The Dream Team:
Testing Implementation of a Sleep Intervention for Perinatal Women Delivered by Direct Care Workers

ClinicalTrials.gov: NCT06737055

Consent Form Document

Document Date: June 22, 2023

Lifespan IRB 1
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Use on or after: June 23, 2023
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Research Consent and Authorization Form

Rhode Island Hospital, The Miriam Hospital, EP Bradley Hospital,
Newport Hospital, and Gateway HealthCare

Name of Study Participant(s): _____

Principal Investigator: Katherine M. Sharkey, MD, PhD

Title of Research Study: The Dream Team: Testing Implementation of a Sleep Intervention for Perinatal Women Delivered by Direct Care Workers

You are being asked to take part in a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care. This form contains information that will help you decide whether to take part in the research. Taking part in this study is completely voluntary. Even if you decide to take part in the study, you are free to leave at any time if you change your mind. In the sections that follow, the word "we" means the study doctor and other research staff. We will explain the study to you and answer any questions you may have. We encourage you to discuss this study with others (your family, friends, or your other doctors) before you agree to participate in the research. If you agree that you would like to participate in this research study, you will be asked to review and sign this consent. A copy will be given to you.

A. What is the purpose of the research?

The purpose of this research is to: (1) test knowledge about sleep and biological rhythms in direct care workers who provide support and services to expectant and new parents *before* and *after* attending an educational lecture on these topics; and (2) get feedback from participants about the content and delivery of our teaching materials. People who participate in this study may be eligible to refer their clients to a future research study of how to best provide education about sleep to expectant and new parents. We plan to enroll up to 35 people in this study. This project is funded by the National Institutes of Health and involves researchers from Rhode Island Hospital, Bradley Hospital, and Brown University.

B. What is experimental/new in this study?

Our home visiting colleagues report that they would like to learn more about sleep and biological rhythms, particularly during pregnancy and the postpartum period, so that they can help their clients adapt to having a baby. However, we do not know what knowledge they

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already have and what areas are most important to teach. This study will allow us to measure knowledge before and after attending a lecture about sleep and biological rhythms. We will also invite participants to attend a meeting where they provide feedback about the training.

C. What do I have to do in this research?

If you choose to participate, you will be asked to complete a quiz about sleep and biological rhythms before and after attending a training session. Each quiz takes about 10-15 minutes to complete. You will also be invited to participate in a 60-minute focus group where you will view videos about sleep and we will ask you to provide feedback about the training. During this time, we will ask you to attend one study visit for the focus group. We expect to schedule the focus group visit within 6 weeks of your initial enrollment in the study. If you refer clients to our project, you could be involved in the project for up to 9 months and we would ask you to attend a second study visit for an additional focus group.

D. What could go wrong?

We do not expect there to be any risks associated with completing the online quizzes, which will be sent through a secure, HIPAA compliant online survey link. If at any time you feel that you no longer wish to participate you may withdraw your participation. You can also skip any question that you do not wish to answer.

The focus groups may be completed in person or remotely (i.e., video conference call). If you are in an in-person focus group, you should not divulge any personal information you do not want other study participants to know. In addition, you should not share information provided by other participants during the focus group with people outside of the study team.

If you participate in a remote focus group, since you will not be on-site with the research team in this instance, it will be your responsibility to ensure your own privacy while completing these remote assessments. Should you complete your remote assessments around or near others, it is possible that your participation in the research or your responses to focus group questions may be inadvertently divulged to others.

The most important potential risks to know about are: loss of privacy or confidentiality of the responses you give in the focus groups.

E. What are the benefits?

There are no direct benefits to you to completing these assessments. We hope to learn more about home visitors' knowledge of sleep and biological rhythms. The results of this study will help us improve the tools available to help expectant and new parents obtain healthy sleep.

F. Other things I should know about this research?

Study participants will be compensated for their time and effort. Participants will receive $25 for attending the training and completing both the pre- and post-training knowledge surveys and $25 for attending a focus group to view educational videos and a sleep app, participate in a discussion of the videos and the app, and complete an online feedback survey. Participants who elect to use the training resources with their home visiting clients and refer expectant and new parents to our study of expectant and new parents will receive $25 for participating in a second focus group. We will also provide a meal at the in-person focus group sessions.

If we find out about new information from this research that may affect your health, safety or willingness to stay in this research, we will let you know as soon as possible.

G. If I don't want to take part in this research what are my other choices?

Your participation in this study is completely voluntary, and you may choose not to participate at any point. Your decision not to participate or to withdraw does not involve any penalty or loss of benefits to which you are otherwise entitled.

- **Please carefully read this form, additional detail about each item just described is found below.**
- **Please listen to the study team explain the study and this form to you.**
- **Please ask questions about anything that is not clear.**

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1. Nature and Purpose of the Study

You are being asked to take part in a research project because you are an adult who works with expectant and new parents as a home visitor in Rhode Island. In this study we are trying to learn more about how to help expectant and new parents obtain healthy sleep.

We expect to enroll 35 participants into this study. The study is sponsored by the National Institutes of Health and involves researchers from Rhode Island Hospital, Bradley Hospital, and Brown University.

2. Explanation of Procedures:

If you enroll in this study you will be sent a link to an online pre-test to evaluate your knowledge about sleep and circadian rhythms in expectant and new parents and their children. After completing the pre-test, you will be scheduled to participate in a training as well as a 60-minute focus group with other home visitors. At the focus group, you will view training videos and see examples of a free smartphone sleep app tailored to help expectant and new parents obtain healthy sleep. You will be asked to participate in a group discussion of what aspects of the videos and app you like, and what suggestions you have for improvement. You will also be asked to complete an online feedback questionnaire about the videos and app. The group discussion will be video and audio recorded so that the researchers can analyze the feedback that you and the other participants provide. The videos will be stored on a secure server at Lifespan and will be destroyed once the study is complete. We expect to schedule the feedback focus groups within 6 weeks from when you sign up for the study.

People who participate in this study may be eligible to refer their clients to a future research study of how to best provide education about sleep to expectant and new parents. If you refer clients to that study, you could be involved in the study for up to 9 months and we would ask you to attend a second study visit for an additional focus group.

Study participants will be compensated for their time and effort. Participants will receive $25 for completing both the pre- and post-training knowledge surveys and $25 for attending a focus group to view educational videos and a sleep app, participate in a discussion of the videos and the app, and complete an online feedback survey. Participants who elect to use the training resources with their home visiting clients and refer expectant and new parents to our other study will receive $25 for participating in a second focus group. We will also provide a meal at the in-person focus group sessions.

Your identifiable private information that is collected as part of the research will not be used or shared with other researchers for future research studies.

We may use text messaging to contact you as part of this research study. This may include you receiving text messages from research staff and/or you are sending text messages to research staff. Lifespan takes your confidentiality seriously and will take steps to protect the information contained in the text messages to the degree permitted by the technology being used.

However, Lifespan can make no guarantees about the secure transmission of texts you send to us, nor can Lifespan guarantee security after you receive the text message from Lifespan. For example, text messages that display on your phone screen may be seen by someone close by or by someone you have allowed to use your phone. Also, if you do not password protect your phone and it is lost or stolen, anyone who finds it might view the information in the texts about your health or other topics. To try to lessen these risks, you should make sure your phone is password protected, only open and view messages where no one will be able to view the screen and delete messages as soon as possible after reading them. Additionally, when you trade in your phone, remember the SIM card (memory card used in cell phones) should be cleared.

Finally, it is also possible that the mobile phone company that transmits the text messages may keep copies of ALL your texts (those from the study, and your other texts) even after the study is ended. Lifespan has no control over these companies and cannot make any guarantees about their conduct.

<u>Costs for participating in this study</u>
There are no costs for participating in this study.

<u>Contact Information:</u>
You can call us with any concerns or questions about the research. If you have questions or comments about this research, please contact Dr. Katie Sharkey by telephone at 401-793-3497 or by email at ksharkey@lifespan.org.

3. Discomforts and Risks

We do not expect there to be any risks associated with completing the online quizzes, which will be sent through a secure, HIPAA compliant online survey link. If at any time you feel that you no longer wish to participate you may withdraw your participation. You can also skip any question that you do not wish to answer.

The focus groups may be completed in person or remotely (i.e., video conference call). If you are in an in-person focus group, you should not divulge any personal information you do not want other study participants to know. In addition, you should not share information provided by other participants during the focus group with people outside of the study team.

If you participate in a remote focus group, since you will not be on-site with the research team in this instance, it will be your responsibility to ensure you are in a private location while completing the remote assessments. Should you complete your remote assessments around or near others, it is possible that your participation in the research or your responses to focus group questions may be inadvertently divulged to others.

The most important potential risks to know about are: loss of privacy or confidentiality of the responses you give in the focus groups.

4. Benefits

There are no direct benefits to you to completing these assessments. We hope to learn more about home visitors' knowledge of sleep and biological rhythms. The results of this study will help us improve the tools available to help expectant and new parents obtain healthy sleep.

5. Alternative Therapies

This is not a treatment study.

6. Refusal/Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study, the researcher will share this information with you as soon as possible.

Reasons the researchers would take you out of the study even if you wanted to stay in:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

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If you decide to quit the study, please tell the head researcher, Katherine M. Sharkey, MD, PhD, Perinatal Sleep Research Laboratory, 146 West River Street, Suite 1K, Providence, RI, 02904; ksharkey@lifespan.org.

7. Medical Treatment/Payment in Case of Injury

This study does not include any treatment or intervention; therefore, a research related injury/illness is unlikely to occur.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study or would like more facts about the rules for research studies, or the rights of people who take part in research studies, you may contact the Director, Research Protection Office in Lifespan Office of Research, at (401) 444-6246.

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information. (HIPAA)

Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. Federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form, you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study, you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record may be used and released for research purposes. The following people or businesses/companies might use, release, or receive such information:

- The researchers from Rhode Island Hospital, Bradley Hospital, and Brown University and their support staff;
- The study sponsor: NIH
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;

- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, the Office of Civil Rights, European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving, and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that, so it is possible they might re-release your information.
You have the right to refuse to sign this form and not participate in the research. Your refusal would have no effect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study.

If you decide to quit the study after signing this form (as described in Section 6: Refusal/Withdrawal), no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research. You will not be allowed to see or copy the information described in this form if the research is open. You may see and copy the information when the study is completed.

10. Additional Information

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

NIH Certificate of Confidentiality

The National Institutes of Health has issued a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you. The researchers may not disclose information that may identify you, even under a court order or subpoena, unless you give permission. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you if required by law (such as to report

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child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your medical treatment); or if it is used for other research as allowed by law. In addition, the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. Any research information that is placed in your medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

SIGNATURE SECTION OF CONSENT

Adult Participant

- I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.
- By signing below, I give my permission to participate in this research study and for the use of associated protected health information as described above (HIPAA). *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice.*
- **The Researcher is required to provide a copy of this consent to you.**

This informed consent document is approved for use with a valid IRB stamp at the top of each page. The document expires for use on the date listed within the IRB stamp.

DO NOT sign this document after this expiration date.

Print name of Study Participant

Signature of Adult Study Participant Date (MM/DD/YEAR) Time when signed

Research Investigator /or Designee's Statement & Signature

- I have fully explained the research described above, including the possible risks and benefits, to all involved parties (participant /parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.

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- I have provided a copy of the consent form signed by the participant/parent/guardian and a copy of the hospital's privacy notification (if requested).

Signature of researcher or designate	Date (MM/DD/YEAR)	Time when signed