Safe Mothers, Safe Children Initiative: A Randomized Controlled Trial

Consent Form

Principal Investigator: Michael Lindsey, Ph.D.

You have been invited to take part in a study to compare the effects of a trauma focused research intervention versus a non-trauma focused intervention in helping mothers who have post-traumatic stress disorder (PTSD), a child age 1-10, and an open child welfare preventive case. The purpose of the study is to compare a new experimental treatment called Parenting-STAIR (P-STAIR) to an active treatment called Supportive Counseling to see if they differ in how they (1) improve parenting skills, (2) improve PTSD and depression symptoms, and (3) prevent new abuse and neglect incidents.

If you agree to be in this study, you will be asked to do the following:

1. Take part in an assessment which will take 1 to 2 hours. Following the assessment, if you are eligible, you will be asked to complete a 15-minute play session with the identified child.
2. You will be randomly assigned to a research intervention (like a flip of a coin). Both interventions consist of 23 weekly individual sessions.
3. You will also complete two mid-treatment assessments and two post-treatment assessments during/after the research intervention.

Participation in this study will involve approximately 30 visits over the course of approximately 30 weeks including treatment sessions and assessments. There are no known serious risks to you or your child in this research intervention beyond those of everyday life. Some benefits include reducing the difficulties connected to the trauma you experienced and helping you feel better and more satisfied with your parenting. The purpose of this study is to evaluate the safety of Parenting-STAIR, our experimental treatment, and to compare its ability to effect change to supportive counseling, our comparison treatment. You should know that if you are assigned to receive the experimental treatment, we cannot guarantee that it will be as effective as the standard treatment.

Participation in this study is voluntary. You may refuse to participate or withdraw at any time without penalty. Please read the rest of this consent form for more information about the study.

A. PURPOSE OF THE STUDY

Experiencing trauma, violence, or abuse sometimes leaves people with lasting difficulties including PTSD and depression. The purpose of this study is to compare the effects of a trauma focused research intervention called P-STAIR with a non-trauma focused intervention called supportive counseling in helping mothers who have PTSD symptoms and an open child welfare preventive case to (1) improve their parenting skills, (2) improve their PTSD and depression symptoms, and (3) prevent new abuse and neglect incidents. This study will be conducted by Dr. Michael Lindsey (PI), New York University, McSilver Institute of Poverty Policy and Research.

B. SUBJECT IDENTIFICATION

Women receiving services at the child welfare preventive services agencies we work with are screened by their case planners. Women who report difficulties related to their past trauma (i.e., abuse, neglect and/or loss) and have a child in the age range of 1 to 10 will be informed of the study.

If you have more than one child within the ages of 1 to 10, the child that you identify as the having the most problematic behavior will participate with you. Because your child will be observed playing with you, s/he is also a study participant. We need to have your permission for your child to participate. We will explain to your child how the study works and ask whether s/he agrees to participate.

C. STUDY PROCEDURES

What will happen in the study?

If you agree to take part in this study, you will be invited to take part in an assessment which will take between 1 - 2 hours. The research staff will ask you questions about your thoughts and feelings, your children, and your parenting. Following the assessment, if you are eligible for the study and choose to join, you will be asked to participate in a recorded 15-minute play session with the identified child. All assessments may be completed virtually via phone or Zoom, WebEx, or a similar application, if necessary.

Research Intervention: Following the assessment, if you qualify, you will be invited to participate in the research intervention. You will be randomly assigned (like a flip of a coin) to either receive the P-STAIR intervention or supportive counseling.

Both interventions will consist of 23 weekly, individual sessions. Each will last about one hour. In case of need, you may also be offered additional sessions to deal with unexpected issues that may arise. Some sessions may or may not be required for completion to test efficacy with reduced number of sessions. All sessions may be offered in-person, or virtually via phone or Zoom, WebEx, or a similar application, based on your preference.

P-STAIR

P-STAIR is a trauma focused intervention. The focus of the sessions is as follows:

- Sessions 1-9 will orient you to the study and teach you skills to deal better with feelings and relationships.
- Mid-point assessment: You will be asked to participate in a brief, 1 to 1.5-hour assessment about your thoughts and feelings when you complete session 9 of the study
- Sessions 10-15 will help you work through the trauma that you've been through and the feelings you have about it by talking with the research staff about the trauma memories and how these memories might affect your parenting. Coping skills will also be reviewed.
- Mid-point assessment: You will be asked to participate in a brief, 1 to 1.5-hour assessment about your thoughts and feelings when you are half-way through the study.
- Sessions 16-22 will focus on practicing the skills you learned as you and your child play together. During session 16, we will ask you to participate in a recorded 15-minute play session with the identified child. During sessions 16-22, research staff will record you and your child and give you on-the-spot coaching. You and the research staff may watch and discuss the recordings together.
- Session 23 will occur with you alone and will focus on reviewing your experience, identifying resources for continued help, and saying goodbye.

Supportive Counseling

Supportive counseling is a non-trauma focused intervention. The focus of the sessions is as follows:

- Sessions 1-9 will consist of identifying and discussing life problems that you wish to discuss, clarifying problems, and exploring potential solutions.
- Mid-point assessment: You will be asked to participate in a brief, 1 to 1.5-hour assessment about your thoughts and feelings when you are half-way through the study.
- Sessions 10-15 will continue to explore your current life problems and look at potential solutions.
- Mid-point assessment: You will be asked to participate in a brief, 1 to 1.5-hour assessment about your thoughts and feelings when you are half-way through the study.

- Sessions 16-22 will continue to explore your current life problems and look at potential solutions.
- Session 23 is the termination session and will focus on reviewing your experience, identifying resources for continued help, and saying goodbye.

How long does the study last?
The research intervention from start to finish consists of approximately 30 visits over the course of approximately 30 weeks.

Will there be audio- or videotaping?
All sessions will be videotaped or audiotaped to make sure that all research staff are working the same and right way. Because of this, your consent to taping individual sessions and play sessions with your child is required for you to participate in the study. If you do not want a specific session to be recorded, you can ask the research staff not to tape that specific session. You may review these tapes and request that all or any portions of the tapes be destroyed. We will be asking you to sign a separate consent for the video and audiotaping. The consent will provide more details regarding this study component.

What happens after the study?
After your final research intervention session, you will be scheduled for an end-of-intervention assessment to answer questions about your thoughts and feelings. We will ask you to participate in a recorded 15-minute play session with the identified child that will be recorded using a coding system. The research staff will also contact you once per month via telephone for six months to check in with you. Three to nine months after completing the research intervention, you will be scheduled for a final assessment to answer questions about your thoughts and feelings. We will also ask you to participate in a recorded 15-minute play session with the identified child.

Where will the intervention take place?
Research intervention sessions will take place at the preventive service agency where you receive services or virtually via Zoom. You are free to receive other mental health services while participating in this study. We will ask you to tell us what other services you receive.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website may include a summary of the results but will never include information that can identify you. You can search this website at any time.

Participant Initials ……..

D. ALTERNATIVES TO PARTICIPATION

What are the alternatives to participation in the research study?
Agreeing to participate in this research will not change the normal mental health care and preventative services care which you are receiving. Your alternatives are to participate in this research or not to participate in this research, but this will change nothing about the preventative services you are participating in or your case with the Administration for Children's Services (ACS).

Participant Initials…….

E. OUR RELATIONSHIP WITH YOUR PREVENTIVE SERVICES AGENCY

This study uses a "collaborative communication model." By agreeing to be in the research study, you give us permission to share and receive information about you and your family with your preventive agency team and case planner. You are also giving us permission to get information from the ACS database about any past or new maltreatment allegations, confirmed allegations, and removal of children to foster care during and after your

participation in the research. This will make it easier for your preventive services agency and the research staff to support your preventive services goals and to create a better support team for you. You also give us permission to review your family's preventive services record. We will keep a record of your unique child welfare identifier. You will be asked to share information about your history of medical, mental health and substance abuse treatment, your home and living circumstances, including domestic partners and history of domestic violence, and any services you and your children receive, such as special education services with the research staff. We will review the agency's assessment of your progress on your preventive services goals. Meetings with you, the research staff, and your preventive agency will take place regularly. You will be told about these meetings. You can also ask that a meeting with your case planner and staff be held to talk about your concerns.

Participant Initials…….

F. CONFIDENTIALITY

How will you keep my information private?

Your privacy and confidentiality are very important to us. All research paperwork and video/audio recordings will be kept on a secure computer network that can only be accessed by a password. If information from this study is published or presented, only group information will be shared. We will not use any information that identifies you personally. Research staff will complete reports following all assessment interviews as well as progress notes following each study session. Assessments will also be stored on REDCap, a HIPAA-compliant data storage software. We will keep one copy of the report and will give a copy to the case planner who referred you. Your case planner will put the report in your preventive services agency file. We will prepare a summary report of your progress to the case planner who works with you to help you meet your goals with preventive services, and to help us work best with you. All research study paperwork and the audio-video recordings will be labeled with a number code and will not show your name or your child's name. The folder linking your name with your code will be kept in a separate place. Other than the exceptions described below, to protect your privacy, only you and members of the research study team will have access to research material. Except when required by law, study information shared with people and organizations outside of New York Universities McSilver Institute of Poverty Policy and Research such as ACS, federal and state monitoring agencies, and the IRB(s) supervising the research, will only identify you by an identification code number and will not identify you by name or any other direct personal information. McSilver Institute of Poverty Policy and Research will not share the code key, except as required by law.

The research material will not be shared with others outside of the study team unless you give your written permission. If you give us permission to use recordings for training purposes, we will use face or voice alteration programs to reduce the chance that you or your child would be identified.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate will not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, even if there is a court subpoena.

Exceptions include:

- A federal, state, or local law requires disclosure, such as information about suspicion of child abuse or neglect or suspicion of harm to yourself or others
- Your explicit approval for the researchers to release your name and/or personally identifiable information

How long will you store my information?

Research paperwork and audio-visual recordings will be kept on a secure computer network that can only be accessed by a password for up to six years at McSilver Institute of Poverty Policy and Research, New York University. At the end of six years, the recordings will be destroyed. Information from your preventive services record will be written on our own research forms. No copies of original documents will be kept in the research

file.

Are there limits to confidentiality?
Most of the things that you talk about with the research staff during study will not be disclosed to any agency personnel. Only in the condition that your research staff is concerned that you or your children are at risk of danger, they are required by law to share this information with your case planner and other emergency service providers. The research staff will work with your preventive services agency to best support you. If your research staff is concerned that your children are being abused or neglected, they are required by law to make a report of abuse or neglect to the New York Statewide Central Register of Child Abuse and Maltreatment.

Participant Initials…….

Access to your records
During the study, you will be able to see information from your research record. By signing this form, you authorize the use and disclosure of the following information for this research. Information not containing identifiers may be used in future research or shared with other researchers without your additional consent.

PLEASE CHECK EACH BOX:
☐ Your research study record
☐ Clinical and research observations made during your time with the study

Participant Initials……..

G. COSTS/REIMBURSEMENTS

There are no costs to you if you choose to be in the study. You will be compensated for taking part in this study to cover the costs of participating, like childcare and transportation. This study is paid for with money from the National Institute of Child Health and Human Development (NICHD).

For sessions and assessments that are conducted in person, you will receive $50 and a Metro Card in return for completing the first assessment interview. If you continue after the first assessment interview, you will receive $30 and a Metro Card for your observed play session with your child. You will receive $10 and a Metro Card for completing each intervention session. You will receive $30 and a Metro Card for your participation in two brief mid-treatment assessment interviews during the study. You will receive $50 and a Metro Card for completing the post-intervention and follow-up assessment interviews. You will receive $30 and a Metro Card for your participation in four observed play sessions with your child.

Sessions and assessments that are conducted virtually will not receive a Metro Card as part of the compensation. To offset data costs, participants will receive $5 per virtual session/assessment.

Compensation for virtual sessions/assessments will be emailed within 1 week after completion of assessments and after each session. Participants will be given a link via email.

Participants will only receive compensation for sessions completed.

Participant Initials……..

H. POTENTIAL RISKS AND DISCOMFORTS

There are no known serious risks to you or your child in this research intervention. Some of the questions we ask may make you uncomfortable. If this happens you should tell the research staff or the study director, Dr. Lindsey.

You may stop answering questions or end research intervention sessions at any time without any consequences. Your preventive services case will not be affected in any way.

You may become upset during sessions when you talk about the trauma you experienced. The research staff will check in with you after each session about your feelings and will check in with your case planner.

During this study, if you feel that participating in this study makes things harder for you or if you are at risk of harming yourself or others, tell your research staff or case planner right away. Also, if you miss too many sessions, we will talk about this with you and your case planner to determine whether this research intervention is appropriate for you or if you would benefit from a referral for services that are a better fit for you.

Participant Initials…….

I. POTENTIAL BENEFITS

Because this is a research intervention, we cannot be sure that our intervention will help you and your child. Some benefits include reducing the difficulties connected to the trauma you experienced and helping you feel better and more satisfied with your parenting. The lessons we learn from the research intervention could also help improve services for other mothers who have experienced trauma such as violence, abuse, or neglect.

Participant Initials…….

J. VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW

Your decision to take part in this research is voluntary (of your free will). You may refuse to participate or withdraw at any time. This will not affect your preventive services case or your relationship with the ACS. It will not result in any loss of benefits for which you are eligible. At any time, you have the right to request and review your data. Data will not automatically be deleted upon withdrawal. If you withdraw from treatment, we will contact you about completing study assessments. You will be compensated for completing the assessments.

Participant Initials…….

K. WITHDRAWAL CONDITIONS

You may be automatically withdrawn from the study if you do not engage consistently in treatment. If this occurs, you will receive a notice in writing inviting you to reengage in treatment. Withdrawal will not impact your ACS case or eligibility to receive preventative services.

Participant Initials…….

L. PERMISSION TO CONTACT YOU ABOUT FUTURE RESEARCH

Your permission to allow us to contact you about future research is voluntary. If you choose not to allow us to contact you, it will not affect your care or preventive services case in any way. Giving your permission to do this may help us find people who may qualify for future research studies. It does not mean that you or your child must join any study.

"I authorize Dr. Lindsey and his team to contact me about future research on post-traumatic stress disorder at the New York University's McSilver Institute of Poverty Policy and Research. At that time, I can decide whether I am interested in participating in that specific study. If I am interested, I will have the opportunity to schedule an appointment to be fully informed about the research project. The future research must be approved by the original IRB of record. Dr. Lindsey and his team must be affiliated with the research protocol."

PLEASE CHECK ONLY ONE BOX:

☐ I agree to be contacted by Dr. Lindsey or any member of the team of the research study titled: Safe Mothers, Safe Children Initiative: A Randomized Control Trial.

☐ I do not want to be contacted by Dr. Lindsey or any member of the team of the research study titled: Safe Mothers, Safe Children Initiative: A Randomized Control Trial.

_____ _____

Signature of participant or legal representative* Date

M. CONTACT PERSON(S)

For questions about your rights as a research participant, you may contact the Institutional Review Board (IRB), New York University, 212-998-4808 or ask.humansubjects@nyu.edu. Please reference the study number (IRB-FY2021-5220) when contacting the IRB.

For questions about the program, Safe Mothers, Safe Children, you may contact the Principal Investigator, Dr. Michael Lindsey, via telephone at 212-998-5959 or via e-mail Michael.Lindsey@nyu.edu.

N. AGREEMENT TO PARTICIPATE

PLEASE CHECK ONLY ONE BOX:

☐ I have read this consent form, or

☐ It was read to me by: _____

_____ _____ _____

Print name of witness** Signature of witness ** Date

**If the subject is unable to read this form and it was read to her, a witness must be present and sign below.

PLEASE CHECK ONLY ONE BOX:

☐ I am participating in another research project currently. (If you are, please discuss with your research staff.)

☐ I am not participating in another research project currently.

PLEASE CHECK EACH BOX:

☐ I voluntarily agree to participate in this research study with New York University's McSilver Institute of Poverty Policy and Research.

☐ I understand that I am entitled to and will be given a copy of this signed Consent/Authorization Form.

By signing this Consent/Authorization form, you give permission for:

- **Your child to participate in the study and to be observed and recorded as part of study procedures.**
- **Video/audio recording.**
- **Your preventive services case planner to share information with your research staff.**
- **Your research staff to share information with your preventive services case planner.**
- **Research staff to access information in the ACS database regarding new maltreatment allegations, confirmed allegations, and removal of children to foster care during and after your participation in the study.**
- **Information gathered about you in the study will not be shared with ACS. Reports to ACS will only be about groups of cases and will not share any participant's identity.**
- **If you physically relocate to another state, are too far from where you were receiving the Safe Mothers Safe Children (SMSC) services or are unable to attend in-person sessions/assessment before/during/after the completion of the SMSC treatment, you agree to participate in the sessions**

and/or assessments via Zoom, WebEx, or a similar application, or phone. Research staff will conduct the interview in a private room and add a password to all sessions, but you will be responsible for your own privacy as you will be in a different location.

Print name of participant or legal representative*	Signature of participant or legal representative*	Date

*For subjects who may not be capable of giving informed consent, the signature of a legal representative is required.