The Children's Hospital of Philadelphia®

Verbal Informed Consent Form and HIPAA Authorization

Study Title: Bending Adolescent Depression Trajectories Through Personalized Prevention

Version Date: April 18, 2017

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You and your child are eligible to take part in a research study. The information that will be discussed gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research staff.

Why are you being asked to take part in this study?

You and your child are being asked to continue to take part in this research study because you have been participating in this study at Rutgers University and the study will now take place at CHOP.

What is the purpose of this research study?

The purpose of the study is to determine if different programs can help prevent depression in teenagers. In particular, we are interested in better understanding which prevention programs would be most beneficial for different teenagers.

What is involved in the study?

You and your child will participate in evaluations every 6 months up to 3 years after your child completed the prevention groups that took place at Rutgers University. At each of these evaluations, you and your child will complete an interview about the child's thoughts and feelings over the phone. These interviews will be audio recorded. At each of these evaluations, you and your child will also complete questionnaires regarding the child's feelings, thoughts, relationships, and functioning. Parents will also complete questionnaires about their own feelings and life events. These questionnaires can be completed by phone and/or online.

If your child begins to feel worse during the project, s/he will be evaluated and referred for more intensive treatment if necessary. We will consult with you about these treatment decisions. If at any time during the project, an evaluation indicates a serious problem that

requires immediate care, such as suicidal ideation or suspected abuse, we will inform you and we will work with you to immediately link your child to emergency mental health services. If your child does not have Medicaid or other health insurance, you will have to pay for the follow-up treatment that occurs in the community. If an evaluation indicates suspected abuse, appropriate authorities will be notified.

How long will you be in this study?

The evaluations will take about 2 hours and will occur every 6 months for 3 years after the prevention groups.

What are the risks of this study?

The evaluations are time consuming and are about personal matters. It is possible that you or your child will feel upset, tired, or anxious. If this happens, you or your child can choose not to answer specific questions or ask to have the evaluation stopped at any time. If your child discloses that s/he intends to harm him/herself or intends to harm someone else, both you and the appropriate authorities will be notified. If your child discloses potential child abuse, this information will be reported to the appropriate authorities.

As with any study involving collection of data, there is the possibility that this information will be shared with others. Every precaution will be taken to secure your personal information to ensure confidentiality.

Are there any benefits to taking part in this study?

There is no direct benefit by participating in this part of the study. The knowledge gained from this research may help doctors learn more about the prevention of depression in teenagers and how to determine which program will be most beneficial for a specific teenager.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must tell us that you agree.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP or in the community.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you and your child will be collected. This will include information from the questions that we ask you. Staff are required to

keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law, such as in the case of concerns about potential harm to your child or others. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data. These groups include:

- Members of the research team and other authorized staff at CHOP;
- Individuals at Rutgers University who were part of the research team prior to the transfer to CHOP;
- Collaborators at the University of Illinois (formerly at the University of Denver) who are conducting the same research study;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections;
- The National Institutes of Health who is sponsoring this research.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By verbally agreeing, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

The identifiable information from this study will be destroyed 5 years after the study is completed. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded

projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing, without your consent, information that they are required by law to disclose to government authorities. For example, researchers must comply with laws requiring the reporting of suspected child abuse and neglect and communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Jami Young
Children's Hospital of Philadelphia
Roberts Center for Pediatric Research
Behavioral Health, 8/8473
2716 South Street
Philadelphia, PA 19146-2305

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Additional Information

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. You will be informed if changes to the study are needed to protect your health. You will be told about any new information that could affect your willingness to stay in the study, such as new risks, benefits or alternative treatments.

Financial Information

Will there be any additional costs?

There will be no costs to you for taking part in this study.

Will you be paid for taking part in this study?

- Parents will be paid $20 for each evaluation for their time and effort.
- Adolescents will be paid $20 for each evaluation for their time and effort.

If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. Jami Young at (267)425-1328. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

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

Documentation of Verbal Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

Name of Child Subject

Name of Parent Subject

The research study and consent form was explained to:

Person Providing Consent

Relation to child subject:
☐ Parent ☐ Legal Guardian

The person who provided consent confirmed that all of their questions had been answered and they agreed to their and their child's participation in this research study.

They confirmed that they were legally authorized to consent to their child's participation.

They agreed to let CHOP use and share their child's health information.

Person Obtaining Consent

Signature of Person Obtaining Consent

Date

Documentation of Verbal Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research (Youth ≥ 18)

The research study and consent form was explained to:

Name of Subject

The person who provided consent confirmed that all of their questions had been answered and they agreed to their participation in this research study.

They agreed to let CHOP use and share their health information.

Person Obtaining Consent

Signature of Person Obtaining Consent

Date

Documentation of Child Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

_____

Person Obtaining Assent

_____ _____

Signature of Person Obtaining Assent Date

Documentation of Verbal Consent and Assent to Contact You About Future Studies

The person obtaining consent will indicate whether you would like us to contact you about future studies.

_____ (initials) Parent requests to be contacted about future studies.

_____ (initials) Parent requests not to be contacted about future studies.

_____ (initials) Child requests to be contacted about future studies.

_____ (initials) Child requests not to be contacted about future studies.