E-consent demo 3

Please carefully read the e-consent below and sign at the end of the document.

Thank you!

Consent title

PRINCIPAL INVESTIGATOR:
First Last

RESEARCH TEAM CONTACT:
First Last (314) xxx-xxxx

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 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 ......
As a voluntary participant, you will be ......
Other requirements......
Stipend/compensations.
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 ......

The purpose of this research study is to ......

WHAT WILL HAPPEN DURING THIS STUDY?
If you choose to participate in this study, you will be ......

GROUPS/STUDY VISITS
BEING CONTACTED DURING THE STUDY
We may call you on the phone to ......

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

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

(If bio sample is collected) My blood and data may be stored and used for future research as described above.  

Initials ____________________________________  

(If bio sample is collected) My blood and data may be shared with other researchers and used by these researchers for the future research as described above.  

Initials ____________________________________  

HOW MANY PEOPLE WILL PARTICIPATE?  

......  

HOW LONG WILL I BE IN THIS STUDY?  

......  

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: ......  

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/not be paid for being in this research study.

WHO IS FUNDING 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) xxx-xxxx and/or the Human Research Protection Office at 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 funding institute. 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
- 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.

[Indicate other entities with whom PHI may be shared and the purpose of sharing, for example, a data safety monitoring board or data coordinating center]

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 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.

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

Initials  ____________________________________________

Initials  ____________________________________________

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: [name(s), phone number(s)]. For Biomedical studies: If you experience a research-related injury, please contact: [name(s), phone number(s)]. For Social Behavioral studies: If you feel that you have been harmed in any way by your participation in this study, please contact [name(s), phone number(s)]. 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

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

☐ AGREE

Participant Full Name (First, Last)

Date of Consent:

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

☐ AGREE

Signature of Person Who Obtained Consent (First, Last)

Date of Consent: