Mass General Brigham

Research Consent Form
General Consent Form Template
Version Date: February 2022

Subject Identification

Protocol Title: Pilot Feasibility of Infant Respite Care for Mothers with Substance Use Disorders

Principal Investigator: Davida M Schiff, MD, MSc

Site Principal Investigator: n/a

Description of Subject Population: This study seeks those who are caring for an infant under 12 months of age, are the primary caretaker for their infant, have a DSM-5 diagnosis of a substance use disorder, and are currently residing in a participating residential treatment program or are living independently in a private home.

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

We are inviting you to be in a research study. This form will tell you what you should expect if you agree to be in the study. You will find more information about each of the following points later in this form.

Participation in this study is entirely voluntary. We are inviting-you to be in this study because you are caring for an infant under 12 months of age, you are the primary caretaker for this infant, you have a diagnosis of a substance use disorder, and are currently residing in a participating residential treatment program or are living independently in a private home. We are doing the research to study the impact of a program providing overnight respite care by a trained newborn care expert on the health of you and your baby. If you agree, you will receive 3 nights of overnight respite care from 11 pm – 7 am, for a total of eight hours each night, for 6 weeks for a

total of 18 nights of respite care. One hour each morning will be used for sharing tips and suggestions for infant care and handling. You will also participate in a 3 research visits and sleep data collection while you're receiving this service. You will be in the study for 4.5 months if you decide to stay for the whole study.

The main risks of being in the study are a potential loss of privacy by having newborn care experts present at your residential treatment program and sharing your health information with the study team.

You might benefit from being in the study because of the opportunity to increase rest and sleep while receiving overnight infant care and from having the opportunity to discuss soothing and care techniques with trained newborn care experts to care for your newborn in the early postpartum period.

You will be paid a total of $125 through gift cards for taking part in all parts of this research study. You will find more information about the payment amount for each visit and a plan if you do not complete all study visits later in this form.

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Davida Schiff, MD, MSc is the person in charge of this research study. You can call her at **617-643-6631, M-F 9 am – 5 pm or email her at davida.schiff@mgh.harvard.edu with any questions or concerns related to the study.**

If you have questions about the scheduling of appointments or study visits, call **Galya Walt at (617) 651-0547.**

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

Why is this research study being done?

We are doing this research to study if it is possible to successfully pilot an overnight infant respite care program for mothers with substance use disorders in residential settings. We are also interested in understanding how receiving respite care may result in improved maternal and infant health, such as decreasing maternal exhaustion, improving maternal physical and mental health, decreasing the need for ED visits, and reducing involvement with child protective services for unsafe sleep incidents.

Who will take part in this research?

We are inviting you to take part in this study because you are the primary caretaker for an infant under 6 months of age, you have a diagnosis of a substance use disorder, and you are currently residing in a participating residential treatment program or are living independently in a private home. About 20 – 25 people will take part in this research study. The Massachusetts Department of Children and Families (DCF) and the National Institute on Drug Abuse (NIDA K23DA048169) are funding the intervention and evaluation in this study.

What will happen in this research study?

Program Details:

All individuals participating in this study will receive the intervention. You will receive 3 nights of overnight respite care from 11 pm – 7 am, for a total of eight hours each night, for 6 weeks for a total of 18 nights of respite care. One hour each morning will be used for sharing tips and suggestions for infant care and handling. Services will be provided by Newborn Care Experts from the New England Doula Support company.

Study Visits and Information:

You will complete 4 research visits and participate in ongoing data collection during the period in which you are receiving overnight infant respite care: one baseline pre-program visit, data collection during the program, one immediately post-program visit, and a final visit 3-months after completing the program.

- Research Visit #1: Screening and Baseline. You will complete an initial research visit where we collect basic information about who you are and your history including

substance use and mental health information and surveys about sleep, parenting stress, bonding, and child protective services involvement.

- Research Visit #2: Sleep Data during Intervention Period. We will collect data on your sleep from a Fitbit movement tracking device beginning 3 days before you start receiving overnight infant respite care until 3 days after you receive your last night of this service. We will collect data on your infant's through a log that you and your newborn care expert fill out each night.

- Research Visit #3: Program Completion Assessment. After completing the program, you will complete a series of surveys and participate in a short interview with research staff to learn about your experience receiving overnight infant respite care and how the program felt to you

- Research Visit #4: Final Assessment, 3 Months After Program Completion. Three months after completing the intervention we will ask a similar set of surveys and ask follow up questions about your health and your infants health.

All research visits will happen either on site at the residential treatment program or via a HIPAA-secure videoconferencing technology.

How may we use and share your samples and health information for other research?

Your samples or health information collected for this study will NOT be used or shared for other research, even if we remove identifiable information like your name, medical record number, or date of birth.

Will you get the results of this research study?

If you are interested in learning about the results of this pilot study, you will be given the opportunity to join a study-specific mailing list. We will not announce the information that you shared or others, but will provide a summary of information that we learned from the study.

What are the risks and possible discomforts from being in this research study?

This study poses minimal risks to participants, primarily in the form of privacy/confidentiality risks of having a respite care provider intimately involved in the care of their newborn.

Risks of being involved in the survey research and semi-structured interview are minimal. We will however work to minimize risks to participants by giving them the opportunity to stop the interview at any time if they begin to feel uncomfortable or no longer want to participate.

Risks primarily concern a breach of confidentiality due to inadequate data protection or people who have access to the raw or analyzed data recognizing the participants based on their quotes. Given that the interview transcripts will not be linked by name or identifying information to the participants, and that any identifiable information will be removed from the transcripts, we aim to eliminate the risk of linking identifiable information to the study.

42-CFR Part 2 protections

As a person staying at a family residential treatment program for women with substance use disorder, there are extra protections in place regarding the confidentiality of your substance use information. The study team will not ask or obtain any substance use history or treatment information from the program you are staying. Additionally, this project is protected by a Certificate of Confidentiality, which means that we will not share any of your data including responses to survey questions about your medical and psychiatric history with any outside agencies including the Department of Children and Families (DCF) or other legal entities.

Identifying concern for abuse or neglect

The newborn care experts providing respite care are mandated reporters with respect to concerns about child abuse or neglect. The newborn care experts must comply with state laws that require them to report to authorities if they have reason to believe a child is being abused or neglected. One potential risk to participating in this intervention includes the need to report situations of child abuse, child neglect, or any life-threatening situation to appropriate authorities.

Communication with DCF

As described above, the research team will not share any identifiable information shared in this study with DCF. MGH will notify the residential treatment program of your involvement and the residential treatment program may notify DCF of your involvement in this pilot program. If you have any questions about what will be communicated, you may talk to your residential treatment program for further information.

What are the possible benefits from being in this research study?

Participants may benefit by partaking in this pilot program through having the opportunity to increase rest and sleep through the provision of respite care. Additionally, the findings of this study may inform improvements in residential treatment program staffing in the future. Participants may also derive some benefit from having the opportunity to openly discuss their experiences with dysregulated sleep and supports needed to care for their newborns in the early postpartum period. Findings from this study may inform program improvements and will also contribute to the body of knowledge on care for mother-infant dyads impacted by substance use disorder, possibly informing the development of programs in other contexts.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

To compensate you for your time in addition to the respite care provided in the intervention, you will be given a $25 gift card to complete the baseline study surveys, $50 gift card for completion of surveys and interview at intervention completion and $50 gift card to complete the final follow up survey 3 months after the intervention. Therefore, completing all components of this

research study will result in compensation of $125 in gift cards. You will be compensated for the research components you complete.

What will you have to pay for if you take part in this research study?

You will not have to pay for any part of this research study.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject	Date	Time

Signature of Person Obtaining Consent:

Statement of Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Person Obtaining Consent	Date	Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter	Date	Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____	_____	_____
Name	Date	Time (optional)

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