

Family Engagement, Cross-System Linkage to Substance Use Treatment for Juvenile Probationers -- Phase 3

NCT03048552

Informed Consent and Assent Forms

7-5-18

Probation Staff Consent Form
Family Engagement, Cross-System Linkage to SU treatment for Juvenile
Probationers
IRB # 7398; Katherine Elkington, PhD; 646-774-6965

PURPOSE OF THE STUDY: We are asking you to participate in the implementation of Family CONNECT, a linkage-to-services program that aims to help link youth on probation to substance use services, at your probation department. When we say link we mean connect; when we say linkage we mean connection. The goal of Family CONNECT is to improve the experience of youth on probation as they connect and start treatment with substance abuse treatment services. Additionally, we are also asking you to participate in four surveys. Including you, there will be up to 36 probation officers participating in this study, along with 50 youth on probation and 50 of their caregivers. This study is a pilot study, meaning that the information from this study will be used to inform a larger study for Family CONNECT.

PARTICIPATION IS VOLUNTARY: Your participation in this study is voluntary. You do not have to take part in this study. Your employment status at the probation department will not be influenced in any way by your decision to participate or not.

ALTERNATIVE TO STUDY PARTICIPATION: The alternative to participating is simply not to participate.

STUDY PROCEDURES: If you agree to participate, you may be randomized to work with a linkage specialist. If you are randomized to work with a linkage specialist, you will be asked to attend training on how to work with a linkage specialist (e.g. referral protocol, communication, etc.). You will also be asked to participate in four surveys throughout the course of the study. These surveys will cover topics about your organization's mission, structure, culture/climate, resources, the procedures related to referral to substance use treatment, and interagency collaboration. You will be asked to complete these surveys at baseline and then at 6-, 12-, and 18- months after. You may complete the survey online or via hardcopy. Research staff will email an individual survey link to you and provide site leadership with hard-copies of the survey. Each of the surveys will take approximately 25 minutes to complete.

RISKS: You may reveal sensitive information in this study, and may possibly experience feelings of discomfort when answering questions about or providing substance abuse treatment for youth on probation and success or failures of working with the substance abuse treatment system. You may feel discussion of such personal information might have implications for your job duties and/or feel your job might be in jeopardy due to the information revealed or shared. You may experience a loss of confidentiality related to your responses; we have several procedures in place to reduce this risk (see Confidentiality section below). Of course, you are free to not answer any of our questions, or discontinue the survey at any point.

BENEFITS: There are no direct benefits to you in participating in the study. The primary benefits from this work are for the progress of science. The results of this study may lead to improvement in referral for and engagement in substance abuse treatment services for youth on probation.



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COMPENSATION: You will receive training credit in the amount of 1 hour for completing two surveys; 2 training hours for completing four surveys.

CONFIDENTIALITY: Your responses will not be shared with supervisors, Unit Chiefs or Department Directors/Deputy Directors. The researchers will keep your responses confidential **except** in the following circumstances: 1) if we learn of threatened violence to self (e.g. thoughts of suicide) or others (e.g. thoughts of homicide) that you discuss, or 2) suspected or known physical abuse, sexual abuse or neglect of minors. If we learn of this information, we will take whatever measures are needed to protect individuals involved, and will voluntarily comply with State reporting laws on child abuse, harm to self or others, including reporting to Child Protective Services as necessary.

The information from the surveys will be collected using Qualtrics, an online survey program that can be accessed through an URL designated by Columbia University. The URL is password protected and information is stored directly onto Qualtrics' secure website. Responses are de-identified which means identifying information like your name will be removed and you will be identified by a unique ID number. Responses are encrypted under a 128-bit SSL encryption (same security used when you enter credit card numbers in online purchases) and are represented by numerical data. The only textual information present is the participants' ID number, IP address, and whether participants chose to enter textual data.

This survey will not be part of your employment record at the probation department and will not be shared with any of the probation department staff. All records and the results of the research will remain confidential to the extent permitted by law. Once you have agreed to participate in this study, you will only be identified by a code number; your name will not be connected with your information in any way so you cannot be identified. All study information including your name and other personal identifying information will be stored in an electronically secure database; all other study information will be coded and kept in locked files at the New York State Psychiatric Institute. Only research staff and institutional personnel, as part of routine audits, will have access to the files. Information from this research may be published but publications will not include the names of any study participants or any information that could identify you. Data stored in computers will only be available with a password. Only the Principal Investigator will have access to that password.

We will apply for a Certificate of Confidentiality, issued by the National Institute of Mental Health (NIMH), for this study. This Certificate prevents the researchers from being forced to release any identifiable research data (including under court order or subpoena) without your written consent. This Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child, or threatened violence to self or others. Such information will be reported to the appropriate authorities.

You should understand that a Certificate of Confidentiality does not prevent you or members of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written



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consent to receive research information, then the researchers may not use the Certificate to withhold that information.

We will register this study as a clinical trial. 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.

New York State Psychiatric Institute does not provide compensation or payment for treatment of research related injuries. However, you should be aware that participation in this research does not waive any of your legal rights to seek such compensation through the courts.

RESEARCH STANDARDS AND RIGHTS OF PARTICIPANTS: Your decision to take part in this is voluntary. Your supervisors will not be informed about your choice to participate or not in this study. Your choice will have no impact on your employment at the probation department. If you chose to participate, you can stop participation at any time. You can also refuse to answer any of the questions you are asked. Doing either will in no way affect your employment at the probation department. Every effort will be made to keep all your research records confidential.

IN CASE OF INJURY: If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator Dr. Katherine Elkington at 646-774-6965 so that you can review the matter and identify the medical resources that may be available to you.

In case of injury, New York State Psychiatric Institute will provide short term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's doctors, and which is within the capability of New York State Psychiatric Institute to provide. In addition, we will provide assistance in arranging follow up care in such instances.

New York State Psychiatric Institute and Research Foundation for Mental Hygiene do not provide compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the court by participating in this research.

Please be aware that:

1. The New York State Psychiatric Institute, Columbia University and New York Presbyterian Hospital will furnish that emergency medical care determined to be necessary to the medical staff of this hospital.
2. You will be responsible for the cost of such care, either personally or through your medical insurance or other form of medical coverage.
3. No monetary compensation for wages lost as a result of injury will be paid to you by Research Foundation for Mental Hygiene, the New York State Psychiatric Institute, Columbia University and New York Presbyterian hospital.
4. By agreeing to the terms of this consent form, you are not waiving any of your legal



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rights to seek compensation through the courts.

QUESTIONS AND COMPLAINTS: The research staff will answer, to the best of their knowledge, any questions concerning the procedures described above. If you have any questions about this study, you may contact Dr. Katherine Elkington at 646-774-6965. If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Main Office at (646) 774-7155 during regular office hours. You will be given a copy of this consent form to keep.

ADDENDUM: We are asking you to participate in a voluntary focus group so that we can hear about your impressions of the Family CONNECT study. Staff who participated in Family CONNECT are eligible to participate. At the focus group we will ask you about your overall impressions of the Family CONNECT study, including the referral process, working with our study staff, working with the Linkage Specialists, and your impressions of the family's experiences participating in the study. The focus group will take approximately 1 hour.



Parent Consent

Family Engagement, Cross-System Linkage to SU treatment for Juvenile Probationers

(IRB#7396: Katherine Elkington, PhD; 646-774-6965)

Purpose of the Study: We are asking you and your child to participate in Family CONNECT, which is a program that aims to help link youth on probation to substance use and/or mental health services. When we say link we mean connect; when we say linkage we mean connection. The goal of Family CONNECT is to improve the experience of youth on probation as they connect and start treatment with substance abuse and/or mental health treatment services. Additionally, we are also asking you and your child to participate in three surveys. Including you and your child, there will be 50 caregivers and 50 youth on probation participating in this study along with up to 36 probation staff. This study is a pilot study, meaning that the information from this study will be used to inform a larger study of Family CONNECT.

Participation is Voluntary: Your and your child's participation in this study is voluntary; to be part of the study you must both volunteer to participate. You and your child do not have to participate in this study in order to get services that are available to you or your child through the probation department.

Alternatives to Study Participation The alternative to participating is simply not to participate; if you do not participate in this study, you and your child will still receive all services as usual through the probation department and his/her terms of probation will not change.

Study Procedures: Study group: If you and your child agree to participate, your child's probation officer will either 1) refer your child to a linkage specialist, who will work with you and your child for up to 6 months to link and enroll your child in substance abuse and/or mental health treatment services, or 2) you and your child will work with your child's probation officer as usual to enroll your child in treatment. Depending on the probation officer your child has been assigned to, there is a 50:50 chance (same chance of flipping a coin) of you and your child getting referred to a linkage specialist or you and your child working with your child's probation officer as usual. If you do get referred to work with a linkage specialist, this person may come to your home, or some other agreed upon place, to work with you and your child and help your child get to treatment. This person will speak with your child's probation officer as well as any substance abuse or mental health treatment provider you and your child may work with in order to help your child successfully enroll and stay in treatment.

Interviews: Regardless of whether you work with a linkage specialist or not, you and your child will also be asked to participate in three online surveys throughout the course of the study (6 months). One will take place now or within a few days from now, one 2 months from now and one 6 months from now; each of your three online surveys will be approximately 60 minutes long. You and your child will be asked questions about experiences, thoughts, and feelings, including those regarding substance use, mental health, substance abuse treatment, probation, linkage specialists (if you are referred to work with a linkage specialist), and Family CONNECT. The interviews will be conducted by a study research staff member at your probation department in private offices or at another agreed upon confidential location such as your home or a local library. You and your child will be interviewed separately. You will not have access to your child's answers and your child will not have access to your answers. If your child is placed in secure or non-secure juvenile justice facility after enrollment in the study, we will attempt to contact your child and ask him/her to conduct any remaining assessments. If we have trouble locating him/her, we may also search secure or non-secure juvenile justice facilities in New York State to locate him/her if you are unclear on your child's whereabouts.

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Audio taping: All interviews will be audio recorded with a digital recorder. The audio digital files help the research team to remember exactly what was said during the survey interviews and to ensure that the survey was done correctly. Your name will not be on the digital audio file. Instead you will be assigned an identification number to ensure confidentiality. All audio recordings will be private and will be kept in an electronically secure database. The files will be listened to only by the people doing the study and will be destroyed after the information has been written down, no later than ten years from now.

Record data: We will also gather information from your child's probation department records on whether or not your child was referred to a treatment program, whether your child attended that program, if your child finished the treatment program as well as the outcome of your child's probation at the end of 6-months (e.g. successfully completed, still ongoing, violated).

Risks: Some of the interview questions will ask about probation, substance abuse, and/or mental health treatment and may make you or your child feel embarrassed, worried, or upset. If this happens, the interviewer will spend time talking with you and/or your child until you and/or your child feel better. You may experience a loss of confidentiality related to your responses; we have several procedures in place to reduce this risk (see Confidentiality section below). You and your child can refuse to answer any questions or stop the interview at any time.

Benefits: There are no direct benefits to you in participating in the study. The results of this study may lead to improvement in referral for and use of substance abuse and/or mental health treatment services, from which your child or others may directly benefit.

Compensation: You and your child will each receive a \$50 gift card for each of the 3 surveys (for a total of \$150 each) that is for both participation in the interview and, if needed, transportation costs to the probation department for face-to-face interviews. If you are working with the Linkage Specialist, your child will receive a \$10 gift card when they attend each of the first three Linkage Specialist Appointments (for a total of \$30). If you are not working with the Linkage Specialist, you and your child will be entered into a raffle each time you respond to a *brief* bi-weekly message from our research team. The raffle prize will be a gift card or movie tickets worth \$50.00. The raffle will run approximately every 4 months. If your child is placed in secure or non-secure juvenile justice facility after enrollment in the study, his/her payment will be held by us until their release or given to a parent or caregiver who they choose.

Confidentiality – when we can and cannot keep this private: All records and the results of the research will remain private and confidential. We will do everything we can to protect the privacy of both you and your child. The researchers will keep your responses private and confidential except in the following circumstances: 1) if we learn of threatened violence to self (e.g. thoughts of suicide) or others (e.g. thoughts of homicide) that you discuss, or 2) suspected or known physical abuse, sexual abuse or neglect of minors. If we learn of this information, we will take whatever measures are needed to protect individuals involved, and will voluntarily comply with State reporting laws on child abuse, harm to self or others, including reporting to Child Protective Services as necessary. If, during the interview with your child, we learn that s/he is suicidal/homicidal, or has experienced abuse at the hands of someone other than you, we will inform you of this in addition to informing your child's probation officer and a mental health provider if they are available onsite at the probation department.

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The information from the surveys will be collected using Qualtrics, an online survey program that can be accessed through an URL designated by Columbia University. The URL is password protected and information is stored directly onto Qualtrics' secure

website. Responses are de-identified which means identifying information like your name and your child's name will be removed and you and your child will be identified by a unique ID number. Responses are encrypted under a 128-bit SSL encryption (same security used when you enter credit card numbers in online purchases) and are represented by numerical data. The only textual information present is the participants' ID number, IP address, and whether participants chose to enter textual data.

All study information including your name and your child's name and other personal identifying information will be stored in an electronically secure database; all other study information will be coded and kept in locked files at the New York State Psychiatric Institute. Only research staff and institutional personnel, as part of routine audits, will have access to the files. No part of your interview or your child's interview will be part of his/her record at the probation department and will not be shared with any of the probation department staff. Your name and your child's name will not go on any forms that will be completed as part of the study. You and your child will be recognized by a number (code) that is specific for each participant. Information from this research may be published but publications will not include the names of any study participants or any information that could identify you or your child. Data stored in computers will only be available with a password. Only the Principal Investigator (the head of the study) will have access to that password.

We have received a Certificate of Confidentiality, issued by the National Institute of Mental Health (NIMH), for this study. This Certificate prevents the researchers from being forced to release any identifiable research data (including under court order or subpoena) without your written consent. This Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child, or threatened violence to self or others. Such information will be reported to the appropriate authorities.

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

We have registered this study as a clinical trial. A description of this clinical trial is 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.

If your child is placed in secure or non-secure juvenile justice facility after enrollment in the study, the study team will facilitate contact with the proper authorities, including your child's probation officer, to obtain permission for their research participation while in a juvenile justice facility. We may need to disclose that your child is participating in a study, if the facility requires this information. However, we will not reveal any details of the study. We will only interview your child if the interview can be conducted in a private setting. Despite these precautions confidentiality cannot be guaranteed.

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New York State Psychiatric Institute does not provide compensation or payment for treatment of research related injuries. However, you should be aware that participation in this research does not waive any of your legal rights to seek such compensation through the courts.

Research Standards and Rights: Your and your child's participation in this study is voluntary. You and your child do not have to participate and can stop participation in this study at any time. You and your child can terminate participation in the study even after the study has started and can also refuse to answer any of the questions asked. If either of you decide not to participate, or later decide to stop participation, you and your child will not lose any benefits to which you both are otherwise entitled, including services and care that are normally available to you and your child through the probation department. A decision not to participate or to terminate participation by you or your child will have absolutely no effect on your child's terms of probation; your child will still have to comply with all the terms and conditions of his/her probation that he/she did before.

In Case of Injury: If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator Dr. Katherine Elkington at 646-774-6965 so that you can review the matter and identify the medical resources that may be available to you.

In case of injury, New York State Psychiatric Institute will provide short term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's doctors, and which is within the capability of New York State Psychiatric Institute to provide. In addition, we will provide assistance in arranging follow up care in such instances.

New York State Psychiatric Institute and Research Foundation for Mental Hygiene do not provide compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the court by participating in this research.

Please be aware that:

1. The New York State Psychiatric Institute, Columbia University and New York Presbyterian Hospital will furnish that emergency medical care determined to be necessary to the medical staff of this hospital.
2. You will be responsible for the cost of such care, either personally or through your medical insurance or other form of medical coverage.
3. No monetary compensation for wages lost as a result of injury will be paid to you by Research Foundation for Mental Hygiene, the New York State Psychiatric Institute,

Columbia University and New York Presbyterian hospital.

4. By agreeing to the terms of this consent form, you are not waiving any of your legal rights to seek compensation through the courts.

Questions: The research staff will answer, to the best of their knowledge, any questions concerning the procedures described above. If you have any questions about this study, you may contact Dr. Katherine Elkington at 646-774-6965. If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the

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NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Main Office at (626) 774-7155 during regular office hours. You will be given a copy of this consent form to keep.



**Youth Informed Assent for Participation in Research
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Family Engagement, Cross-System Linkage to SU treatment for Juvenile Probationers

Purpose and Overview

We are asking you and your caregiver to participate in Family CONNECT, which is a program seeking to help link youth on probation to substance use and/or mental health services. When we say link we mean connect; when we say linkage we mean connection. The goal of Family CONNECT is to improve the experience of youth on probation as they connect and start treatment with substance abuse and/or mental health treatment services. We are also asking you and your caregiver to participate in three surveys. You are being asked to participate in this study because you are 1) 10-18 years old, 2) currently on probation, and 3) currently use substances and/or are in need of mental health treatment. Including you and your caregiver, there will be 50 youth on probation and 50 caregivers participating in this study along with up to 36 probation staff. This study is a pilot study; this means that the information from this study will be used to inform a larger study of Family CONNECT.

Voluntary

Participation in this research is voluntary. Please talk this over with your caregiver before you decide if you want to be in the study. We also asked your caregiver to give their permission for you to be in this study. But even if your caregiver says "yes," you can still say "no". If you don't want to be in this study, you don't have to be. Remember, being in this study is up to you, and no one will be upset if you don't want to, even if you decide to stop participating halfway through the interview. You can decide not to participate or to stop participation at any point during the study. A decision not to participate or to stop participation will have absolutely no effect on your terms of probation; whether you participate or not, you will still have to follow all the terms and conditions of your probation that you did before. This means that whether you participate or not, you will still have to do all the things for your probation that you did before. Also, if you choose not to be part of this study or if you decide to stop participation at any time, you will not lose any benefits to which you would normally get, including current services usually available to you through the probation department. Additionally, a decision not to participate or to stop your participation will not affect your current or future treatment at the New York State Psychiatric Institute or Columbia University.



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Procedures

Study group: If you and your caregiver agree to participate, your probation officer will either refer you to 1) a linkage specialist, who will work with you and your caregiver for up to 6 months to link and enroll you in substance abuse and/or mental health treatment services, or 2) you and your caregiver will work with your probation officer as usual to enroll you in treatment. Depending on the probation officer you were assigned to, there is a 50:50 chance (same chance of flipping a coin) of you and your caregiver working with a linkage specialist or you and your caregiver working with your probation officer as usual. If you do work with a linkage specialist, this person may come to your home, or some other agreed upon place, to work with you and your caregiver and help you get to treatment. This person will speak with your probation officer as well as any substance abuse or mental health treatment provider you work with in order to help you successfully enroll and stay in treatment.

Interviews: Whether you work with a linkage specialist or not, you and your caregiver will also be asked to participate in three online surveys throughout the course of the study (6 months). One will take place now or within a few days from now, one 2 months from now and one 6 months from now; each of your three online surveys will be approximately 60 minutes long. You and your caregiver will be asked questions about experiences, thoughts, and feelings, including those involving substance use, mental health, substance abuse treatment, probation, linkage specialists (if you are referred to work with a linkage specialist), and Family CONNECT. The interviews will be conducted by a study research staff member at your probation department in private offices or at another agreed upon confidential location such as your home or a local library. You and your caregiver will be interviewed separately. You will not have access to your caregiver's answers and your caregiver will not have access to your answers. If you are placed in secure or non-secure juvenile justice facility after enrollment in the study, we will continue to make efforts to reach out to you for interviews. If we have

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trouble finding you, we may also search non-secure juvenile justice facilities in New York State to find you if your caregiver is not sure where you are.

Audio taping: All interviews will be audio recorded with a digital recorder. The audio digital files help the research team to remember exactly what was said during the survey interviews and to ensure that the survey was done correctly. Your name will not be on the digital audio file. Instead you will be assigned an identification number to ensure confidentiality. All audio recordings will be private and will be kept in an electronically secure database. The files will be listened to only by the people doing the study and will be destroyed after the information has been written down, no later than ten years from now.

Record data: We will also gather information from your probation department records on whether or not you were referred to a treatment program, whether you attended that program, if you finished the treatment program as well as the outcome of your probation at the end of 6- months (e.g. successfully completed, still ongoing, violated).

Risks and Inconveniences

Some of the interview questions will ask about probation, substance abuse, and/or mental health treatment. They may make you feel embarrassed, worried, or upset. If this happens, the interviewer will spend time talking with you until you feel better. It is possible that your answers may not be kept private; we take several steps we take to try as much as possible to make sure this does not happen (see Confidentiality section below). You can refuse to answer any questions or stop the interview at any time.

Benefits

There are no direct benefits to you in participating in the study. The results of this study may **improve** the way youth on probation like you get to substance abuse and/or mental health treatment services.

Confidentiality

All records and the results of the research will remain private and confidential. We will do everything we can to protect your privacy. The researchers will keep your responses private and confidential **except** in the following circumstances: 1) if we learn of threatened violence to self (e.g. thoughts of suicide) or others (e.g. thoughts of homicide) that you discuss, or 2) suspected or known physical abuse, sexual abuse or neglect of minors. If we learn of this information, we will take whatever

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measures are needed to protect individuals involved, and will voluntarily comply with State reporting laws on child abuse, harm to self or others, including reporting to Child Protective Services as necessary. If we learn of this information, we will do whatever is necessary to protect anyone involved, including you. Part of what we will do is let your caregiver know if you tell us you want to hurt yourself or someone else. If someone else has been hurting you, and it is not your caregiver, we will tell your caregiver about that too. We will also report it to your probation officer, and to the Child Protective Services, if necessary. Research staff may not be able to discuss this with you first.

The information from the surveys will be collected using Qualtrics, an online survey program that can be accessed through an URL designated by Columbia University. The URL is password protected and information is stored directly onto Qualtrics' secure website. Responses are de-identified which means identifying information like your name will be removed and you will be identified by a unique ID number. Responses are encrypted under a 128-bit SSL encryption (same security used when you enter credit card numbers in online purchases) and are represented by numerical data. The only textual information present is the participants' ID number, IP address, and whether participants chose to enter textual data.

All study information including your name and other personal identifying information will be stored in an electronically secure database; all other study information will be coded and kept in locked files at the New York State Psychiatric Institute. Only research staff and institutional personnel, as part of routine audits, will have access to the files. No part of your interview will be part of your record at the probation department and will not be shared with any of the probation department staff. Your name will not go on any forms that will be completed as part of the study. You will be recognized by a number (code) that is specific for each participant. Information from this research may be published but publications will not include the names of any study participants or any information that could identify you. Data stored in computers will only be available with a password. Only the Principal Investigator (the head of the study) will have access to that password.

We have received a Certificate of Confidentiality, issued by the National Institute of Mental Health (NIMH), for this study. This Certificate prevents the researchers from being forced to release any identifiable research data (including under court order or subpoena) without your written consent. This Certificate does not prevent the researchers from reporting suspected or known

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neglect or sexual or physical abuse of a child, or threatened violence to self or others. Such information will be reported to the appropriate authorities. You should understand that a Certificate of Confidentiality does not prevent you or members of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

We have registered this study as a clinical trial. A description of this clinical trial is 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.

If you are placed in secure or non-secure juvenile justice facility after enrollment in the study, the study team will contact with the proper authorities, including your probation officer, to get permission for you to take part in the interviews while placed in a juvenile justice facility. We may need to tell them that you are participating in a research study if the facility requires this information. However, we will not tell them exactly what the study is about – that is private. We will only interview you if the interview can be done in a private place (this is for both in-person and online interviews). Although we will try our best to keep the interview private while you are in a placement facility, we cannot guarantee it.

New York State Psychiatric Institute does not provide compensation or payment for treatment of research related injuries. However, you should be aware that participation in this research does not waive any of your legal rights to seek such compensation through the courts.

Study Compensation

You will receive a \$50 gift card for each of the 3 online surveys (for a total of \$150) that is for both your participation in the interview and, if needed, your transportation costs to the probation department for face-to-face surveys. If you are working with the Linkage Specialist, you will receive a \$10 gift card when you attend each of the first three Linkage Specialist Appointments (for a total of \$30). If you are not working with the Linkage Specialist, you will be entered into a raffle each time you respond to a *brief* bi-weekly message from our research team. The raffle prize will be a gift card or movie tickets worth \$50.00. The raffle will run approximately every 4

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months. If you are placed in secure or non-secure juvenile justice facility after enrollment in the study, your compensation will be held for you by us until your release or given to a parent or caregiver who you choose.

In Case of Injury

If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator Dr. Katherine Elkington at 646-774-6965 so that you can review the matter and identify the medical resources that may be available to you.

In case of injury, New York State Psychiatric Institute will provide short term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's doctors, and which is within the capability of New York State Psychiatric Institute to provide. In addition, we will provide assistance in arranging follow up care in such instances.

New York State Psychiatric Institute and Research Foundation for Mental Hygiene do not provide compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the court by participating in this research.

Please be aware that:

1. The New York State Psychiatric Institute, Columbia University and New York Presbyterian Hospital will furnish that emergency medical care determined to be necessary to the medical staff of this hospital.
2. You will be responsible for the cost of such care, either personally or through your medical insurance or other form of medical coverage.
3. No monetary compensation for wages lost as a result of injury will be paid to you by Research Foundation for Mental Hygiene, the New York State Psychiatric Institute, Columbia University and New York Presbyterian hospital.
4. By agreeing to the terms of this consent form, you are not waiving any of your legal rights to seek compensation through the courts.

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Questions

The research staff will answer, to the best of their knowledge, any questions concerning the procedures described above. If you have any questions about this study, you may contact Dr. Katherine Elkington at 646-774-6965. If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Main Office at (646) 774-7155 during regular office hours. You will be given a copy of this consent form to keep.



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Purpose of the Study: We are asking you and your caregiver to participate in Family CONNECT, which is a program that aims to help link youth on probation to substance use and/or mental health services. When we say link we mean connect; when we say linkage we mean connection. The goal of Family CONNECT is to improve the experience of youth on probation as they connect and start treatment with substance abuse and/or mental health treatment services. Additionally, we are also asking you and your caregiver to participate in three surveys. You are being asked to participate in this study because you are 1) 10-18 years old, 2) currently on probation, and 3) currently use substances and/or are in need of mental health treatment. Including you and your caregiver, there will be 50 youth on probation and 50 caregivers participating in this study along with up to 36 probation staff. This study is a pilot study, meaning that the information from this study will be used to inform a larger study of Family CONNECT.

Alternatives to Study Participation: Your participation is voluntary. You do not have to participate in this study in order to get services that are available to you through the probation department. The alternative to participating is simply not to take part; if you do not take part in this study, you will still receive all services as usual through the probation department and your terms of probation will not change.

Study Procedures: Study group: If you and your caregiver agree to participate, your probation officer will either 1) refer you to a linkage specialist, who will work with you and your caregiver for up to 6 months to link and enroll you in substance abuse and/or mental health treatment services, or 2) you and your caregiver will work with your probation officer as usual to enroll you in treatment. Depending on the probation officer you were assigned to, there is a 50:50 chance (same chance of flipping a coin) of you and your caregiver getting referred to a linkage specialist or you and your caregiver working with your probation officer as usual. If you do get referred to work with a linkage specialist, this person may come to your home, or some other agreed upon place, to work with you and your caregiver and help you get to treatment. This person will speak with both your probation officer as well as any substance abuse or mental health treatment provider you work with in order to help you successfully enroll and stay in treatment.

Interviews: Regardless of whether you work with a linkage specialist or not, you and your caregiver will also be asked to participate in three online surveys throughout the course of the study (6 months). One will take place now or within a few days from now, one 2 months from now and one 6 months from now; each of your three online surveys will be approximately 60 minutes long. You and your caregiver will be asked questions about experiences, thoughts, and feelings, including those regarding substance use, mental health, substance abuse treatment, probation, linkage specialists (if you are referred to work with a linkage specialist), and Family CONNECT. The interviews will be conducted by a study research staff member at your probation department in private offices or at another agreed upon confidential location such as your home or a local library. You and your caregiver will be interviewed separately. You will not have access to your caregiver's answers and your caregiver will not have access to your answers. If you are placed in secure or non-secure juvenile justice facility after enrollment in the study, we will continue to make efforts to reach out to you for interviews. If we have trouble finding you, we may also search non-secure juvenile justice facilities in New York State to find you if your caregiver is not sure where you are.

Audio taping: All interviews will be audio recorded with a digital recorder. The audio digital files help the research team to remember exactly what was said during the survey interviews and to ensure that



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the survey was done correctly. Your name will not be on the digital audio file. Instead you will be assigned an identification number to ensure confidentiality. All audio recordings will be private and will be kept in an electronically secure database. The files will be listened to only by the people doing the study and will be destroyed after the information has been written down, no later than ten years from now.

Record data: We will also gather information from your probation department records on whether or not you were referred to a treatment program, whether you attended that program, if you finished the treatment program as well as the outcome of your probation at the end of 6-months (e.g. successfully completed, still ongoing, violated).

Risks: Some of the interview questions will ask about probation and substance abuse and/or mental health treatment. They may make you feel embarrassed, worried, or upset. If this happens, the interviewer will spend time talking with you until you feel better. You may experience a loss of confidentiality related to your responses; we have several procedures in place to reduce this risk (see Confidentiality section below). You can refuse to answer any questions or stop the interview at any time.

Benefits: There are no direct benefits to you in participating in the study. The results of this study may improve the way people get to substance abuse and/or mental health treatment services.

Compensation: You will receive a \$50 gift card for each of the 3 online surveys (for a total of \$150 through gift card) that is for both your participation in the interview and, if needed, your transportation costs to the online survey at the probation department. If you are in the Study Group, you will receive a \$10 gift card when you attend each of the first three Linkage Specialist Appointments (for a total of \$30). If you are not working with a Linkage Specialist, you will be entered into a raffle each time you respond to a *brief* bi-weekly message from our research team. The raffle prize will be a gift card or movie tickets worth \$50.00. The raffle will run approximately every 4 months. If you are placed in secure or non-secure juvenile justice facility after enrollment in the study, your compensation will be held for you by us until your release or given to a parent or caregiver who you choose.

Confidentiality – when we can and cannot keep this private: All records and the results of the research will remain private and confidential. We will do everything we can to protect your privacy. The researchers will keep your responses private and confidential except in the following circumstances: 1) if we learn of threatened violence to self (e.g. thoughts of suicide) or others (e.g. thoughts of homicide) that you discuss, or 2) suspected or known physical abuse, sexual abuse or neglect of minors. If we learn of this information, we will take whatever measures are needed to protect individuals involved, and will voluntarily comply with State reporting laws on child abuse, harm to self or others, including reporting to Child Protective Services as necessary. If we learn of this information, we will do whatever is necessary to protect anyone involved, including you. Part of what we will do is let your caregiver know if you tell us you want to hurt yourself or someone else. If someone else has been hurting you, and it is not your caregiver, we will tell your caregiver about that too. We will also report it to your probation officer, and to the Child Protective Services, if necessary. Research staff may not be able to discuss this with you first.

The information from the surveys will be collected using Qualtrics, an online survey program

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that can be accessed through an URL designated by Columbia University. The URL is password protected and information is stored directly onto Qualtrics' secure website. Responses are de-identified which means identifying information like your name will be removed and you will be identified by a unique ID number. Responses are encrypted under a 128-bit SSL encryption (same security used when you enter credit card numbers in online purchases) and are represented by numerical data. The only textual information present is the participants' ID number, IP address, and whether participants chose to enter textual data.

All study information including your name and other personal identifying information will be stored in an electronically secure database; all other study information will be coded and kept in locked files at the New York State Psychiatric Institute. Only research staff and institutional personnel, as part of routine audits, will have access to the files. No part of your interview will be part of your record at the probation department and will not be shared with any of the probation department staff. Your name will not go on any forms that will be completed as part of the study. You will be recognized by a number (code) that is specific for each participant. Information from this research may be published but publications will not include the names of any study participants or any information that could identify you. Data stored in computers will only be available with a password. Only the Principal Investigator (the head of the study) will have access to that password.

We have received a Certificate of Confidentiality, issued by the National Institute of Mental Health (NIMH), for this study. This Certificate prevents the researchers from being forced to release any identifiable research data (including under court order or subpoena) without your written consent. This Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child, or threatened violence to self or others. Such information will be reported to the appropriate authorities.

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

We have registered this study as a clinical trial. A description of this clinical trial is 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.

If you are placed in secure or non-secure juvenile justice facility after enrollment in the study, the study team will contact with the proper authorities, including your probation officer, to get permission for you to take part in the interviews while placed in a juvenile justice facility. We may need to tell them that you are participating in a research study if the facility requires this information. However, we will not tell them exactly what the study is about – that is private. We will only interview you if the interview can be done in a private place (this is for both in-person and online interviews). Although we will try our best to keep the interview private while you are in a placement facility, we cannot guarantee it.

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Research Standards and Rights: Your participation in this study is voluntary. You do not have to participate and can stop participation in this study at any time. You can terminate participation in the study even after the study has started and can also refuse to answer any of the questions you are asked. If you decide not to participate, or if you later decide to stop participation, you will not lose any benefits to which you both are otherwise entitled, including services and care that are normally available to you through the probation department. You can decide not to participate or to stop participation at any point during the study. A decision not to participate or to terminate participation will have absolutely no effect on your terms of probation; whether you participate or not, you will still have to comply with all the terms and conditions of your probation that you did before.

In Case of Injury: If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator Dr. Katherine Elkington at 646-774-6965 so that you can review the matter and identify the medical resources that may be available to you.

In case of injury, New York State Psychiatric Institute will provide short term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's doctors, and which is within the capability of New York State Psychiatric Institute to provide. In addition, we will provide assistance in arranging follow up care in such instances.

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2. You will be responsible for the cost of such care, either personally or through your medical insurance or other form of medical coverage.
3. No monetary compensation for wages lost as a result of injury will be paid to you by
4. Research Foundation for Mental Hygiene, the New York State Psychiatric Institute, Columbia University and New York Presbyterian hospital.
5. By agreeing to the terms of this consent form, you are not waiving any of your legal
6. rights to seek compensation through the courts.

Questions: The research staff will answer, to the best of their knowledge, any questions concerning the procedures described above. If you have any questions about this study, you may contact Dr. Katherine Elkington at 646-774-6965. If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Main Office at (646) 774-7155 during regular office hours. You will be given a copy of this consent form to keep.