Screening Wizard, Component 1 of iCHART (Integrated Care to Help At-Risk Teens)-Feasibility/Pilot Phase

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Screening Wizard 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 care and community settings. Our goal is to enroll 70 youth and their parents and young adults from to pilot the Screening Wizard intervention.

This study is sponsored by a Grant from the National Institute of Mental Health

What will the study involve?

You and your child have already answered questions on a tablet about your child's emotions and behaviors, as well as your and your child's thoughts about behavioral health care at your primary care office. We are recruiting youth and their parents to participate in 1 of 2 groups based on the time your doctor's office received a report from the mental health questions. While answering questions at your primary care office, your doctor may or may not have discussed mental health treatment recommendations with you from a report that the questionnaire produced. In other words, your doctor either had a report with treatment recommendations based on the answers to the questions you and your child answered or did not.

We are inviting you and your child 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 authorization to allow us 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.

If you cancel your authorization, no other health information about you/your child will be collected for this research. However, the health information that was received with your authorization 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.

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, please let us know in writing. Write to the study's Principal Investigator: Dr. Lindhiem, 3811 O'Hara St Pittsburgh, PA 15213.

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 child 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.

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 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 $20 for the first phone assessment, $30 for the second phone assessment, and $40 for the thirdphone 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. Oliver Lindhiem, at the following address: 3811 O'Hara St BFT 5th Floor 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.