Official Title:	Examining the Impact of Family Connectors
NCT Number:	NCT05195489
Study Number:	21-01486
Document Type:	Informed Consent Form
Date of the Document:	• June 14, 2023

NYU Langone Health

Research Subject Informed Consent Form

Title of Study:	Examining the Impact of Family Connectors S12-01116
Principal Investigator:	Kimberly Hoagwood, PhD Department of Child & Adolescent Psychiatry NYU Grossman School of Medicine One Park Avenue, 7th Floor, Room 310 New York, NY 10016 646-754-4888
Emergency Contact:	Mary Acri, PhD 203-675-4691

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to understand the impact of Family Connectors, a peer-to-peer support and education program for family members who have participated in OnTrack, a treatment program for adolescents and young adults.

3. How long will I be in the study? How many other people will be in the study?

If you agree, you will be involved in this study for up to 15 months. It is expected that 96 family members will participate in this study.

4. What will I be asked to do in the study?

You will be randomly assigned to receive either the Family Connectors program or be given a list of resources. If you are assigned to the Family Connectors program, your study participation will consist of participating in weekly calls with a Family Connector (a peer) who will provide support and information. These calls will take approximately one hour per week. In addition, you will be asked to complete a questionnaire at three timepoints: the first after consenting, the second at the beginning of the study, and the third at the end. You will also receive a list of community supports for your family.

If you are randomly assigned to receive a list of resources, you will also be asked to complete a questionnaire at three timepoints: the first after consenting, the second at the beginning of the study, and the third at the end. After completing your third survey, if interested, you will have the opportunity to work with a Family Connector for the next six months. If you select to do this, you will be asked to complete an additional questionnaire at the end of your time working with the Family Connector.

REDCap will be used to administer electronic questionnaires, with no identifying information appearing on the questionnaires. Any identifiable information collected and/or used for the purposes of this research will not be used or distributed for future research studies.

5. What are the possible risks or discomforts?

The primary risks associated with this study are (1) a loss of confidentiality and (2) possible discomfort in answering some of the questions. To address concerns of breach of confidentiality, all electronic records will be stored on REDCap, a HIPAA-compliant electronic data format platform. All files and will be kept confidential to the extent permitted by law. Records will only be available to research staff, and Federal, State and Institutional regulatory personnel (who may view records as part of the routine audits). Privacy will be protected through the use of codes (an ID number). Any hard copy contact forms and ID logs will be kept in a locked cabinet at NYU. All electronic data will be kept on password-protected computers. If results are published, only group information will be reported and they will not contain any identifying information about any individuals.

Second, you may feel discomfort responding to some of the questions in the interview. You do not have to answer any questions that make you uncomfortable.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

In other studies, family members who received Family Connectors reported high rates of satisfaction and family empowerment. Youth also showed higher rates of attendance at school and mental health service visits. It is possible that your family may experience similar benefits.

8. What other choices do I have if I do not participate?

The other option is to not participate.

9. Will I be paid for being in this study?

You will be paid $50 for completion of the questionnaires at up to four timepoints, for a total of up to $200.00. If you chose to leave or are withdrawn from the study for any reason before finishing the entire study, you will only be paid $50 for each set of questionnaires that you have completed.

You are required to track all payments made to you by NYU Langone for your participation in any research for this calendar year. You must let us know immediately if/when the total research payments presently equal or is likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please advise Dr. Kimberly Hoagwood at 646-754-4888.

10. Will I have to pay for anything?

There is no cost to you for participating in this study.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

Due to the coronavirus public health crisis (COVID-19), the federal government has issued an order that may limit your right to bring a claim if you are injured or harmed while participating in this COVID-19 clinical study. If the order applies to this study, it limits your right to bring a claim against the researchers, healthcare providers, and any study sponsor, manufacturer, and/or distributor involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this "Countermeasures Injury Compensation Program" go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by the Principal Investigator or study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.

- The study sponsor, the principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

13. How will you protect my confidentiality?

To address concerns of breach of confidentiality, all electronic records will be stored on REDCap, a HIPAA-compliant electronic data format platform. All files and will be kept confidential to the extent permitted by law. Records will only be available to research staff, and Federal, State and Institutional regulatory personnel (who may view records as part of the routine audits). Privacy will be protected through the use of codes (an ID number). Any hard copy contact forms and ID logs will be kept in a locked cabinet at NYU. All electronic data will be kept on password-protected computers. If results are published, only group information will be reported and they will not contain any identifying information about any individuals.

There are some important things that you need to know. We protect your information from disclosure to others to the extent required by law. Some examples are laws that require reporting of child abuse/neglect and threats to harm yourself or others.

14. HIPAA Authorization

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section.

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: *National Institute of Mental Health (NIMH) and NIMH's Data Archive (NDA)*

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?

Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

15. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

16. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

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.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

DC 05/08/2020

Last Updated: 5/7/2020