Official Title: RECOVER-SLEEP: A Platform Protocol for Evaluation of Interventions for Sleep Disturbances in Post-Acute Sequelae of SARS-CoV-2 Infection (PASC)

NCT: NCT06404099

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HYPERSOMNIA SUB-STUDY INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Duke Clinical Research Institute (DCRI) / "RECOVER-SLEEP: A Platform Protocol for Evaluation of Interventions for Sleep Disturbances in Post-Acute Sequelae of SARS-CoV-2 Infection (PASC)"**
Protocol Number:	**Pro00112484 / RECOVER-SLEEP**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

Concise Master Consent Summary
This is a research study to find out if certain study interventions can help treat sleep disturbances that started or got worse following a COVID infection and have lasted for at least 12 weeks. Sleep disturbances include excessive drowsiness, problems falling and staying asleep, and problems with sleep-wake patterns. These sleep disturbances are known to be associated with Post-Acute Sequelae of SARS-CoV-2 Infection (PASC) or Long COVID. This study will look at the effects the study interventions may have on your ability to get better and recover from the sleep disturbances associated with Long COVID.

This study will enroll adults who experience sleep disturbances as a symptom of Long COVID and who have not had another COVID infection in the past 4 weeks. These studies are being supported by the National Institutes of Health (NIH) through the Researching COVID to Enhance Recovery (RECOVER) Initiative.

Hypersomnia Sub-Study
People with hypersomnia are those who experience excessive daytime sleepiness, or drowsiness, even though they get 6 or more hours of sleep each night. After being assigned to this sub-study, you will be asked to do the following:

- *Take an active study drug or placebo pill for 10 weeks. The placebo pill looks like the active study drug but has no active ingredients and should have no effect.*

This sub-study will include approximately 500 participants from many study sites across the United States.

As a sub-study participant, you will be asked to do the following:

- *Answer questions about your symptoms and quality of life*
- *Complete a Sleep Diary*
- *Wear an activity tracker (a Fitbit or similar device) to record your rest and activity patterns*
- *Monitor your blood pressure at home*
- *Provide a blood sample*
- *Complete tests to measure your memory and thinking abilities (referred to as "brain quizzes")*
- *Complete various questionnaires*

If you are involved in multiple RECOVER trials and/or the RECOVER longitudinal cohort, your study data (including a limited number of identifiers such as date of birth, dates of study and health events) may be linked between RECOVER studies and analyzed together across RECOVER studies.

There is no guarantee of benefit to you, and there are some possible risks from participating in this study. Possible risks, such as possible side effects and loss of confidentiality, are detailed later in this consent form. Every effort will be made to minimize these risks. You do not have to participate in this research to be treated for your condition. If you choose not to participate, your usual healthcare will not be affected. Refer to the Master Consent Form for information on study-wide risks.

SUB-STUDY CONSENT

You have been asked to participate in the study called "RECOVER-SLEEP: A Platform Protocol for Evaluation of Interventions for Sleep Disturbances in Post-Acute Sequelae of SARS-CoV-2 Infection (PASC)". This study is part of the Researching COVID to Enhance Recovery (RECOVER) Initiative. Refer to your Master Consent for details.

The RECOVER-SLEEP Study offers this Sub-Study (referred to as "study" for the remainder of this form) for participants experiencing hypersomnia (excessive daytime sleepiness), and will be referred to as the Hypersomnia Study. You are being asked to participate in the Hypersomnia Study.

Your participation is voluntary. Please review the information in this consent form to help you decide if you want to take part in the study. The use of the study drug and some of the study

devices in this study are investigational. An investigational use is one that is not approved by the United States Food and Drug Administration (FDA).

INTRODUCTION

Why am I being asked to take part in this study?

You are being asked to take part in this study because you are at least 18 years old, had a COVID infection that caused new or worsened daytime sleepiness, and have been experiencing worsened nighttime sleep and/or increased daytime sleepiness for at least 12 weeks since the COVID infection.

Why is this study being done?

The number of people experiencing Long COVID is increasing in both hospitals and communities, and the symptoms of Long COVID affect quality of life. This study aims to improve the quality of life for people with sleep-related Long COVID symptoms. This study will look at multiple study interventions and their ability to treat sleep disturbances associated with Long COVID. Results from this study may help researchers better understand the condition and how to treat it.

VOLUNTARY PARTICIPATION/POTENTIAL BENEFITS

What if I don't want to participate?

You do not have to participate if you do not want to. Participation is voluntary. If you decide not to participate, your usual healthcare will not be affected. If you decide to participate, you can stop at any time.

Will there be any benefit to others or me?

We do not know if you will benefit from taking part in this study. The study intervention may have a role in treating sleep-related Long COVID symptoms. You may want to participate to help doctors learn how to best care for adults with Long COVID. The information learned from this study may benefit others like you in the future. You may be given monitoring study devices for use during the study (for example, an activity tracker and a portable blood pressure monitor). You may be able to keep these study devices for personal health monitoring after the study ends if these were provided to you.

Will I be told about any new findings?

Yes. You will learn of any new, important information that is discovered during the study and any information that may influence your decision to continue participating in the study.

HYPERSOMNIA STUDY INTERVENTIONS (STUDY DRUGS)

If you decide to participate in the Hypersomnia Study, you may receive the following:

- Either an active study drug (you would be assigned to the active study drug group) or a placebo (you would be assigned to the inactive study drug group).

About the Study Drugs: The study drug will be either modafinil (Provigil) or a placebo pill. Modafinil (pronounced mow-DAH-fuh-nil) is a pill taken by mouth and is used to help people to stay awake during the day. A placebo pill looks like the active study drug but has no active ingredients and should have no effect. If you cannot take modafinil because of interactions with your current medicines, you may receive either solriamfetol (Sunosi) or a placebo pill. Solriamfetol (pronounced soul-ree-AM-fuh-tall) is also a pill taken by mouth and is used to help people to stay awake during the day.

You will be randomly assigned by chance (like rolling a die) to receive either the active study drug or placebo. However, you, your study doctor, and the study team will not know if you are receiving the active or inactive study drug, but they can quickly find out if there is ever a need to know for your safety or well-being. The use of modafinil and solriamfetol in this study are investigational. An investigational use is one that is not approved by the United States Food and Drug Administration (FDA).

Total Length of Participation: Your participation in this study will last about 15 weeks. Before you start your study drug, this study consists of a 1-week period during which information will be obtained on your health and sleep patterns. The study drug should be taken for approximately 10 weeks, immediately followed by an in-person clinic visit. You will also have a phone call about 4 weeks later, to check on how you are doing.

- The first 3 weeks of the 10-week study drug will be a titration period. A titration period means that you will start with a low dose of the study drug and then increase the dose to find the best dose for you. You will then take this dose for another 7 weeks.

If you decide to stop participating in the study before your approximate 15-week study has completed, you will be asked to come into the study site to complete activities (referenced below under week 11) so we can collect important study data.

SCREENING

Refer to your Master Consent Form to reference activities occurring within 6 weeks before starting your sub-study. If this study appears to be a good match for you and you choose to participate, you will be asked to sign the Study Consent Form.

RANDOMIZATION

This visit may happen over one or more days, and some assessments may be able to be completed by phone and/or electronically (internet-based), depending upon your needs.

During the randomization visit, you will be asked to do the following:

- Repeat, if necessary, some activities from screening
- Be randomized (like rolling a die) to either an active study drug group or an inactive study drug group
- Have your height and weight measured
- Give a blood sample
- Receive a home stool collection kit with instructions
- Complete brain quizzes and various questionnaires, (these all take less than 60 minutes to complete)
- Receive an activity tracker (a Fitbit or similar device) to record rest and activity patterns
    - These patterns are used to measure times when you are asleep and awake
    - These study devices require the use of a compatible mobile device
        - If you do not have a mobile device or a data plan compatible with the activity tracker, then one may be provided. If a mobile device is provided, you may keep it at the end of the study.
- Receive a blood pressure monitor to take home with instructions
- Receive instructions for an internet-based Sleep Diary (or receive a paper version, if needed) to record rest and activity patterns and factors that may influence sleep
    - These patterns are used to measure times when you are asleep and awake
- Receive study drug (active or placebo modafinil or solriamfetol)
    - Receive instructions regarding titration
- Report any new or worsening symptoms since screening

Personal Information

If you decide to take part in the study, we will ask for your:

- Date of birth so we can confirm your age
- Social Security number so we can pay you for your time and complete the tax form
- Home address so we can send your payment to you
- Phone number and email address so we can contact you to see if you have any questions or problems during the study
- Contact information for a person you trust, like a family member or friend, so we can contact them if we cannot reach you. Your trusted contact may give us some information about your health if you are not able to

Additionally, we will ask for some information about your health, including:

- Details about your COVID infection(s) and COVID vaccination status
- Your health history including sleep-specific history, general health, and well-being
- Your allergies and a list of medicines (prescription and non-prescription) you are taking

We will also ask you to sign a medical release form. This will allow the study team to access your medical record to review relevant health history and any hospitalizations that may occur while you are participating in the study.

Blood Sample Collection

We will ask you to give blood samples for study-specific tests and for biorepository storage 2 times during the study. We will take about 5 ½ tablespoons (80 ml) of blood from your arm each visit to run study-specific tests and to store samples for future research, if possible. See the "Biorepository: Research Use of Data and Biospecimens" section of the Master Consent Form for more information.

Stool Sample Collection

You will be given a stool sample home kit and instructions 2 times during the study. We will ask that you collect the stool and place it in the provided collection container during your next bowel movement. We will ask you to mail the stool sample per our instructions. The stool samples may be used for future research; see the "Biorepository: Research Use of Data and Biospecimens" section of the Master Consent Form for more information.

WEEK 1

During week 1, which occurs immediately following the randomization visit, you will be asked to do the following:

- Use the activity tracker when you are awake and asleep
    - You will be asked to wear this study device for 7 days before starting your study drug
- Complete the Sleep Diary
    - You will be asked to complete this Diary for 7 days before starting your study drug

WEEKS 2 TO 11

During weeks 2 to 11, you will be asked to do the following:

- Take modafinil (or placebo) or solriamfetol (or placebo)
- Use the activity tracker when you are awake and asleep

- You will be encouraged to wear this study device for the duration of the study, but use is optional during weeks 2-10

Titration Period: During the 3-week titration period, which occurs from weeks 2 to 4, you will be asked to answer phone calls as your dose of modafinil (or placebo) or solriamfetol (or placebo) is being titrated. The study team will call you about every 5 days to discuss titrating your study drug dose. During this time, you will be asked to check your blood pressure and pulse using the blood pressure monitor. This dosage will be depending on your individual symptoms and tolerance to the study drug.

Middle of Study Phone Call: You will be asked to answer a phone call around the middle of the study. This will occur between weeks 5 and 7.

During this call, we will ask you to:

- Provide details about how you are completing your study drug
- Report any new or worsening symptoms
- Review your current medications

If you report certain symptoms, you may be asked to make an additional in-person visit to your study site.

WEEK 11

During week 11, at or near the end of intervention period, you will be asked to come to the study site for an in-person visit. You will continue taking your study drug until this visit.

7 days prior to your scheduled in-person visit, we will ask you to do the following:

- Use the activity tracker when you are awake and asleep
- Complete the Sleep Diary

During this visit, which will mark the end of the study intervention, you will be asked to do the following:

- Complete questionnaires about your current sleep habits (these take less than 10 minutes to complete)
- Review your current medications
- Have your weight measured
- Complete brain quizzes and various questionnaires (these all take less than 60 minutes to complete)
- Give a blood sample
- Have your blood pressure and pulse measured

- Receive a home stool collection kit with instructions
- Provide details about how you completed your study drug
- Report any new or worsening symptoms
- Return the remaining study drug and study devices, if applicable

Additionally, we will ask if any of the following information about your health has changed, including:

- Your health history including sleep-specific history, general health, and well-being
- Your allergies and the list of medicines (prescription and non-prescription) you are taking

If you decide to stop participating in the study before the study ends, you will be asked to come into the study site to complete a visit so we can collect important study data. This visit will include all of the activities referenced above for week 11.

WEEK 14

During week 14, about 3 weeks after week 11 (when you stopped taking the study drug), you will be asked to do the following:

- Use the activity tracker when you are awake and asleep
    - You will be asked to wear this study device for 7 days before week 15 activities

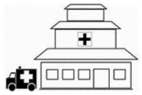
WEEK 15

A study team member will call you about 4 weeks after week 11.

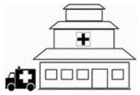
During this call, we will ask you to:

- Report any new or worsening symptoms
- Complete questionnaires (these take less than 10 minutes to complete)

HYPERSOMNIA STUDY SCHEDULE OF ACTIVITIES

Randomization	**Week 1**	**Weeks 2 to 10**
Clinic Visit	**At-Home Activities (Phone and Internet-Based)**	**At-Home Activities (Phone and Internet-Based)**
		
Clinic Visit: ● Repeat any screening activities, as necessary ● Blood collection ● Receive blood pressure monitor and measure blood pressure and pulse on provided monitor ● Measure height and weight ● Stool Sample* ● Receive activity tracker ● Receive Sleep Diary ● Safety assessment ● Receive study drug assignment and corresponding study drug ● Brain quizzes and questionnaires	● Wear activity tracker ● Complete the Sleep Diary	● Wear activity tracker (use required during week 2 and for one week leading up to the End of Intervention visit in week 11; use encouraged during weeks 3-10) ● Safety assessment phone call between weeks 5 and 7 ● Provide details about how you are completing your study drug ● Take study drug daily (including the 3-week titration period) ● Use blood pressure monitor during titration period and as needed throughout the study drug period ● Complete the Sleep Diary for 7 days before the week 11 End of Intervention visit

**Stool samples will be collected after the visit with a home stool sample collection kit*

Week 11	**Week 14**	**Week 15**
Clinic Visit	**At-Home Activities**	**At-Home Activities (Phone and Internet-Based)**
		
● Questionnaires and brain quizzes ● Review medications ● Sleep history ● Measure weight ● Blood collection ● Measure blood pressure and pulse on provided monitor ● Stool Sample* ● Safety assessment ● Provide details about how you are completing the study drug ● Return study drug and study devices, as applicable	● Wear activity tracker for 7 days before week 15 activities	● Questionnaires ● Safety assessment

**Stool samples will be collected after the visit with a home stool sample collection kit*

What if I decide to stop participating before the study is over?

You can stop participating in this study at any time. If possible, we would like you to stay in the study until it is over because your information and experiences are valuable to this research. Even if you stop the study drug early, such as stopping the study drug, we may ask that you continue to complete the study visits, if and when possible.

If you are thinking about stopping your participation, please let your study doctor know as soon as possible. Your study doctor can talk to you about options that might work for you to stay in the study, though you may continue to stop your participation if you so choose.

We will tell you if we learn anything new that might affect your decision about whether to continue participating in the study. If we lose contact with you, you will be automatically withdrawn from the study, and no further information will be collected from your medical record.

Your participation in the study may be stopped by your study doctor at any time without your consent. The study doctor may stop the study and end your participation at any time for any reason in order to ensure your safety. Some of the possible reasons include:

- Failure to follow study instructions
- Continuing could be harmful to you
- Termination of the study
- Other unanticipated circumstances

If your participation is stopped by your study doctor without your consent, you will be notified of the decision and reasoning.

HOW WILL YOU PROTECT MY PRIVACY?

In all research, there is a possible risk of the loss of confidentiality. We will make every effort to keep your personal and health information secure, but absolute confidentiality cannot be guaranteed.

To help us protect your privacy, this study is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH) and the U.S. Department of Health and Human Services. This means that the study team cannot share any information that could identify you with anyone who is not involved in the research except for specific situations, such as when it is required by law to report child or elder abuse, some communicable diseases, and threats to harm yourself or others. The study team cannot be forced to share information that could identify you for use as evidence in any court of law or legal processes unless you give your permission.

Your information that is protected by the Certificate of Confidentiality may still be shared or used when the information:

1. Is disclosed to people connected with the research. For example, the information may be used internally by the NIH for program evaluation.
2. Is required to be disclosed by federal, state, or local laws. For example, when information must be disclosed to meet the legal requirements of the U.S. Food and Drug Administration (FDA).
3. Is necessary for your medical treatment and you have given your permission for the information to be shared.
4. Is used for other research that is allowed by federal regulations.
5. Is shared with your permission. For example, if an insurance or healthcare provider gets your written consent for us to disclose the research information.

By signing and dating this consent form, you consent to your information being used as described above.

You should understand that a Certificate of Confidentiality does not prevent you or a loved one from voluntarily releasing information about yourself or your involvement in this research. If you want your research information to be released to an insurer, medical care provider, or any other person not connected with the research, you must give your permission for the researchers to release it. This means that you and your loved ones must also actively protect your own privacy.

Finally, you should understand that the study doctor is not prevented from taking steps to prevent serious harm to yourself or others, including reporting to authorities.

Receiving Information from Your Medical Record

We may review your medical record while you are in the study. Your medical record may include information about visits to your study site, the hospital, or emergency room during the study. We may also collect information about medicines, lab results from blood or urine tests, and other information that may be useful to the study. Reviewing your medical record will help us understand your health status while you are participating in the study.

ALTERNATIVES

What other choices are there?

Your other choice is not to participate. You can continue to get your usual healthcare whether or not you participate in the study.

Currently, no FDA-approved medicines or interventions are available to treat Long COVID. However, other options may be available to you if you choose not to participate in this study. Talk to the study doctor or your healthcare provider about these other options. The study doctor will discuss with you the major risks and benefits of usual care and alternative options.

RESULTS AND STUDY PROGRESS

Will I be told the results of the research?

We will summarize what we have learned when the final study results become available. We will share the summary of results on the study website. However, we may contact you by email, letter, newsletters, or other updates related to the study prior to the final study results.

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.

The research summaries or articles published about the study will not include any information that could identify you.

POSSIBLE RISKS AND DISCOMFORTS

A team of health experts called the Data and Safety Monitoring Board, chosen by the NIH, will regularly monitor the safety of study participants and the progress of the study overall.

Any intervention (e.g., drugs) may have associated risks. Because of this, it is important to notify the study team of any new or worsening symptoms you may experience during or after using the study drug. There may be unknown risks from participation.

Below are some possible, known risks about the study interventions (study drugs) and activities. There is also the risk of loss of confidentiality. Every effort will be made to protect your information, as described throughout this consent form. There may also be risks from participation that we do not know about yet. Refer to the Main Consent for additional study-wide possible risks and discomforts.

Modafinil (Provigil) Risks

Modafinil has been evaluated for safety in many patients with excessive sleepiness associated with disorders of sleep and wakefulness. In clinical trials, modafinil has been found to be generally well tolerated and most side effects were mild to moderate. In clinical trials of participants with narcolepsy (excessive uncontrollable daytime sleepiness), obstructive sleep apnea, and shift-work sleep disorder, modafinil is generally reported to be well tolerated.

The most common side effects reported is headache, occurring in approximately 34% of adult patients. Nausea can occur in 11% of individuals.

Less common side effects of modafinil include:

- Dizziness (5%)
- Anxiety (5%)
- Nervousness (7%)
- Insomnia (trouble sleeping, 5%)
- Depression (2%)
- Drowsiness (2%)
- Paresthesia (pins and needles feeling, 2%)
- Agitation (1%)
- Chills (1%)
- Confusion (1%)
- Emotional lability (mood swings, 1%)
- Hypertonia (muscle tightness, 1%)
- Vertigo (dizziness, 1%)

Uncommon side effects of modafinil include:

- Chest pain (3%)
- Hypertension (high blood pressure, 3%)
- Palpitations (irregular heartbeat, 2%)
- Fast heart rate (2%)
- Flushing (redness, 2%)
- Leg swelling (1%)
- Excessive sweating (1%)
- Increased thirst (1%)
- Diarrhea (6%)
- Indigestion (5%)
- Dry mouth (4%)
- Loss of appetite (4%)
- Constipation (2%)
- Altered taste (1%)
- Abdominal gas (1%)
- Mouth ulcer (sores, 1%)
- Liver problems (2%)

Other less-reported effects of modafinil include:

- Back pain (6%)
- Abnormal or excessive limb movements (2%)
- Tremor (1%)
- Visual disturbance (1%)
- Nasal congestion (7%)
- Sore throat (4%)
- Asthma (lung disease associated with tightening of the air passages, 1%)
- Bloody nose (1%)

Rare side effects of modafinil include:

- Anaphylaxis (severe allergic reaction)
- Angioedema (facial swelling)
- Asystole (sudden stopping of the heart)
- Cerebrovascular accident (stroke)
- Delusions (loss of contact with reality)
- Hallucination (seeing or hearing things that are not there)
- Hypersensitivity reaction, such as:
    - Hives
    - Trouble swallowing or breathing
    - Swelling of the mouth lips or face
    - Throat tightness
    - Hoarseness
    - Skin rash
- Mania (mood disorder with extremes of happiness and sadness)
- Multiorgan hypersensitivity
- Agitation
- Psychosis (loss of contact with reality)
- Skin rash (DRESS syndrome when it occurs extensively with swollen lymph glands, which can be life-threatening)
- Stevens-Johnson syndrome (which can be serious or life-threatening)
- Suicidal ideation
    - If you are having suicidal thoughts or feel in crisis, call the study doctor at the telephone number listed on the first page of this form. You can also call or text the National Suicide & Crisis Lifeline at 9-8-8 or 1-800-273-TALK (8255). The Lifeline numbers are answered 24 hours a day every day of the year by a skilled, trained counselor. You can also present to a healthcare provider, your local emergency room, or call 9-1-1 to be connected to local emergency services.
- Toxic epidermal necrolysis (a skin condition, which can be serious or life-threatening)

For people who could become pregnant while taking modafinil:

- There is an increased risk for congenital malformations of the newborn when pregnant women consume modafinil in the first trimester of pregnancy.
- People who have a known allergy to modafinil, people with severe anxiety, and people who are pregnant or could become pregnant should avoid modafinil.
- Some birth control pills may be less effective
- **See the "Risks Associated with Pregnancy While Participating" section for more information.**

Potential for substance abuse while taking modafinil:

- Because modafinil elevated people's moods in prior studies, it may have some potential for substance abuse. This means that taking this study drug may put you at risk for wanting to misuse it for mood-altering or relaxation purposes.
- Modafinil is a federally controlled substance because it has the potential to be abused. We may ask you questions about how you've used the study drug and feelings of craving the study drug during follow-up assessments to determine whether you may be at risk for potential substance abuse. We may use that information to determine whether you should quit taking the study drug.

Solriamfetol (Sunosi) Risks

Solriamfetol has been evaluated in several studies. The following symptoms were more common in people who took solriamfetol than in those who took the placebo:

- Headache (1%-9% more common)
- Nausea (0%-4% more common)
- Decreased appetite (6%-7% more common)
- Anxiety (2%-6% more common)
- Insomnia (1% more common)

People who took solriamfetol for a longer period of time were more likely to lose a small amount of weight.

For people who could become pregnant while taking solriamfetol:

- In animal reproduction studies with solriamfetol, negative side effects were observed in the mother and fetus.
- People who have a known allergy to solriamfetol and people who are pregnant or could become pregnant should avoid solriamfetol.
- See the "Risks Associated with Pregnancy While Participating" section for more information.

Potential for substance abuse while taking solriamfetol:

- Because solriamfetol elevated people's moods in prior studies, it may have some potential for substance abuse. This means that taking this study drug may put you at risk for wanting to misuse it for mood-altering or relaxation purposes.
- Solriamfetol is a federally controlled substance because it has the potential to be abused. We may ask you questions about how you've used the study drug and feelings of craving the study drug during follow-up assessments to determine whether you may be at risk for potential substance abuse. We may use that information to determine whether you should quit taking the study drug.

If you receive placebo (the inactive substance) as part of this study, your symptoms of sleep disturbances may not improve or may get worse.

Risks Associated with Blood Pressure Monitors

Blood pressure monitors are a non-invasive method of monitoring your blood pressure and pulse. The risks include possible irritation or discomfort where the monitor is worn.

Risks Associated with Terms of Use

As part of this research, you may be required to use one or more of the following: a phone or web app/ site, an electronic study diary (eDiary), or a device that tracks information about you. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, electronic study diary (eDiary), or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the study doctor.

While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app, electronic study diary (eDiary), or device in this study, you do not release the study doctor, sponsor, study site, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant.

Risks Associated with Blood Draws

The risks of getting your blood drawn include bleeding at the puncture site, bruising, and pain. Bleeding and bruising occur in a very small number of people who have their blood drawn. A very short period of pain from the needle stick occurs in most people. Some people may become dizzy, lightheaded, or feel faint. On rare occasions, infection of the area where the blood was drawn may occur.

Risks Associated with Tests to Measure Memory and Thinking Abilities ("Brain Quizzes")

Brain Quizzes may cause frustration, tiredness, or headaches during and/or after completion.

Risks Associated with Nasal Swabs

The risks of nasal swabs include possible discomfort, mild irritation, mild local pain, and minor bleeding.

Risks Associated with Activity Tracking Wearable Study Devices

An activity tracking wearable study device (a Fitbit, or similar device) is a non-invasive device that records changes to your rest and activity patterns. The risks include possible irritation or discomfort where the study device is worn.

Risks Associated with Pregnancy While Participating

If you could become pregnant (you have not had a hysterectomy and/or both tubes and/or both ovaries removed and/or you are not postmenopausal and over the age of 45) and you have a sexual partner who is able to have children (has not had a vasectomy with a negative post-surgery semen analysis), **you must avoid becoming pregnant during the study and for at least 7 days after finishing the study drug.** Avoiding pregnancy is important due to potential side effects of the study drugs. There may be unknown risks to a pregnancy, embryo, or fetus if you become pregnant. The study team can tell you about effective methods of birth control.

However, because no birth control method is 100% effective, except abstinence, you should notify your study doctor immediately if you think there is any chance you could be pregnant, even if you have had a recent negative pregnancy test. If you become pregnant, we may want to review your medical history before and after you give birth. The study team will ask pregnant participants to complete a pregnancy-specific consent form in order to follow the pregnancy to its outcome.

Future Contact

We may contact you to ask if you are interested in participating in additional research related to the RECOVER Initiative. The additional follow-up calls, visits, and/or participation in

additional research are optional and are not included as part of this consent form. You will be asked to sign a separate consent form if you agree to participate in additional research.

PAYMENT AND COSTS

Will I be paid for being in this study?
«Compensation»

If you participate in the Hypersomnia Sub-Study, you may receive up to $700 to cover study-related costs such as parking, and for your time and effort to complete the visits. You will receive:

- $250 after completing the randomization visit
- $50 after completing the middle of study phone call
- $350 after completion of the week 11 clinic visit (or completion of the week 11 clinic visit activities, even if your participation ends before week 11)
- $50 after completing the week 15 phone call

For Biorepository Samples, you may also receive up to $300 for your stool samples ($0 for the first sample, and $300 for the second sample).

Do I have to pay anything to be in this study?
No. There will be no charge to you or your health insurance provider for taking part in this study. All tests and the study drugs that are needed for this study that are not part of your usual medical care will be covered by the study. “Usual medical care” is the care you would receive whether or not you are part of this study. If you receive your usual medical care during the study, your health insurance provider will be billed for that care, as it is unrelated to the study.

What should I do if I become ill or injured during the study?
If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare provider treating you that you are participating in this study. If you tell the study team that you think you have been injured, they will help you get the care you need.

However, there is no commitment by **the study site,** your healthcare providers, study drug or study device providers, study doctors, Duke University (Duke Clinical Research Institute), or the NIH to provide monetary compensation or free medical care to you in the event of a study-related injury. The Sponsor has no plans to pay for the cost of any additional care beyond what is provided as part of the study.

By signing this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for possible mistakes.

USE OF PROTECTED HEALTH INFORMATION FOR RESEARCH

What is Protected Health Information (PHI)?

The PHI collected for this research study includes your name, address, phone number, email address, date of birth, Social Security number, and health information.

Will my PHI remain private?

We will make every effort to keep your PHI safe. We will store records in a locked cabinet or office or on a password-protected computer. We will assign your study information a code and keep it separately from your personal record. Your identity and your PHI will not be shared unless it is required to protect your safety, the safety of others, or if you give us permission to share it.

Who will have access to or receive my PHI?

Your PHI may be given to others only if needed for reasons like determining the results of the study, making sure the study is being done correctly, and providing required reports.

Your medical and research records may be accessed by:

- Your study doctor and other study team members.
- The Sponsor (DCRI) and its representatives (including its affiliated companies that help carry out the research).
- People, or organizations providing services for, or collaborating with, the Sponsor.
- Other researchers, including researchers involved in the study at study sites other than the one where you are participating in the study.
- Any organization that obtains all or part of the Sponsor's business or rights to the product under study.
- Government or regulatory authorities, such as the FDA, including those located in other countries.
- Advarra Institutional Review Board, an independent committee established to oversee the study and help protect the rights of research participants.
- A team of health experts called the Data and Safety Monitoring Board, chosen by the NIH, who will regularly monitor the safety of study participants and the progress of the study overall.

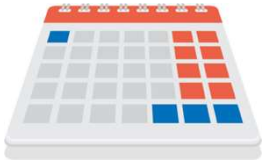
In addition:

- If we cannot reach you during the study period to confirm your health status, we may search for you or delegate a search for you using publicly available data to check on your well-being and health status.

Those who receive your information for the purpose of conducting the study may share it without your permission. Federal privacy rules may not apply to these groups; however, they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

How long will you keep my PHI?

We will keep your permission to use and share your PHI unless you take it back sooner. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign and date this authorization document.



You may take back your permission to use and share your PHI at any time by writing to the study doctor at the address listed on page 1 of this consent form. If you do this, you will not be able to stay in this study. No new PHI will be collected after your written request is received. However, PHI that has already been collected may still be used and given to others as described in this authorization form.

What about my medical record?

Information about your participation in this research will be in your medical record. Other than you, only people who have access to your medical record (like your study doctor and the study team) will be able to see this part of your medical record. The study team may send copies of parts of your medical record to the Duke Clinical Research Institute (DCRI) to monitor the study. Monitoring means DCRI staff will review study records, including your signed consent, to make sure that your information was entered correctly in the study records.

Like all your other information, we will keep this data as safe and secure as possible.

During the study, you will not be able to access your health data in the study records to make sure the study results are accurate. You will be able to access your study health data when the study is over.

What happens if I do not want to share my PHI with you?

If you decide not to sign this authorization form, you will not be able to take part in the study. If you take back your permission for us to use your PHI, you will not be able to continue in this study.

How can I learn more about my legal rights while participating in this study?
After declaring COVID-19 to be a public health emergency, the US Department of Health and Human Services issued a public health declaration called the Public Readiness and Emergency Preparedness Act Declaration for Countermeasures Against COVID-19 (PREP). Since being issued in March 2020, PREP has limited the legal rights of a subject participating in a COVID-19 clinical study that uses a drug, device or vaccine designed to treat, diagnose, cure or prevent COVID-19.

The ending of the public health emergency on May 11, 2023 does not automatically terminate PREP coverage for activities related to COVID-19. Whether PREP can continue to limit the legal rights of subjects participating in a COVID-19 clinical study after the public health emergency ends depends on a number of complex factors that can be subject to change. If PREP limitations on subjects' legal rights apply to the study drug(s) and study device(s), subjects using the study drug(s) and study device(s) in the study may have limits on their right to sue the manufacturers, the study sponsor, healthcare providers and others for significant injuries and adverse reactions.

STATEMENT OF AUTHORIZATION

I have read this authorization form, its contents were explained, and my questions have been answered. I voluntarily agree to allow the study team to collect, use, and share my personal and health information as specified in this authorization form. I will receive a signed and dated copy of this authorization form for my records. I understand that I am not giving up any of my legal rights by signing this form.

Participant:

Print name: _____

Signature: _____

Date: _____ **Time:** _____

WITNESS SIGNATURE FOR PARTICIPANTS WHO CANNOT READ

The study participant has indicated that he/she is unable to read. This Authorization document has been read to the participant by a member of the study team, discussed with the participant by a member of the study team, and the participant has been given an opportunity to ask questions of the study team.

Print name: _____

Signature: _____

Date: _____ **Time:** _____

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.comadviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00073133.

STATEMENT OF CONSENT

A copy of this consent form will be given to you. The purpose of this study, the procedures to be followed, and the risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told who to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to get information about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form.

Participant:

Print name: _____

Signature: _____

Date: _____ **Time:** _____

Person Who Obtained Consent:

Print name: _____

Signature: _____

Date: _____ **Time:** _____

WITNESS SIGNATURE FOR PARTICIPANTS WHO CANNOT READ, IF APPLICABLE

The study participant has indicated that he/she is unable to read. The consent document has been read to the participant by a member of the study team, discussed with the participant by a member of the study team, and the participant has been given an opportunity to ask questions of the study team.

Print name: _____

Signature: _____

Date: _____ **Time:** _____