



E-Consent

Modified Application of Cardiac Rehabilitation for Older Adults(MACRO)

PRINCIPAL INVESTIGATOR:

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This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

KEY INFORMATION

This is a research study conducted by Dr. Eric Lenze focusing on improving cardiac rehabilitation for older adults. You should carefully consider the information in this consent document and discuss it with the research team. Be sure you understand why you might want to participate, or why you might not want to participate. You may choose whether or not to participate.

If you agree and sign this consent, you will be volunteering to participate in the research study. All of the information in this section will be explained in more detail in the consent document below. The research team must give you a copy of this signed consent document.

How will this study affect me?

- The purpose of this study is to see if cardiac rehabilitation can be improved for older adults by customizing it to your needs, making transitions easier, providing more education, and calling you on the phone regularly.
- As a voluntary participant, you will be asked to spend approximately 2 hours with our staff for research assessments at 4 different times during the study (baseline, 3 months, 6 months, and 12 months). We may also call you over the phone 1-2 times per week for the first 3 months of the study. We may also visit you at your home 2 times during the study.
- You were selected because you are at least 70 years old and have a cardiac diagnosis.
- You will be in this study for approximately 1 year. Over the course of the year we will do research assessments with you to see how you are recovering and improving. These tests will include physical assessments, like walking and rising from a chair, and questionnaires about your quality of life, thinking ability, mood, diet, and medications. There may also be a blood draw at each assessment.
 - Baseline assessments: 2 hours
 - 3-Month assessments: 1-2 hours

- **6-Month assessments: 1-2 hours**
- **12-Month assessments: 1-2 hours**
- **Visits may take place at Washington University School of Medicine, Barnes-Jewish Hospital or in your home.**
- **The main risks to you are falls, injuries, or cardiac events related to participating in physical exercise as part of your cardiac rehabilitation program. More detail about risks is provided below.**
- **You will be paid up to \$80 for participating in this study. You will not have costs for participating.**
- **If you withdraw from the study, the research team may continue to use information already collected about you in this study.**

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are age 70 or older and have a cardiac diagnosis that makes you a good candidate for cardiac rehabilitation. Cardiac rehabilitation is recommended to people with heart problems, but few older adults participate. There are many reasons that patients may not participate, such as not getting a referral from their doctor, not having a rehabilitation center that is convenient for them to drive to, or simply feeling too Overwhelmed by other health or family issues.

The purpose of this research study is to see if we can help older adults participate in cardiac rehabilitation by making transitions smoother and tailoring care to the participant's individual needs.

WHAT WILL HAPPEN DURING THIS STUDY?

If you choose to participate in this study, you will be enrolled in one of two groups. One is called the MACRO group and one is called the Standard of Care (SOC) group. Whichever group you are in, we will ask you to come to Washington University School of Medicine for on-site study visits.

INTERVENTION

You will be randomly assigned (like flipping a coin) to be in either the MACRO group or the Standard of Care group. You will find out which group you have been assigned to at the end of your baseline assessments.

MACRO Group

If you are assigned to the MACRO group, study staff will provide extra support in your transition from the hospital to your home and cardiac rehabilitation program. Study staff will work with you, your family, and your physician(s) to make a plan for cardiac rehabilitation. For example, study staff will make sure that your physician refers you to an outpatient cardiac rehabilitation program (meaning you would go to a facility, like the Heart Care Institute, on a weekly basis). Study staff will also call you regularly, approximately 1-2 times weekly, as a supplement to your cardiac rehabilitation program.

Everyone assigned to the MACRO group will receive a phone call each week (for approximately the first 12 weeks of your participation) that will last approximately 45 minutes. These phone calls are intended to help you feel motivated and encouraged. For example, if you forget to attend your cardiac rehabilitation session, study staff will help you strategize about how to prevent this from happening in the future. They will also reassure you that even though you missed a session, you are still doing great and can get back on track the next week. After the first 12 weeks of the study, you'll receive these phone calls once a month until the end of your participation. For quality assurance, additional study staff members may listen in or join the phone calls. This could include study staff from the coordinating site, the University of Pittsburgh. This is to ensure consistency between the two sites, and the calls will not be recorded.

If you are unable to attend a cardiac rehabilitation facility, a member of our research team who is supervised by our study cardiologists will call you approximately once per week (until your cardiac rehabilitation program materials end, which is approximately 12 weeks) to go over your cardiac rehabilitation remotely. This is called "home-based" cardiac rehabilitation, because you can do it from your home. Just like regular cardiac rehabilitation, home-based cardiac rehabilitation involves education about diet, medication management, and cardiac symptoms. There might be approximately one page of education material that you'll be asked to review each week. During the calls, we will also ask what kinds of physical activity you have been doing, and will encourage you to meet your physician's recommendations. For quality assurance, additional study staff members may listen in or join the phone calls. This could include study staff from the coordinating site, the University of Pittsburgh. This is to ensure consistency between the two sites, and the calls will not be recorded.

You may also be asked to keep a participant diary where you'll track your vitals (e.g., resting heart rate and blood pressure), physical symptoms (e.g., shortness of breath), physical activity (e.g., steps taken), and food eaten. If necessary, we can lend you items to help track this (e.g., heart and blood pressure monitor and pedometer). We can also lend you a foot peddler if you do not have a good setting for walking. Only individuals who are in the MACRO group and unable to attend a cardiac rehabilitation facility will receive these phone calls.

You will also receive up to two home visits, where study staff visits your home at a planned time and are available to talk with you in person. The home visit will last approximately an hour. The main thing study staff will do, with your permission, is a brief walk-through of your home to identify hazards like loose rugs or cords that put you at risk for tripping and falling.

Finally, as part of the research, you will be asked to complete the four study visits (described below) at Washington University School of Medicine.

STANDARD OF CARE Group

The phrase "standard of care" means normal care from your physician(s). Your physician(s) will use all the normal and proven standards (medications, procedures, including cardiac rehabilitation, and anything else you may need) to help you recover. Study staff may call you during the course of the study to see how you are doing. For quality assurance, additional study staff members may listen in or join the phone calls. This could include study staff from the coordinating site, the University of Pittsburgh. This is to ensure consistency between the two sites, and the calls will not be recorded. For the purposes of research, you will also be asked to complete 4 study visits.

STUDY VISITS

Study visits are for research purposes and will occur at 4 time points: baseline, 3, 6, and 12 months. These assessments will be used to see if there is a benefit to being in the MACRO group over the Standard of Care group.

Baseline Assessment

This will occur within approximately one week of your cardiac event. The evaluation will last about 2 hours. You will be asked to do some physical performance assessments, like walking a short distance, standing up from a chair several times, and balance tests. If any of these are too difficult for you, you may skip them. We will also ask you to answer questionnaires about your quality of life, thinking ability, mood, and day-to-day physical activities. These will take approximately twenty minutes to answer, and you are free to skip any questions that make you uncomfortable or that you prefer not to answer. Blood testing may be completed at this visit (approximately 2 teaspoons) so that we can assess inflammation levels, which may be related to heart health. Your medications and diet will be reviewed. We will also ask that you wear a watch-like device on your wrist called an Actigraph for 7-10 days to measure your sleep and activity. We'll give you this actigraph to take home, and after 10 days you'll have the option to either mail it back to us or return it in person. At the end of the baseline assessments, you will be told which study group you have been randomly assigned to: MACRO group, or Standard of Care group.

3-month Assessment

In approximately 3 months you will be asked to return to Washington University School of Medicine. At this visit, you will repeat the same testing and questionnaires that you completed at the baseline visit. Blood testing may be completed at this visit (approximately 2 teaspoons) so that we can assess inflammation levels, which may be related to heart health. We will give you an Actigraph to take home and wear for 7-10 days. After 10 days you'll have the option to either mail it back to us or return it in person. In addition, we will ask you about any medical changes or updates since your last visit.

6-month Assessment

In approximately 6 months you will be asked to return to Washington University School of Medicine. At this visit, you will repeat the same testing and questionnaires that you completed at the baseline and 3-month visits, minus the cognitive testing. Blood testing may be completed at this visit (approximately 2 teaspoons) so that we can assess inflammation levels, which may be related to heart health. We will give you an Actigraph to take home and wear for 7-10 days. After 10 days you'll have the option to either mail it back to us or return it in person. Additionally, just as in the 3-month visit, you will be asked about any medical changes or updates since your last visit.

12month Assessment

In approximately 12 months will be asked to return to Washington University School of Medicine. At this visit, you will repeat the same testing and questionnaires that you completed at the previous three visits. Blood testing may be completed at this visit (approximately 2 teaspoons) so that we can assess inflammation levels, which may be related to heart health. We will give you an Actigraph to take home and wear for 7-10 days. After 10 days you'll have the option to either mail it back to us or return it in person. Additionally, just as in the other visits, you will be asked about any medical changes or updates since your last visit.

As part of the study, we will collect and use information from your medical records, including the details of your cardiac diagnosis, medical history, and medications.

BEING CONTACTED DURING THE STUDY

We may call you on the phone to schedule your research assessment visits at a time that works for you. We may then call you prior to the appointment to remind you of the date and time.

If you are in the MACRO group, we will also call you on the phone approximately 1-2 times per week for months 1-3 of your participation in the study. These weekly phone calls last approximately 45 minutes and are described above in the section called "MACRO Group." After that, we will call you once per month for months 4-12. These monthly phone calls are the same as the weekly motivation phone calls, except they are only once per month.

For quality assurance, additional study staff members may listen in or join the phone calls. This could include study staff from the coordinating site, the University of Pittsburgh. This is to ensure consistency between the two sites, and the calls will not be recorded.

If you we call you to schedule your research assessment visits and are unable to reach you, we may call whomever you have provided as your emergency contact.

WILL YOU SAVE MY RESEARCH INFORMATION AND BIOSPECIMENS TO USE IN FUTURE RESEARCH STUDIES?

We would like to use the blood and data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding cardiovascular disease, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your blood and data you give up any property rights you may have in the blood and data.

We might remove identifiers from your private information and your blood and data and then use the information and your blood and data for future research studies or share them with other researchers for their future research. If this occurs we will not ask you for additional consent for these uses of your information or blood and data.

Your blood samples and data may also be used for future genetic research. "Genetic research" means that we will test whether your genes (your biology that you inherited from your parents) are associated with your health conditions.

We will share your blood and data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your blood and data for future research you should contact the research team member identified at the top of this document. The blood and data will no longer be used for research purposes. However, if some research with your blood and data has already been completed, the information from that research may still be used. Also, if the blood and data has been shared with other researchers it might not be possible to withdraw the blood and data to the extent it has been shared.

Please place your initials in the blank next to Yes or No for each of the questions below:

My blood and data may be stored and used for future research as described above.

YES NO

[reset](#)

* must provide value

My blood and data may be shared with other researchers and used by these researchers for the future research as described above. YES NO

[reset](#)

* must provide value

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 240 people will take part in this study conducted by investigators at Washington University School of Medicine. An additional 240 people will take part in the study at the University of Pittsburgh site, for a total of 480 people.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 1 year. Over the course of the year we will do research assessments with you to see how you are recovering and improving at the following time points:

- Baseline assessments: 2 hours
- 3-Month assessments: 1-2 hours
- 6-Month assessments: 1-2 hours
- 12-Month assessments: 1-2 hours

If you are assigned to the MACRO group, your participation may also include the following:

- Approximately 1-2 weekly phone calls for 3 months
- Up to two home visits
- Approximately monthly phone calls for months 4-12

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study. Some risks described in this consent document, if severe, may cause death.

The risks from study procedures include the following:

Walking/balance Assessments and Exercise:

- **Likely:** It is common to experience delayed-onset muscle soreness, musculoskeletal irritation, shortness of breath, or fatigue from increased physical activity.
- **Less Likely:** You may experience light-headedness, chest discomfort, or nausea during exercise. There is also a small risk of falling while walking or performing a balance test. However, the research staff working with you has been trained to help prevent falling during these tests. The risk of falling during these tests is less than 1 in 200, and the risk of fracture secondary to a fall during the walking tests is less than 1 in 5,000.
- **Rare:** There is a rare and small risk of a cardiovascular event, such as a heart attack, cardiac arrest, dangerous arrhythmia (an irregular or abnormal heartbeat), or stroke as part of exercise.

Actigraphy:

- **Likely:** Wearing this device around your wrist may be an inconvenience.
- **Rare:** There may be a small chance of causing a rash or irritation of the skin, but should not be more of that than wearing a watch. It has a small flashing light that may slightly bother some people.

Blood Draws:

- **Likely:** The risks of blood drawing include discomfort, bruising, and/or minimal bleeding.
- **Less Likely:** Occasionally during blood drawing procedures, some people experience dizziness or feel faint.
- **Rare:** The site of needle insertion could become irritated or infected.

Study Instruments and Measures (questionnaires):

- **Rare:** During these questionnaires you may experience minor discomfort, answering behavioral and functional questionnaires and assessments, etc. Please let the staff know if you feel any discomfort so they may discuss this with you. You may choose not to answer any question with which you still feel uncomfortable.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled "How will you keep my information confidential?" for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because our results might lead to improvements in cardiac rehabilitation for older adults.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could ask your doctor for a referral to cardiac rehabilitation.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address.

You might be paid for your participation using a Forte reloadable, prepaid card (like a debit card). If you have participated in another research study at Washington University that has also used a Forte card, we will add your participant payments to that card. If you do not already have a Forte card, this card will be given to you after you complete your baseline assessments. All future assessment payments will be added to this same card.

If you choose not to use the Forte card, you might be paid with a check that will be mailed to you. The check may take up to 6-8 weeks to arrive.

You will be paid for your time based on the number of visits you complete for the study. The maximum amount you may receive is **\$80**.

- Baseline Assessments: \$20
- 3-Month Assessments: \$20
- 6-Month Assessments: \$20
- 12-Month Assessments: \$20

WHO IS FUNDING THIS STUDY?

The National Institutes of Health (NIH) is funding this research study. This means that Washington University School of Medicine is receiving payments from NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at [\(314\) 362-1671](tel:314-362-1671) and/or the Human Research Protection Office at [1-\(800\)-438-0445](tel:1-800-438-0445).

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University and National Institutes of Health. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- National Institutes of Health (NIH)
- Hospital or University representatives to complete Hospital or University responsibilities

- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- The Data and Safety Monitoring Board (DSMB)
- The University of Pittsburgh, which is the coordinating site
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality we will store all paper documents in locked file cabinets within a locked office. Electronic records will be password-protected. Blood samples will only be identified with your study ID number, collection date/time, and assessment time point. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

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.

We will disclose to the proper authorities information shared with us or activities we observe concerning abuse, neglect or harm to others or yourself.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical records is protected in other ways.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "*How will you keep my information confidential?*"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in

this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at [866-747-4975](tel:866-747-4975).

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
 - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at <https://hrpo.wustl.edu/participants/withdrawing-from-a-study/> or you may request that the investigator send you a copy of the letter.
 - If you revoke your authorization:
 - The research team may only use and share information already collected for the study.
 - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
 - You will not be allowed to continue to participate in the study.

Can we contact you by email?

We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- Scheduling research assessment visits
- Reminders about scheduled visits
- Follow-up to a question or adverse event

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email? YES NO

[reset](#)

* must provide value

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I DECIDE TO WITHDRAW FROM THE STUDY?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at <https://hrpo.wustl.edu/participants/withdrawing-from-a-study/> under Withdrawing from a Research Study.

If you decide to leave the study early, we may ask you to come in for a final research assessment visit so that we can get an accurate "endpoint" for you. However, you can decline to do this.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen if you are no longer healthy enough to participate.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: [Angie Stevens, \(314\) 362-6291](#). If you experience a research-related injury, please contact: [Eric Lenze, \(314\)362-5154](#). If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, <http://hrpo.wustl.edu>. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Statement by person agreeing to be in this study:**VOLUNTARY CONSENT**

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Research Protection Office at Washington University (1-800-438-0445) or email hrpo@wustl.edu to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form I consent to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be emailed or given to me.

* must provide value

AGREE

Participant Full Name (First, Last)

* must provide value

Date of Consent:

03-16-2020 13:45  M-D-Y H:M

* must provide value

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