18 yo Adult Participant RESEARCH Consent Form (written on first screen of Qualtrics or WebDataExpress survey to obtain electronically signed consent)

Project Title: Text2Connect Phase 2 (T2C)
Principal Investigator: Tina Goldstein, Ph.D, (faculty, Psychiatry, University of Pittsburgh)
Co-Investigators:
Consultants: Brian Suffoletto, MD (faculty, Emergency Medicine, Stanford University); Dawn Gotkiewicz, MD (faculty, Children's Community Pediatrics, Waterdam locations)

The information in this form is being used to seek your consent to be in a research study. Being in the study is voluntary; it is up to you. This research is being done to find out whether a text messaging intervention can increase independence in college age youth to manage their own healthcare as they transition into adulthood. Participation will last up to 4 months and will take about 2 hours of your time. There will be a total of 50 young adults who are at least 18 years old or older enrolled in this study. We are inviting patients at Children's Community Pediatric primary care offices and specialty mental health care providers to take part in the research study. Your choice to take part in the study will not affect any future relationship you may have with the University of Pittsburgh Medical Center (UPMC), or Children's Community Pediatrics (CCP). This text message intervention is not managed by a live person in real time. The intervention is not meant to aid in the actual scheduling of appointments or managing mental health crises or general mental health care. You should understand that **we will not be able to respond to any immediate or emergency concern you have that is sent to our phone number, nor any text message outside the scope of the questions we ask.**

You are being asked to be a volunteer in a research study led by Tina Goldstein, Ph.D, Associate Professor of Psychiatry University of Pittsburgh, David Brent, MD at University of Pittsburgh and Dr. Brian Suffoletto, at Stanford University along with physicians, nurses, and providers at Children's Community Pediatric practices and specialty mental health care practices. You have been invited to take part because you met study inclusion criteria, determined through a review of your Electronic Medical Record by your doctors at CCP, from your mental health office, or after speaking with you and you indicated interest in hearing about the study.

This intervention in no way changes, improves, or modifies the care you will be receiving. Rather the goal of the study is to promote "mental health self-efficacy" through text messages and videos or other information. Mental health self-efficacy is a concept aimed at providing people with the knowledge, skills and beliefs to manage their mental healthcare independently.

We are testing a text messaging intervention for young adults and comparing it to young adults who do not receive the text messages but instead receive information called psychoeducation (PE) through links to video libraries , about self-care during their transition to college. You will be randomly assigned to receive either T2C or PE. Links to PE videos will be sent (via text or email) by the research staff to all those in the PE arm of the study and research staff will assist with any technical difficulties you may have in viewing them.

The Text2Connect (T2C) intervention aims to increase mental health self-efficacy through psychoeducation, self-monitoring of symptoms and stressors, and cues to action for college-bound youth. Specifically, each monthly check-in starts with a text prompt inquiring about general well-being. Based on the response, participants then receive either general psychoeducational videos and prompts to continue to monitor mental health (in the event of wellness) or are then prompted to endorse stressors and symptoms they are experiencing to prompt awareness of symptoms in daily life. A text prompt then assesses a participant's self-reported confidence in ability to manage stressors and symptoms. Tailored knowledge and skills are then texted to the participant to enhance self-efficacy. Participants who endorse stressors/symptoms can opt to receive follow-up texts one week later to re-assess. Participants who endorse low confidence in ability to manage stressors and symptoms are prompted to seek treatment and provided resources.

Both T2C and PE aim to teach awareness about self-care measures that can be taken when you transition to college.

If you decide to be in this study, you will be asked to complete Online questionnaires through a web-based survey. The study will involve 4 online surveys. One survey at the start of the study (baseline), and surveys for 3 months following, 1 survey per month.

During the surveys, which may be completed at any location you would like on any internet-equipped electronic device, you will be asked to fill out online surveys through a secure data collection system. We will send you a link to this survey by email or text message (based on your preference). The topics covered in the survey include your recent mood and emotions; how you think about yourself; your coping skills, demographic information, and medical services you used. At the monthly follow up surveys, the same questions will be asked via online survey and/or phone interview.

When you finish the monthly surveys, you will receive a $20 payment card for each survey. When you complete all the follow up surveys, you will receive an additional $20 payment card, for a possible total of $100 for taking part in this study. The study involves approximately 2 hours total of time. There will be no costs to you.

We are also requesting your authorization for our research team to access your medical records. If you agree, we will access diagnoses, use of medications, and the course of your mental health treatment. This information will be used to learn whether our research interventions affect the mental health services an young person receives. Your permission to allow us to access these medical records will not expire, but you may cancel it at any time. Cancelling authorization does not impact your participation in the rest of the study activities.

You may choose not to answer any questions or disclose any information that you do not want to share because your participation is voluntary. **You can text STOP/QUIT at any time. If you do, you will not receive any further text messages.** 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. Goldstein, 3811 O'Hara St Pittsburgh, PA 15213.

If you cancel your permission, no other health information about you 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.

The data collected about your use of health services, the intervention, and responses to the online questionnaires will not be shared. Any dates of service use will be replaced with an interval such as number of days since you last saw your pediatrician or received a referral. You may choose to cancel authorization to access this information at anytime.

The following are risks and/or discomforts of taking part in this research study. The 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. It is possible that some of the questions may ask things that you would rather not answer. Of course, you may choose not to answer any question or to stop the study at any time.

There is potential for a breach in confidentiality if your answers were somehow to become available to non-study personnel.

We can't guarantee that taking part in this study will help you. The information we get from you and other young adults who participate, may help researchers find better ways to help young people who are going through hard times in their lives.

The information we receive from you will be labeled with a code number that we assign and not with anything that directly identifies you. Digital records will be kept on secure servers behind UPMC's firewall. You will not be identified

by name in any publication of research results unless you sign a separate form giving your permission (release). You 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 e.g., your name, date of birth, or other private information.

A description of this clinical trial will be available on *http://www.clinicaltrials.gov*, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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 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 to change your mind about your continued participation.

Your alternative to being in this study is to simply not participate. Your participation in the study will not influence any of the services you might be receiving, including those at Children's Community Pediatrics and University of Pittsburgh Medical Center. Everyone in this study will receive usual care or the standard of care at their doctor's office which includes Information, Psychoeducation, and Referral (IPR) if a patient endorsed mood or behavioral concerns. If at any point you decide not to participate in this study, the Principal Investigator can provide you with a list of community resources and/or treatment options for young people experiencing emotional difficulties.

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.

To formally withdraw your consent for your 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. Tina Goldstein, 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 for the research staff, please reach out to Brandie George-Milford at 412-246-5629 or georgeba2@upmc.edu. You can also reach out to your doctor's office, at any time with questions about your care and how they are involved in this research project at (724) 548-2283

The above information has been explained to me and all of my current questions have been answered. To indicate my agreement to participate in this research study, and to allow the use and disclosure of my medical record information for the purposes described above, I consent to participate in the study by clicking the 'I agree' box and by completing the fields below

Click here to print a copy of the consent form to keep for your records.

I Agree

Full Name: _____ ___ _____(first, middle initial, last name)
Birthdate: ____ / _____ / _____ (mm/dd/year)

Answer to ONE of 3 questions from drop-down box:
What is your mother's maiden name?
In what city were you born?
What high school did you attend?