed notifications that alert the participant 2 times per day, 7 days per week. These notifications involve reminders of the identified social goal and associated steps—once in the morning and once in the evening. All notifications expire after a period of one hour.

If the phone is lost, that we will do whatever we can to replace the phone. If the phone cannot be replaced (e.g., due to budget availability), we will notify the consumer that their study participation will be discontinued. Data collected up to the point of the phone being lost will be used for analysis.

Follow-Up Assessments. Participants will return again after the 60-day intervention period for a 2-hour follow-up session to complete outcome measures. They will again complete an in-person assessment 90 days following intervention termination. Audio and video recordings of participants may also be collected during interviews and assessments for training purposes and to verify records collected during the study. Recordings will be kept for 7 years per Boston University (BU) Record Retention Policy.

Some participants may endorse distress during interview-based and self-report measures. For example, the BPRS asks questions around suicidal ideation. To clarify any potential risk reported using these measures, immediately following completion of these measures the researcher will follow up with any participants reporting on any suicidal ideation. They will ask the participant a series of follow up questions to better understand the general level of risk (see attached SI Follow-up Script). For those participants in which there is any concern of current suicidal ideation, as indicated by the follow up questions, the research assistant will notify one of the study staff clinical psychologists by cellular phone (a clinical psychologist will always be available by phone during all study sessions).

The clinical team member on call will then perform a standard risk assessment with the participant, guided by the Suicidal Ideation Follow Up Script document. In this situation, the clinician will provide recommendations/referrals for mental health services for those deemed at any level of risk of suicide. In addition, the clinician will counsel the subject on the benefits of seeking help (i.e., with a therapist or other professional). For those expressing suicidal ideation with a plan and/or intent (as indicated by responses to the standard follow up questions), the clinician will follow standard protocol by assessing risk for *immediate* harm to self. If harm is immediate, the clinical team member will request to contact the subject's treatment provider. Should no treatment provider be available, the research assistant will arrange for transportation to the relevant clinic (i.e., emergency room) with the subject's confidant (e.g., therapist, friend, loved one). If the participant is unwilling/able to do this, the clinician will call 911 to have the participant escorted to an emergency room. For those participants for whom there is not considered to be a risk of suicide, study staff will provide the participant with information regarding local mental health clinics (i.e., contact information for local community mental health centers; these materials are located in the PI's lab and readily available for distribution). In

addition, the researcher will counsel the subject regarding the benefits of seeking help from a therapist or other provider.

Measures

Name	**Domain**	**Time Point**
Social Functioning Scale (SFS)	Social Functioning	B, T, F
Quality of Life Scale (QLS)	Social Functioning	B, T, F
Brief Psychiatric Rating Scale (BPRS)	Psychiatric Symptoms	B, T, F
Clinical Assessment Interview for Negative Symptoms (CAINS)	Psychiatric Symptoms	B, T, F
Stop Distance Paradigm	Social Cognition	B, T, F
Penn Emotion Recognition Task (ER-40)	Social Cognition	B
Brief Assessment of Cognition Schizophrenia (BACS)	Neurocognition	B
Wide Range Achievement Test (WRAT)	Neurocognition	F
Self-reports: Implicit Theory of Motivation (TOM), Implicit Theory of Social Skills (TOSS)	Social Cognition	B
Self-Reports: Birchwood Social Functioning Scale	Social Functioning	B, T, F
Satisfaction Questionnaire.	N/A	T, F
Demographics	N/A	B

*B = Baseline; T = Termination; F = Follow-up

Analyses

Primary analyses will examine changes in social functioning across the study period using multivariate models accounting for covariates of interest (e.g., demographics, cognition). This mobile application is both an intervention and assessment tool. Thus, during the intervention we will be able to measure additional targets of interest, social motivation and functioning, using the EMA reports of positive affect in anticipation of social interactions, as well as reports of actual engagement in interactions, throughout the intervention period.

This study is a within-subject experimental design. Consistent with an experimental therapeutics approach, our primary goal is to identify change within the treatment targets (social anticipatory pleasure and presence of social interaction). Accounting for up to 20% attrition, we aim to recruit 50 participants, allowing for 20 participants to drop out/not meet criteria and still leave adequate power for primary analyses. Our primary aims are to pilot test the intervention to determine feasibility and efficacy in the treatment targets (social skills and motivation) and outcome (social functioning).

SECTION M: RISKS

Describe any expected risks to subjects. Consider physical, psychological, social, political, legal, economic, or other risks that are related to the study.

There are some risks associated with participation in the study. The primary risks involve loss of confidentiality associated with pilot testing of the mobile application. It is also possible that some participants may feel some frustration when participating in the MASS application. Participants may also feel discomfort answering questions about their health in the clinical assessments.

Describe the plan to minimize risks. Include in the description the availability of any medical or psychological resources.

Research staff will receive guidelines and supervision about how to respond to consumers' distress that may arise (albeit rarely) during the pilot testing (during phone or in-person check-ins). A number of options are available for dealing with such distress, including discussing the distress with the consumer, practicing a relaxation exercise (e.g., relaxed breathing), taking a break from app use, evaluating the cause of the distress and addressing it, or meeting with their clinician. These strategies have proved useful for our active mobile assessment and intervention studies.

To address possible discomfort that might arise during interviews, all consumers will be informed that information obtained during assessments is confidential and that they can choose not to answer certain questions if they prefer not to. If consumers feel uncomfortable they will be encouraged to take a break and continue the assessment later, or will be offered to stop the interview. The research interviewer may also offer to call the consumer's case manager, another staff member, or concerned others (such as a close friend) to make sure the consumer has someone to talk to about the assessment. In our prior research on consumers over the past several decades, few consumers have expressed discomfort from participating in interviews and assessments. In regards to interviews, we will remind all participants before and during the sessions that all information shared in these sessions should be held in the strictest confidence.

Participants will be clearly informed that they may choose not to participate in any of the tasks should they experience any discomfort at any time. If a participant chooses to discontinue participation at any time, he or she will still receive payment for his or her participation. Participants will have the option to turn off the app at any time—they will be informed of this option verbally and on the consent form, and shown how to do it prior to initiating the study.

SECTION N: BENEFITS

Describe the potential benefits to subjects related to the study. State if there are no direct benefits. **NOTE: Compensation and/or course credit are not considered benefits.**
There are no known direct benefits related to participation in the study.

Describe the potential benefits to society and/or others related to the study
Innovations stemming from this study may help future patients with schizophrenia in coping and improving deficits in social functioning. The benefits of this study outweigh the minimal risks of psychological discomfort and/or minimal risks of loss of confidentiality. Given possibility of only minimal risks, combined with the prospect of improving key aspects of social functioning, this study results in a favorable risk/benefit analysis.

SECTION O: COSTS/PAYMENTS

YES*	NO	
☐	☒	Are there any costs to subjects as a result of participating in this study? *If YES, provide a description of the costs:
☒	☐	Will subjects be compensated for participating in the study? Compensation may include cash, checks, gift cards, lotteries, course credit, etc. *If YES, provide a description of the compensation: Those involved in the pilot testing will be paid $15 per hour for the baseline assessment (4 hours total), $50 for completing the 60-day mobile intervention, and $15 per hour (2 hours) for completing the follow-up assessments. We will also give them the mobile phone used during the study to keep. In addition, those who complete the SCID-5 as a screening procedure will be paid $10. The $15 per hour rate begins after screening procedures. **NOTE:** Payments should be prorated to compensate subjects for time and procedures completed

☐	☒	Will identifiable information be sent to Central University departments (Accounts Payable, Post Award Financial Operations, etc.) for payment purposes? *If YES, this information must be disclosed in the consent form.

SECTION P: CONFIDENTIALITY OF DATA

Describe how data will be stored (e.g. paper, electronic database, etc.)
All study staff will be trained on the protection of confidentiality of data at regular project meetings. Steps to ensure confidentiality include: confidentiality training for all new employees and refresher seminars annually for all clinical referrers; identifying subjects by an arbitrary number; filing ID number key lists separately from data; removing or obscuring participant names from any forms; using an acronym in return addresses on any correspondence to participants; sorting all data in locked file cabinets; securing all computers that store data; and destroying audio files used for interviewers at the end of the project. All data gathered on mobile devices is encrypted using industry standard techniques. In the event that the phone is lost or stolen, the data is protected. Data is stored in an encrypted format in a directory on the phone allocated by operating system for this purpose. Data from this directory is periodically uploaded to the server in its encrypted format. Even if the phone were hacked, and the upload redirected to another server, the data would be useless to the hacker without the key, stored separately on a secure server. Once on the secure server, the data is decrypted, parsed, and inserted into an internal server. As soon as the data is successfully uploaded to the servers, uploaded data is validated, and then the data is wiped from the phones. All collected data will be de-identified before being shared between research sites. All research staff will fulfill the educational requirements set forth by NIMH and the Office for Human Research Protections.

Per Boston University (BU) Record Retention Policy, records concerning human subjects must be retained for 7 years. Please refer to the policy at: http://www.bu.edu/policies/finance/record-retention/. As the investigator, you must also adhere to all applicable requirements as defined by regulatory agencies (e.g. FDA, etc.) or Sponsors.

YES*	NO	
☒	☐	Will you collect identifiable information? (e.g. names, social security numbers, addresses, telephone numbers, etc.) *If YES, complete the box below

Describe the coding system* that will be used to protect the information including who will have access to the code

***Coding system: Coding systems are used to: 1) protect the confidentiality of the research data and 2) allow the investigator to link subjects to their responses. Each subject is assigned a unique study ID at the beginning of the study. A separate document (key) should be maintained that links the names of the subjects to the study ID numbers.**

All participants will be assigned a (non-identifying) subject number and all data pertaining to that consumer for the study will use that number and no identifying information (e.g., name, Social Security number). A record linking the assigned research number and consumer identity will be maintained in a locked file by the Project Coordinator at each site, which will be accessible only to research staff.

YES*	NO	
☒	☐	Will you share data with others outside of the study? *If YES, complete the box below

Describe how data will be transferred and how confidentiality will be maintained (e.g. identifying information will not be sent outside, etc.)

Quality assurance measures will be utilized for subject recruitment, enrollment, enrollment targets, and for the validity and integrity of the data. These will involve standard operating procedures to ensure that the study is conducted in compliance with Good Clinical Practice. Following each in-person interview/assessment, study staff will ensure no personal information is included on any study documents (aside from demographics and informed consent), and that all questions are answered (unless the participant refuses to do so). Study staff will also regularly check EMA data accuracy (e.g., are reports completed and within the expected range?). The data will be generated, documented (recorded), and reported in compliance with these standards.

Describe how you will maintain the confidentiality of the data (e.g. locked cabinet, password-protected files, encryption, etc.)

Note: Confidentiality refers to the researcher's agreement with the participant about how the subject's identifiable private information will be handled, managed, and disseminated

For further assistance and/or access to resources regarding information security, please refer to the BU Information Security website: http://www.bu.edu/tech/security/

All paper-based information collected during the research will be kept in a locked in a secure file cabinet under the PI and Co-I's supervision. The key to code of names of individual participants will be kept in a separate, locked file. Only the PI, Co-I, and associates (collaborating researchers and research assistants) involved with the study will have access to the data. All participants will have the option to exclude any of their other data from the study. In regards to audio/video recordings captured during interviews, all recordings will be saved on password-protected study computers. These files will be encrypted for transfer to a professional transcription service. No identifiable information will be included in these transcripts.

SECTION Q: CERTIFICATE OF CONFIDENTIALITY

Complete this box if the study is UNFUNDED or FUNDED by any entity (e.g department, foundation, NSF, or other federal agencies) other than the NIH

On October 1, 2017 the NIH updated its policy for issuing Certificates of Confidentiality. The updated policy is located at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

Additional information regarding the policy can be found on the NIH FAQ's website at: https://humansubjects.nih.gov/coc/faqs. Note: Sections C and D describe the process for obtaining a Certificate for studies not funded by NIH

YES	NO	
☐	☐	Will you obtain a Certificate of Confidentiality? The NIH has updated the required consent form language. The language is at the following website: https://humansubjects.nih.gov/coc/suggested-consent-language. **Note:** A consent form with the applicable language must be included with this submission. Certificates of Confidentiality are issued by the National Institutes of Health (NIH). A Certificate of Confidentiality (Certificate) protects the privacy of research participants enrolled in biomedical, behavioral, clinical or other research. With limited exceptions, researchers may not disclose names or any information, documents or biospecimens containing identifiable, sensitive

		information. The Certificate prohibits disclosure in response to legal demands, such as a subpoena.

Complete this box if the study is FUNDED by the NIH

On October 1, 2017 the NIH updated its policy for issuing Certificates of Confidentiality. The updated policy is located at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

Note: Under the new policy, the investigator will not need to apply for a Certificate. All eligible research studies that are funded by NIH are automatically issued a certificate under the NIH Policy on Certificates of Confidentiality

Additional information regarding the policy can be found on the NIH FAQ's website at: https://humansubjects.nih.gov/coc/faqs

YES	NO	
☒	☐	Does this study qualify for a Certificate of Confidentiality under the NIH Policy or Issuing Certificates of Confidentiality? To determine if this study (which is conducted or supported by NIH) qualifies for a Certificate of Confidentiality, please answer the following question: • Is the activity biomedical, behavioral, clinical, or other research? ☒ YES ☐ NO If the answer to the above question is "NO", then this study will not be issued a Certificate of Confidentiality by the NIH. If the answer is "YES", please consider the questions below: ▪ Does the research involve Human Subjects as defined by 45 CFR 46?

		▪ Are you collecting or using biospecimens that are identifiable to an individual as part of the research? ▪ If collecting or using biospecimens as part of the research, is there a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual? ▪ Does the research involve the generation of individual level, human genomic data? If the answer to any one of the four questions above is "YES", then this NIH policy will apply and will be considered to have a Certificate of Confidentiality by the NIH. If this study is covered under this policy, the consent form must include language about the protections and exceptions allowed with the Certificate. The NIH has updated the required consent form language. The language is at the following website: https://humansubjects.nih.gov/coc/suggested-consent-language. **Note:** A consent form with the applicable language must be included with this submission. Certificates of Confidentiality are issued by the National Institutes of Health (NIH). A Certificate of Confidentiality (Certificate) protects the privacy of research participants enrolled in biomedical, behavioral, clinical or other research. With limited exceptions, researchers may not disclose names or any information, documents or biospecimens containing identifiable, sensitive information. The Certificate prohibits disclosure in response to legal demands, such as a subpoena

SECTION R: PRIVACY

Describe how you will protect the privacy of subjects. Include the following information: location of data storage, who will have access to study information, and location of study visits **Note: Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others**
In-person meetings will take place in private rooms either at BU's Center for Psychiatric Rehabilitation or Dr. Fulford's research laboratory at Sargent College. All phone calls between

study staff and participants will be conducted in the research teams' private offices and inaudible to people not affiliated with the study. Procedures for ensuring compliance with the monitoring plan at both sites include training of all study staff on the contents of the document and regular meetings among Investigative team, including regular review of the plan. Steps to ensure confidentiality include: confidentiality training for all new employees and refresher seminars annually for all clinical referrers; identifying subjects by an arbitrary number; filing ID number key lists separately from data; removing or obscuring participant names from any forms; using an acronym in return addresses on any correspondence to participants; sorting all data in locked file cabinets; securing all computers that store data; and destroying audio files used for interviewer reliability checks and fidelity ratings at the end of the project. All research staff will fulfill the educational requirements set forth by NIMH and the Office for Human Research Protections.

SECTION S: MONITORING STUDY DATA

How will data be monitored?: **Note: The Data and Safety Monitoring Plan should be tailored to the nature, size, and complexity of the research protocol, the expected risks of the research, and the type of subject population being studied**	
☒	Principal Investigator
☐	Monitor/Monitoring Group
☐	Data and Safety Monitoring Board (DSMB) Note: The DSMB Charter must be submitted with this Application For more information regarding a DSMB, please refer to the following website: http://www.nidcr.nih.gov/Research/ToolsforResearchers/Toolkit/DSMBGuidelines.htm

Describe the plan for monitoring study data. This should include a description of how data will be collected and analyzed as the project progresses to assure the appropriateness of the research, its design, and subject protections.

Data will be collected until we reach our pre-determined sample sizes. Analyses will be conducted only after all data have been collected (for each phase of the project). The PI will observe data collection during both piloting and during active study recruitment to determine if particular tasks and/or procedures are problematic. If this is the case, modifications will be made and the IRB will be notified of such changes.

SECTION T: HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

YES*	NO	

☐	☒	Is this research being conducted in a covered entity?
		
		The following components have been determined to be covered entities on the Boston University Charles River Campus:
		
		• Sargent College Rehabilitation Services
		  o Physical Therapy Center at the Ryan Center for Sports Medicine and Rehabilitation
		  o Sargent Choice Nutrition Center
		• The Danielsen Institute
		• Boston University Health Plan
		
		*If YES, contact the IRB office for assistance.

SECTION U: FAMILY EDUCATIONAL RIGHTS AND PRIVACY ACT (FERPA):

FERPA is the federal law that protects the privacy of student education records. Research funded by the Department of Education or research conducted in educational institutions that receive funds from the Department of Education (for research or other purposes) must comply with FERPA.

YES*	NO	
☐	☒	Does this study involve collection of information from student school/university records? *If YES, refer to the following websites for guidance on FERPA:

		• http://www.bu.edu/researchsupport/compliance/human-subjects/ • http://www.bu.edu/reg/general-information/ferpa/ • http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html **If FERPA applies, you must complete the box below:**

In accordance with FERPA, written consent must be obtained to access student records. The consent must: • Specify the records that may be disclosed • State the purpose of the disclosure • Identify the person or class of parties to whom the disclosure can be made	
☐ YES **(REQUIRED)**	I confirm that I will comply with the FERPA policy that is in place at the educational institution where I am conducting my research. This includes, if applicable, the requirements for written agreement when requesting a waiver of consent for personally identifiable information. **If an agreement is required, this agreement must be submitted to the IRB.**

SECTION V: PROTECTION OF PUPIL RIGHTS AMENDMENT (PPRA):

PPRA is a federal law that affords certain rights to parents of minor students with regard to surveys that ask questions of a personal nature. Research funded by the Department of Education or research conducted in educational institutions that receive funds (for research or other purposes) from the Department of Education must comply with the PPRA.

YES*	NO	
☐	☒	Does PPRA apply to this study? *If YES, refer to the following websites for guidance: • http://www2.ed.gov/policy/gen/guid/fpco/ppra/index.html • http://www.bu.edu/researchsupport/compliance/human-subjects/ **If PPRA applies, you must complete the box below:**

In accordance with PPRA, written parental consent must be obtained prior to subjects participation in the study.	
☐ YES **(REQUIRED)**	I confirm that I will comply with the PPRA policy that is in place at the educational institution where I am conducting my research.

SECTION W: CLINICAL TRIALS REGISTRATION:

The Food Drug and Administration Amendments Act (known as FDAAA 801) requires that "applicable clinical trials" be registered and have results reported on clinicaltrials.gov. The Responsible Party for a clinical trial must register the trial and submit results information. In addition, the International Committee of Medical Journal Editors (ICJME) and the National Institutes of Health (NIH) also have requirements for registration. Please see box below to determine if your study requires registration in accordance with either FDAAA 801, ICJME, or NIH.

YES	NO	FDAAA 801 Requirements
☐	☒	Does your study meet the definition of an applicable clinical trial and require registration **AND** results submission in accordance with FDAAA 801? . Applicable Clinical Trials include the following: • Trials of drugs and biologics: Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation • Trials of devices (see note): 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) pediatric postmarket surveillance required by FDA The Responsible Party is defined as: • The sponsor of the clinical trial or • The principal investigator (PI) of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the PI is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of FDAAA's requirements for the submission of clinical trial information Refer to the following website for guidance:

		• FDAA 801 Requirements: https://clinicaltrials.gov/ct2/manage-recs/fdaaa **Note: If your study meets the requirement for registration and reporting, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval.** NCT #:_____
YES	**NO**	**ICMJE Requirements**
☒	☐	Does your study meet the definition of a clinical trial and require registration in accordance with ICMJE? ICMJE definition of clinical trial: Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration. Refer to the following websites for guidance: • ICMJE Clinical Trials Registration: http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/ **Note: If your study meets the requirement for registration, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval.** NCT _03404219___

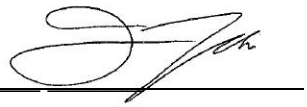
YES	**NO**	**NIH Requirements**
☒	☐	Does your study meet the definition of an applicable clinical trial and require registration **AND** results submission in accordance with NIH? As of January 18, 2017, NIH is requiring that clinical trials be registered at ClinicalTrials.gov. Confirm whether this study meets the registration requirements for clinical trial registration in accordance with the definition of a clinical trial as defined by NIH. See definition below. **Clinical Trial**: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those intervention on health-related biomedical or behavioral outcomes". This definition encompasses phase 1 trials of FDA-regulated drug and biological products, small feasibility studies of FDA-regulated device products, and studies of any intervention not regulated by the FDA, e.g. behavioral interventions. Of note, this requirement for registering and results reporting includes clinical trials beyond those already required by the FDA. The requirements are expanded to include to Phase I drug studies and NIH-funded clinical trials of social-behavioral interventions. For more information on this policy please refer to: • NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information: https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-22379.pdf • Checklist: https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf • NIH Definition of Clinical Trial: http://osp.od.nih.gov/sites/default/files/NIH%20Definition%20of%20Clinical%20Trial%2010-23-2014-UPDATED_0.pdf

		Note: If your study meets the requirement for registration and reporting, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval. NCT #:__03404219___

Certification / Signatures

- By submitting this protocol I attest to the fact that all research activities to be implemented related to human subjects have been completely and accurately described herein.
- I agree to conduct the describe research in an ethical manner.
- I agree to comply with all institutional policies and procedures related to human subjects research and will not begin any human subjects research activities until I have obtained full approval from the IRB.
- I agree to conduct the research as described in this protocol and not to make any changes (except to eliminate immediate harm to subjects) without first obtaining approval for the changes from the IRB.
- I agree to immediately report any unanticipated problems involving risks to subjects or others, any subject complaints, and any incidents of non-compliance with the requirements of this protocol as soon as I become aware of them.
- I agree to comply with any relevant HIPAA and FERPA regulations if applicable.
- I verify that all those responsible for the design, conduct, or reporting of the proposed program, including at minimum, all Senior/key personnel in the grant application, have completed the financial interest disclosure forms and completed training as dictated at http://www.bu.edu/orc/coi/forms/, and returned the forms to the Office for Research Compliance COI Unit. **NOTE: If anyone checked "yes" to any of the questions on either the FIND1 or NONFIND1 form, the IRB Director will contact the COI office to obtain the disclosure information.**

PI printed name ___Daniel Fulford, PhD_____

PI Signature:  Date: 4/8/2020

Submission
This form can be completed, signed, scanned and submitted to the IRB at irb@bu.edu. Faxed documents and handwritten materials are not accepted. Be sure to include all relevant attachments.

FACULTY Research:

The Department Chair signature is required: This application must be signed by the Department Chair for all faculty researchers. If the PI is the Department Chair then signature by the appropriate Dean is required. Department Chair signature is not required for student research. **By signing this form you are indicating that you have reviewed the application, the faculty/staff person listed as PI on this protocol is a member of your department, hat he/she is qualified to serve as the PI for this study, he/she has the adequate resources, and the research utilizes acceptable practice for the discipline.**

Department Chair (print name): Wendy Coster

Department/School: Occupational Therapy; College of Health & Rehab Sciences: Sargent

Signature: *Wendy Coster*

Date: 6/26/18

STUDENT Research

Student research: Student research must be signed by the faculty advisor AND the designated School IRB pre-reviewer (if applicable) PRIOR TO submission to the IRB. Students should check with their School to determine if School IRB pre-review is required. Students must submit a copy of their dissertation with the IRB Application

By signing this form you are indicating that you have reviewed the application, that you agree to serve as the Co-PI for this study with the student and that you will be responsible for the ethical conduct of this student's human subjects research.

Faculty Advisor (print name):

Signature: _____

Date: _____

IRB School Reviewer, if applicable (print name): _____

Signature: _____

Date: _____