**INFORMED CONSENT FORM**
**AND**
**AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION**

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

## KEY INFORMATION

***Concise Summary***

*This is a research study to find out if certain investigational treatments can help treat autonomic dysfunction symptoms (symptoms relating to nerve damage of the autonomic nervous system, the system that controls automatic body functions such as heartbeat, blood pressure, and digestion) associated with Long COVID, also known as Post-Acute Sequelae of SARS-CoV-2 Infection (PASC). Long COVID is defined as symptoms associated with COVID that have lasted for at least 3 months and occur or worsen at least 1 month after infection.*

*This study will enroll adult participants with Long COVID who experience Postural Orthostatic Tachycardia Syndrome (POTS), which is due to autonomic nervous system dysfunction. POTS is a condition that causes a number of symptoms when you transition from laying down to standing up, such as a fast heart rate, dizziness, and fatigue. Some POTS symptoms can also occur when laying down or seated.*

*Your participation in the study could last either 6 or 12 months (1 year), depending on which study arm or group you are enrolled in. You will be randomly assigned to either an active study drug group or to a control group.*

- *The active study drug group will be given an active study drug.*
- *The control group will be given a placebo. A placebo looks like the study drug but has no active ingredients.*

*In addition to being assigned to the active study drug group or the control group, you will have an equal chance of being randomly assigned to the coordinated non-drug (non-pharmacologic) care or usual non-drug care group.*

- *The coordinated non-drug care will involve lifestyle changes, such as diet modification, wearing a compression belt around the stomach (abdominal binder), measuring blood pressure, physical activity, assisted care and motivation through weekly phone calls with a care coordinator at your study site.*
- *The usual non-drug care is the usual healthcare guidelines, such as general recommendations for diet and lifestyle changes, that patients may receive as part of their normal or routine healthcare.*

*The study will explore whether your symptoms improve from the different treatments being studied. During the study, you will be asked to answer questions about your symptoms and your quality of life and to complete tests to measure your physical ability (which are detailed later in this consent form). You will also provide blood samples and measure your blood pressure at home at certain time points if you are assigned to the coordinated non-drug care group. You will be asked to wear a fitness tracker (similar to a wristwatch) to track various health data. The fitness tracker needs to be connected to a mobile device in order to share your health data with the study team. If you do not have a mobile device or data plan compatible with the fitness tracker being used in this study, then one may be provided to you. You may keep the fitness tracker and mobile device (if provided) without the data plan, at the end of the study.*

*If you are involved in multiple RECOVER clinical trials and/or the RECOVER longitudinal cohort study, 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 include side effects from the study treatments (which are detailed later in this consent form); risks associated with blood draws, nasal swabs, and physical ability tests; and a loss of confidentiality. However, every effort will be made to minimize these risks. You do not have to participate in this research to be treated for your condition. You can continue with your usual healthcare.*

## STUDY CONSENT

You are being asked to participate in the "RECOVER-AUTONOMIC" study, which is part of the Researching COVID to Enhance Recovery (RECOVER) Initiative. Your participation is voluntary.

Please review the important information below to help you decide if you want to take part in the study or not.

This study will include about 380 adult participants from many study sites across the United States. If you are eligible and interested in participating, you will be enrolled in one of the study arms or groups. A study arm or group refers to a subset of participants in a clinical study that is assigned to a specific treatment(s) or no treatment(s).

## 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 or older, have had COVID, and you are currently experiencing POTS symptoms due to autonomic dysfunction. Examples of POTS symptoms may include heart palpitations (a fast-beating, fluttering, or pounding heart), abnormal blood pressure, fatigue (exhaustion, low energy), fainting, dizziness, lightheadedness, shortness of breath, upset stomach or digestion problems, cognitive impairment/brain fog, and headaches.

**Why is this study being done?**
To reduce the impact of long-term COVID symptoms in adults across the United States, researchers in this study will look at different possible study treatments. If successful, this study may help people with Long COVID live with fewer symptoms, and may help researchers better understand the condition and how to treat it.

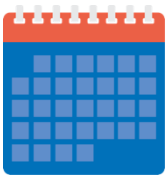
## VOLUNTARY PARTICIPATION/POTENTIAL BENEFITS

**What if I don't want to participate?**
You do not have to participate if you do not want to. If you decide to participate, you can decide to stop at any time. You can continue to get your usual healthcare even if you do not take part in this study.

**Will there be any benefit to me or others?**
We do not know if you will benefit from taking part in this study. The study treatment(s) may have a role in treating 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.

**Will I be told about any new findings?**
Yes. Any new, important information that is discovered during the study and that may influence your decision to continue participating in the study will be provided to you. When the study is done and the data have been analyzed, the researchers will publish their results in a journal article that will be open to the public to read. No personal or identifying information about you will be shared publicly.

## WHAT YOU CAN EXPECT IF YOU DECIDE TO PARTICIPATE



**How long will I be in this study?**
Your participation in the study can last up to either 6 or 12 months (1 year), depending on which study arm, or group, you are enrolled in.

**What is involved in this study?**
At the beginning of the study, you will be asked to answer several questions about your symptoms, general health, and well-being. Based on your answers, if you are eligible and interested in participating, you will be enrolled in one of the study arms.

In each study arm, you and other participants will be randomly assigned by chance (like the flip of a coin) to either an active study drug group or to a control group.

- The active study drug group will be given an active study drug.
- The control group will be given a placebo. A placebo looks like the active study drug but has no active ingredients.

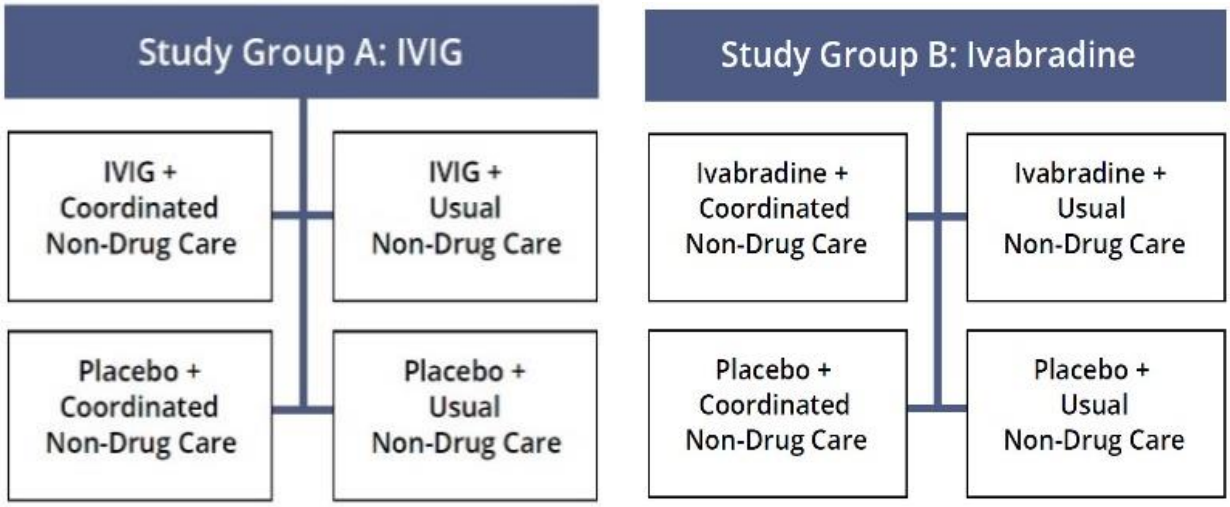
In addition to being assigned to the active study drug group or the control group, you will have an equal chance of being randomly assigned to the coordinated non-drug care group or to the usual non-drug care group.

- The coordinated non-drug care will involve lifestyle changes, such as diet modification, wearing a compression belt around the stomach (abdominal binder), physical activity, measuring blood pressure, assisted care and motivation through weekly phone calls with a care coordinator at your study site.
- The usual non-drug care is the usual healthcare guidelines, such as general recommendations for diet and lifestyle changes, that participants may receive as part of their normal or routine healthcare.

## STUDY ARMS

Gamunex-C (a form of intravenous immunoglobulin, also known as IVIG) is the active study drug in the IVIG study arm, and ivabradine is the active drug in the other study arm. Both drugs are approved by the United States Food and Drug Administration (FDA) for other uses but not for

treatment of COVID, Long COVID, or POTS; therefore, they are considered investigational in this study. Additional study drugs (arms) may be added to the study in the future. You will be enrolled in only one study arm (IVIG or ivabradine).




**IVIG Study Arm**

- This study arm will include about 200 participants.
- Participants will be given either IVIG or saline placebo through intravenous (IV) infusion, which is a common medical technique used to get fluid, medications, and nutrients into a person's bloodstream.
- The administration of IVIG or saline placebo will require a visit at an infusion center about once a week (about 4 to 6 hours each visit), about 36 visits over 9 months.
- Participants' heart rate, blood pressure, temperature, and breathing will be monitored before, during, and after the infusion. Their infusion dose could be paused, changed, or stopped based on specific conditions.
- Participants may receive medications before and after their infusions.
    - Before IVIG or placebo, participants may receive intravenous (IV) fluids, acetaminophen, and antihistamines (such as loratadine), to prevent or reduce any side effects. Participants may also receive these medications after IVIG or placebo.
    - Some participants may require stronger medication (steroids) or additional IV fluids before or after their infusions.

- In addition to receiving IVIG or placebo, participants will receive coordinated non-drug care or usual non-drug care for the first 3 months of the study.

**Ivabradine Study Arm**

- This study arm will include about 180 participants.
- Participants will take ivabradine or a sugar pill placebo twice a day by mouth for 3 months.
- The dose of ivabradine or placebo may be adjusted during the study based on participant's heart rate.
- In addition to receiving ivabradine or placebo, participants will receive coordinated non-drug care or usual non-drug care for 3 months.

## HOW TO PARTICIPATE IN THE STUDY

### What can I expect if I decide to participate?

**IVIG Study Arm:**

- Your participation in the study will last about 12 months.
- This includes a 21-day screening period, a 9-month study treatment period, and a follow-up visit 3 months after the end of the study treatment period.
- You will have 5 to 6 in-person study visits: screening (likely to be completed remotely), baseline, 2 visits during the study treatment (at 3 months and 6 months), at the end of the treatment (at 9 months), and at the end of the study (at 12 months).
- You will also have a visit about once a week at an infusion center (may last 4 to 6 hours each visit), about 36 visits over 9 months.

**Ivabradine Study Arm:**

- Your participation in the study will last about 6 months.
- This includes a 21-day screening period, a 3-month treatment period and a follow-up visit 3 months after the end of the treatment period.
- You will have 4 to 5 in-person visits: screening (likely to be completed remotely), baseline, during the study treatment (at 1 month), at the end of the treatment (at 3 months), and at the end of the study (at 6 months).

For all study arms, if you decide to stop participating in the study before the end of the study treatment period, you will be asked to come into the clinic to complete an Early Termination Visit, so we can collect important study data.

**Will I know which study drug I am assigned to?**
You will know which study drug arm you are assigned to (IVIG or ivabradine). However, you, your study doctor, and the study team will not know if you are assigned to the active study drug group or the control (placebo) group within each arm, but they can quickly find out if there is ever a need to know for your safety or well-being. You will have an equal chance of being assigned to either the active study drug group or the control group in one of the study arms.

**Can I participate in this study if I am already enrolled in other studies?**
It depends. As long as the other studies do not interfere with your eligibility for this study, such as treating you with contraindicated medicine(s), you should be able to participate in this study. A contraindicated medicine is one that is not recommended for use with the active study drug in this study because it may be harmful to take them at the same time. You should notify your study doctor if you are participating in any other studies.

**Can I take other medications or supplements during this study?**
All medications and supplements that you are currently taking will be reviewed with your study doctor at each visit. Please contact your study team if you are starting any new medications or supplements during the study.

## SCREENING VISIT

At the beginning of the study, you will be asked to answer several questions about your symptoms, general health and well-being, and any new or worsening health problems you have to make sure this study is a good fit for you. This visit will take about 2.5 hours (likely to be completed remotely).

## BASELINE VISIT

After screening, if this study appears to be a good fit for you and you decide to participate, you will have a baseline visit. The purpose of this visit is to determine which study arm, or group, you are eligible for, enroll you in a study group, and tell you about what to expect during the study. you will have an equal chance of being assigned to the active study drug or placebo group and to the coordinated or usual non-drug care group.

**This visit will take about 5.5 hours to complete.**

During the baseline visit, you will be asked to:

- Answer questions about your symptoms, general health, and well-being

- Have your height and weight measured
- Give a blood sample
- Take home a stool sample collection kit. When you are home, you will collect the stool and place it in the at-home kit during your next bowel movement. You will mail the stool sample per our instructions
- Give a nasal swab sample to test for COVID. The study doctor may be required by law to report the results of this test to local health authorities
- Take a pregnancy test, if you are a person who could become pregnant
- Complete tests to measure your vital signs (heart rate, blood pressure, pulse, etc.) and physical abilities which may involve lying down, walking, and standing
- Complete autonomic function tests, at specific sites as detailed below
- Have 3 skin biopsy samples taken, if participating in the IVIG study arm
- Begin wearing a fitness tracker to record your various health data, which are automatically captured by the tracker
- Report any new or worsening symptoms
- You will be assigned to the study drug or placebo group and to the coordinated or usual non-drug care group

You will receive a follow-up phone call or online survey within one day of this visit to ask how you are feeling.

## 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 send you surveys and contact you to ask 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 (medical conditions), general health, and well-being.
- Your allergies and a list of medicines you are taking (prescription and non-prescription).

## Blood Sample Collection

We will ask you to give blood samples (about 5 ½ tablespoons [80 ml]) at specific visits noted in the study schedule below. Your blood samples may be used to run study-specific tests, check your overall health, or they may be sent to a biorepository for future biomarker testing.

A biomarker is a signal in the blood that can be measured. In this study, we will be looking for biomarkers that can help us learn how the study drug may affect the virus that causes COVID-19. Some of your blood samples may also be used for future research; see the "Biorepository: Research Use of Data and Biospecimens" section for more information.

## Stool Sample Collection

We will ask you to give a stool sample 2 times during the study (at the baseline visit and at the end of treatment visit). Like the blood samples, your stool samples will be sent to a biorepository and can also help us learn about the study drug, the virus that causes COVID-19, and your health. At the baseline and end of treatment visits, the study coordinator will give you a kit so you can collect your stool sample at home and mail it directly to a biorepository using a confidential, pre-paid box. Some of your stool samples may also be used for future research; see the "Biorepository: Research Use of Data and Biospecimens" section for more information.

## Physical Ability Tests

We may ask you to do tasks that test your physical abilities like lying down, walking, and standing. During and after these tasks, we will measure your vital signs (heart rate, blood pressure, pulse, etc.).

## Weekly Contact

### Coordinated Non-Drug Care Group

If you are enrolled in the coordinated non-drug care group, a study team member will contact you once a week for 3 months to talk with you about the required activities that are part of the coordinated non-drug care group.

During the session, the study team member will ask you about your diet, the use of a compression belt worn around your stomach (abdominal binder), physical activity, and other required study activities. We will also ask you to keep a weekly log of these activities to provide to the study team. The study team member will also discuss any questions you may have about these activities.

### Ivabradine Study Arm

If you are enrolled in the ivabradine study arm, during the first month of the study treatment period, you will receive weekly phone calls from your study team member to review how consistently you have been taking the study treatment and following other study requirements.

## Autonomic Function Tests at Specific Sites

Autonomic function tests are designed to cause the autonomic nervous system to produce changes in blood pressure, heart rate, and blood flow during a short period of time so the study doctor can assess how your autonomic nervous system functions. Your heart rate and blood pressure will be monitored during these tests. These tests will be performed only at specific sites and may include:

- Head-up Tilt Test: You will lie flat on a motorized table while the table is tilted to different angles. This test measures your blood pressure and heart rate as you change positions.
- Valsalva Maneuver: You will breathe out forcefully through a mouthpiece while your nose is held shut. Your heart rate and blood pressure will be recorded during the test.
- Deep Breathing Test: You will take slow, deep breaths for about 1 minute while your heart rate and blood pressure are recorded.
- Transcranial Doppler Ultrasound: This is a non-invasive test that uses sound waves to detect blood flow in your brain, similar to other types of ultrasounds.

**IVIG Study Arm: Skin Biopsy Procedure**

The skin biopsy test only applies to participants in the IVIG study arm.

In this procedure, 3 small samples of skin will be removed to test for autonomic neuropathy. Autonomic neuropathy is when there is damage to the nerves that control automatic body functions.

Some participants will be asked to have another skin biopsy test after completing the study treatment. Any skin samples left over after testing will be sent to a biorepository; see the "Biorepository: Research Use of Data and Biospecimens" section for more information.

## VISITS DURING THE STUDY TREATMENT PERIOD

The visits during the study treatment period will be similar to the baseline visit, but shorter. We will ask if any information about your health has changed, including:

- Details about your COVID infection(s) and COVID vaccination status
- Your allergies and the list of medicines you are taking (prescription and non-prescription)

**IVIG Study Arm**

During the 9-month IVIG study treatment period, you will be asked to go back to the study doctor's office 2 times. Each visit will take about 1.5 hours to complete:

- At about Week 12 (3-month clinic visit)

- At about Week 24 (6-month clinic visit)

During these 2 visits, we will ask you to:

- Give a blood sample, if requested by the study doctor
- Answer questions about your symptoms, general health, and well-being
- Complete tests to measure your physical ability and vital signs
- Report any new or worsening symptoms
- Provide details about how consistently you have completed the study treatment

**Ivabradine Study Arm**

During the 3-month ivabradine treatment period, you will be asked to go back to the study doctor's office at about Week 4 (1-month clinic visit). This visit will take about 1.5 hours to complete. Your dose of the study drug may be adjusted at this visit based on your heart rate.

During this visit, we will ask you to:

- Give a blood sample, if requested by the study doctor
- Answer questions about your symptoms, general health, and well-being
- Complete tests to measure your physical ability and vital signs
- Report any new or worsening symptoms
- Provide details about how consistently you have been taking the study drug and following other instructions you have received. You will be asked to bring your bottle of the study drug to this visit.

## END OF TREATMENT VISIT OR EARLY TERMINATION VISIT

You will be asked to go back to the study doctor's office at the end of the study treatment period. We will ask if any information about your health has changed, including:

- Details about your COVID infection(s) and COVID vaccination status
- Your allergies and the list of medicines you are taking (prescription and non-prescription)

You will receive a follow-up phone call or online survey within one day of this visit to ask how you are feeling.

**IVIG Study Arm**

For the IVIG study arm, this visit will be at about Week 36 (9-month clinic visit), and will take about 5 hours to complete.

During your 9-month clinic visit, you will be asked to:

- Give a blood sample
- Take home a stool sample collection kit. When you are home, you will collect the stool and place it in the at-home kit during your next bowel movement. You will mail the stool sample per our instructions
- Answer survey questions about your symptoms, general health, and well-being
- Complete tests to measure your physical ability and vital signs
- Complete autonomic function tests (only at specific sites)
- Provide another skin biopsy sample, if needed
- Report any new or worsening symptoms
- Provide details about how consistently you have completed the study treatment

**Ivabradine Study Arm**

For the ivabradine study arm, this visit will take place around Week 12 (3-month clinic visit), and will take about 2 hours to complete.

During your 3-month clinic visit, you will be asked to:

- Give a blood sample
- Take home a stool sample collection kit. When you are home, you will collect the stool and place it in the at-home kit during your next bowel movement. You will mail the stool sample per our instructions.
- Answer questions about your symptoms, general health, and well-being
- Complete tests to measure your physical ability and vital signs
- Complete autonomic function tests (only at specific sites)
- Report any new or worsening symptoms
- Provide details about how consistently you have been taking the study drug and following other study requirements. You will be asked to bring your bottle and any remaining study drug to this visit

## FOLLOW UP: END OF STUDY VISIT

You will be asked to come back to the study doctor's office 3 months after the end of the study treatment period. For the IVIG study arm, this visit will be at about Week 48 (12-month clinic visit) and for the ivabradine study arm, this visit will be at about Week 24 (the 6-month clinic visit). These visits will take about 2 hours to complete.

During this visit, we will ask you to:

- Give a blood sample
- Answer questions about your symptoms, general health, and well-being
- Complete tests to measure your physical ability and vital signs
- Report any new or worsening symptoms

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

- Details about your COVID infection(s) and COVID vaccination status
- Your allergies and the list of medicines you are taking (prescription and non-prescription)

You will receive a follow-up phone call or online survey within one day of this visit to ask how you are feeling.

## IVIG STUDY ARM SCHEDULE (12 MONTHS)

| **Screening:**<br><br>**Visit 1 (Day -28 to -7)** | **Baseline:**<br><br>**Visit 2 (Day -10 to -7) *** | **Weekly Call (Week 1 to 12)** | **Infusion Visits**<br><br>**(Week 1 to 36)** | **3 & 6-month Study Treatment:**<br><br>**Visit 3 (Week 12) ***<br><br>**Visit 4 (Week 24) *** | **9-month End of Study Treatment OR Early Termination:**<br><br>**Visit 5 (Week 36) *** | **End of Study:**<br><br>**Visit 6 (Week 48) *** |
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|  |  |  |  |  |  |  |
| • Informed consent<br>• Surveys<br>• Demographics<br>• Medical history<br>• Review medicines | • Surveys<br>• Measure height and weight<br>• Blood sample<br>• Stool sample kit<br>• Nasal swab sample<br>• Pregnancy test (if applicable)<br>• Physical ability tests | Weekly reminder and review of study activities if assigned to coordinated non-drug care | Infusion about once a week at an infusion center | • Surveys<br>• Physical ability tests<br>• Safety assessment<br>• Review how consistently you have completed the study treatment | • Surveys<br>• Physical ability tests<br>• Blood sample<br>• Stool sample kit<br>• Safety assessment<br>• Review medicines<br>• Review how consistently you have | • Surveys<br>• Physical ability tests<br>• Blood sample<br>• Safety assessment |

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| | • Safety assessment<br>• Review medicines<br>• Study group assignment<br>• Study treatment period begins<br>• Autonomic function tests (only at specific sites)<br>• Skin biopsy | | | | completed the study treatment<br>• Autonomic function tests (only at specific sites)<br>• Skin biopsy (if needed) | |

* You will receive a follow-up phone call or online survey within one day of this visit to ask how you are feeling.

## IVABRADINE STUDY ARM SCHEDULE (6 MONTHS)

| **Screening:**<br><br>**Visit 1**<br>**(Day -28 to -7)** | **Baseline:**<br><br>**Visit 2**<br>**(Day -10 to -7) *** | **Weekly Call (Week 1 to 4 site coordinator/ Week 1 to 12 care coordinator)** | **1-month Study Treatment:**<br><br>**Visit 3**<br>**(Week 4) *** | **3-month End of Study Treatment OR Early Termination:**<br><br>**Visit 4**<br>**(Week 12) *** | **End of Study: Visit 5 (Week 24) *** |
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| • Informed consent<br>• Surveys<br>• Demographics<br>• Medical history<br>• Review medicines | • Surveys<br>• Measure height and weight<br>• Blood sample<br>• Stool sample kit<br>• Nasal swab sample<br>• Pregnancy test (if applicable)<br>• Physical ability tests<br>• Safety assessment<br>• Review medicines<br>• Study group assignment<br>• Study treatment period begins<br>• Autonomic function tests (only at specific sites) | • Week 1-4: Review how consistently you have taken the study treatment and followed other study requirements<br>• Week 1-12: Reminder and review of study activities if assigned to coordinated non-drug care | • Vital Signs<br>• Surveys<br>• Physical ability tests<br>• Safety assessment<br>• Review medicines<br>• Review how consistently you have completed the study treatment | • Surveys<br>• Blood sample<br>• Stool sample kit<br>• Physical ability tests<br>• Safety assessment<br>• Review medicines<br>• Review how consistently you have taken the study treatment<br>• Autonomic function tests (only at specific sites) | • Surveys<br>• Blood sample<br>• Physical ability tests<br>• Safety assessment |

* You will receive a follow-up phone call or online survey within one day of this visit to ask how you are feeling.

## 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 your planned visits are completed because your information and experiences are valuable to this research. Even if you stop the study drug treatment early, your health information is still very important to the study. We will ask that you continue to complete the study visits and non-drug care.

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.

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 your participation in the study may be stopped include: failure to follow study instructions, possible harm to your health if you continue, termination of the study, and other unanticipated circumstances. If you stop participating and you agree to be contacted, we will follow up with you about 28 days after your last study drug treatment dose for safety reasons.

## 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.
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, healthcare provider, or any

other person not connected with the research, you must give your permission for the researchers to release it.

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. The sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB), will be able to inspect and copy confidential study-related records which identify you by name. Your medical record may include information about visits to your study doctor's office, 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.

No dedicated therapies have been developed or approved by the FDA for the management of 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 regular healthcare provider about other options. The study doctor will discuss with you the major risks and benefits of usual care and alternative treatment 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 with notes, 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.

**What risks can I expect from taking part in this study?**
Below are possible risks associated with study procedures and study treatments. 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.

**Risks associated with the study treatment(s)**
Any drug may have side effects. Because of this, it is important to notify the study team of any new or worsening symptoms you may experience during or after participating in the study. It is also important to tell the study team about any new or current medicines you are taking because some medicines can interact with the study drug and cause serious or life-threatening side effects.

Below are some possible, known risks associated with the study treatment. There may also be risks from participation that we do not know about yet.

**Potential side effects of IVIG:**
IVIG is a complex therapy and can lead to a number of side effects, such as:

- Headache
- Fatigue (tiredness)
- Nausea (feeling sick to the stomach or feeling a need to vomit)
- Chills
- Flushing (reddening of the face, neck, or upper chest)
- Vomiting
- Pain
- Diarrhea (loose, watery poop)
- Cough
- Chest pain
- Joint swelling
- Flu-like illness
- Dizziness
- Increased body temperature
- High blood pressure

- Rash
- Hives
- Pharyngitis (sore throat)
- Decrease in kidney function

Tell your study doctor right away if you have any of the following symptoms. They could be signs of a rare, but serious problem.

- Decreased urination, sudden weight gain, fluid retention/swelling in your legs, and/or shortness of breath. They could be signs of a serious kidney problem called renal failure.
- Pain and/or swelling of an arm or leg with warmth over the affected area, discoloration of an arm or leg, unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, or numbness or weakness on one side of the body. These could be signs of a blood clot in your body (thrombosis). Immediately report symptoms of thrombosis.
- Severe headache, stiff neck, fatigue, fever, sensitivity to light, painful eye movements, nausea, and vomiting. These could be signs of a type of brain inflammation called aseptic meningitis.
- Increased heart rate, fatigue, yellow skin or eyes, and dark colored urine. These could be signs of a type of blood problem called hemolytic anemia.
- Chest pains, trouble breathing, blue lips or extremities, and fever. These could be signs of a lung problem called TRALI (transfusion-related acute lung injury).
- Hypersensitivity reaction (allergic reaction which can be severe or life threatening).

IVIG comes from human blood and might have germs that can cause diseases, for example, viruses such as the type of Creutzfeldt-Jakob disease (vCJD) and in theory, the Creutzfeldt-Jakob disease (CJD).

Slowing and/or stopping the infusion rate prevents or reverses many reactions. Pre- and post-infusion treatment with oral fluids, IV saline, acetaminophen, antihistamines (such as loratadine), or steroids may also prevent or reduce side effects. To monitor side effects, your vital signs (heart rate, blood pressure, temperature, breathing) will also be monitored closely before, during, and for 30 minutes after you receive each infusion.

**Potential side effects of ivabradine:**

- Blurred vision
- Chest pain or discomfort
- Fast or irregular heartbeat
- Slow or irregular heartbeat
- Headache

- Lightheadedness, dizziness, or fainting
- Nervousness
- Pounding in the ears
- Unusual tiredness
- Symptomatic bradycardia (slow resting heart rate) and cardiac arrhythmia (irregular heart rate)

As with taking any drug, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat, or eyes
- A fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study team if you have any of these symptoms. You will be given information on how to understand the signs of allergic reactions and when to seek medical attention for possible allergic reactions.

**IVIG Study Arm: Risks associated with pre-and post-infusion medications**

Though side effects related to the pre- and post-infusion medications (such as loratadine, acetaminophen, and steroids) are rare, they can occur. Common risks associated with these medications are listed below.

- Loratadine: headache, drowsiness, tiredness, and dry mouth.

- Acetaminophen: nausea (feeling sick to the stomach or feeling a need to vomit), stomach pain, headache, hoarseness, loss of appetite, itching, rash, dark urine, clay-colored stools, and swelling of the face, throat, tongue, or limbs.

In a few cases, participants may require steroids before their infusions. General risks associated with steroids are increased appetite, acne, rapid mood swings, muscle weakness, and delayed wound healing.

**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. Experienced study team members will perform the blood draws and will monitor you.

**Risks associated with nasal swabs**

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

**Risks associated with physical ability tests**

Physical ability tests may cause some people to feel frustrated, tired, lightheaded, weak, and/or to experience shortness of breath or palpitations (a fast-beating, fluttering, or pounding heart). There is a risk of falling during the physical testing. The study team will decrease this risk by being at your side if you need help. The study team will follow up with a phone call or online survey within one day of the visits with physical ability testing to check on your physical and mental well-being.

**Risks associated with fitness tracker**

Wearing a fitness tracker is a non-invasive way to record your health data. The risks include possible irritation or discomfort in the area where the fitness tracker is worn.

**Risks associated with autonomic function tests at specific sites**

Autonomic function tests are generally safe; however, you may experience some of the side effects listed below.

- Head-up tilt test: dizziness, nausea (feeling sick to the stomach or feeling a need to vomit), or feeling lightheaded
- Valsalva maneuver: chest pain, low blood pressure, fainting or abnormal heart rhythm
- Deep breathing test: dizziness or shortness of breath
- Transcranial Doppler ultrasound (non-invasive medical imaging): discomfort or pressure from the probe

**IVIG Study Arm: Risks associated with skin biopsies**

Some of the risks associated with punch skin biopsies include local bleeding, bruising, scarring, soreness, redness, pain, allergic reaction to the numbing medicine used in the procedure, and minor risk of infection.

**Risks associated with terms of use**

As part of this research, you will be required to use one or more of the following: a phone, website, app, 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, 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. You will be required to agree to the Terms of Use, End User License Agreement, or Privacy Policy prior to using the associated software or device.

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, eDiary, or device in this study, you do not release the study doctor, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant.

**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 conceive children (has not had a vasectomy with a negative post-surgery semen analysis), it will be important for you to practice effective birth control methods while taking the active study drug or placebo during the study and for 7 days after your last dose of the active study drug or placebo. Please ask the study team about acceptable methods. Since the study drug is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you become pregnant.

**Risks associated with pregnancy while taking IVIG**

No human data are available to indicate the presence or absence of IVIG-associated risks to pregnancy. If you become pregnant while taking the study drug, please inform the study doctor immediately. You will be told to stop taking the study drug, and you will be asked to sign a pregnancy-specific consent form. Your pregnancy will be followed to its outcome unless you refuse to provide consent.

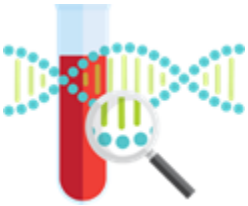
### Risks associated with pregnancy while taking ivabradine

No ivabradine human data are currently available to evaluate for a drug-associated risk of major birth defects, miscarriage, adverse maternal or fetal outcomes, or lactation effects. The risk/benefit of treatment with ivabradine for PASC has not been established in pregnant women. If you become pregnant while taking the study drug, please inform the study doctor immediately. You will be told to stop taking the study drug, and you will be asked to sign a pregnancy-specific consent form. Your pregnancy will be followed to its outcome unless you refuse to provide consent.

### FUTURE CONTACT

We may contact you to ask if you are interested in participating in additional visits related to the RECOVER Initiative. The additional follow-up calls and visits 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. If you agree, you will be told which additional follow-up calls or visits to expect.

## BIOREPOSITORY: RESEARCH USE OF DATA AND BIOSPECIMENS



A biospecimen is a sample such as urine or blood collected from the body for tests. With your permission, the biospecimens collected during this study—blood, stool, and skin (IVIG arm only)—will be sent to a storage place called a biorepository. These samples will be used for research on COVID and the long-term effects of COVID, but they may also be used for research on other health problems.

### Why are biospecimens needed?

Biospecimens can provide valuable information to researchers. For example, blood is composed of serum and plasma, which are clear fluids that contains substances like hormones, antibodies, and other things that can be measured. Another part of blood includes cells that float in the bloodstream. These cells include red blood cells (which give blood its red color and provide oxygen to our bodies), platelets (which help our blood to clot), and white blood cells (which fight infection).

Plasma and serum from a blood sample contain many substances. New substances are still being discovered, and methods for measuring these substances are being developed all the time. Tests to measure the amount or presence of a substance are used by doctors to assess health.

Some substances found in biospecimens are called "biomarkers." Biomarkers can be measured and may provide important information about Long COVID. Blood sugar level is an example of a biomarker for diabetes. Biomarkers may also predict how a patient will respond to a treatment.

**How will my biospecimens be used for research?**
For this study, biospecimens will be used to try to understand how the study treatment may impact the immune system (body's defense against infection). We will also look for evidence that the virus that causes COVID-19 or that other infectious agents can be identified in the biospecimens. The collection of these biospecimens is required as part of this study.

We would also like to make your data and biospecimens available for future research. The research may be about similar diseases or conditions related to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities.

Although you will not receive any direct benefits, sharing your data and biospecimens with our biorepositories may:

- Contribute to research that could help others in the future and improve medical care and public health
- Help researchers make important discoveries about medical conditions and possible therapies
- Improve our understanding of how the study treatments may work to reduce Long COVID symptoms
- Increase the possibility of developing new treatments and treatments related to Long COVID
- Enhance our understanding of how and why Long COVID affects people differently

**Will my biospecimens be used for genetic testing?**
Researchers can look closely at large amounts of your genetic information by sequencing, or "reading", every letter in your DNA (your genome). Reading a person's entire genetic code is called whole genome sequencing. The research will include whole genome sequencing (for example, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). The use of your samples for genetic testing is optional. At the end of this consent form, you will have the chance to tell us whether or not you want to allow researchers to use the samples we collect for genetic testing. Genetic testing looks at your DNA, the material that makes up your genes. Genes are the part of cells that tell our bodies how to grow and function, and they are passed from parent to child. Researchers may also perform a whole genome analysis on your DNA samples. Usually, researchers study just a few areas of your genetic code that are linked to a disease or condition. In whole genome

studies, all or most of your genes are analyzed and used to study links to Long COVID. Genetic tests can determine if a person or groups of people are more likely to have certain genetic diseases or conditions.

**Will researchers be able to identify me based on my data and biospecimens?**

We will do our best to protect your data and biospecimens during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data and biospecimens. In either case, we cannot reduce the risk to zero.

To protect your privacy, your name and identifying information will be removed from any data and biospecimens you provide during this study before they are used for future research studies or shared with other researchers for future research studies without additional informed consent. Your de-identified data and biospecimens may be shared with researchers around the world. However, the decision to share your data is controlled by the National Institutes of Health (NIH). To get your data and biospecimens, future researchers must seek approval from the NIH. The data and biospecimens submitted to a storage place or shared for research use will not include any information that can personally identify you, and researchers cannot easily link your identifying information to the data and biospecimens.

Genetic Information Nondiscrimination Act. Your data and biospecimens from this study are also protected by a federal law in the United States called the Genetic Information Nondiscrimination Act (GINA), which prevents health insurers from using genetic information to determine the cost of health insurance and prevents certain genetic discrimination. GINA does not protect against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA does not protect you against discrimination based on a genetic disease or condition that is already diagnosed.

**Will I need to give additional permission for researchers to use my data?**

No. The research use or sharing of your data and biospecimens can be done without getting additional permission from you. However, all future research studies will be approved by an independent scientific committee or ethics board.

**Will I be paid for any future use of my data and biospecimens?**

No. You will not be paid for any future use of your data or biospecimens. Your data and biospecimens will not be sold, but the use of your information or samples may lead to new tests, drugs, devices, or other products or services with commercial value. These products or services could be patented or licensed. There are no plans to provide any payment to you

should this occur. Your biospecimens collected during this study may be used for commercial profit (even if identifiers are removed) and you will not share in this profit.

**How long will my data and biospecimens be stored for future use?**
Your data will be stored indefinitely. Your biospecimens from this study will be kept until they are used up.

**Will I get any results back from future research use of my data and biospecimens?**
No. You should not expect to receive results from any future research that may use your data and biospecimens. Research results that are clinically relevant, including individual research results, will not be disclosed to you.

**What if I change my mind about future use of my data and biospecimens?**
Participating in this study means you agree to share your data and biospecimens. You can change your mind later, but researchers might still use your data and biospecimens if they have already been shared. If you do not want your data and biospecimens used for other research projects, you should not participate in this study.

If you decide that you do not want us to use or share your data and biospecimens, you can contact your study doctor's office to request they destroy any remaining samples. Please see the contact information at the end of this consent form. You will be notified of compliance with such a request, and supporting materials will be maintained for tracking.

If we are not able to link your samples back to you because they have already been de-identified, we will not be able to locate the samples to destroy them. In addition, if the data are needed to preserve the integrity of the study database for regulatory purposes, we will not be able to remove individual data until the regulatory processes are completed. We will also not be able to destroy any samples that have already been used or shared.

## PAYMENT AND COSTS

**Will I be paid for being in this study?**
You will be compensated for participating in this study to cover study-related costs, such as transportation or parking and for your time and effort to complete the study activities. See tables below for details.

**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 treatments (including the study drug) that are needed for this study that are not part of your usual medical care will be paid 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.

**IVIG Study Arm: Payment Information**

| **Visit/Activity** | **IVIG + Coordinated Non-Drug Care Group** | **IVIG + Usual Non-Drug Care Group** |
|---|---|---|
| Screening and Baseline Visit* | $450.00 | $450.00 |
| Baseline Autonomic Function Tests (available at specific sites only)<br>*Tilt Table Test, Valsalva maneuver, Deep breathing test, Transcranial Doppler ultrasound* | Up to $175.00 | Up to $175.00 |
| 3-month Clinic Visit* | $100.00 | $100.00 |
| 6-month Clinic Visit* | $100.00 | $100.00 |
| 9-month Clinic Visit (End of Treatment) * | Up to $325.00 | Up to $325.00 |
| 9-month Autonomic Function Tests (at specific sites only)<br>*Tilt Table Test, Valsalva maneuver, Deep breathing test, Transcranial Doppler ultrasound* | Up to $175.00 | Up to $175.00 |
| 12-month Clinic Visit (End of Study) * | $200.00 | $200.00 |
| Infusion Visits (Max of 40 at $300 per visit) | $12,000.00 | $12,000.00 |
| Weekly Calls-Coordinated Non-Drug Care Group (Max of 12 calls at $125 per call) | $1,500.00 | *NA* |
| Stool Collection (Baseline and End of Intervention Visits) ** | $300.00 | $300.00 |
| **Total Max Payment** | **$15,325.00** | **$13,825.00** |

*See sections above for a full list of study procedures completed at each visit

** Must send both samples to receive the $300

**Ivabradine Study Arm: Payment Information**

| Visit/Activity | Ivabradine + Coordinated Non-Drug Care Group | Ivabradine + Usual Non-Drug Care Group |
|---|---|---|
| Screening and Baseline Visit* | $325.00 | $325.00 |
| Baseline Autonomic Function Tests (available at specific sites only)<br>*Tilt Table Test, Valsalva maneuver, Deep breathing test, Transcranial Doppler ultrasound* | Up to $175.00 | Up to $175.00 |
| 1-month Clinic Visit* | $100.00 | $100.00 |
| 3-month Clinic Visit (End of Treatment) * | $200.00 | $200.00 |
| 3-month Autonomic Function Tests (available at specific sites only)<br>*Tilt Table Test, Valsalva maneuver, Deep breathing test, Transcranial Doppler ultrasound* | Up to $175.00 | Up to $175.00 |
| 6-month Clinic Visit (End of Study) * | $200.00 | $200.00 |
| Weekly Study Drug Calls (Max of 4 at $25 per call) | $100.00 | $100.00 |
| Weekly Calls-Coordinated Non-Drug Care Group (Max of 12 calls at $125 per call) | $1,500.00 | *NA* |
| Stool Collection (Baseline and End of Intervention Visits) * * | $300.00 | $300.00 |
| **Total Max Payment** | **$3,075.00** | **$1,575.00** |

*See sections above for a full list of study procedures completed at each visit
* * Must send both samples to receive the $300

## COMPENSATION FOR INJURY

**What should I do if I become ill or injured during the study?**
If you become ill or are injured during the study, get the medical care that you need right away by seeing your study doctor or regular doctor, going to urgent care or the emergency room if necessary. Medical care will not be provided as part of this study. 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 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 will 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

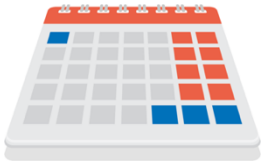
- A team of health experts called the Data and Safety Monitoring Board, chosen by the NIH, who will regularly monitor the safety of study participants and the progress of the study overall
- Future researchers who access study data from the National Heart, Lung and Blood Institute's BioData Catalyst© (the data repository for the study)

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 ensure that all efforts, within reason, will be made to keep your PHI private.

**How long will you keep my Protected Health Information PHI?**



We will keep your permission to use and share your PHI for up to 6 years, unless you take it back sooner.

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 form, to make sure that your information was entered correctly in the study records.

Like all your other information, we will keep your 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 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 this study. If you take back your permission for us to use your PHI, you will not be able to continue in this study.

**STATEMENT OF AUTHORIZATION**
I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

## Participant

**Print name:** _____

**Signature:** _____

**Date:** _____ **Time:** _____

## HOW CAN I LEARN MORE ABOUT MY LEGAL RIGHTS WHILE PARTICIPATING IN THIS STUDY?

The Public Readiness and Emergency Preparedness (PREP) Declaration was issued by the U.S. Department of Health and Human Services on March 10, 2020. This declaration may limit the legal rights of a participant in a COVID-19 clinical study that uses a drug, device, or vaccine designed to treat, diagnose, cure, or prevent COVID-19. This includes the study drug. Participants using the study drug may have limits on their right to sue the manufacturers, the study sponsor, healthcare providers, and others for significant injuries and adverse reactions. Under some circumstances, compensation may still be available under the PREP Declaration for certain participants who sustain injuries. To find out more, go to hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

## 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.com

Please reference the following number when contacting the IRB's Study Subject Adviser: Pro00072562.

## OPTIONAL: SAMPLE COLLECTION FOR GENETIC TESTING

Please **initial** the appropriate line below to let us know whether or not you want to allow your samples to be used for genetic testing. By initialing below, you confirm you have been told that you can still participate in the study without providing samples for genetic testing.

| | |
|---|---|
| **Initials** _____ | **Yes,** I give the study team permission to collect samples for future unspecified genetic testing. |
| **Initials** _____ | **No,** I do not give the study team permission to collect samples for future unspecified genetic testing. |

## 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:** _____