The following includes the full study protocol for project
"SibACCESS: Developing a Telehealth Intervention to Address Unmet Psychosocial Needs of Siblings of Children with Cancer" (NCT04889755)

Protocol most recently approved by the Boston University Charles River IRB on March 31, 2024

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

SECTION A: PROTOCOL AND CONTACT INFORMATION

Protocol Title:	SibACCESS: Developing a Telehealth Intervention to Address Unmet Psychosocial Needs of Siblings of Children with Cancer
Principal Investigator **(Name, degrees, licenses, etc.):** ☐ Mr. ☐ Ms.	Kristin Long, PhD
Department/School:	Department of Psychological and Brain Sciences, CAS
BU Mailing Address:	900 Commonwealth Ave., 2nd Floor, Boston MA 02215
Email:	kalong@bu.edu
Telephone:	(617) 358-4296
Additional Contact Person:	Alix Paredes Molina
Email:	apmolina@bu.edu
Telephone:	(617) 358-1633

☒ 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 for this project, including existing funding, pending funding, and funding that has been applied for to support this research.

Please check all that apply:	
☒	This research is funded
☐	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. 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 Cancer Institute (NCI)
Title of Grant/Proposal	SibACCESS: Developing a Telehealth Intervention to Address Unmet Psychosocial Needs of Siblings of Children with Cancer
Sponsor Award # **(REQUIRED)*** *If Award is pending, put "pending".	R03 CA259898

YES	NO	
☒	☐	Is Boston University the Prime Awardee of the grant?
☐	☒	Is Boston University receiving a sub-award? Name of Prime Recipient:
☐	☒	Is the research being supported by an Industry Contract or Clinical Trial Agreement?

***NOTES:**

- Provide a copy of the grant application, funding proposal, contract/agreement, scope of work, or sub-award agreement supporting the research. If an award is pending, once the funding has been awarded, submit an amendment to the IRB to add the funding source.
- If this research study is for your dissertation, provide a copy of your prospectus (if available).

SECTION C: CONFLCT OF INTEREST

☒ YES **(REQUIRED)**	I confirm that **ALL** those responsible for the design, conduct, or reporting of the proposed research, 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 CRC IRB website

I. **FULL BOARD** ☐
Please refer to the CRC IRB website for Full Board submission deadlines and meeting dates.

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:
   - 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
   - Weighing or testing sensory acuity
   - Magnetic resonance imaging
   - Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
   - 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 non-research 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:
The 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)**	***Training**
Kristin Long, PhD, Dept. Psychological and Brain Sciences, CAS	Principal Investigator	☒ CITI 06/14/2023 ☐ **Other:
Suma Suswaram, PhD, Dept. of Psychological and Brain Sciences, CAS	Post-Doctoral Associate	☒ CITI 07/12/2022 ☐ **Other:
Monica Gordillo, M.A., Dept. Psychological and Brain Sciences, CAS	Doctoral Student Researcher	☒ CITI 5/08/2022 ☐ **Other:
Jenna Eilenberg, M.A., MPH, Dept. of Psychological and Brain Sciences, CAS	Doctoral Student Researcher	☒ CITI 09/25/2023 ☐ **Other:
Nicole Cardona, M.A., Dept. Psychological and Brain Sciences, CAS	Doctoral Student Researcher	☒ CITI 08/22/2021 ☐ **Other:
Ariel Blakey, M.A., Dept. Psychological and Brain Sciences, CAS	Doctoral Student Researcher	☒ CITI 09/06/2022 ☐ **Other:
Kathryn Davis, M.A., Dept. Psychological and Brain Sciences, CAS	Doctoral Student Researcher	☒ CITI 08/05/2022 ☐ **Other:

John "Jay" Wilson, M.A., Dept. of Psychological and Brain Sciences, CAS	Doctoral Student Researcher	☒ CITI 09/08/2023 ☐ **Other:
Mikaela De Lemos, B.A., Dept. Psychological and Brain Sciences, CAS	Doctoral Student Researcher	☒ CITI 09/10/2023 ☐ **Other:
Alix Paredes, BA Dept. of Psychological and Brain Sciences, CAS	Lab Manager	☒ CITI 01/28/2022 ☐ **Other:
Shumin Guan, Dept. of Psychological and Brain Sciences, CAS	Undergraduate Student Researcher (Staff)	☒ CITI 10/25/2021 ☐ **Other:
Samuel Lai, Dept. of Psychological and Brain Sciences, CAS	Undergraduate Student Researcher	☒ CITI 5/15/2022 ☐ **Other:
Illari Cazorla-Garcia, Dept. of Psychological and Brain Sciences, CAS	Undergraduate Student Researcher	☒ CITI 09/30/2022 ☐ **Other:
Dara Oliveira, Dept. of Psychological and Brain Sciences, CAS	Undergraduate Student Researcher	☒ CITI 09/29/2022 ☐ **Other:
Samantha Brayton, Dept. of Psychological and Brain Sciences, CAS	Undergraduate Student Researcher	☒ CITI 04/17/2022 ☐ **Other:
Joshua Dela Cruz, Dept. of Psychological and Brain Sciences, CAS	Undergraduate Student Researcher	☒ CITI 01/11/2023 ☐ **Other:
Yudi Wang, Dept. of Psychological and Brain Sciences, CAS	Undergraduate Student Researcher	☒ CITI 02/03/2023 ☐ **Other:

- *For more information regarding the Human Subjects Training Policy, refer to the 'Training' section of the Policies & Guidance section IRB website.
- **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 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, Institution	Study Role	Staff Information	Will IRB Approval be Obtained from Non-BU Institution?
Anna Muriel, M.D., MPH Dana Farber Cancer Institute	Collaborator	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 their role or coursework at their institution.? ☒ Yes ☐ No	☐ Yes; provide copy of IRB approval letter ☒ No (provide reason): Dana Farber Cancer Institute will be a recruitment site only. Dr. Muriel will have access to deidentified data.
Melissa Alderfer, PhD Nemours Children's Health System	Collaborator	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 their role or coursework at their institution.? ☒ Yes ☐ No	☐ Yes; provide copy of IRB approval letter ☒ No (provide reason): No study activities will take place at Nemours. Dr. Alderfer will have access to deidentified data.

*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 affiliate 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. Anna Muriel will act as collaborator on the present study. She will contribute to the design of the research (e.g., finalizing the qualitative interview guide and crafting the treatment manual) and will contribute to interpretation and dissemination of findings. She will have access to de-

identified data only. IRB approval will not be obtained from Dana Farber Cancer Institute (DFCI) as DFCI will serve only as a recruitment site for parts 1 and 2 of the present study.

Dr. Melissa Alderfer will act as collaborator on the present study. She will contribute to the design of the research (e.g., finalizing the qualitative interview guide and crafting the treatment manual) and will contribute to the analysis, interpretation, and dissemination of findings. She will have access to de-identified data only. IRB approval will not be obtained from Nemours Children's Health System, as no study activities will take place at this site.

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 in the NIH policy?

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): Due to the remote operation plans implemented in response to SARS-CoV-2, Boston University study staff completing interviews or group pilot sessions remotely will conduct study activities via telephone or the Zoom video-teleconferencing platform from a private room or office with a door that can be closed to ensure that interviews and research calls are not heard by individuals not on the Boston University study staff.

*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.**

[1]Guidance on Engagement of Institutions in Human Subjects Research
[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"

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
- The plan for reporting and evaluating:
- Unanticipated problems
- Serious and/or continuing non-compliance
- Suspensions and terminations of research
- Interim results
- Protocol modifications
- The name of the Principal Investigator from each site
- 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.

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.

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

Prolonged, complicated, and intensive cancer treatment regimens challenge and disrupt the entire family (Alderfer & Kazak, 2006; Faulkner & Davey, 2002) Adolescents and young adults who are the child of or sibling to an immediate family member with cancer are a psychosocially at-risk and underserved group. Siblings of youth with cancer frequently report strong negative emotions, disruptions to family life, poorer academic functioning, more school absenteeism (school-aged siblings), and riskier health behaviors and poorer health outcomes than comparisons (adult siblings) (Long et al., 2018). Similarly, adolescent and young adult children affected by parental cancer report anxiety, depression, low self-esteem, poor health-related

quality of life, and higher school absenteeism (Walczak et al., 2018; Zheng et al., 2022). Approximately one-quarter of siblings (Kaplan et al., 2013) and one quarter of children (Egberts et al., 2022) of individuals with cancer meet diagnostic criteria for cancer-related posttraumatic stress disorders (PTSD). Additionally, both siblings and children of immediate family members with cancer report feelings of isolation and indicate a strong desire to connect with peers with similar experiences (Long et al., 2018; Geertz et al., 2023). The need psychosocial supports for siblings of children with cancer (Gerhardt et al., 2015) and children of parents with cancer (Ohan et al., 2020) is well established. Unfortunately, these supports are not routinely available in clinical practice (Davis et al., 2022; Alexander et al., 2019) and the psychosocial needs of adolescents and young adultsh affected by an immediate family member's cancer remain largely unmet (Patterson et al., 2014; Ohan et al., 2020).

The present study aims to address barriers to psychosocial care for siblings and children of individuals with cancer by developing a group-based telehealth program with an accompanying parent session. In Phase 1 of the present study, study staff will interview a diverse sample of English- and Spanish-speaking families and psychosocial providers to assess preferences for program content, format, timing, and cultural feasibility and acceptability, while considering ideas to minimize participation barriers. In Phase 2, a pilot version of the SibACCESS program will be tested with a small group of families located in Massachusetts, Rhode Island, and/or Delaware using video-teleconferencing technology. The pilot trial includes a preliminary joining session, a parent informational webinar, and 9 program sessions. Families will complete pre- and post-intervention quantitative measures in addition to exit interviews to assess preliminary program acceptability and perceived benefits.

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

☒	Collection of audio, video, digital, or image recordings
☐	Biological samples → Complete Biological Samples Form 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. (e.g. Illegal behaviors, HIV status, psychiatric illness, information related to sexual behaviors, etc.
☐	Coordinating Center/Lead Site
☐	Deception
☐	Devices → Complete Devices Form

☐	Drugs → Complete Drugs Form
☐	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
☐	MRI
☐	Placebo
☐	Pregnancy Testing
☐	Randomization
☒	Surveys, interviews, questionnaires
☐	Secondary Data Analysis
☐	Other (please describe):

SECTION I: PARTICIPANT POPULATION

Provide the Number of Participants to be Enrolled. If you have sub-groups or more than one arm, please separate out these enrollment numbers. Note: Please account for participants who may drop out or be withdrawn from the study. Anyone who signs a consent form is considered to be enrolled in the research regardless of whether they complete any study procedures.

Phase 1 (Development of the SibACCESS Telehealth Program)

N = 35 Families (For adolescent participants between the age of 12-17 years old, a family unit will include both a parent and the adolescent. Up to 2 parents and 2 adolescents can participate from each family. Young adult participants (i.e. 18-30 year old siblings or children of an immediate family member who has been diagnosed with cancer) may participate as individuals or with a parent).
N = 15 Psychosocial Providers

Phase 2 (Pilot of the SibACCESS Telehealth Program)

N=20 Families (This will include 20 parents and 20 siblings, for a total of 40 family members. Up to 2 siblings can participate from each family).

Check all categories that apply to your participant population:	
☒	Adults
☒	Children (< 18 years of age)
☐	Adults with Limited Decision-Making Capacity
☒	Non-English Speaking
☐	Prisoners
☐	BU Employees
☐	BU Students
☐	Wards of the state
☐	Other (please describe):

If a population other than 'Adults' has been checked, describe the additional safeguards that have or will be put in place to protect those individuals, and provide the rationale for including this population in the research study. For information on additional protections, please see the 'Supplemental Guidance' section of the CRC IRB webpage.

Children or young adults diagnosed with cancer are not eligible to participate in the present study. Only siblings or children of an immediate family member diagnosed children with cancer are eligible to participate. The present study involves youth and young adults ages 12 to 30 in Phase 1 and only youth 12-17 in Phase 2.

Phase 1 (Development of the SibACCESS Telehealth Program)

In Phase 1, youth/young adults and parents will complete qualitative interviews with a member of the research team in their primary language (English or Spanish). A member of the research team will explain to the participant Phase 1 study details (e.g., details regarding purpose of the qualitative interview) in developmentally-appropriate language and in their native language (Spanish or English). Staff will emphasize that study participation is voluntary. Participants will be given ample time to ask questions and decide whether or not to

participate. Youth participants under the age of 18 will have at least one parent indicate their consent for the youth's participation in the qualitative interview and the youth will be asked to provide verbal assent (see **Phase 1 Verbal Consent Form** and **Phase 1 Child Verbal Assent Form**). Young adults who are ages 18-30 will complete their own consent form if they choose to participate (see **Phase 1 Verbal Consent Form)**.During interviews, interviewers will attempt to minimize distress associated with discussion of sensitive topics surrounding cancer diagnoses and treatment by re-iterating to participants that they are not required to answer questions that they are uncomfortable answering. No greater than minimal risk is present for participants in this research study.

Phase 2 (Pilot of the SibACCESS Telehealth Program)

In Phase 2, families will be enrolled in a pilot version of the SibACCESS program and will complete pre/post-quantitative measures and qualitative exit interviews. A member of the research team will explain Phase 2 study details (e.g., how many meetings are included in the program, who will be at the meeting, what information might be covered in the meetings, the purpose of the qualitative exit interview, etc.) to the sibling and parent participants. At least one parent will indicate their consent for the sibling's participation in the SibACCESS pilot program and data collection, and siblings will be asked to provide verbal assent (see **Phase 2 SibACCESS Altered Consent Script [REDCap]** and **Phase 2 SibACCESS Sibling Assent Script [REDCap]**).

As in Phase 1, study staff conducting Phase 2 qualitative exit interviews with siblings and parents will attempt to minimize distress associated with discussion of sensitive topics surrounding cancer and treatment by re-iterating to particpants that they are not required to answer questions that make them uncomfortable to answer.

Phase 1 and Phase 2 (Pertaining to the Disclosure of Mental Health Risk)

Should a youth/young adult participant or parent disclose imminent mental health risks to study staff during qualitative interviews (Phase 1 or Phase 2) or during the course of the SibACCESS pilot intervention trial or associated research procedures (Phase 2), study staff will immediately contact the PI (Kristin Long, PhD). Dr. Long is a licensed clinical psychologist (licensed in MA and RI) who is trained in management of mental health risk. She will be on call at all times and will be available to provide guidance to address imminent risk discovered during research activities. Should a parent provide written consent, a mental health referral may be made as indicated. Additionally, a list of crisis resources (**see Phase 2 SibACCESS Crisis Resource List**) for the states in which participating families reside will be available to families at the time of risk disclosure.

Eligibility Criteria
Inclusion Criteria:

Phase 1 (Development of the SibACCESS Telehealth Program)

Family Inclusion Criteria

- Youth/young adult participants who are either the sibling or child of an immediate family member with a current or past cancer diagnosis.
    - Youth/young adult can be biologically-related sibling/child, step-sibling/child, or adopted sibling/child of the individual diagnosed with cancer
- Youth/young adult 12-30 years of age
    - Youth/young adult must report at least mild posttraumatic stress (for youth <18 years of age, score ≥11 on Child Posttraumatic Stress Scale for DSM-5; for young adults ≥18 years of age, score ≥11 on the Posttraumatic Diagnostic Scale (PDS) for DSM-5)
- Youth/young adult must be fluent in English or Spanish
    - For families with youth <18 years of age, participating parent must also be fluent in English or Spanish

Provider Inclusion Criteria

- Psychosocial provider (i.e., psychologist, psychiatrist, or licensed clinical social worker) within an oncology program
- ≥ two years of experience in cancer (does not have to be current or consecutive)
- Fluency in English or Spanish

Phase 2 (Pilot of the SibACCESS Telehealth Program)

Family Inclusion Criteria

- 2 or more children in the family (i.e., child with cancer and ≥1 sibling)
    - Sibling(s) and child with cancer each under the age of 18 at the time of cancer diagnosis
    - Sibling(s) can be biologically-related, step-siblings, foster-siblings, or adopted-siblings
- Parent and sibling(s) fluent in English
- Sibling(s) 12-17 years of age
- Sibling report of at least mild posttraumatic stress (score ≥11 on the Child Posttraumatic Stress Scale for DSM-5)
- Child with cancer must have received cancer diagnosis at least 3 months prior to the family's enrollment in the study

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):

Phase 1 (Development of the SibACCESS Telehealth Program)

Family Exclusion Criteria

- A cognitive impairment that would interfere with interview completion (as reported by a parent or by the young adult)
- Bereavement
- Immediate family member with cancer residing and receiving cancer treatment outside of the United States
- Family residing outside of the United States

Provider Exclusion Criteria

- Practicing outside of the United States

Phase 2 (Pilot of the SibACCESS Telehealth Program)

Family Exclusion Criteria

- A cognitive impairment that would interfere with pilot program and interview completion (as reported by parent)
- Bereavement
- Significant externalizing behaviors that would interfere with group participation (as reported by parent)
- Child with cancer residing and receiving cancer treatment outside of the United States
- Family residing outside of the United States

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

Submit all recruitment materials (e.g. advertisements, brochures, flyers, letters/e-mails, scripts, etc.) as separate documents in either Word or PDF format.

Families will be recruited in four ways. First, Boston University study staff will re-contact families who participated in past research studies and consented to be re-contacted about future study opportunities. Families may only participate in phase 1 or phase 2 of the present study (not both). Second, Boston University study staff will recruit from the pediatric oncology service within health care centers to ensure the inclusion of culturally diverse families and those who are receiving active cancer treatment. These sites (e.g., Dana Farber Cancer Institute) will serve as recruitment-only sites and will not be involved in consenting or data collection. Third, Boston University study staff will recruit from a contact list provided

by Alex's Lemonade Stand Foundation. Finally, Boston University study staff will use other forms of community outreach to reach families who would otherwise not be aware of the study through the two recruitment methods described above. This may include social media postings in order to communicate information about the present study (see **Phase 1 and Phase 2 Social Media Phrasing** document).

Phase 1 (Development of the SibACCESS Telehealth Program)

For previous participants (families and providers) for whom we have email addresses, we will send an email outlining the present study's purpose and details (e.g., outline qualitative interview process) (see **Phase 1 Young Adult – Study Details Email, Phase 1 Family Study Details Email and Phase 1 Provider Study Details Email**). In addition to study details, the email will indicate to families and providers that they should expect follow-up telephone outreach from Boston University study staff, unless they "opt-out" of further contact by responding to the study details email within 1-week. Families and providers who do not opt-out will be eligible to be contacted via text, telephone call, and/or email by Boston University study staff once the 1-week opt-out period has elapsed.

For previous participants (families and providers) for whom we have email addresses, we will send an email outlining the present study's purpose and details (e.g., outline qualitative interview process) (see **Phase 1 Young Adult – Study Details Email, Phase 1 Family Study Details Email and Phase 1 Provider Study Details Email**). In addition to study details, the email will indicate to families and providers that they should expect follow-up telephone outreach from Boston University study staff, unless they "opt-out" of further contact by responding to the study details email within 1-week. Families and providers who do not opt-out will be eligible to be contacted via text, telephone call, and/or email by Boston University study staff once the 1-week opt-out period has elapsed.

For previous participants (families and providers) for whom we only have telephone numbers (and no email addresses) or for whom the email address proves to be outdated (e.g., delivery failure message is received), we will reach out by telephone to determine interest in the present study (see **Phase 1 Family Telephone Script and Eligibility Screen** and **Phase 1 Provider Telephone Script and Eligibility Screen**).

For families recruited from Alex's Lemonade Stand foundation, we will mail and/or email an informational letter regarding the present study (**ALSF Recruitment Letter (Mail Version) and ALSF Recruitment Letter (Email Version)**) to those for whom we have contact information. Approximately 2 weeks after the mailing and/or emailing of the letters, Boston University study staff will reach out via telephone to gauge family interest in hearing more about the student and to determine eligibility **(Phase 1 Family Telephone Script and Eligibility Screen**).

Families recruited from the pediatric oncology service within healthcare centers will need to "opt-in" to be contacted by Boston University study staff. Families may be approached by their psychosocial provider in person at a clinic visit and given a brief overview of the study, or they may receive information about the study from newsletters, fliers, or other media. Families interested in study participation will be directed to independently complete an online consent-to-contact form located on the Child and Family Health Lab website (see **Consent-to-Contact Webpage Summary**) or to call study staff to indicate their interest in learning more about the study. Families who complete the consent-to-contact form, can be contact by email or telephone to confirm their interest and schedule a time for an eligibility screen (see **Phase 1 Family Study Details Email [Opt-In Families] 5.03.2021**).

Boston University study staff will contact interested families and providers via telephone to provide additional details about the study and answer any questions (see **Phase 1 Family Telephone Script and Eligibility Screen** and **Phase 1 Provider Telephone Script and Eligibility Screen**).). For youth under the age of 18, parents will answer eligibility questions about the family and the Child Posttraumatic Stress Scale for DSM-5 (as part of the eligibility screen) will be administered verbally to the youth. Young adults ages 18-30 will answer eligibility questions themselves and will be verbally administered the Posttraumatic Diagnostic Scale for DSM-5 (to assess eligibility). Eligible families and providers will then be scheduled to complete a qualitative interview (Phase 1). Note that, in cases where a parent or guardian is enrolled, that parent or guardian may or may not be a parent or guardian of the child with cancer, and may or may not be a parent/guardian with cancer.According to purposive sampling procedures that are considered the "gold standard" of qualitative research, we will occasionally review the characteristics of enrolled participants and target future recruitment activities to ensure breadth in our sample. Purposive sampling for families will be based on youth/young adult age, youth/young adult gender, family race/ethnicity, and cancer treatment status (i.e., on/off active treatment). Note that we will collect information about these purposive sampling variables within the phone screen and will explain to parents/guardians and or young adults the reason for collecting this information.

Phase 2 (Pilot of the SibACCESS Telehealth Program)

Families being re-contacted from past research, for whom we have email addresses, will first receive an emailing outlining the present study's purpose and details regarding a pilot intervention trial (e.g., length of each individual session, information on the group format, etc.; see **Phase 2 SibACCESS Family Study Details Email**). Similar to recruitment procedure for Phase 1, it will be indicated to families that they should expect telephone outreach from the Boston University study staff, unless they "opt-out" of this telephone outreach by responding to the study details email within 1-week. Families who do not opt-out will be contacted a maximum of 10 times via text, telephone call, and/or email.

For families who are being re-contacted from past research, for whom we only have a telephone number (no email address) or for whom an email address is determined to be outdated we will reach out via telephone (text or call) to determine interest in the present study (see **Phase 2 SibACCESS Family Telephone Script and Eligibility Screen**).

As with Phase 1, families recruited from the pediatric oncology service within healthcare centers for the pilot intervention trail (Phase 2) need to "opt-in" to be contacted by Boston University study staff. Families may be approached by their psychosocial provider in person at a clinic visit and given a brief overview of the study, or they may receive information about the study from newsletters, fliers, or other media. Families interested in study participation will be directed to independently complete an online consent-to-contact form located on the Child and Family Health Lab website (see **Phase 2 SibACCESS Consent-to-Contact Page**) or to call study staff to indicate their interest in learning more about the study.

For families recruited from Alex's Lemonade Stand foundation, we will mail and/or email an informational letter regarding the present study (**Phase 2 ALSF Recruitment Mailer** and **Phase 2 ALSF Recruitment)** to those for whom we have contact information. Approximately 1 week after the mailing and/or emailing of the letters, Boston University study staff will reach out via telephone (text or call) and email to gauge family interest in hearing more about the student and to determine eligibility **(Phase 2 Family Telephone Script and Eligibility Screen**).

Boston University study staff will contact interested families via telephone to provide additional details about the study and answer any questions (see **Phase 2 SibACCESS Family Telephone Script and Eligibility Screen**). Parents will answer eligibility questions, and the Child Posttraumatic Stress Scale for DSM-5 (as part of eligibility screen) will be administered verbally to the sibling. Eligible families will then be provided with a link from which to complete consent and assesnt forms, quantitative study measures, and they will be scheduled to participate in the pilot intervention trial and complete a qualitative exit interview (Phase 2).

Additional Recruitment Procedure for Phase 1 and 2

Additionally, information regarding the present study will be shared with clinicians and families at healthcare centers via listings in newsletters and resource lists (see **Phase 2 SibACCESS Brief Advertisement** and **Phase 2 SibACCESS Website Text and Full-Length Advertisement** Document). Additional outreach may occur via fliers, emails, or other social media from relevant community organizations.

Once Phase 1 and 2 of the study are closed to enrollment, contact information for families for whom study staff were unable to make contact will be destroyed.

SECTION K: CONSENT AND ASSENT

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.

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 participants, when and where consent will occur. The summary should include, as appropriate, any waiting period between informing the prospective participant about the research and obtaining consent, such 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.

Submit copies of all consent forms and scripts; materials should be submitted as separate documents in Word format.

Phase 1 (Development of the SibACCESS Telehealth Program)

Families and providers interested in participating in Phase 1 of the present study will be contacted by Boston University study staff to complete an eligibility screen. Eligible families and providers will then be scheduled to complete a qualitative interview. At the time of the interview appointment, youth/young adults, parents (if applicable) and providers will be asked to provide verbal consent to indicate their agreement to participate in a semi-structured qualitative interview and completion of background form in Qualtrics to collect cancer-related information, demographic information, and information posttraumatic stress symptoms in response to immediate family member's cancer (see **Family Background Form**, **Provider Background Form**, and **Phase 1 Verbal Consent Form**). For youth participants under 18 years old, parents will also be asked to provide consent to indicate their agreement for their participation. Youth under 18 years old will also be asked to provide verbal assent (see **Phase 1 Child Verbal Assent Form)**. Only Boston University study staff will be involved in obtaining informed consent (for parents and young adult participants) and assent (for youth under 18 years old) in qualitative interviews.

Phase 2 (Pilot of the SibACCESS Telehealth Program)

Eligible families choosing to participate in Phase 2 of the present study will be asked to provide informed consent indicating their agreement to participate in a pilot intervention trial (and its included quantitative measures, qualitative exit interview, and parent-focused intervention activities) via e-consent and assent forms on the REDCap platform prior to the pre-intervention data collection and the preliminary joining session of the intervention. Parents will also be asked to provide e-consent for up eligible siblings to participate in the pilot trial (see **Phase 2 SibACCESS Altered Consent Script [REDCap]**). Enrolled siblings will range in age from 12 to 17; therefore, siblings will be asked to provide e-assent to participate in

sessions 1 through 7 of the pilot intervention trial, pre/post-intervention quantitative measures, and a qualitative exit interview (see **Phase 2 SibACCESS Sibling Assent Script [REDCap]**). Should an adolescent sibling turn 18 during the pilot intervention, the sibling will be re-consent via the REDCap platform (see **Phase 2 SibACCESS Altered Consent Script**) prior to the next pilot intervention trial session. Should the primary caregiver be unavailable for one or more of the program sessions involving parents, an alternate supportive adult can consent to participation limited to those sessions (**Phase 2 Altered Consent Form – Supportive Adult).** The supportive adult will not be asked to complete pre-program and post-program questionnaires, but may be asked to complete a brief exit interview.

Only Boston University study staff will be involved in obtaining informed consent (for parents) and assent (for siblings) for participation in the pilot intervention trail, associated quantitative measures, and qualitative exit interviews via the REDCap platform. Should a family require assistance completing e-consent measures, Boston University study staff will have access to their REDCap study files, and will be able to walk family through the consent form via Zoom at the family's request.

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

Consent: Adults (≥18 years old); One of the following MUST apply	**N/A ☐**
☐	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 old); One of the following MUST apply	**N/A ☐**
☐	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; 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)**
Guidance on age requirements for obtaining assent: • **Parental Permission for minors under 6 years old** • **Verbal assent for minors 6-11 years old** • **Written assent from minors ages 12-17 (unless verbal consent is approved for the parents/adult subjects**	
Parental Permission; One of the following MUST apply	**N/A ☐**
☐	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; **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).**

Consent: Adults with Limited Decisional Capacity to Consent (≥18 years old) N/A ☒ **Describe the consent and/or assent process for enrolling adults with limited decisional capacity to consent to research. Including how decisional capacity will determined, and who will serve as Legally Authorized Representative.**
Assent will be obtained from: ☐ All Subjects ☐ Some participants, specify: ☐ No participants. If no participants will assent, provide a rationale:

☐	Consent will be obtained from the subject's Legally Authorized Representative (LAR) **(REQUIRED).** **Who will serve as LAR:**

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 on the IRB website.
Phase 1 (Development of the SibACCESS Telehealth Program) Only The process for obtaining consent from non-English speaking participants will be the same as the process indicated above for English speaking participants. A Spanish-speaking member of the Boston University study staff will obtain consent from Spanish-speaking participants verbally for Phase 1 of the study. English versions of the **Phase 1 Verbal Consent Form** and **Phase 1 Child Verbal Assent Form** will be translated into Spanish once approved by the IRB. The translated consent forms will then be submitted along with the appropriate attestation form to the BU-CRC IRB for approval prior to use.

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:	☒	☐
☐ **Criteria 3**		
The research is **NOT** FDA Regulated	☐	☐
The research presents no more than minimal risk of harm to subjects	☐	☐
The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm	☐	☐
There is an appropriate mechanism for documenting that informed consent was obtained	☐	☐
A written statement/information sheet will be provided to subjects. If **NO**, provide rationale for not providing this information:	☐	☐

BOX 2—WAIVER OR ALTERATION OF CONSENT

NON-FDA REGULATED STUDIES

WAIVER OR ALTERATION OF CONSENT N/A ☐ **45 CFR 46.116 Waiver or alteration of consent. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents ALL of the criteria listed below:**	**Yes**	**No**
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;	☒	☐
If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;	☒	☐
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): Due to the current social-distancing guidelines implemented in response to the SARS-CoV-2 pandemic, and continuation of remote operation of research activities by Boston University study staff, qualitative interviews for Phase 1 of the study will be completed entirely remotely using the telephone or the Zoom-teleconferencing platform. Additionally, the background forms		

will be complete remotely using the Qualtrics survey platform (see **Family Background Form** and **Provider Background Form).** For this reason, the Boston University study staff are requesting the approval of verbal consent for young adult participants age 18 and older, for parents and for psychosocial providers, and verbal assent for youth participants in Phase 1 (see **Phase 1 Verbal Consent** and **Phase 1 Child Verbal Assent Form**). Please note that in-person contact in the context of COVID-19 can be particularly risky for families who have a member with cancer due that individual's immunocompromised state.

For Phase 2 of the study, the pilot program is intentionally designed to be implemented via telehealth sessions in order to make the program more accessible to siblings of children with cancer. Boston University study staff are requesting that parental consent and sibling assent be obtained verbally (see **Phase 2 Verbal Consent Form/Information Sheet** and **Phase 2 Sibling Assent Form/Information**).

FDA-REGULATED STUDIES

Per FDA guidance issued in July 2017, the IRB may waive or alter informed consent requirements for certain minimal risk clinical investigations when the IRB finds and documents ALL of the criteria listed below:	**Yes**	**No**
The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects;	☐	☐
The waiver or alteration will not adversely affect the rights and welfare of the subjects;	☐	☐
The clinical investigation 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:	☐	☐
Additional Comments:		

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 and 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; materials should be submitted as separate documents in either Word or PDF format.

Phase 1 (Development of the Sibling Telehealth Program)

Potentially eligible families and providers will be contacted by Boston University study staff to complete a 15 to 30-minute eligibility screen (see **Phase 1 Family Telephone Script and Eligibility Screen** and **Phase 1 Provider Telephone Script and Eligibility Screen**). If a family is found to be eligible, the youth/young adults and parent(s) (if applicable) each will be scheduled to complete a qualitative interview. Participants will participate in a 60 to 75-minute remote qualitative interview via the Zoom platform (audio-recording only). Young adults, parents and providers will also complete a brief background form via Qualtrics to collect cancer-related information, demographic information, and information about posttraumatic stress symptoms in response to immediate family member's cancer (see **Family Background Form** and **Provider Background Form**). Qualitative data collection and interim analyses will be iterative, with findings from earlier interviews incorporated into the evolving interview guide (see **Sample Interview Questions**) and SibACCESS program description until thematic saturation is reached (i.e., when interviews no longer yield new information).

For providers re-contacted from the 5019E study: Responses to the following demographic interview questions will be shared with study staff of protocol 5870E, if a provider is re-contacted, consented (including a question on whether they agree to their information being shared across studies), and enrolled in the new study. The sharing of this information across studies will prevent this specific group of providers from needing to answer demographic questions for which they have answered in the past 2 years. Additionally, if a provider does not consent to this demographic information being shared across the 5019E and 5870E studies, they will be re-asked demographic questions such as those listed below as part of semi-structured qualitative interview procedures.

1. **Tell me a little bit about the role you play in the provision of psychosocial support to families of individuals with cancer.**
   a. What is your professional title?
   b. What is your discipline (e.g., child life specialist, social worker, psychologist, psychiatrist, nurse, oncologist)?

2. **Tell me about your center.**
   a. Is your center located within a free-standing children's hospital or a university medical center?
   b. Do you have trainees (e.g., child life specialist trainees?)

c. How many new childhood cancer patients does your center serve annually?
d. Does your center care for hematopoietic cell transplant patients and their families?
e. What percentage of patients travel >50 miles to receive care?
f. How many psychosocial providers do you employ (full or part-time)?
g. How are psychosocial providers supported – e.g., are they salaried? Do they bill for services?
h. How would describe your patient demographics?
    ii. (E.g., primarily rural/urban, largely international, large/small percentage of racial/ethnic minority families, high/low percentage of non-English speakers, low/high-SES, (not) very religious)?

Interviews will be recorded and transcribed verbatim in one of two ways: 1) using a password protected account on Amazon Transcribe or 2) by undergraduate or graduate student researchers with training in research ethics. Only approved study staff will have access to the Amazon Transcribe account. Audio recordings will be temporarily uploaded to the account for transcription (a process that takes approximately an hour) and then deleted from the account immediately following transcription. All transcripts (whether transcribed by an approved study staff member or Amazon Transcribe) will be reviewed a second time by a study staff member to check for accuracy and ensure that all potentially identifying information has been removed. All transcripts will be labeled with unique participant ID numbers. Audio recordings will be moved to the limited-access folder after transcription is complete. Audio recordings will be kept until data analysis is complete in case it is necessary to reference the original recording to clarify information during analysis. Study data will be retained for 7 years. Identifying information about families who are not eligible or decline participation will be destroyed. Spanish transcripts will be translated into English. All transcripts will be entered into a qualitative software program, NVivo to facilitate coding and analysis. Information from the interviews will be used to inform content, formatting, and feasibility of the telehealth pilot program to address cancer-related trauma symptoms.

Phase 2 (Pilot of the SibACCESS Telehealth Program)

Please Note: While multiple eligible siblings can be enrolled from each family in the present study, only one sibling per family will be enrolled in each cohort of the pilot intervention trial (e.g., one sibling per cohort of the SibACCESS pilot program).

Potentially eligible families will be contacted to complete a 15 to 30-minute eligibility screen (see **Phase 2 SibACCESS Family Telephone and Eligibility Screen**). Eligible families (one parent and an eligible) will be enrolled to participate in a sibling-focused pilot telehealth group program focusing on increasing siblings' exposure to cancer-related cues and opportunities to process those cues. The program will consist of 1 preliminary family joining session, a parent-focused educational webinar, and 9 sibling intervention sessions (7 group sessions, 1 individual session, and 1 parent check-in). Group sessions will include between 3 and 10 sibling participants. The aim of this pilot program is to decrease the onset or intensity post-traumatic

stress for siblings of children with cancer. Sessions will be held over the HIPAA-compliant version of the Zoom video-teleconferencing platform. Each session of the pilot program will be video-recorded in order to assess program fidelity. Parents and siblings will also be asked to complete brief post-session surveys after each program session (**Phase 2 Post-Session Survey 03.06.2023**) Parents and siblings will complete a battery of quantitative measures pre- and post-intervention. Should a parent/sibling need assistance in completing measures, a member of the study staff will have access to their study record in REDCap and can assist the family in completion of measures via Zoom at the family's request. Should the primary caregiver be unavailable for one or more of the program sessions involving parents, an alternate supportive adult can consent to participation limited to those sessions. A supportive adult who has consented to limited participation (participation limited only to sessions where parent involvement is needed), may be asked to complete brief exit interview 30-45 minutes regarding their experience with the program. The potential for exit interview will be based on the number of sessions the alternate supportive adult attended in support of the enrolled sibling.
Upon completion of the program, enrolled members of families (parents and siblings) also will complete 30-45 minute exit interviews (**Sample Exit Interview Questions**). Interviews will be recorded and transcribed verbatim using one of two methods described above

Phase 2: Measures

Measures for SibACCESS Pilot Trial (S = Sibling, P = Parent)			
	Upon IRB Approval: REDCap will be set-up to calculate time to complete EACH proposed measure		
	Construct	Time to Complete	Description
Background (Pre Only)	Background Information (P)		A background form will include questions that assess family composition & income; family members' age, gender, race/ethnicity, native language, immigration, education, & employment; sibling's medical, mental health, or developmental conditions and psychotherapy treatment history; & information about cancer (specific cancer diagnosis, date of diagnosis, treatment type, relapse status).
	Emotional Avoidance (S)		The Emotional Avoidance Strategy Inventory for Adolescents [86] is a 17-item measure of emotional avoidance with acceptable psychometrics in English [86] and Spanish [87] versions.
	Coping (S, P)		One of the following (not both): 1) Coping self-efficacy scale (26 items)

			2) Responses to Stress Questionnaire (57 + 13 = 70 items)	
	Communication (S)		The 4-item Communication scale of the Sibling Perception Questionnaire [91] is specific to cancer and has adequate reliability [92] and a Spanish translation [93].	
	Interpersonal Functioning (S)		One of the following (not both): 1) The Interpersonal Relationships scale of the Sibling Perception Questionnaire [91] is specific to cancer and has adequate reliability [92] and a Spanish translation [93]. 2) PFSES	
Outcomes (Pre & Post)	Posttraumatic Stress (S)		The Child PTSD Symptom Scale for DSM-5 [80] is a 27-item measure of posttraumatic stress. Strong test-retest reliability, internal consistency, and convergent validity with other child PTSD measures have been established [80], and a validated Spanish translation of the CPSS-5 exists [95].	
	Emotional & Behavioral Functioning (S, P)		The Strengths & Difficulties Questionnaire [96, 97] is a 25-item measure of children's psychosocial adjustment. It has five scales: Emotional Symptoms, Conduct Symptoms, Hyperactivity/ Inattention Symptoms, Peer Relationship Problems, and Prosocial Behavior. It has adequate construct validity, internal consistency, and test-retest reliability [98] and a validated Spanish translation [99].	
	Unmet needs (S)		The Sibling Cancer Needs Inventory [32] is a 45-item measure with seven domains: information, practical assistance, recreation, feelings, support, understanding from my family, and sibling relationship. It has adequate construct validity,	

			internal consistency, and test-retest reliability [100].
	Acceptability of program (S, P) – **Post Only**		The Client Satisfaction Questionnaire – 8 [101] is an established measure of client satisfaction with English and Spanish versions [102]. Feedback on acceptability also will be included in the post-program survey.
	Global Assessment Ratings (S, P) – **Post Only**		A one-item global assessment rating of parents'/siblings' beliefs that the program led to improvement, decline, or no change in siblings' functioning will be used. This will serve as the anchor-based method for determining clinical significance.[93, 94]

Phase 2: SibACCESS Program Description

SibACCESS (**A**cceptance, **C**oping, **C**ommunication, **E**ngagement, and **S**ocial **S**upport) targets the proposed mechanisms of sibling difficulties. The primary goal is to increase siblings' exposure and opportunities to process cancer-related cues to decrease the onset or intensification of posttraumatic stress (PTS). Treatment targets include emotion awareness, emotional acceptance / distress tolerance, adaptive thinking, family communication (via between-session assignments), and social support (fostered by the group format).

SibACCESS is based on acceptance-based cognitive-behavioral frameworks, drawing primarily on trauma-focused CBT (TF-CBT). TF-CBT is a structured, short-term treatment that incorporates cognitive-behavioral approaches to promote recovery from trauma. It is a logical starting point for the present study for multiple reasons: (a) TF-CBT was developed specifically for children and adolescents; parent participation is recommended but not required; (b) it has been tested in a group format and using telehealth; (c) it has demonstrated effectiveness across cultural groups; and (d) it is appropriate for youth who meet diagnostic criteria for PTSD and those with sub-clinical PTS. TF-CBT has not yet been evaluated in the context of childhood cancer. To better match the needs of siblings of youth with cancer specifically, we also incorporated skills from Dialectical and Behavioral Therapy (i.e., self-validation of emotions, mindfulness, radical acceptance) to better address distress tolerance and acceptance of the aspects of cancer that are beyond siblings' control.

SibACCESS group sessions will be facilitated remotely using Zoom. The intervention includes a preliminary joining session, one parent-focused educational webinar, seven group sibling

sessions, one individual sibling session, and one parent check-in. The parent webinar will provide a program overview, psychoeducation about sibling functioning in the context of cancer, and brief skills training. Parents will be given "discussion starter" questions to facilitate communication throughout the program. Sibling group sessions are approximately 75 minutes and will include an ice breaker, review of last week's homework, introduction of new topics, interactive practice of new skills, and assignment of home practice. Exposure to cancer-related emotions and cues will be emphasized across all program sessions; in addition to emotion exposures and cancer-related sibling narratives, siblings will confront information about cancer, uncomfortable thoughts and feelings, and communication about cancer throughout the program.

	Objectives of SibACCESS Program Sessions *Starred items indicate objectives that involve exposure to cancer-related thoughts, emotions, or situations Shaded sessions indicate parent involvement	
Joining Session	Brief Individual Family Meeting (30 min.)	Parents will be able to: • Provide information for the facilitator about the family's specific cancer context (e.g., child with cancer's diagnosis, prognosis, treatment status) • Express initial questions or concerns about involvement in the program, and receive individualized feedback from facilitators Siblings will be able to: • Begin to build rapport with facilitators • Express initial questions or concerns about involvement in the program, and receive individualized feedback from facilitators
Parent Pre-session: Supporting siblings	Pre-recorded caregiver webinar	Parents will be able to: • Identify the goals and structure of the SibACCESS program • Recognize common sibling emotional and behavioral responses to a cancer diagnosis • Acquire key foundational skills to support sibling through the program (e.g., validation, emotion self-management)
Session 1: Program introduction	Sibling group (75 min.)	Siblings will be able to: • Identify the goals and structure of the SibACCESS program • Begin to build rapport and connection with facilitators and other sibling group members • Establish a high-level understanding of what cancer is and types of treatments • Practice sharing factual information about sibling's cancer with peers*
Session 2: Understanding Emotions	Sibling group (75 min.)	Siblings will be able to: • Name primary emotions, their functions, and associated action urges • Map the "before" (antecedent), "during" (response), and "after" (consequences) of a recent cancer-related emotional experience* • Reflect on the thoughts, physical sensations, and behavioral urges that came with recent cancer-related emotional experience* • Practice sharing with peers about one recent cancer-related emotion (including the before, during, and after, and thoughts, physical sensations, and action urges)*
Session 3: Adaptive thinking	Sibling group (75 min.)	Siblings will be able to: • Define automatic thoughts and articulate how these relate to strong emotions • Identify common "thinking traps" and reflect on which ones come up most often for them • Practice sharing one cancer-related automatic thought with peers* • Apply the steps of cognitive restructuring to engage with and challenge the thought*
Session 4: Distress tolerance: Mindfulness and Radical Acceptance	Sibling group (75 min.)	Siblings will be able to: • Articulate the goal of mindfulness • Practice one mindfulness skill for nonjudgmentally experiencing emotions, without pushing them away or holding on to them* • Define radical acceptance and how it is different from "liking" • Reflect on one aspect of cancer siblings would like to work to radically accept*

Session 5: Introduction to Exposures	Sibling Group (75 min.)	Siblings will be able to: • Describe the avoidance cycle and its consequences • Articulate the rationale for confronting cancer-related thoughts, situations, and emotions that siblings might typically avoid • Enhance self-efficacy and motivation through identifying exposures siblings have already completed to counter avoidance • Begin to create an individualized list of exposure tasks that siblings can continue to work towards* • Select one exposure to attempt for homework and share this exposure goal with a peer*
Session 6: Introduction to Sibling Narrative and Exposure Goals	Individual Sibling Session (45-60 min.)	Siblings will be able to: • Reflect on exposure practices to date, including successes and difficulties • In consultation with the facilitator, continue to develop 2-3 individualized exposure goals* • Identify at least one exposure goal that will involve sharing an emotion-based narrative of their cancer experience • Describe the modality (e.g., song, picture, poem, story, letter, video) of their sibling narrative to the facilitator and begin to identify thoughts and emotions in narrative* • Articulate a plan for when, how, and with whom siblings will practice these exposures and share this sibling narrative
Session 7: Exposures / Narrative Follow-Up and Problem-Solving Skills	Sibling group	Siblings will be able to: • Reflect on successes and challenges in practicing exposures, and identify trouble-shooting strategies to facilitate ongoing practice • Identify emotions that arose with exposure practices and how siblings responded to these emotions* • Refine a near-complete sibling narrative • Share about the thoughts and emotions included in their narrative with peer*
Session 8: Parent Skill-Building and Check-In	Brief Individual Parent Session (45 min.)	Parents will be able to: • Discuss siblings' treatment gains and areas for continued growth with facilitators • Describe effective strategies for communicating about cancer and cancer-related emotions within the family • Identify at least one way they can support siblings in continuing to develop their narratives and practice exposures
Session 9: Wrap-up	Siblings & caregivers (caregivers join for second half of the session)	Siblings will be able to: • Share with peers about what they learned through exposure practices and creation of the sibling narrative* • Reflect on and share treatment gains, as well as areas for continued practice • Identify skills that siblings would like to practice in the future, and develop a practice plan Parents will be able to: • Reflect on and share treatment gains that they have observed • Identify strategies to support siblings' continued skill practice

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.
Risks are considered minimal for the present study. In Phase 1, the qualitative interview methodology used in this study has been used routinely in minimal risk research. Families

participating may experience emotional discomfort answering questions and discussing their family's experience with cancer. Providers may also experience emotional discomfort in discussing the experience of families they have treated and interacted with in the context of cancer. In Phase 2, families participating will likely experience some emotional distress during pilot intervention sessions, which is an expected and intentional aspect of the intervention.

There is also a small risk for breach of confidentiality.

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

Boston University study staff who conduct the qualitative interviews (Phase 1 and Phase 2) will work to minimize the emotional distress experienced by youth/young adults, parents and providers pertaining to discussion surrounding family and professional experiences in the context of cancer. Interviewers will assure participants that they are not required to answer questions that make them uncomfortable. Regarding completion of the screening items (Phase 1 and Phase 2) and quantitative measures (Phase 2), study staff will monitor completion of questionnaires. In particular, staff will immediately check the response to the youth/young adult screening question regarding active suicidal ideation; if active suicidal ideation is endorsed by the youth/young adult, study staff will contact Dr. Long (PI and licensed psychologist) and will ask follow-up questions to determine the level of risk. If imminent risk is discovered, staff will be in contact with parents (in the case of youth under the age of 18) or with the young adult directly (in the case of young adults age 18 or above) and will provide referrals for mental health care. (Individuals with active suicidal ideation will not be enrolled in the study).

Study staff leading the pilot intervention will also be trained in how to manage parent and youth emotional discomfort, including how to assess clinical risk and deescalate emotional situations. Should parent or sibling participants endorse mental health risk to Boston University study staff, Kristin Long PhD (principal investigator and licensed clinical psychologist) will be on call to provide guidance to address imminent risk discovered during study activities (i.e., qualitative interviews, pilot program sessions, exit interviews, etc.). With parent written consent, a formal mental health referral may be made as indicated.

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 direct benefits to participating in this study, though it is possible participants may perceive a benefit of research contributing to development of more comprehensive services to address the needs of siblings of children with cancer.

Describe the potential benefits to society and/or others related to the study

The needs of siblings and children of immediate family members with cancer are not often met within oncology programs. The present study works to develop a telehealth-based support program targeting posttraumatic stress symptoms of siblings of children with cancer that is culturally sensitive and meets the logistic and clinical needs of families. This is expected to improve trajectories of siblings' functioning and reduce the overall burden of cancer on families.

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. Payments should be prorated to compensate subjects for time and procedures completed **If YES**, provide a description of the compensation: *Phase 1 (Development of the SibACCESS Telehealth Program)* Participants (parents, siblings, and providers) will each receive a $30 gift card. *Phase 2 (Pilot of the SibACCESS Telehealth Program)* Participants (parents and siblings) each will receive a $30 gift card after completion of pre-intervention questionnaires (for a total of $60 per parent/sibling dyad). Participants will receive a $100 gift card after completion of post-intervention questionnaires and exit interviews (for a total of $200 per parent/sibling dyad). Alternate supportive adults, whose level of participation necessitates an exit interview, will receive a $30 gift card for their participation in the brief exit interview. Families will NOT be compensated for their involvement in intervention sessions.
☐	☒	Will identifiable information be sent to Central University departments (e.g. 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.)
Phase 1 (Pertaining to Qualtrics Data, Qualitative Interview, and Exit Interviews) Interviews for Phase 1 and 2 of the present study will be audio recorded using digital recorders for telephone interviews. For interviews completed using the Zoom platform, interviews will be audio-recorded using both the record function on the Zoom-platform and a digital audio recorder as back-up. Audio recordings will be transferred from digital audio recorders to a limited access network drive for the Child and Family Health Lab. Audio recordings will then be deleted from the audio recorder once moved to the limited access network drive. While interviewing remotely, recordings will also be saved on secure cloud storage (i.e., SharePoint) only accessible by approved study staff, to minimize for loss of data. Should any participant opt-out of recordings but still wish to participate, the data will be collected in the form of notes taken by the interviewer. These notes will be typed and saved in a password-protected files on the limited access network drive for the Child and Family Health

Lab. For data collected from the brief background forms, data will be stored in the Qualtrics platform, and will only be accessible to the Boston University study staff approved in Section E of this protocol. When Qualtrics data is downloaded to the limited-access network drive, identifiers will be removed, and the file will be password protected.

Phase 2 (Pilot Sessions of the SibACCESS Telehealth Program)

Pilot sessions for Phase 2 of the present study will be video- and audio-recorded in order for Boston University study staff to assess program fidelity. Video and audio recordings collected from Zoom pilot sessions will be saved to the Zoom cloud storage, and will be downloaded to the limited access network drive for the Child and Family Health Lab. Back-up audio recordings a digital audio-recorder will be transferred to a limited access network drive for the Child and Family Health Lab. Audio recordings from the digital audio-recorder will then be deleted from the audio-recorder once moved to the limited access network drive and secure cloud storage (i.e, SharePoint during remote operation).

For data collected from pre-/post-intervention quantitative measures, data will be stored on the REDCap platform, and will only be accessible to the Boston University study. When REDCap data is downloaded to the limited-access network drive, identifiers will be removed and files will be password protected.

Video- and/or audio-recordings of exit interviews will be collected by the Zoom-platform recording feature (or handheld digital audio-recorder if interview occurs via telephone only). Video- and/or audio-recordings will be downloaded to the limited access network drive. Audio-recordings from the digital audio recorder will then be deleted from the audio-recorder once moved to the limited access network drive and/or secure cloud storage (i.e., SharePoint during remote operation of studies).

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 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.

Each participant will receive a unique identifier (e.g., SibACCESS101). The tracking document that connects the participant name to the information that they provide (e.g. recorded interviews, questionnaire data, etc.) will be kept in a password-protected computer file in a limited-access network drive for the Child and Family Health Lab at Boston University. Only members of the Boston University study staff will have access to this document.

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.):

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**.**
Phase 1 and 2 (Pertaining to Qualtrics Data, Qualitative Interviews, and Exit Interviews) Transcribed interviews, or interview notes for families opting out of audio or video recording, will be stored in a password-protected file on a limited-access network drive that can only be accessed by members of the Boston University study staff. All identifying information (e.g., participant names) will be kept in a separate file password-protected file in a limited-access network drive for the Child and Family Health Lab at Boston University. For data from the brief background forms and Phase 2 quantitative surveys in Qualtrics, data will be stored on the Qualtrics platform and will only be accessible by study staff approved in section E of this protocol. When data is downloaded to the limited-access network drive, identifiers will be removed and the data will be saved in a password protected-document (e.g. excel file). Only identification codes will be used to present data at conferences or in publications. *Phase 2 (Pilot Sessions of the SibACCESS Telehealth Program)* Video and audio recordings of the pilot program will be saved to Zoom cloud storage and also downloaded to the limited access network drive for the Child and Family Health Lab and secure cloud storage (i.e., SharePoint during remote operation). Video recordings will not be shared as part of presented data as conferences or in publications.

Per Boston University (BU) Record Retention Policy, records concerning human subjects must be retained for 7 years. As the investigator, you must also adhere to all applicable requirements as defined by regulatory agencies (e.g. FDA, etc.) or Sponsors.

SECTION Q: CERTIFICATE OF CONFIDENTIALITY

In 2017 the NIH updated its policy for issuing **Certificates of Confidentiality**. Under the policy, all **eligible** research studies funded by the NIH are automatically issued a certificate of confidentiality. Investigators whose research is not funded or supported by the NIH may request and obtain from the NIH a Certificate of Confidentiality. Investigators who request and receive Certificates must follow the NIH and PHS policies governing such certifications.

YES	**NO**	

☒	☐	Is your research funded by the NIH and eligible for a Certificate of Confidentiality?
☐	☒	If your research is not funded by the NIH, will you be applying for a Certificate of Confidentiality?

SECTION R: PRIVACY

Describe how you will protect the privacy of subjects (e.g. where will consent procedures take place, if interviews or other interventions, where will these procedures take place)
Storage of electronic data (i.e., audio recordings, video recordings, questionnaire data, etc.) will be stored on the limited access network drive and secure cloud storage (i.e., SharePoint during remote operation) for the PI's (Kristin Long, PhD) research lab, the Child and Family Health Lab at Boston University. Only Boston University study staff will have access to study data. Families participating in this study and engaging in qualitative interviews (Phase 1), quantitative data collection (Phase 2), pilot program sessions (Phase 2), and exit interviews (Phase 2) will be directed to complete research activities from a private location of their choosing to safeguard their privacy. Boston University study staff completing interviews or group pilot sessions remotely will conduct study activities via telephone or the Zoom video-teleconferencing platform from a private room or office with a door that can be closed to ensure that interviews and research calls are not heard by individuals not on the Boston University study staff.

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 NIH website.

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 collected in the form of qualitative interviews will be analyzed according to applied thematic analysis methodology. This methodology includes assessment of data to build familiarity and create preliminary codes, creating initial codes and coding structures, combining codes into themes, and defining themes and the ways in which they fit together. The initial draft of the coding structure would be developed using a priori research questions and probes from the

semi-structured interviews. Phase 2 quantitative data will be analyzed descriptively (e.g., frequency of completion / missing data, mean scores on study measures).

Data for Phase 1 and 2 of the study will be monitored weekly by the PI (Kristin Long, PhD) who will meet with the study staff to discuss data collected from interviews, pilot program sessions, pre- and post-intervention quantitative surveys, and exit interviews. The PI will also monitor all research activities to ensure the procedures are carried out according to the approved IRB protocol. Due to the minimal risk designation for the study, adverse events are not anticipated to occur. If an adverse event occurs, the PI will complete an Adverse Events Form as part of this IRB protocol and submit the form to the IRB within one week of the event's occurrence.

SECTION T: HIPAA

Health Insurance Portability and Accountability Act

YES*	NO	

☐	☒	Is this research being conducted in a covered entity?
		The following BU CRC Departments are considered covered entities:
		• Sargent College Rehabilitation Services
		  ○ Physical Therapy Center at the Ryan Center for Sports Medicine and Rehabilitation
		  ○ 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. 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 (ACT) and require registration **AND** results submission in accordance with FDAAA 801? ACTs include: • 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 post-market surveillance required by FDA **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?

		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 #:
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? For more information on this policy please refer to: • NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information • Checklist **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 #:

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: Kristin Long, PhD

PI Signature: **Date:** 03/25/2024

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): David Somers, PhD.

Department/School: Psychological & Brain Sciences, CAS

Signature: 

Date: 1/4/2021

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: _____