# Study Consent

**Official Title:** BRITEPath, Component 3 of iCHART (Integrated Care to Help At-Risk Teens)

**ClinicalTrials.gov ID (NCT number):** NCT04000399

**Approval Date:** 04/19/2021

**University of Pittsburgh**
***Institutional Review Board***

Human Research Protection Office
3500 Fifth Avenue, Suite 106
Pittsburgh, PA 15213
Tel (412) 383-1480
www.hrpo.pitt.edu

# APPROVAL OF SUBMISSION (Expedited)

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|---|---|
| Date: | November 4, 2019 |
| IRB: | MOD18120080-003 |
| PI: | Stephanie Stepp |
| Title: | The Center for Enhancing Treatment & Utilization for Depression and Emergent Suicidality Phase 1b-Study 3-BRITEPath |
| Funding: | Name: National Institute of Mental Health , Funding Source ID: MH115838 |
| Grant Title: | *<Indicate "None" if there is none.>* |

The Institutional Review Board reviewed and approved the above referenced study. The study may begin as outlined in the University of Pittsburgh approved application and documents.

**Approval Documentation**

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|---|---|
| Review type: | Modification / Update |
| Approval Date: | 11/4/2019 |
| Expiration Date: | 5/20/2020 |

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| Determinations: | • Waiver/alteration of the consent process<br>• Children<br>• Waiver of consent documentation |
| Approved Documents: | • Approaching for Eligibility, Category: Data Collection;<br>• AWARE exit interview @ 12 weeks, Category: Data Collection;<br>• Movisens exit interview @ 1 week, Category: Data Collection;<br>• BPA flyer, Category: Recruitment Materials;<br>• Fact Sheet, Category: Consent Form;<br>• Passive Sensing Addendum Consent, Category: Consent Form;<br>• Pitch script and FAQs, Category: Recruitment Materials;<br>• Practice Letter to potential participants, Category: Recruitment Materials;<br>• Simple BPA flyer, Category: Recruitment Materials; |

As the Principal Investigator, you are responsible for the conduct of the research and to ensure accurate documentation, protocol compliance, reporting of possibly study-related adverse events and unanticipated problems involving risk to participants or others. The HRPO Reportable Events policy, Chapter 17, is available at http://www.hrpo.pitt.edu/.

Continuing review (CR) can be submitted by clicking "Create Modification/CR" from the active study at least 5 weeks prior to the expiration date.

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Clinical research being conducted in an UPMC facility cannot begin until fiscal approval is received from the UPMC Office of Sponsored Programs and Research Support (OSPARS).

If you have any questions, please contact the University of Pittsburgh IRB Coordinator, Jean Barone.

*Please take a moment to complete our* Satisfaction Survey *as we appreciate your feedback.*

**BRITEPath Research Study-ETUDES Center Phase 1b-MINOR & PARENT**

***Description of this research study***

This research is being conducted to enhance screening for behavioral health conditions among adolescents attending visits in pediatric primary & community care settings. Our goal is to enroll 50 youth and their parents from pediatric primary care offices who have been referred to mental health treatment to pilot the BRITEPath intervention. This study is sponsored by a Grant from the National Institute of Mental Health.

***What will the study involve?***

If you and your child choose to participate, you will either be assigned to the "Intervention" group or the "Treatment as Usual" group. Those assigned to the intervention group will receive BRITE, which is a safety planning smartphone application, to use in place of the "Treatment As Usual" paper-based safety plan that is used as part of standard clinical care.

In the treatment as usual group, embedded mental health therapists will work to develop a safety plan of which you may also receive a copy. Your child's care experience could be approached differently depending on what he/she discusses with the therapist at the time. Please note that the research team will not act as your child's treatment team and will not know the content of the discussions between your child and the therapist.

In the intervention group, through the use of a web-based platform we call Guide2BRITE, therapists will receive step by step instructions for how to assist adolescents in loading personalized content (like photos, videos, or favorite websites) onto the BRITE app that is used in conjunction with clinician-recommended content. BRITE lists steps in your child's safety plan, techniques for lessening distress, and ways to reach out to friends, family, and other social supports (such as professionals who can assist in a crisis). For those assigned to receive BRITE, information on use of the app will be sent to an online portal, called BRITEBoard, that will be reviewed by therapists. In the "Treatment as Usual" group, your child's mental health therapist will not use the Guide2BRITE and clinician portal, BRITEBoard.

For youth using the BRITE app safety plan, youth will be able to log into the BRITE app at any time with a pin code. If a pin code is lost, a text will be sent with the pin. The content of the safety plan will be available, even when the phone or device does not have access to wifi/data. We ask that you consult with your child's therapist before removing access to their phone to assure they maintain access to their safety plan.

While staff do not monitor the app 24 hours a day, your child could use the app to connect with a crisis line in your county in an emergency. The crisis information will be populated with your child's mental health therapist and I can also give you the contact information today, if you're interested. Additionally, the therapist is trained to be available to meet with parents and children to introduce the app and answer questions. The child will discuss his/her use of the app with their therapist on an ongoing basis. The ETUDES research assessor who calls you and your child will be "blinded" or not know if your child is using the BRITE app or a paper safety plan. This is to ensure as unbiased a phone assessment as possible for our research. We ask that you try to remember not to tell the researcher assessor who calls you which safety plan mode your child is using.

In both the treatment as usual group and intervention group, your son or daughter will be asked to participate in three one-hour phone calls with our research team. The first phone assessment will occur after you have agreed to participate in this study. The next call will take place 4 weeks later, and the third call will be made 12 weeks after to initial call. During the three phone calls, we will ask him or her about physical, emotional, social, behavioral and academic functioning. The phone calls will be recorded.

We are also requesting your authorization for our research team to access your child's medical records. If you agree, we will access their diagnoses, use of medications, and the course of their mental health treatment. This information will be used to learn whether our research interventions effect the mental health services an adolescent receives. Our research team may also enter information about your daughter or son's imminent safety such as suicidal ideation with a plan,

intent, and/or attempt to the treatment provider. Your permission to allow use to access these medical records will not expire, but you may cancel it at any time. If you choose to cancel this authorization, only information regarding your child's imminent safety will be documented in the child's medical records to the treatment provider. Cancelling authorization does not impact your child's participation in the rest of the study activities.

The data collected about your child's use of health services during the phone call study visits will be shared with the Kaiser Permanente Center for Health Research for analysis. Dates of your child's use of health services will be shared. Names of providers or other identifiable information will not be shared. You may choose to cancel authorization to access this information at anytime.

You may choose not to answer any questions or disclose any information that you do not want to share because your participation is voluntary. Even after agreeing to participate in this study, if you change your mind and want to cancel your authorization and permission, please let us know in writing. Write to the study's Principal Investigator: Dr. Stepp, 3811 O'Hara St Pittsburgh, PA 15213.

If you cancel your permission, no other health information about you/your child will be collected for this research. However, the health information that was received with your permission may be shared or used. For example, researchers may need to use or share this information:

- for safety reasons;
- to verify the research data;
- if required by law.

***Will your adolescent benefit from participating in this study?***

Your child will not directly benefit from participating in this study.

***What are the risks?***

The interviews and self-reported questions may potentially cause psychological distress. There is a risk of feeling embarrassed by providing responses about mental health questions. There is a risk of feeling tired or inconvenienced. Trained and experienced research clinicians will conduct the interviews. If your son or daughter becomes upset, the interviewer can assist.

There is potential for a breach in confidentiality if your answers were somehow to become available to non-study personnel. As such, transmissions like texting a crisis line or calling a crisis line on your personal device may be unknowingly and/or unintentionally intercepted by third parties. Someone not associated with the research study may see the messages on your phone. We ask that you minimize this risk by (1) setting up a password protection on your cellular phone and (2) immediately erasing messages after responding to our queries.

***How will we protect your child's information?***

The information we receive from your child and you will be labeled with a code number that we assign and not with anything that directly identifies either of you. All recordings will be coded by participant identification number, date, study name, and initials of interviewer. Digital records will be kept on secure servers behind UPMC's firewall. Any hard copy notes will be kept in locked research offices in locked storage cabinets to which only research study staff has access. Your child will not be identified by name in any publication of research results unless you sign a separate form giving your permission (release). Both you and your adolescent may choose not to answer any questions or disclose any information that you do not want to share because your participation is voluntary.

This research study is supported by the National Institute of Mental Health (NIMH) and representatives of NIMH may review the information we collect. Authorized representatives from the University of Pittsburgh Office of Research Protections may review our research records for the purpose of monitoring the conduct of this study.

Our research team may later share the information we have collected in this study with other investigators who are

studying adolescent behavioral health. But the information will be de-identified before it is shared by removing identifiable information about you or your child, i.e. your name, date of birth, or other private information.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIMH. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about your child's involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

You will be promptly notified if any new information develops during the conduct of this research study which may cause you or your child to change your mind about your continued participation.

***Will my adolescent be paid?*** Neither you nor your insurance provider will be charged for participation in this research study.
To thank you and your child for your time and efforts you will be paid $40 for the first phone assessment, $60 for the second phone assessment, and $80 for the third phone assessment. Payment will be mailed to your address to be shared with your child for your joint participation.

***Can we stop our participation in this study?*** You can, at any time withdraw from this research study. Withdrawing means you will be withdrawn from further participation in this research study. Any identifiable research information obtained as part of this study prior to the date that you withdrew your consent will remain. To formally withdraw your consent for your child's participation in this research study, you should provide a written and dated letter of this decision to the principal investigator of this research study Dr. Stephanie Stepp, at the following address: 3811 O'Hara St Pittsburgh, PA 15213. Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh.

If you have any questions about your rights as a research subject, please contact the Human Subjects Protection Advocate at the University of Pittsburgh IRB Office, 1.866.212.2668.

If you have any questions for the research staff, please reach out to Brandie George-Milford at 412-246-5629 or georgeba2@upmc.edu or Amy Anderson at 412-586-9851 or amy.anderson2@chp.edu.