Cover Page

Informed Consent Document

PROTOCOL TITLE: Modified Application of Cardiac Rehabilitation for Older Adults (MACRO)

Principal Investigator Daniel E. Forman, MD

VERSION DATE: 1/10/2024

NCT Number: NCT03922529

University of Pittsburgh
School of Medicine
Vascular Medicine Institute

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

Project Title: Modified Application of Cardiac Rehabilitation for Older Adults (**MACRO**)

Principal Investigator: **Daniel E. Forman, M.D.**
Professor of Medicine
Medicine-Geriatric Cardiology
3471 Fifth Avenue, Suite 500
Pittsburgh, PA 15213
412-864-2507

Research Team Contact:
Tara Stakich: 412-720-0246
Garrett Kellar, Thomas Byard, Alyssa Mathews, Cody Wolf, Vanessa Legeza, Nathaniel Weiland

SOURCE OF SUPPORT: National Institutes of Health, National Institute on Aging (NIH/NIA)

KEY INFORMATION

This is a research study about 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 whether you want to participate.

Cardiac rehabilitation is suggested for people with heart problems, but few older adults participate. The purpose of this research study is to compare how older people do in a standard cardiac rehab program compared to one that has extra features to tailor the program more specifically to each person.

We invite you to participate in MACRO because:

- you are age 70 or older
- you have a cardiac diagnosis that makes you a good candidate for cardiac rehabilitation.

Being in a research study is entirely a choice. You do not have to do it, and if you start, you can still drop out at any time. The doctors and other people doing the study will do everything possible to keep you safe. This is separate from your regular care, which will go on as normal whether or not you are in the study.
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 will give you a copy of the consent document.

WHAT WILL BEING A PART OF THIS STUDY INVOLVE?

1. You will be in this study for approximately 1 year. Over the course of the year, we will do research assessments by phone or video with you to see how you are recovering and improving. These tests will include questionnaires about your quality of life, thinking ability, mood, diet, and medications.

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

2. We may also call you over the phone 1-2 times per week for the first 3 months of the study. The main risks to you are falls, injuries, or cardiac events related to participating in exercise as part of your cardiac rehabilitation program. More detail about risks is provided below.
3. You will be paid up to $120 for participating in this study.
4. If you withdraw from the study, the research team may continue to use information already collected about you in this study.

WHAT WILL HAPPEN DURING THIS STUDY?

If you choose to participate in this study, you will be randomly assigned (like flipping a coin) to one of two groups, 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 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 UPMC Shadyside Cardiac Rehabilitation Institute, or video sessions 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 30 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 PI, who is both a Geriatrician and a Cardiologist, will call you approximately once per week (until your cardiac rehabilitation program end, which is approximately 12 weeks) to go over your cardiac rehabilitation remotely. This is called "homebased" 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 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. This will be in the form of a 3 day food record where you record everything you eat. If necessary, we can lend you items to help track this (e.g., heart and blood pressure monitors, and an ActiGraph: a small device that measures the number of steps you take). If these particular exercise resources are not provided by the clinical cardiac rehab program, MACRO will offer to provide at no extra cost to you. Only individuals who are in the MACRO group and unable to attend a cardiac rehabilitation facility will receive these phone calls.

If you are in the MACRO arm, the study team and study doctor will review your medications.

We may make suggestions to your cardiologist or primary care doctor about them. This is commonly called “de-prescribing eligible medications” or “DEM.” It may benefit you by decreasing side effects caused by medications. Your PCP or cardiologist may be contacted regarding your medications. Your PCP or cardiologist will make the decision whether to discontinue any medications.

If you are in the MACRO arm, there is also the opportunity for you to have one home visit with an occupational therapist to see your home and provide suggestions to help you exercise safety. Participation in this visit is dependent on COVID-19 restrictions, your interest, and if you live within approximately 30 miles radius of the city. During the home visit, the participant’s home will be assessed for environmental and safety hazards. Should environmental or safety concerns be identified during this visit, the occupational therapist will discuss ways to eliminate or reduce risks with you, such as but not limited to installing grab-bars, ramps etc. If moderate or severe issues are identified, the occupational therapist will recommend to the participant that they seek support through local agencies, such as the Area Agency on Aging for assistance.

Finally, as part of the research, you will be asked to complete the four study visits (described below) by phone or video call.

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 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 three weeks after your cardiac event. The evaluation will last about 2 hours. We will ask you to answer questions 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. 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. If you are still in the hospital we will give to you, or mail if you are outpatient, the Actigraph with instructions to wear at home, and after 10 days you'll mail it back to us in a return envelope that we provide. 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. If you are still in the hospital during this time period, the Baseline Assessment may be in-person or over the phone.

3-month Assessment, 6-month Assessment, and 12-month Assessment:
At approximately each 3, 6, and 12 months you will be asked to speak with a study team member again, either by phone or video call. At this visit, you will repeat the same testing and questionnaires that you completed at the baseline visit. We will mail you an Actigraph with instructions to wear at home for 7-10 days. After 10 days you'll mail it back to us in a return envelope that we provide. In addition, we will ask you 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 your name, date of birth, medications, lab values, and medical history.

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 30 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 is to ensure consistency between the two sites, and the calls will not be recorded.

If 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.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 374 total people will take part in this study by University of Pittsburgh Investigators, including the Pittsburgh VA Medical Center and the Washington University School of Medicine. We will recruit 100 people to take part at UPMC.

WHAT ARE THE RISKS OF THIS STUDY?

The following is a list of known risks from being in this study. In addition to these, there may be other unknown risks associated with being in this study. Some risks described in this consent document, if severe, may cause death. A "risk" means there is a chance it could happen.

The risks from study procedures include the following:

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.

Collection and storage of private health information:

One risk of participating in this study is that confidential information about you may be disclosed or accessed by someone who is not authorized. 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.

Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed. It is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

Deprescribing Eligible Medications (DEM):

The study team will make suggestions to your care team about taking you off of certain medications. There is a risk for increased pain, if any of the medications that are discontinued have been helping you with pain control.

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.

Home Assessment

Possible risks during home visit assessments included: 1) Fatigue during home assessment visit (can last up to 60 minutes), 2) Potential for falls as a result of increased function and mobility because of increased ability to be physically active in home, 3) Breach of confidentiality.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may benefit from the additional assessments being done that will monitor your health or from participation in either group.

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. Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purpose of this research study. If you think that you or your health insurance has been charged, please contact a member of the research team and the UPMC billing office that sent the bill.

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 compensated based on the number of visits you complete for the study. The maximum amount you may receive is $120. Reimbursement breakdown:

Baseline Assessments	**$20**
3-Month Assessments	**$20**

6-Month Assessments	**$20**
12-Month Assessments	**$20**
Actigraph Return	**Up to $40**

Since you are being compensated for your participation in this study, your name, address, and social security number will be released to the Accounting Office. If the total reimbursement for your participation in research is greater than $600 in a year, this will be reported to the Internal Revenue Service (IRS) as income. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

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

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not give up any of your legal rights by signing this form.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

In addition to the investigators listed and their research staff, individuals from the following groups may have access to your identifiable information related to your participation in this research study:

1. The University of Pittsburgh Office of Research Protections, the Department of Health and Human Services Office for Human Research Protections and the National Institutes of Health (NIH, the funding agent) for the purpose of monitoring the study
2. Authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide services and addressing billing and operational issues.

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. 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information or documents that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations. Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

ARE THERE ADDITIONAL PROTECTIONS FOR MY HEALTH INFORMATION?

We will do our best to protect your privacy and the confidentiality of your research information by:

- Using a number code to label your information.
- Keeping your number code separate from your name, address, and other personal information. We will look at your information using the number code and not your personal information.
- Keeping your test results collected and other information in a secure computer database.

Representatives from the other sites of this study at Washington University and the Veteran's Administration Pittsburgh Healthcare System may view your de-identified data as part of ongoing monitoring by the study team.

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

We may share your de-identified data with other researchers or large federal data repositories in the future.

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.

Per University of Pittsburgh research record retention policy, all research data must be maintained for a period of at least 7 years following final reporting or publication of a project.

IS BEING IN THIS STUDY VOLUNTARY?

Your participation in this research study is completely voluntary and you may withdraw your consent at any time.

Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh, current or future medical care at a UPMC hospital or affiliated health care provider, or current or future relationship with a health care insurance provider.

If you choose to withdraw from this study, any identifiable research or medical information recorded from your participation in this research study prior to the date that you formally withdrew your participation may continue to be used and disclosed by the investigators for the purposes described above.

Your doctor may be involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

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.

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.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Tara Stakich, (412) 864-2082. If you experience a research-related injury, please contact: Dan Forman, MD, (412) 864-2507.

If you have any questions about your rights as a research subject or wish to talk to someone other the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

HIPAA Authorization for Disclosure of Protected Health Information (PHI)

As part of this research study, we are requesting your authorization or permission to review your medical records to determine whether you qualify, based on study specific eligibility criteria, for study participation and to collect data about hospitalizations or other care you receive during the study period. We will obtain the following information: your diagnosis, age, past medical history, diagnostic procedures, results of any clinical tests or blood tests, or relevant physical examination notes, that were already done as part of your standard medical care. The study team will collect information from your medical record about your clinical care.

FOR HOW LONG WILL THE INVESTIGATORS BE PERMITTED TO USE AND DISCLOSE IDENTIFIABLE INFORMATION RELATED TO MY PARTICIPATION IN THIS RESEARCH STUDY?

This authorization is valid for an indefinite period of time. This identifiable medical record information will be made available to members of the research team for an indefinite period of time.

No information collected in this study will be placed in your medical record. If any information that is collected indicates there is a medical concern, the study doctor or a member of the study team (under the study doctor's direction) will notify your primary care provider.

We will protect the confidentiality of your records, as described in this document, but cannot guarantee confidentiality, including information obtained from your medical records once your personal information is disclosed to others outside UPMC or the University.

You can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up that point will continue to be used by the research team.

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, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints 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 Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) 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 agree to participate in this research study and provide my authorization to use and share my medical records for research. A copy of this consent form will be given to me.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date/Time

CERTIFICATION OF INFORMED CONSENT:

I certify that I have explained the nature and purpose of this research study to the above named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date/Time