Title: “A Wearable Morning Light Treatment for Postpartum Depression”

NCT04845347

Date of IRB approval: 5/28/2025

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: A Wearable Morning Light Treatment for Postpartum Depression

Company or agency sponsoring the study: National Institute of Mental Health

Names, degrees, and affiliations of the principal investigator:
Principal Investigator: Leslie Swanson, Ph.D., Department of Psychiatry, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying a light therapy device, called the Re-Timer, to learn about its effects as a treatment for postpartum depression. This study will test light therapy for women with postpartum depression using the Re-Timer to begin to understand how it affects mood and the body clock (also called the circadian clock). Your health-related information, including about your sleep, mood, and saliva (used to estimate your body clock's timing), will be collected for this research study.

This study involves a process called randomization. This means that the Re-Timer light glasses version you receive (active or inactive) in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a

coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include no improvement of your current depression and/or new symptoms from use of light therapy, such as sleep disturbance, hypomania, irritability, headache, eyestrain, light sensitivity, and nausea.

This study may offer some benefit to you now or others in the future; some participants may benefit from light therapy, including improvement of their depression or sleep. Possible benefits of the research for society include better understanding of treatments for postpartum depression.

We expect the amount of time you will participate in the study will be approximately 5-6 weeks during the baseline and active treatment phase, followed by completion of study questionnaires online again approximately 3 months later, for a total time of 4-5 months.

You can decide not to be in this study. Alternatives to joining this study include other clinical trials, or other standard treatments such as psychotherapy or medications.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Depression is common during the postpartum period. Available treatments, such as medications and psychotherapy, may not provide enough relief from depression symptoms and can be difficult for women with young infants to access. Further, some women may not wish to take medications when breastfeeding. For these reasons, there is an urgent need to develop fast-acting, non-medication therapies for postpartum depression that can be used in patient's homes. The purpose of this study is to test 5 weeks of light therapy for women with postpartum depression, and to begin to understand how it affects mood and the body clock (also called the circadian clock). Please note that as your infant's sleep may impact your mood, as part of the study, your infant will undergo monitoring of their sleep. The Re-Timer light therapy device is a commercially available device, however, its use in this study is investigational.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

You may be eligible to take part in this study if you are:

- Age 18 or older
- Have given birth to a baby within the last 6 months
- Currently experiencing depression
- Able to start light treatment at 5:00 am or later (e.g. you wake up at 5:00 am or later)
- Your infant is also eligible to take part in this study. We will ask you to place a small wrist-watch like device on your infant's ankle for about 5 days at the start, middle, and end of the study to monitor their sleep patterns. This is required for participation in the study, as your infant's sleep can influence your mood.

You may be excluded from the study if you have/are:

- History of bipolar disorder, mania or hypomania, or other certain psychiatric conditions
- A sleep disorder, such as insomnia, sleep-disordered breathing, narcolepsy, or restless legs syndrome
- Currently receiving treatment for depression; including a prescription medication, psychotherapy ("talk therapy"), or any other treatment/no use of prescription medications for depression for the past 4 weeks
- Currently taking melatonin or medications that may interfere with the measurement of melatonin (NSAIDs if used daily, and beta-blockers)
- Eye disease or a history of eye surgery
- Conditions for which light therapy is contraindicated (for example, epilepsy or any history of seizures; lupus)
- Color blind

- Night shift work
- Currently taking a photosensitizing medication (including an antibiotic, medication that contains hydrochlorothiazide, or isotretinoin (Accutane))
- Currently pregnant

3.2 How many people are expected to take part in this study?
120 people are expected to take part in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
First, you will review this consent form with study staff. After you sign the form indicating your consent to participate, you will then meet virtually (via a secure online videoconferencing platform such as Zoom) with a study staff member for an eligibility interview about your sleep, health, and mood to determine if you are eligible for the study. We may ask that this session be videorecorded for training purposes.

2. If you are eligible for the study, you'll then start the baseline period of the study, which lasts about one week. During the baseline period of the study you will:

- Keep a daily log of your sleep using a secure website for 4-7 days.
- Wear a small wrist-watch like device called an actigraph, which records activity and light exposure for approximately 4-7 days.
- Complete questionnaires about your sleep, functioning, eating habits, and mood using a secure website.
- Keep a daily log of your baby's sleep for about 5 days using a secure website.
- Your baby will wear a small wrist-watch like device called an actigraph on his/her left ankle for about 5 days.

On one day during the baseline period you will also: collect samples of your saliva during one evening. We will use your saliva samples to study levels of the hormone melatonin.

- Study staff will deliver a kit to your home for you to use to collect your saliva, and they will review the procedures with you in detail in-person or virtually via secure videoconference or telephone call.
- We will ask you to be in dim light and wear blue-blocking glasses (called Uvex) during the saliva sample collection period.
- You will collect your saliva by chewing on a piece of cotton (called a salivette) every 30 minutes, starting six hours before your bedtime, until your bedtime, for one day (13 saliva samples in total).
- Study staff will return to your home to pick up the saliva collection kit and samples.

3. After the baseline period of the study, you will be randomly assigned (like flipping a coin) to one of 2 study groups: the active Re-Timer group (you will receive an active version of the Re-

Timer) OR the placebo group (you will receive an inactive version of the Re-Timer). You will be blinded to group assignment (that is, you will not know which group you are assigned to).

For the next 5 weeks, you will begin daily use of the Re-Timer glasses, shown in this picture. The glasses have two small lights (light-emitting diodes, or LEDs) placed near each eye that produce UV-free blue-green light. You will receive either active light glasses, or a pair of inactive light glasses (also called placebo) which look the same and both produce light. We will ask you to use the light glasses for 60 minutes per day, every day, for 5 weeks. We will tell you a specific time to use them every morning; most people will wear them soon after their usual wake time. It is very important that you use the glasses only during your scheduled time! The glasses are designed so you can freely move and engage in your usual activities while wearing them. You will be given detailed instructions on the use of the glasses if you are eligible for the study.

For the first week of the study, we will call you and/or message you to remind you to use the glasses, and to see if you are having any problems using them. Note that your use of the glasses will be tracked by a small monitor placed on the arm of the glasses. This monitor will tell us when you are using the glasses, and for how long. You may be discontinued from the study if you do not use the glasses as directed. You will return the glasses to study staff when you have completed the study; study staff will travel to your home to pick up the glasses from you when you have completed the study.

4. In addition to wearing the glasses, for approximately 5 weeks after you start using the glasses, you will:

- Keep daily logs of your use of the glasses using a secure website.
- Complete questionnaires about your mood and side effects once per week using a secure website.
- Once per week, meet with a study clinician via telephone or virtually through a secure online meeting platform (such as Zoom) so the clinician can complete an assessment of your mood and a suicide risk screening. Please be advised that these meetings will be recorded via video and/or audio recording for quality assurance—another study team member will access the recording to complete a second rating of your answers to the questions. You can still participate in the study if you do not agree to be video and/or audio recorded for the study.

5. Approximately halfway through the 5-week period when you are using the glasses (about 2.5 weeks after you started using the glasses) you will:

- Wear the actigraph again for approximately 4-7 days.
- Keep a daily log of your sleep for 4-7 days and your baby's sleep for approximately 5 days.
- Your baby will wear a small wrist-watch like device called an actigraph on his/her ankle for approximately 5 days.

- Additionally, you will collect samples of your saliva again on one evening, using the same procedures described above (you will collect 13 saliva samples in total on one day).
- At this time, study staff will come to your home to drop off and pick up the equipment for the saliva collection. They will also download your glasses monitor to make sure you have been using the glasses regularly and at the right time. You may be discontinued from the study if you do not use the glasses as directed.
- You will also complete some additional questionnaires about your functioning and eating habits using a secure website.

6. In the final week of using the glasses, in addition to the procedures described in #3 above, you will:

- Wear the actigraph again for approximately 4-7 days.
- Keep a daily log of your sleep for 4-7 days and your baby's sleep for approximately 5 days.
- Your baby will wear a small wrist-watch like device called an actigraph on his/her ankle for approximately 5 days.
- At the end of this week, you will collect samples of your saliva again on one evening, using the same procedures described above (you will collect 13 saliva samples in total on one day).
- Complete post-treatment questionnaires about your sleep, mood, functioning, eating habits, and experiences with the light therapy using a secure website.
- Study staff will come to your home to drop off and pick up the saliva samples and glasses.

7. About three months after you stopped using the glasses, we will ask you to complete a 3-month follow-up assessment, which involves completing questionnaires about your sleep, mood, and functioning via a secure website.

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you attend all of your scheduled appointments, use the glasses as directed, and report any adverse reactions you may have during the study.

Please be aware of the following changes to study procedures that may be implemented in the event of a pandemic or viral outbreak: All screening visits will take place virtually as described above. In order to minimize in-person contact, a curbside pickup procedure will be used to pick up and drop off study equipment. You will have a scheduled time when to a staff member will be at your home to transfer equipment to you outdoors.

4.2 How much of my time will be needed to take part in this study?

The first part of the study—baseline period and 5-week treatment phase—will last about 5-7 weeks. We will ask you to complete follow-up questionnaires using a secure website about 3 months after you stopped wearing the glasses.

1. The in-person eligibility interview will take about 45-120 minutes.
2. You will wear the light glasses for 60 minutes each day, daily over 5 weeks.
3. Completing the daily light therapy logs will take about 2 minutes each day, daily over 5 weeks.
4. The saliva sample collection process will last about 6 hours on one day at 3 different time points (start, middle, and end of study).
5. It will take approximately 20-40 minutes once per week to complete the questionnaires online, over 5 weeks.
6. The mood ratings with the study clinician will take approximately 45-60 minutes, once per week, over 5 weeks.
7. The post-treatment questionnaires will take about 45-65 minutes.
8. Completing the sleep diaries for you and your baby will take about 5-8 minutes each day for 5-7 days, at 3 different time points (start, middle, and end of study).
9. Completing the 3-month follow-up questionnaires will take about 30-45 minutes.

4.3 When will my participation in the study be over?
Your participation in the study will be over after you complete the 3-month follow-up assessments, approximately 4-5 months after you began the study.

4.4 What will happen with my information and/or biospecimens used in this study?
Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

With appropriate permissions, your samples and collected information may also be shared with other researchers, here, around the world, and with companies.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Risk of psychological discomfort during assessments:
You may be uncomfortable answering the questions about your medical conditions, mood, sleep, and mental health during the eligibility interview, when completing the questionnaires, and during the mood assessments with the study clinician.

Side effects from light therapy:
The most common side effects of light therapy include:

- Sleep disturbance
- Hypomania
- Irritability
- Headache
- Eyestrain

- Photophobia (light sensitivity)
- Nausea

These symptoms are usually mild and go away on their own after several days of therapy. You should not use light therapy if you have: bipolar disorder or a history of mania or hypomania; epilepsy or a history of seizures; eye disease; eye surgery; lupus; a medical condition which causes sensitivity to light; or if you are taking a medication which causes light sensitivity.

Risks from wearing the actigraph (wrist-watch like device to monitor sleep-wake patterns, including light exposure via a light sensor):
Slight risks involved with wearable devices such as actigraphs, or watches, include risk of skin irritation. As we will ask both you and your infant to use the actigraph, skin irritation is also a potential risk to your infant.

Risks from saliva collection:
Choking on the salivette chewing swab used to collect your saliva is a rare risk associated with saliva collection.

Risk of worsening of depression:
There is a risk that your depression may not improve or become worse. A risk of suicide is also possible with worsening of depression symptoms.

Risk of breach of confidentiality:
There may be a risk of loss to confidentiality or privacy. This risk includes the potential for the video and/or audio recording of your mood assessments with the study clinician to be listed to or viewed by someone outside of the study team.

The researchers will try to minimize these risks by:

Risk of psychological discomfort during assessments:
The eligibility interview and mood assessments will be completed by trained research staff. You may refuse to answer a question at any time or end the interview at any time. You may also take a break at any time.

Side effects from light therapy:
We will monitor you for side effects from light therapy throughout the study. You should report any side effects to study staff immediately. The dose of light may be adjusted to reduce any side effects you may experience. If we believe you are experiencing mania or hypomania, we may ask you to stop the light therapy entirely.

Risks from wearing actigraph (wrist-watch like device to monitor sleep-wake patterns):
To minimize these risks participants will be advised to keep the band clean, dry, and appropriately tightened. You can sanitize the watch with a mild antibacterial soap, if needed. If

irritation persists you are advised to cease wearing the device or to remove the device from your infant's ankle and to notify members of the study team. The watch is not waterproof so please remove the watch when your wrist or your infant's ankle will be submerged in water (i.e. showering, bathing, washing the dishes, swimming, etc.). Additionally, you will be instructed to place your infant's watch over clothing (i.e., socks, onesie) in order to minimize direct skin contact.

Risks from saliva collection:
We will minimize the risk of choking by instructing you how to take the saliva sample and providing you with written and oral instructions as well.

Risk of worsening of depression:
We will monitor your depression symptoms, including thoughts of suicide, on a regular basis.

- Should you experience significant worsening of symptoms, we will provide you with referrals for further clinical care of your depression. Your participation in the study may be discontinued.
    - If you are struggling or in crisis, help is available. You can call or text '988', 24/7 for access to trained crisis counselor who can help.
- If we believe you are at risk for suicide, we may encourage you to contact the University of Michigan Hospital Psychiatric Emergency Services (734-936-5900) for help (available 24 hours a day, 7 days per week).
- If you choose not to seek help, it may be necessary for us to seek help for you against your wishes to keep you safe.

Risk of breach of confidentiality:
We have taken numerous precautions to protect your information.

- All information that we collect about you for the study will be coded with your study ID and will not contain identifying information (such as your name).
- Your study information will be maintained in a secure database in a locked office, and only certain members of the research team will have access to this database.
- Only your study ID will be used when collecting your data, including the questionnaires you complete online.
- As noted above, with your permission, we will be video and/or audio recording your mood assessments with our study clinician for quality assurance purposes. The recordings will not be transcribed and instead maintained only in digital form, not in hardcopy. These recordings will be stored on a secure, University of Michigan-maintained electronic drive accessible only to study staff and maintained separate from any electronic files which may contain your research data. Each recording file will also be password protected. They will be deleted after the quality assurance check has been completed.
- There are some limits to confidentiality.

  - If you tell us, or we learn something, that makes us believe that you, your child, or others have been or may be physically harmed or neglected, we may be required to report that information to the authorities.
  - In the event that we determine that you are at risk for suicide, you will be encouraged to seek the help of Psychiatric Emergency Services, and it may be necessary for us to disclose your personal information and/or contact the authorities to protect you.
- See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

We will ask you about any side effects from the light therapy in the weekly questionnaires you will complete with the study. The dose of light may be adjusted (or the light may be stopped entirely) to reduce any side effects you may experience. If we believe you are experiencing mania or hypomania, we may ask you to stop the light therapy entirely.

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, some participants may experience improvement of their depression or sleep. This research may benefit others in the future if we find that light therapy is an effective treatment for postpartum depression.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

There may be other ways of treating your condition. These include: talk therapy or medications available through standard treatment. Light therapy devices, including the one used in this study, are available commercially over-the-counter. You should check with the researcher and/or your primary care physician to discuss your options including how to obtain any alternative treatments and whether they must be obtained through a physician or require medical supervision.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

There is no danger in terminating your participation in the study before it is finished. However, we encourage you to discuss treatment options with your doctor.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers, including using the glasses as directed.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will be paid up to $765 for your participation in the study. You have the option to be paid three ways: by check which will be mailed to you at different time points, voucher which can be redeemed for cash at the University of Michigan cashier's office (located on central campus and the hospital) at the end of the study or gift card which can be mailed to you at the end of the

study. If you leave the study early, you will be paid only for the parts of the study you completed.

Payments are as follows:

Screening	$15
Completing the first baseline sample collection	$100
Study midpoint for adhering to treatment, sample collection, and completing outcome assessments	$330
Post-treatment endpoint for adhering to treatment, sample collection, and completing outcome assessment	$270
3-month follow up questionnaires online	$50
Total for the entire study	$765

8.3 Who could profit or financially benefit from the study results?
No person or organization has a financial interest in the outcome of the study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have

consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Mental Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of (such as child abuse and neglect, or harm to self or others).

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

If you tell us or we learn something that makes us believe that your child or others have been or may be physically harmed, we may be required to report that information to the appropriate agencies.

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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- Health plan/health insurance records

- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many NIH studies are stored and managed. Sharing your deidentified study data helps researchers learn new and important things about brain science more quickly than before.

Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your personal information from you in order to make that code number. The code number cannot be used to identify you. The study researchers will never send your personal information to NDA.

It is possible that you will participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number on your deidentified data

from each study. This data matching helps researchers who use NDA data to count you only one time. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for different research projects. Every researcher (and the institution to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to NDA. You can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you know now that you do not want your data in NDA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available on-line at http://nda.nih.gov.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)

- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Leslie Swanson, Ph.D.
Mailing Address: 4250 Plymouth Rd, Ann Arbor, MI 48109
Telephone: 734-764-2242
Email: LMSwan@med.umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent to video/audio recording solely for purposes of this research
This study involves video and/or audio recording. If you do not agree to be recorded, you CAN STILL take part in the study.

_____ Yes, I agree to be video/audio recorded.

_____ No, I do not agree to be video/audio recorded.

Print Legal Name: _____

Signature: _____

Sig-E

Consent for Infant's Participation in the Study

Legally Authorized Representative or Parent Permission

Subject Name: _____

Parent/Legally Authorized Representative:

Printed Legal Name: _____

Signature: _____

Address: _____

Date of Signature (mm/dd/yy): _____

Relationship to subject: □ Parent □ Spouse □ Child □ Sibling □ Legal guardian □ Other

If "Other," explain: _____

Reason subject is unable to consent: _____

If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact IRBMED.

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____