FORM: IRB Proposal - Standard Submission	
NUMBER	VERSION DATE
HRP-UT901	8/11/2023

IRB Application and Study Protocol Information

Study Title:

Estimating Recovery in Cardiac Rehabilitation using Mobile Health Technology and Personalized Machine Learning

NCT: TBD

Version Date: 8/11/2023

INSTRUCTIONS

- **This form is only for studies that are considered greater than minimal risk (full board) or qualify for expedited review (fits in one or more expedited review categories)**. See section 5.3 of the UT IRB Policies and Procedures Manual for details regarding expedited research.
- **Do NOT submit this form if the study will qualify for exempt review**. If your study is exempt, submit HRP-UT902 Template IRB Proposal Exempt Submission. You can download proposal templates from the Templates tab in UTRMS-IRB Library.
- **If you are only using secondary data that will not be initially collected solely for this research project, do not complete this form**. Instead, use HRP-UT903 Template IRB Proposal Secondary Use form instead. You can download proposal templates from the Templates tab in UTRMS-IRB Library.
- For studies following a sponsor protocol, please use this guidance to assist in your completion of this form.
- **Answer all questions**. If a question is not applicable to the research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, click on the check box (or double click and type an "X" if using Google Docs). Please note, Word online does not support Word checkboxes. Please download the file and use your desktop version of Microsoft Word.
- To fill in a text box, make sure your cursor is within the grey text box before typing or pasting text.
- **Do not convert this Word document to PDF.** The ability for UTRMS-IRB to implement "tracked changes" is required to facilitate efficient review.

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GENERAL STUDY INFORMATION

Study Title

Include the study title below.

Estimating Recovery in Cardiac Rehabilitation using Mobile Health Technology and Personalized Machine Learning

1 Review Type (Choose one)

Please choose which level of review best fits your research. This is an investigator's assessment of review and does not preclude the IRB from alternate determinations. In cases where the investigator and the IRB's determination of review conflict, the IRB's determination will be considered the official determination.

***Note**: Expedited review does not refer to the timeliness of the review of your protocol, but specific categories of research defined by OHRP. If you would like help determining which type of review best fits your research study, please contact the IRB staff in the Office of Research Support & Compliance:*
https://research.utexas.edu/ors/human-subjects/get-help/

a ☐ **Full Board Review – Greater than Minimal Risk Research**

b ☒ **Expedited Review – Minimal Risk Research**

2 Research Hypotheses

Please describe the research aims and hypotheses in the box below. To input text, click in the box below and start typing.
Note: Procedures will be explained in a separate section below.

That by measuring both wearable data during cardiac rehabilitation visits and wearable at-rest data (and during sleep), we are able to build trajectory models that estimate progress through cardiac rehabilitation and improvement performance throughout the trial, as a measure of cardiac fitness, captured by 6 minute walk tests.

3 Study Background

Provide the rationale and the scientific or scholarly background for the proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that the project is intended to address.

Exercise-based CR programs reduce cardiovascular mortality risks and improve patient outcomes in a longitudinal fashion. Despite the reduction in mortality and readmissions, participation and adherence in CR programs remains a challenge, especially in underserved communities because of limited program availability, the distance and transportation access to a program, its hours of operation, as well as a lack of diversity and gender-dominated programs. Home-based programs using smartphones have shown to increase adherence and achieve similar outcomes. While home-based programs also improved resting heart rate, systolic blood pressure, and levels of physical activity achieved through metabolic equivalent of tasks at the end of the study, users expressed a desire to have individualized education and treatment. Home-based systems still do not achieve real-time interaction, feedback, and monitoring that center-based CR does that make understanding survival and recovery in current systems too general. The unmet need is an unobtrusive system and analytic models that allow for

personalized quantification of rehabilitation trajectories in patients enrolled in center-based CR programs, which can monitor patient improvement in exercise as well as measures at rest in the center and in the evenings prior to sleep for a 12-week, 36-session CR program. The 6 minute walk, which is a submaximal exercise test to test aerobic activity, will be used as the primary measure.

4 Design and Methodology

Provide a brief description of the study design or data collection methodologies. Details regarding protocol specific research procedures will be discussed in a later section.

The goal of this study is to collect wearable sensor data that we hypothesize will be useful in future algorithm development.

Participants will be provided one or more smartwatches and/or smart rings to wear during a 14 week study which includes 2 weeks of baseline data collection and a 12-week, 36-session cardiac rehabilitation program. They will capture a pre-assessment 6 minute walk tests and a post-assessment 6 minute walk test. They will otherwise conduct standard cardiac rehabilitation program procedures and our sensors will capture data and sleep information throughout the study period.

The participant experience through this study will be to conduct a standard of care cardiac rehabilitation program but wear these commercial devices that we hypothesize may provide impactful data in future use. The device data that will be captured will be on heart rate, respiratory rate, galvanic skin response, skin temperature, and acceleration (as a measure of motion intensity), and this data will be collected at cardiac rehab and at rest in the evenings across the devices.

The participants will not see this data, aside from summaries available in commercial applications. Staff will not see this data or make any decisions based upon this data. We hypothesize that the high sampling rate of this data will enable future model design to better describe participant progress through cardiac rehab and eventually make predictions based upon the data, including designing new algorithms to handle the data, if needed or use existing off-the-shelf statistical techniques.

5 Data Analysis

Describe the data analysis plan, including any statistical procedures or power analysis.

We conducted an analysis to determine how many participants would be needed to identify an improvement in 6 minute walk test performance over a standard of care, 12-week period of cardiac rehabilitation. Using standard deviations made available by the Ellingsen et al, with a power of 0.8 and significance level of 0.05, requiring at least 41 participants.

We will collect data from smartwatches and smartrings to determine an association between the data gathered from those devices and the change in performance in the 6 minute walk test, which represents improvement throughout cardiac rehabilitation. The data that will be used will be frequently captured data on motion (through acceleration), heart rate, respiratory rate, galvanic skin response, skin temperature, and identification of when such data is being captured during sleep. No

additional data will be used from these (for example, no location data will be captured or stored from these commercial devices).

We hypothesize that the time varying nature of this data can provide, in the future, data to better estimate trajectories of recovery. This includes using this data in existing time-to-event analysis or determining the need for new algorithms that handle more frequent, time-varying data.

The analysis will be conducted retrospectively at the end of the study after all the data is collected. Therefore, no algorithms will be trained during this study, no predictions made based upon the data here, and no decisions about standard of care made by any additional data captured here.

If a future algorithm, using these data, is found to be more accurate in estimating trajectory of care, this data would serve as pilot data to design and develop new human subjects studies which would need their own protocols and own evaluations. Should any changes to the analysis plan be made, the necessary modifications/amendments will be supplied for this study immediately.

No medical decisions will be made based on the results of the developing software algorithm.

STUDY ELEMENT IDENTIFICATION

6 Study Elements

Check each research procedure included in your study.
A full description of all study procedures should be provided in the Procedures (Details) section below.
Procedures denoted with "" below have supplemental forms. Navigate to the UTRMS-IRB Library, Templates tab to download the applicable supplemental form.*

☐	Bio-specimens*	☒	Biometrics	☐	Registry or Repository*
☐	Focus Group	☐	Genetic Analysis	☐	Genomic Data Sharing
☐	International Research*	☒	Interview/Survey	☐	MRI
☒	Protected Health Information*	☒	Observation	☐	Radioactive Material/PET/Nuc. Med
☒	Record Review	☒	Sensors (Externally Placed)	☐	Sensors (Inserted)
☐	Audio (only) Recording	☐	Video Recording	☐	X-Ray/CT/DEXA

7 Study Intervention

Click on the check box (or double click and type an "X" if using Google Docs) if you will implement any of the following interventions.
A full description of all study interventions should be provided in the Procedures (Details) section below.
** Interventions denoted with "*" below have supplemental forms. Navigate to the UTRMS-IRB Library, Templates tab to download the applicable supplemental form.*

☐	**Behavioral**	☒	**Device***	☐	**Drug/Biologic***

8 Clinical Trial

Click on the following check box (or double click and type an "X" if using Google Docs) if the research meets the below definition of a clinical trial.

☒ **This study meets the definition of a clinical trial according to clinical trials.gov in that it involves one or more human subjects who are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.**

9 Additional Oversight

Check the box(es) below if you are implementing research procedures that require oversight from additional UT committees.

☐	**Energy introduced to the subject (electrical, magnetic, light)**	☐	**Human embryonic, human induced pluripotent, or human totipotent stem cells; or human gametes or embryos**	☐	**Radiation exposure without direct clinical benefit**

☐ **Biological Samples, Biohazards, Recombinant DNA, or Gene Transfer**

If biological samples are used and stored on UT campus UT IBC approval is needed.

a ☐ **UT IBC has (or will have) oversight.**

Provide UT IBC Number:

b ☐ **Biological samples collected will not be stored at UT Austin and another agency has responsibility for biospecimen safety.**

10 Alternatives to Participation in This Study

Provide a description of alternatives to participation in this study, as applicable.

Not to participate in this study and conduct standard cardiac rehabilitation without wearing additional sensors.

STUDY PROCEDURE DESCRIPTION

11 Procedure Description

Describe all study procedures, including a step-by-step outline of what participants will be asked to do or how data will be used. Be sure to describe all of the following in detail, as applicable:

- *Description of all research procedures being performed and when they are performed, in sequential order.*
- *Describe/list all research measures/tests that will be used [**NOTE: upload copies of all measures, surveys, scripts, data collection forms, etc., in "Other Attachments" in UTRMS-IRB**].*
- *Secondary data or specimens that will be obtained, how they are collected, how are they used.*
- *Where research activities will take place and duration (include expected time commitment of participants).*
- *Study elements checked in #6 above should be described here.*

Note: if this is a multi-site or collaborative study include the following:

- *This is a "Multi-site Study that involves more than one site performing ALL aspects of the research procedures as outlined above." OR "This is a collaborative study that involves UT Austin researchers working with external researchers who are engaged in performing the following study activities (list activities)."*
- *For assistance with multi-site/collaborative research, download HRP-UT932 Request to Rely Assessment Form from the UTRMS-IRB Library and email irbreliance@austin.utexas.edu.*

Participants that are enrolled into standard of care cardiac rehabilitation will be screened for eligibility. Eligible participants will then be contacted via phone prior to cardiac rehab to gauge interest. If potential participants are agreeable, they will be consented into our study in-person by Ascension clinical research coordinators at their next cardiac rehab session.
After consent has been obtained, these participants will be given one Garmin watch (Fenix Pro, Vivo Active or equivalent) and an Oura Smart Ring (ring 2, ring 3, or equivalent).

Participants will be asked to download the Garmin and Oura apps associated with these applications. They will be provided study accounts to use these applications. In addition there will be the Empatica Core Lab app and asked to fill out surveys through the TAMU RedCap app.

The apps and smart devices will be utilized to solely measure biometrics and the data gathered from collection will be analyzed retrospectively. These participants will be shown how to sync that data through their smartphones to our cloud servers.

The pre-assessment session will be around 2 hours long and will involve getting the patients' cellphone apps set up and synced with the wearable devices, as well as teaching them how to fill out daily surveys and how to use the wearable devices.

The daily surveys will be completed on patient's cell phones off the Tamu RedCap app. For questions or concerns related to the app/smart devices, patients will contact Ascension study investigators, who will then direct the issue to the TAMU investigators if needed or will be able to answer questions themselves based on their training. TAMU investigators will have no participant interaction.

Patients will also use Empatica watches during each cardiac rehabilitation visit and will return the device before leaving the cardiac rehab facility. The data from Empatica watch will be synced via QR code that will be scanned prior to exercise initiation.
In addition to sensor data captured during the study period automatically, we will capture participant condition information including comorbidities, primary myocardial infarction data for CR eligibility (if applicable), height, weight, age, sex. This information is not captured by TAMU or via apps/devices but will be recorded in a secured Google document. Other data, like GPS, text messages, device information such as the serial number, etc., WILL NOT be captured from the device that the app is installed on. The apps are provided by commercial entities that must maintain licensing in accordance with local, state, and federal law. Apple App Store and Google Play store remove applications that are no longer in accordance with these laws, and we rely on that mechanism.
The app and smartwatch devices will be monitored every day remotely to ensure data collection is working properly and will be monitored by the TAMU investigators in accordance with Ascension investigators. The app will run in the background but will not use excessive amounts of battery, which has been tested. The app will work on iOS and Android devices. The devices are meant to still have full day battery usage. The device's operating system being updated will not impact the app's functionality to the best of our knowledge as applications are maintained by commercial entities.
The process to ensure the removal of the app from the participants phones will be to delete the app off the participants cellular device when participants return to provide devices in their post-assessment visit. There are no requirements for returning the devices, and there are no consequences for not returning them or if the device becomes damaged. The participant will be compensated for participating in the study and this compensation is prorated to encouraged returning of the devices when participation is finished (either at the natural end or if they choose to withdraw early).
Participants will complete a 6 minute walk test during this pre-assessment session, facilitated by clinical research coordinators, who will observe participants and record distance walked.
This 6 minute walk test will involve wearing the Empatica watch and, at the participants pace, begin walking from a chair towards a marker (cone or chair), then turning around and walking back, repeating this for up to 6 minutes or until the participant needs to stop from fatigue or is having any difficulty breathing. The participant may rest at any point during the 6 minute walk test. The participant will be given an update of the time every minute. The distance total traveled during the 6 minutes will be recorded.

TAMU investigators do not perform any observation. Biomarker data is collected and remotely monitored through the sensor channels. Investigators will train participants on how to use the app and smart devices, including the TAMU Data extractor. This training will be done during the pre-assessment period.
The study will occur over 12 weeks and will be conducted through 36 cardiac rehab sessions, and each session will be around 3 hours long. The pre- and post- assessment will be 2 hours each.
The participants will also fill out a daily survey, which will be take about 2 minutes to be completed each day (Ecological Momentary Assessment data) via RedCap.
Participants will also answer daily EMA questions to determine sleep quality via redcap survey. Every morning they will be asked 6 questions using a 1-5 likert scale.
After their final cardiac rehab visit, patients will complete another 6-minute walk test conducted by clinical research coordinators. Research coordinators will observe participants during the 6-minute walk test and record results.
PHI will not be accessibly by TAMU, only Ascension Texas Cardiovascular research coordinators.

12 Protected Subject Populations

Click on the check box (or double click and type an "X" if using Google Docs) each population, if they are specifically studied for this research.

☐ Active Military Personnel	☐ Children/Minors	☐ Decisionally Impaired Adults
☐ Emancipated Minors	☐ Fetuses	☐ Individuals with Limited English Proficiency
☐ Neonates (Uncertain Viability)	☐ Neonates (Non-Viable)	☐ Prisoners
☐ Pregnant Women	☐ UT Staff/Employees	☐ UT Students

13 Research Participant Information

Describe the general characteristics of the subject populations or groups including gender, health status, and any other relevant characteristics. ***If you have multiple research populations (e.g., teachers and students), clearly outline characteristics for each group.***

Participants in this study will come from eligible all-comers to cardiac rehabilitation (CR). After participants have been referred to CR for enrollment, they will be eligible for this study. That includes includes those that may have experienced a heart attack, have a heart condition such as coronary artery disease or heart failure, or have had a heart procedure including coronary artery bypass graft surgery, percutaneous coronary intervention, pacemakers or implantable cardio defibrillators. Additional considerations include anyone ages 18 or older, any gender, able to walk unassisted and are comfortable using a smartphone and wearing a smartwatch and smartring for biometric data collection.

b Minimum Age

Include the minimum age range for target population. If you have multiple research populations ***(e.g., teachers and students), clearly state the minimum age for each group.***

18

c Maximum Age

Include the maximum age range for target population. If you have multiple research populations ***(e.g., teachers and students), clearly state maximum age for each group.***

None

d Inclusion Criteria

Describe the specific criteria that will be used to decide who will be INCLUDED in the research from interested or potential subjects. Define technical terms in lay language, as applicable.

- Enrollment in Cardiac Rehabilitation – eligible all-comers to CR
- Age 18 or older
-Native English speaker

e Exclusion Criteria

Describe the specific criteria that will be used to decide who will be EXCLUDED from the research. Define technical terms in lay language, as applicable.

-Inability to wear one or more SmartWatches or Smartring
-Inability to walk unassisted
-Inability to participate in cardiac rehabilitation
-Inability to use a smartphone to aid in upload of remote data through the Garmin and Oura applications.
-Lack of smartphone to use in the study
-There is a change in your health such that you meet any of the exclusion criteria for this study during the course of the cardiac rehab sessions

14 Total Sample Size

Enter the total target sample size below.

50 participants

15 Sample size rationale

Describe your sample size rational below.

Power analysis – plus increased numbers for participant dropout + appropriate sampling based upon sex and race/ethnicity.

16 Identification and Screening

*Check the box below if this study involves a screening process **prior** to the informed consent process.*

☒ **This study involves obtaining information or biospecimens for the purpose of screening, recruiting or determining eligibility of prospective subjects prior to informed consent by either:**
1. Oral or written communication with the prospective subject or LAR
2. By accessing records containing identifiable private information or stored identifiable biospecimens.

17 Identification and/or Screening Procedures

Describe the identification and/or screening procedures below.

Individuals who have been referred to cardiac rehab and are scheduled to begin Cardiac Rehab regimen at Ascension Seton Medical Center Austin will have their records reviewed to determine if they meet eligibility criteria.

18 Recruitment Overview

Check box indicating all recruitment methods utilized for this research.

☐	**E-mail**	☐	**Flyer**
☒	**In-Person**	☐	**Letter**
☐	**Social Media**	☐	**Research Pool**
☒	**Telephone/Text**	☐	**Snowball Sampling**
☐	**Web-post**	☐	**Word of Mouth**

19 Describe the recruitment process, including where recruitment will take place.

Describe recruitment procedures in the box below. Describe all elements checked above to provide a complete understanding of the recruitment strategies/methods.
NOTE: Upload copies of all recruitment materials to UTRMS-IRB in the "Recruitment Materials" section.

All patients who are being considered for cardiac rehab will be recruited and have the option to join this trial if eligibility requirements are met. Recruitment will take place at the cardiac rehab department. The study investigator and/or referring cardiologist, along with the research team, may

also contact the patient via phone prior to participants cardiac rehab session to inform them of the study and gauge potential interest in participating.

OBTAINING INFORMED CONSENT

20 Consent Overview

Check the box(es) for consenting procedures that will be used.

☒	**Obtaining Written Informed Consent/Parental Permission**	☐	**Requesting a Waiver of Documentation of Informed Consent**
☐	**Requesting a Waiver of Informed Consent**	☐	**Requesting an Alteration of the Required Elements of Informed Consent**
☐	**Obtaining Child Assent**	☐	**Obtain Consent Using a Short Form with a Witness**

21 Consent and Assent Processes

Provide a detailed description of consent/assent procedures in the box below. Include: who will obtain consent, where will consent be obtained, how is consent obtained, how consent/assent is documented, and when the consent process will occur in such a manner that participants will have sufficient time for adequate consideration.

NOTE: Upload copies of all consent/assent/permission forms/scripts to UTRMS-IRB in the "Consent Forms" section. This is required for UTRMS-IRB to appropriately stamp consent forms for approval.

Patients enrolled in Cardiac Rehab will be screened for eligibility. If eligible, Ascension coordinators will either gauge interest by calling patient prior to CR session or discuss in person at cardiac rehab facility. If interested, coordinator will review informed consent document in depth. Participants will be provided the opportunity to take ICF home to review with the option of coordinator calling patient to follow-up and answer any questions or coordinator meeting with patient prior to next cardiac rehab session.

Once informed consent has been obtained, patient will receive a copy of the ICF per site standard operating procedures. Coordinator will then educate patient on smart devices to be used, assist patient in downloading any needed applications on smartphone and collect baseline data. Our consent form is in line with the apps terms of service, and participants will be able to read the apps terms of services during the pre-assessment session when they download the app.

22 Electronic Consent

Check the box below if this study involves obtaining consent with an electronic signature. Be sure the section above is consistent.
NOTE: This box should NOT be checked participants are responding "yes" or clicking "I Agree" on a consent form. ***This section should only be completed if an electronic signature is being obtained.***

☐ **This study involves documenting informed consent/parental permission using an electronic signature.**

If true, specify method for obtaining e-consent below (e.g., DocuSign):

N/A

23 Consent and Translation

Check the box below to indicate that consent documents/scripts will be translated to a language other than English.

☐ **The study population will likely include participants whose limited English speaking status requires translation of the consent form.**

Translation Process

If above is checked, complete the below information describing the translation process. Either A or B must be checked.

A ☐ **The consent documents will be translated by a certified translator.**

B ☐ **A non-certified translator will translate the consent documents.**

If selected, complete the next two items below. Section describing qualifications must be completed and backtranslation (ii) must be true.

i **Describe the translator's qualifications**

To input text, click in the light grey area below.

ii ☐ **Another individual will confirm that the translation is accurate and appropriate**

26 Waiver of Documentation of Informed Consent

Only complete this section if a waiver of documentation of consent is requested (checked above in #21). To approve a waiver of documentation of consent, one of the following options must be appropriate and justified by the researcher.
*Please choose **one** waiver option and provide additional information as prompted.* ***Waiver option 2 is most common.***

A Waiver Option 1

Check the box below for each item (all required – #1-4) and provide protocol-specific information as to how the criteria below are met.
NOTE: This is the only applicable waiver of documentation option for greater than minimal risk research. If your study is greater than minimal risk and does not meet Option 1 criteria, you will need to obtain written consent.

1 ☐ The only record linking the subject and the research would be the consent document.

i Provide protocol specific information as to how this criterion is met.

To input text, click in the light grey area below

2 ☐ The principal risk would be potential harm resulting from a breach of confidentiality.

i Provide protocol specific information as to how this criterion is met.

To input text, click in the light grey area below

3 ☐ Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

i Provide protocol specific information as to how this criterion is met.

To input text, click in the light grey area below

4 ☐ Describe the mechanism for documenting that informed consent was obtained

Briefly explain how the researcher will document that consent was obtained from participants.

B Waiver Option 2

Check the box below for each item (all required – 1-3) and provide protocol-specific information as to how the criteria below are met.

1 ☐ **The study is minimal risk.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

2 ☐ **Written consent would not be required outside the research context.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below

3 ☐ **Describe the mechanism for documenting that informed consent was obtained**

Briefly explain how the researcher will document that consent was obtained from participants. To input text, click in the light grey area below.

i

C Waiver Option 3

Check the box below for each item (all required – 1-4) and provide protocol-specific information as to how the criteria below are met.

1 ☐ **The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm**

i **Describe the cultural group or community.**

2 ☐ **The research presents no more than minimal risk of harm to subjects.**

i **Provide protocol specific information as to how this criterion is met.**
To input text, click in the light grey area below

3 ☐ **There is an appropriate alternative mechanism for documenting that informed consent was obtained.**

i **Provide protocol specific information as to how this criterion is met.**
To input text, click in the light grey area below

4 **Describe mechanism for documenting that informed consent was obtained**
To input text, click in the light grey area below

27 Waiver or Alteration of Informed Consent

Only complete this section if a waiver or alteration of consent is requested. *To approve a waiver or alteration of consent, all of the following criteria must be appropriate and justified by the researcher.* ***All boxes must be checked.***

SKIP THIS SECTION IF NOT REQUESTING A WAIVER/ALTERATION OF CONSENT

A ☐ **The research involves no more than minimal risk to the subjects.**

i **Provide protocol specific information as to how this criterion is met.**
To input text, click in the light grey area below

B ☐ **The waiver or alteration will not adversely affect the rights and welfare of the subjects.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below.

C ☐ **The research could not practicably be carried out without the waiver or alteration (it is impracticable to perform the research if obtaining consent is required and not just impracticable to obtain consent).**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below.

D ☐ **If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.**

i **Provide protocol specific information as to how this criterion is met.**

To input text, click in the light grey area below.

28 Deception/Incomplete Disclosure and Debriefing

Only complete the sections below if requesting an alteration of informed consent for research that involves deception/incomplete disclosure.

Deception (as applies to research) means intentionally giving research subjects false information in order to establish false beliefs during the course of a research study.

Incomplete disclosure means that the principal investigator withholds some information about the real purpose of the study or the nature of the research procedures.

See IRB Policies and Procedures Section 15 for a description of deception.

If this study does not involve deception/incomplete disclosure, skip this section.

A ☐ **It is appropriate to provide additional pertinent information to the subject after research activities are complete (e.g., the researcher needed to deceive the subject to the nature of the study).**

B ☐ **Research participants will have the opportunity to withdrawal their data during the debriefing.**

C **Describe the nature of deception/incomplete disclosure and why it is necessary to conduct the research.**

To input text, click in the light grey area below.

D **Describe debriefing procedures.**

To input text, click in the light grey area below. ***NOTE: Upload the debriefing form to UTRMS-IRB in the "Consent Forms" section.***

BENEFITS

29 **Benefits to Society**

Describe the scientific and societal benefit(s) below.

Wearable sensors to determine ability to properly track progress through cardiac rehabilitation even at home, to enhance interventions and enable more accurate, immersive home-based programs

30 **Potential Direct Benefits to Participants**

Click on the applicable check box. A or B must be checked.

A ☒ **There is no anticipated direct benefit to participants.**

B ☐ **There are anticipated benefits to participants.**

i **If applicable, describe the potential direct benefits to participants.**

Describe potential direct benefits to participants below.

It is possible the additional study data will lead to more personalized rehabilitation progress, based upon the discretion of the rehabilitation staff, leading to improved outcomes. This is unlikely to be a statistically significant benefit.

RISKS

31 Describe the risks associated with each activity in this research

To input text, click in the light grey area below. Note: Risks should also be outlined in the consent form(s).

-Rash from skin irritation when wearing devices
-Other common risks: falls during the 6-minute walk; boredom from surveys, potential loss of privacy and confidentiality, time out of participant's day to participate in survey.

32 Describe how each risk is mitigated/minimized.

To input text, click in the light grey area below. Note: Risks mitigation should be outlined in the consent form(s), as applicable.

- participant is educated on what is involved in the 6 minute walk test. Research coordinators will facilitate 6MWT and ensure that the walking area is clear of any hazards that may cause falls or harm to participant
- If there is skin irritation from the wearable devices, the participant will be provided with information on treating this and given the option to remove the devices and withdraw from the study should they chose.
- We will only use participant coded information on smart devices to prevent participant information from being stored on device
- PHI and coded information will be stored in Ascension's secured google drive, secured via username and password, per Site policy.

Other risk mitigation is standard of care/procedures in cardiac rehabilitation.

33 Data Safety Monitoring

For additional information regarding data safety monitoring boards and data safety monitoring plans, please see Section 21 of our Policies and Procedures.
One of the following must be checked (A, B, or C).

A ☒ **In the investigator's opinion, this study is minimal risk and does not require a Data Safety Monitoring Plan (DSMP) or a Data Safety Monitoring Board (DMSB).**

PLEASE NOTE: The IRB may determine minimal risk studies do require data safety monitoring under certain circumstances (e.g., if there is a known risk with an expected frequency).

B ☐ **This study does not have a Data Safety Monitoring Board, but researchers have an internal plan to monitor for safety (Data Safety Monitoring Plan (DSMP)).**

Complete Data Safety Monitoring Details

C ☐ **This study has a Data Safety Monitoring Board (DSMB).**

*Complete Data Safety Monitoring Details section below **or** upload this study's Data Safety Monitoring Board's charter that contains the information below.*

34 Data Safety Monitoring (Details)

Complete this section if the study has a Data Safety Monitoring Plan. ***SKIP this section there is not a DSMP/DSMB.***

If the study has a DSMB, ensure all items below are addressed in the charter (and charted uploaded to UTRMS-IRB) or provide additional information below, as needed.

A How is safety information collected?

To input text, click in the light grey area below.

B When will safety data collection start (for each participant or for the whole study, as applicable)?

To input text, click in the light grey area below.

C How frequently will safety data be collected?

To input text, click in the light grey area below.

D Who will review the data for safety?

To input text, click in the light grey area below.

E How frequently will data be monitored for safety concerns?

To input text, click in the light grey area below.

F What data will be reviewed?

To input text, click in the light grey area below.

G **State the frequency or periodicity of the review of cumulative data.**

To input text, click in the light grey area below.

H **State any conditions that would trigger an immediate suspension of the research.**

To input text, click in the light grey area below.

35 Early Withdrawal

Only complete this section if there are planned conditions under which a participant will be withdrawn from the study. *If not applicable, skip to next section. Include this information in your consent form.*

A **List the criteria for withdrawing individual participants from the study (e.g., safety or toxicity concerns, emotional distress, inability to comply with the protocol, or requirements from study sponsor).**

To input text, click in the light grey area below.

-- if patient is recommended to withdraw from standard of care cardiac rehab due to safety concerns based on standard of care criteria (If cardiologist or cardiac rehab staff believe it is unsafe for patient to continue normal cardiac rehab sessions due to mobility issues, vital sign instability, unstable medical conditions, etc.)
-Personal requests from individuals due to concern of wearing sensors
-Identification by rehabilitation staff that participants are not adhering to sensor collection and data upload procedures.
-The staff will review these concerns, particularly for privacy and confidentiality.
- Due to lack of parti:

- Completing less than 75% of scheduled cardiac rehab sessions
- Completing less than 75% of the daily surveys
- Wearing Empatica and/or Oura ring less than 75% of the time
- Wearing garmin watch less than 75% of the time during cardiac rehab sessions

The participant will receive a daily remainder to adhere to the daily surveys. It will become apparent if the participant is not adherent. If the participant is missing cardiac rehabilitation sessions they will be contacted in accordance with standard processes.

B **Describe any necessary procedures for ensuring the safety of a participant who has withdrawn early.**

To input text, click in the light grey area below.

Return of devices and deletion of data collection applications from phones.
Early withdraw procedures will be handled by Ascension coordinators. Coordinator will contact the patient to obtain the request to withdraw in writing in accordance of site's SOP.

36 **Describe any pre-specified criteria for stopping or changing the study protocol due to safety concerns.**

To input text, click in the light grey area below.

N/A; since Devices provided by TAMU collect non-invasive data passively, with no additional hazards or safety concerns.

REQUIRED DISCLOSURES

37 **Required Consent Disclosures**

Identify each element below that may require additional information to be disclosed in the consent form. Click on the check box (or double click and type an "X" if using Google Docs).

A ☐ **It is reasonable that researchers could discover or suspect child or elder abuse.**

Add appropriate disclosure in consent form(s).

B ☐ **It is reasonable that researchers could learn of an incident that could require reporting under Title IX.**

Add appropriate disclosure in consent form(s). See Title IX and Research Guidance for information and download the Title IX Reporting Form on the Special Topics page.

C ☐ **It is reasonable that researchers could discover incidental findings or other information of medical interest about a participant's previously unknown condition.**

Add appropriate language to consent form(s).

i **Articulate methods for addressing and reporting incidental findings, if applicable.**

Ensure appropriate information is in consent form(s), as applicable.

38 Privacy

Describe how you will protect the identity and privacy of study participants during each phase of research. Privacy focuses on the individual participants rather than data. In this section, researchers should focus on issues such as where research activities take place and how participant involvement is protected from non-participants. Describe methods to ensure participants' privacy during identification, recruitment, screening, the consent process, the conduct of the study, and dissemination of data.
To input text, click in the light grey area below.

Participant smartphone applications will only collect non-identifiable sensor data – any location data, while used by Garmin while monitoring activity, is not stored. Participant logins will be by study ID – and identifiable linkages to this ID will only be kept by study staff in a separate, secured location.
A list of pre-registered anonymous accounts is provided to the CR staff; the CR staff maps each anonymous account to its specific participant but only communicates with STMI based on the anonymous account number.

Additional privacy procedures include conducting screening and consent in a private, controlled space. Subject's participation will not be advertised at the Cardiac Rehab facility or announced to nonparticipants by research coordinators or cardiac rehab staff during that participants cardiac rehab session.

39 Confidentiality and Data Security Plan

Provide general information below regarding confidentiality and data security plan. Provide additional details regarding how you will protect the confidentiality of data or address confidentiality concerns.
Include the following, as applicable:

- *If identifiers will be coded to protect confidentiality describe how and where identifiers are stored.*
- *Describe where and how data is stored and maintained.*
- *Include details regarding storage of consent forms, if applicable.*

To input text, click in the light grey area below.

Identifiers will be coded to protect confidentiality. No identifier information is collected or accessed by TAMU, only CR staff maintain identifier information. Information will be stored in Ascension's Google Drive per facility requirements. Drive is secured via username and password and users are only granted access if they are employed by Ascension Texas Cardiovascular Research department. These users have undergone specific training on enforcing HIPAA and maintaining privacy and confidentiality (through Ascension and CITI Program). Paper consent forms will be stored in locked cabinet at Ascension Texas Cardiovascular that is only accessible by key. Doors to the Ascension Texas Cardiovascular site are badge access only

Ownership: Garmin==User; Oura==User; Empatica==User; TAMU Data Tools – TAMU Investigators;
- Privacy Information: none of the three capture any privacy information

User/phone information can be accessed by the commercial app owner but never used by TAMU or Ascension staff

- All apps require usernames and passwords, generated by the researchers but encrypted
- Ascension staff keep all credentials and help participant recover username/password

40 Research Data/Records Destruction Details

Confirm general research data/information (including consent forms, as applicable) destruction timeline. ***One of the following must be checked.***

☒ **Research Data/Records will be retained for 3 years after study completion per UT record retention policy.**

☐ **Research Data/Records will be retained for longer than 3 years and retention information is provided below.**

Describe data retention timeline below. To input text, click in the light grey area below.

41 Confirm identifiable data destruction details

One of the following must be checked.

☒ **Identifiable data will be destroyed.**

If checked, ensure the below section describes identifiable data destruction plan and timeline.

Following study closure, study documents, including PHI, will be stored for a period of 3 years at our long-term storage location. After that time, documents will be destroyed.

☐ **Identifiable data will not be destroyed.**

If checked, explain below the rationale for retaining identifiable data indefinitely.

42 Data Access

Click on the check box (or double click and type an "X" if using Google Docs) for each group of individuals that will have access to study data.
If you plan on creating a repository, complete the repository form as well (download from Library in UTRMS-IRB).

☒ **Study Team Members**	☒ **External Collaborators**	☐ **Data coordinating center**
☐ **Sponsor**	☒ **Future Sharing with other researchers**	

☐ **Others**

Describe below. To input text, click in the light grey area below.

43 **Describe data sharing plan for each group checked above and state whether researchers plan on sharing identifiable, coded, or de-identified data.**

To input text, click in the light grey area below. Ensure that data sharing and future use is addressed in the consent form(s).

Only de-identified data will be shared with external collaborators and made available for future secondary research use. TAMU collects all biomarkers generated by all three devices and distribution. TAMU personnel will only have access do de-identified data.

44 **Certificate of Confidentiality**

Click on the check box (or double click and type an "X" if using Google Docs) to identify each element below that may require additional information to be disclosed in the consent form.
If a Certificate of Confidentiality is not applicable for this study, skip this section.

A ☒ **NIH has issued a Certificate of Confidentiality for this study.**

Ensure CoC language is included in the consent form(s).

B ☐ **A Certificate of Confidentiality has not been obtained, but there are plans to apply for one.**

Ensure appropriate CoC language is included in consent form(s). Apply for a CoC for non-NIH funded research here: NIH Certificate of Confidentiality System. Once CoC is granted by NIH, you must update the consent form language and ensure a copy of the CoC approval (only for non-NIH funded research) is uploaded to UTRMS-IRB.

COMPENSATION AND COSTS

45 **Compensation**

Click on the check box (or double click and type an "X" if using Google Docs). A or B must be checked.

A ☒ **Subjects receive compensation.**

i ☒ **Confirm: Amount of compensation and its form is reasonable for this population for the activities requested of them.**

ii **Total Amount of Compensation**

Include the total amount of compensation below.

$175

iii **Type of Compensation**

☐ Cash ☐ Check ☐ Gift Card

☐ Course Credit ☒ ClinCard ☐ Tango Card

☐ Other

Describe other form of compensation below.

iv **Proration Schedule**

Describe the proration schedule for multi-visit/session studies. Skip if not applicable.

$50 at enrollment
$25 for initial 12 cardiac rehab sessions (Received at the 12th Cardiac rehab session)
$25 for completing another 12 cardiac rehab sessions (Received at the 24th cardiac rehab session)
$25 for completing final 12 cardiac rehab sessions (received at the 36th rehab session)
$50 for completing final assessment (pre- and post- 6 MWT) and returning devices (either at the 36th cardiac rehab session or after).

Participants will only receive compensation for each step they have completed.

B ☐ **Subjects will not receive compensation.**

46 Costs

A or B must be checked.

A ☐ **Participants will have no costs associated with this study**

B ☒ **Participants will have the following costs associated with this study.**

☒ **Standard of care procedures contributing to study data**

☐ **Research procedures not associated with standard of care**

☐ **Administration of drugs / devices**

☐ **Study drugs or devices**

☐ **Transportation and parking**

i **Describe all costs below.**

To input text, click in the light grey area below.

Participant smartphone plans should have sufficient data allocation to not increase cost of phone plans – remaining costs are standard of care costs associated with cardiac rehabilitation and not increased due to our study. None of the apps incur additional costs.