Post-Market Surveillance With a Novel mHealth Platform

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HRP-503B – BIOMEDICAL RESEARCH PROTOCOL
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Protocol Title: Post-Market Surveillance with a Novel mHealth Platform

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Version Date:

(*If applicable*) **Clinicaltrials.gov Registration #:** NCT03436082

INSTRUCTIONS
This template is intended to help investigators prepare a protocol that includes all of the necessary information needed by the IRB to determine whether a study meets approval criteria. **Read the following instructions before proceeding:** 1. Use this protocol template for a PI initiated study that includes direct interactions with research subjects. Additional templates for other types of research protocols are available in the system Library. 2. If a section or question does not apply to your research study, type "Not Applicable" underneath. 3. Once completed, upload your protocol in the "Basic Information" screen in IRES IRB system.

SECTION I: RESEARCH PLAN

1. **Statement of Purpose:** State the scientific aim(s) of the study, or the hypotheses to be tested.

We plan to pilot test a novel patient-led, smartphone-based mobile health platform (called Hugo) for real-world surveillance of outcomes in 60 total patients after medical device use. We propose recruiting patients at 2 clinical sites, Yale-New Haven Hospital and the Mayo Clinic, before they undergo a bariatric surgical procedure (either sleeve gastrectomy or gastric bypass) and catheter-based atrial fibrillation ablation. We will enroll 30 patients at each site and 30 patients for each procedure. Patients will then be queried about specific symptoms related to their procedure at enrollment, one week post-procedure, every Monday and Thursday for a total of 10 times post-procedure, at 4 weeks, and again at 8 weeks. Patients will also be given syncable devices to use that will provide additional insights into their health and health outcomes. This pilot project will engage patients to report outcomes while also synchronizing data from their electronic health records and pharmacy accounts to ascertain the ability of emerging mobile health technologies to aid in post-marketing surveillance.

Specific Aim 1: To pilot test the feasibility of using this mobile health platform for post-market surveillance of patients after sleeve gastrectomy or gastric bypass by describing enrollment times, patient participation, dropout, completion of patient-reported outcome measure queries, syncing of mobile device data, obtaining of electronic medical record data, obtaining of pharmacy data, and user satisfaction and burden.

Specific Aim 2: To pilot test the feasibility of using this mobile health platform for post-market surveillance of patients after catheter-based atrial fibrillation ablation by describing enrollment times, patient participation, dropout, completion of patient-reported outcome measure queries, syncing of mobile device data, obtaining of electronic medical record data, obtaining of pharmacy data, and user satisfaction and burden.

2. Probable Duration of Project: State the expected duration of the project, including all follow-up and data analysis activities.

   The project is expected to be completed no later than August 2018 with enrollment beginning in February 2018. Recruitment for patients is expected to take 2-4 months depending on the implanting physicians' schedules, with monitoring of each patient lasting 8 weeks post procedure. As each patient's 8-week post-operative period is concluded, we will begin to clean, review and verify the data as it is received from the Hugo Platform on a rolling basis.

3. Background: Describe the background information that led to the plan for this project. Provide references to support the expectation of obtaining useful scientific data.

   The FDA has several mechanisms through which it collects information and generates evidence once a medical device is available for clinical use, including voluntary adverse event reporting, establishing medical device registries, and requiring post-marketing studies. While each offers important and valuable insights into medical device performance, each also has well-understood limitations [1]. Most importantly, none of these mechanisms can capture longitudinal patient-reported outcomes for a large cohort of patients to characterize device performance on endpoints that matter most to patients. Further, none integrate data from multiple sources (including patient-reported outcomes through self-report or sync-able devices, electronic health record data, and pharmacy data). To this point, collecting all of this data would have been considered impractical because it would have involved large volumes of data collected from disparate sources without any meaningful integration. Additionally, obtaining patient-reported outcomes would have required significant resources to contact patients and administer questionnaires.

However, in recent years, mobile health technologies have emerged that can capture and integrate disparate data sources, offering tremendous potential to collect many types of data from patients to inform regulatory decision-making. For example, a recent smartphone app monitoring activity and sleep patterns received both sensor and patient questionnaire-reported data uploaded from over 30,000 individuals over a 6-month period and enabled researchers to estimate cardiovascular risk [2]. A recent mobile health platform (called Hugo) has been created which enables patients to receive pre-designed queries requesting reporting of specific information on function, symptoms and other patient-centered outcomes, while also integrating patient health data from multiple sources including health systems' electronic health records and wearables/sensors, thus enabling synchronization of patient-reported outcomes with medical records. The platform can also be set up to include medication data from pharmacies by linking to patient pharmacy portals, if pharmacies have enabled this functionality.

To advance the science and inform how FDA may use novel and emerging technologies as it increasingly adopts a life-cycle evaluation approach to medical device regulation,[3] we propose a project to test the feasibility of using a mobile health platform as part of post-market surveillance efforts for two procedures, both of which have significant clinical relevance and require use of medical devices. Sleeve gastrectomy has been increasing in volume, particularly with a decline in gastric banding, and is now the most common bariatric surgical procedure performed [4]. Gastric bypass remains the second most common surgical procedure. Similarly, rates of catheter ablation for atrial fibrillation ablation have also increased substantially over the past 15 years [5]. We propose recruiting patients at two clinical sites, Yale-New Haven Hospital and the Mayo Clinic, before they undergo a bariatric surgical procedure (either sleeve gastrectomy or gastric bypass) and catheter-based atrial fibrillation ablation. Patients will then be queried about specific symptoms at enrollment, at one week post-procedure, every Monday and Thursday a total of 10 times post-procedure, at 4 weeks, and again at 8 weeks. Patients will also use sync-able devices that will provide additional insights into their health and health outcomes. This pilot project will engage patients to report outcomes while also synchronizing data from their electronic health records and pharmacy data to ascertain the ability of emerging mobile health technologies to aid in post-marketing surveillance.

4. Research Plan: Summarize the study design and research procedures using non-technical language that can be readily understood by someone outside the discipline. Be sure to distinguish between standard of care vs. research procedures when applicable, and include any flowcharts of visits specifying their individual times and lengths. Describe the setting in which the research will take place.

   We will recruit patients undergoing 1 of 2 procedures (either bariatric surgery or catheter-based atrial fibrillation ablation) at Yale-New Haven Hospital. Bariatric surgical patients undergoing sleeve gastrectomy or gastric bypass only will be enrolled. Patients will be contacted through their treating/implanting physician's office via phone around the same time that their final pre-operative appointment is confirmed by an automated system (2 days prior). At this time, the office staff will inform eligible patients that if they are interested, a research associate (RA) will be onsite the day of their appointment to discuss participating in a study looking to monitor post-procedure safety and effectiveness. Eligibility will be determined by the cardiac electrophysiologist stating that the patient is being seen pre-procedurally for catheter ablation of atrial fibrillation or the bariatric surgeon stating that the patient is being seen pre-operatively for sleeve gastrectomy or gastric bypass. On the phone call, patients will be informed that participation is optional but if they would like to learn more that they should plan to be at the office for additional time and to bring their smartphone and MyChart login information, any phone account passwords, and a recent prescription if possible (please see Appendix for script). Patients not reached will have a message left stating the same. If a patient has been deemed eligible by their treating physician but is not scheduled to be seen in office again prior to their procedure, the RA may reach out directly via phone to ask if the patient would be interested in

learning more and if so, schedule time for the patient to come in and discuss the project further. In clinic, patients who assent will then be introduced to the RA by the physician after the conclusion of their appointment. The RA will then confirm the patient meets the eligibility requirements and discuss the specifics of the study described below. If, after reviewing, the patient agrees to the study, then he/she will be asked to sign the standard consent and authorization form for YNHH. We will ensure that the patient has full and clear understanding that enrollment will not in any way impact his/her care nor alter the standard post-procedure follow-up visits. As a part of the consent process, the RA will also make clear to the patient that this study will not replace their normal medical care and advise him/her that should they begin having new or worrying symptoms to contact their doctor or emergency services directly, exactly as the patient would have done if he/she were not enrolled in our study. We will also provide patients with an emergency contact card to be used in case of severe or adverse symptoms; these cards document the standard information for study participants (please see Appendix for the cards).

Because the mobile health platform (Hugo) obtains patient data through patient portals, all patients who connect will need a YNHH MyChart account. The RA will assist the patients in creating a MyChart account. On a desktop computer, the RA will log into her YNHH Epic Hyperspace account. She will look up the given patient and then enable the patient to obtain a MyChart account through the "Launch MyChart Signup" functionality. The patient will then confidentially create a MyChart account (the RA's YNHH Epic Hyperspace account is automatically locked) by entering his/her own username, password, and retyping the password. Once the patient has completed the MyChart sign-up process, then the RA will assist the patient in creating and activating an account for the mobile health platform, Hugo, on the patient's personal smartphone. Some patients may need to reset their MyChart password, and the RA will enable them to do so. Some patients may have forgotten their MyChart username, and the RA will be able to provide this information to them through the "Launch MyChart Signup" functionality. The RA will also assist the patient in connecting their mobile health platform account with other health systems where they have received care by showing the study participant how to enter their patient portal credentials, provided that these health systems are connected to the mobile application, as well as to pharmacy portals where they have received medications (if that includes CVS or Walgreens). Patients will also receive a syncable device relevant to their procedure (i.e. AliveCor Kardia Mobile for catheter ablation of atrial fibrillation or Nokia Body digital weight scale for bariatric surgery patients and Fitbit for all patients). At this time, patients will also complete their pre-operative/baseline questionnaires so that the RA is present to assist them. The RA will also ask patients to obtain and upload their continuity of care document (CCD) if they receive care in a health system that is not connected to Hugo, at both enrollment and again at 8 weeks; the RA will also ask patients to obtain credentials, if necessary, and connect portals to health systems where they receive care that are connected to Hugo but were unable to connect at enrollment. Patients will also receive a follow-up email from the RA that includes user guides for the devices they have received (Appendix).

The RA will then follow-up with study participants in-person on the first post-procedure day (i.e. after catheter ablation of atrial fibrillation or sleeve gastrectomy/gastric bypass) to ensure all devices are working properly, and to answer any questions that study participants may have.

The RA will collect the following data at enrollment:

- Number of people asked for study participation and number enrolled
- Number of study participants who required assistance setting up Yale-New Haven Hospital or Mayo Clinic portals
- Number who had YNHH or Mayo portals who could not be enrolled (e.g. because they had forgotten password, no space on mobile device, technical glitch, etc)
- Time to set up new Hugo account and enroll patient in study

- Total enrollment time (from initiation of conversation with RA to completion of connecting health system portals)

If a patient refuses to participate, then we will note the number of people who refused. If the patient is agreeable, we will then administer a short questionnaire to understand his/her rationale for not participating in the study, to understand potential reasons for non-participation. We will also ask these people who chose not to participate about basic demographics, if they are willing to answer (age, sex, race/ethnicity, major co-morbidities, insurance status). Please see Appendix for questionnaire.

Inclusion criteria:

- Age >18
- English-speaking
- Planned for either a bariatric surgical procedure (either sleeve gastrectomy or gastric bypass) or catheter-based atrial fibrillation ablation
- Participant is willing and able to read and sign consent and participate in study
- Participant has an email account and a mobile device (smartphone or tablet) able to download the necessary applications
- Participant is willing to use the mobile health platform and syncable devices (e.g. Fitbit Charge 2)
- Attending bariatric surgeon or electrophysiologist (as appropriate) concurs that patient is a candidate for enrollment

We will test the ability/feasibility of the Hugo platform to merge together 4 unique data sources and make these data available in a research-ready database:

1. Electronic health record data which is made available through the patient portals (encounters, vital signs, labs, test, diagnoses for inpatient and outpatient encounters, medications, physician visits, repeat procedures, notes)
2. Patient reported outcome measures (PROMs), prompted via mobile-friendly questionnaires to study participants
3. Data from syncable devices provided to patients (Fitbit and Nokia Body digital weight scale for sleeve gastrectomy and gastric bypass patients; Fitbit and AliveCor, Kardia Mobile for catheter-based atrial fibrillation ablation patients)
4. Medication data from 2 major pharmacy chains (CVS or Walgreens)

Additionally, patients will be contacted by the RA via phone at 2 months to ascertain the health systems in which they sought care and the Hugo platform will be checked to ensure that data from those health systems is included (and patients will be asked to link those health systems or provide data, as appropriate). Multiple attempts will be made to contact patients if they are not contacted on the first attempt.

Bariatric surgery (either Sleeve Gastrectomy or Gastric Bypass) Patients Only

1. All patients enrolled in the study will then be asked to answer questions administered using the mobile health platform at baseline (pre-procedure), 1 week, 4 weeks, and 8 weeks post-procedure using validated symptom questionnaires from the National Institute of Health's PROMIS® (Patient-Reported Outcomes Measurement Information System), which we will adapt to a mobile format (See Appendix for original paper and mobile versions). These will ask about global health, pain, gastroesophageal reflux, nausea and vomiting, diarrhea,

constipation, and sleep. In addition, every Monday and Thursday for a total of 10 times immediately following their procedure, patients will be asked 2-4 questions on a visual analog scale related to pain and appetite. Please see Appendix for questionnaires as inputted into the mobile health platform as well as the original paper version.

2. We will attempt to sync the following data from syncable devices for study participants:

   - Fitbit (Ambulation, heart rate, and other activity), synced weekly
   - Digital weight scale, synced weekly

3. We will attempt to retrieve the following data from the electronic health record into Hugo for study participants:

   Pre-procedural information
   - Co-morbidities, prior surgeries, medications, and allergies
   - Physician outpatient notes, including History & Physical

   Intra- and post-procedural information during index hospitalization
   - Duration of hospitalization
   - Co-incident procedures at the time of sleeve gastrectomy or gastric bypass
   - Re-operation or re-intervention
   - Vital signs
   - All associated secondary diagnoses during incident hospitalization
   - Transfer to intensive care unit
   - Post-operative imaging tests obtained (e.g. CT scans)
   - Physician notes, including Operative Report and Discharge Summary

   Post-procedural encounters after hospital discharge for 8 weeks
   - Number of encounters
   - Encounter type (e.g. outpatient visit, inpatient visit, labs, imaging)
   - Diagnoses associated with encounters
   - Physician notes
   - Lab tests and Imaging test results

4. We will test the feasibility of obtaining medication data from major pharmacy chains (Walgreens or CVS), including active prescription names, formulations and dosages, days' supply or # dispensed, frequency of fills, and prescriber.

Patients will receive automatic reminders to complete questionnaires daily for 2 days via email. Similarly, patients will receive automatic reminders to sync their digital scale and Fitbit weekly for 2 days after the planned sync date.

<u>Catheter-based atrial fibrillation ablation patients only:</u>

1. All patients enrolled in the study will then be asked to answer questions administered using the mobile health platform at baseline (pre-procedure), 1 week, 4 weeks, and 8 weeks post-

procedure using validated, symptom questionnaires from the National Institute of Health's PROMIS® (Patient-Reported Outcomes Measurement Information System) as well as the C-CAP1 and C-CAP 2 (Cardiff Cardiac Ablation PROMS 1 and 2)[6], which we will adapt to a mobile-friendly format (See Appendix for original paper and mobile versions). These will relate to global health, dyspnea, and fatigue as well as symptoms related to atrial fibrillation and symptoms after ablation, including possible complications. In addition, every Monday and Thursday for a total of 10 times immediately following their procedure, patients will be asked 2-4 questions on a visual analog scale related to pain and palpitations. Please see Appendix for questionnaires as inputted into the mobile health platform as well as the original paper version.

2. We will attempt to sync the following data from syncable devices for study participants:

   - Fitbit (Ambulation, heart rate, and other activity), synced weekly
   - AliveCor (single lead electrocardiographic recording), synced weekly

3. We will attempt to retrieve the following data from the electronic health record into Hugo for study participants:

   Pre-procedural information
   - Co-morbidities, prior surgeries, medications, and allergies
   - Physician outpatient notes, including History & Physical

   Intra- and post-procedural information during index hospitalization
   - Duration of hospitalization
   - Co-incident procedures at the time of atrial fibrillation ablation
   - Re-intervention or other procedures (pericardiocentesis, cardioversion)
   - Vital signs
   - All associated secondary diagnoses during incident hospitalization
   - Transfer to intensive care unit
   - Post-operative imaging tests obtained (e.g. CT scans)
   - Physician notes, including Operative Report and Discharge Summary

   Post-procedural encounters after hospital discharge for 8 weeks
   - Number of encounters
   - Encounter type (e.g. outpatient visit, inpatient visit, labs, imaging)
   - Diagnoses associated with encounters
   - Physician notes
   - Lab tests and Imaging test results

4. We will test the feasibility of obtaining medication data from major pharmacy chains (Walgreens or CVS), including active prescription names, formulations and dosages, days' supply or # dispensed, frequency of fills, and prescriber.

Patients will receive automatic reminders to complete questionnaires daily for 2 days via email. Similarly, patients will receive automatic reminders to sync their AliveCor and Fitbit weekly for 2 days after the planned sync date.

The metrics we plan to collect are as follows:

A. Enrollment-related
- Number of people asked for study participation and number enrolled
- Number of study participants who required assistance setting up Yale-New Haven Hospital or Mayo Clinic portals
- Number who had YNHH or Mayo portals who could not be enrolled (e.g. because they had forgotten password, no space on mobile device, technical glitch, etc)
- Time to set up new Hugo account and enroll patient in study
- Total enrollment time (from initiation of conversation with RA to completion of connecting health system portals)

B. PROM-related (for all PROMs)
- Rate of opening PROM emails
- Rate of PROM survey response
- Mean time to PROM survey response
- Proportion of items completed
- Proportion of people who completed PROM survey after initial email or after 1 reminder

C. Mobile Device-related
- Proportion of people who sync their devices (AliveCor, digital scale, and FitBit) at 1, 2, 3, 4, 5, 6, 7, 8 weeks

As each patient completes 8 weeks of follow-up, all patient data will be sent to the Mayo Clinic, where an analyst will clean and curate the data made available through the Hugo platform. The analyst will then send the cleaned data for the YNHH patients to the Yale investigator team. The RA will then confirm the primary diagnoses in the YNHH Electronic Medical Record (EMR) for physician visits, emergency department visits, and inpatient admissions during the 8-week period by examining and comparing to the research database to determine if any encounters or diagnoses are missing in the research database.

The data points that we will validate in the Hugo Research Database from the YNHH Epic EMR will be:
- Encounter date
- Encounter type
- Primary diagnosis for encounter

We will also note if any additional physician visits, emergency department visits, and inpatient admissions are seen in either system (in the case of additional points in Hugo, we will also determine if they are from another health system). If any diagnoses are missing in the Hugo Research Database, we will determine from which visit that they were missing.

In addition, we will examine YNHH EMR data to determine what new medications were prescribed at discharge, and then we will examine pharmacy data to determine which of these prescriptions were filled by the patient.

Finally, at the end of the pilot study (i.e. at 8 weeks post-procedure), study participants will be called by the RA and asked to complete a close-out questionnaire (see Appendix) to determine their satisfaction with the process of answering queries and provide the opportunity for them to offer comments and suggestions for

improvement. They will also be asked at what health systems they received care over the past 8 weeks (including hospitalization, emergency department visit, repeat procedure), to assess if all pertinent data was captured in Hugo.

Close-Out Questionnaire, whereby study participants are called by RA at 8 weeks on a HIPAA-protected secure phone line and asked:

1. How was your overall experience using this technology (open-ended)?

2. How long did it take you, on average, to answer the questions that you were sent weekly?

3. How was the experience of answering questions (open-ended)?

4. Did you have any of the following in the past 8 weeks:
   a. emergency department visit
   b. admission to a hospital
   c. re-operation
   d. major complication

5. If yes to #4, what was the reason(s) for the emergency department visit, hospital admission, or re-operation?

6. In the past 60 days, at what health systems did you receive medical care? Do you have a portal with access for those health systems?
   a. For patients who received care in a health system(s) connected to Hugo, we will ask the patient to obtain portal access and then link it to Hugo
   b. For patients who received care in a health system(s) not connected to Hugo, we will ask the patient to obtain and upload their Continuity of Care Document (CCD) at the end of the study.

At the end of the study period, we will perform additional data abstraction by viewing the YNHH Electronic Medical Record, with the goal of augmenting our understanding of the specific procedures. If notes are available through Hugo at that time, then these notes will preferentially be viewed instead of those in the YNHH Electronic Medical Record. The specific elements that will be abstracted, with the anticipated sources, are as follows:

Pre-Operative History & Physical
-Indications for procedure (for example, for bariatric surgery the patient's BMI and presence of obesity-related co-morbidities; for atrial fibrillation, if the patient has failed pharmacologic therapies)

Operative Notes
-Bariatric surgeon or cardiac electrophysiologist's technique
-Additional procedures performed at time of index procedure
-Medical devices used intra-procedure (if these are not available within the operative note, then we will determine if they can be found in a different place within the YNHH EMR)
-Device failures or interventions (examples: staple line suturing, clips, or application of fibrin glue; additional devices required)

Discharge Summary
-In-hospital adverse events
-Diagnoses (including noting which diagnoses were present on admission and which were co-morbidities)
-Discharge medications, where the prescribed medications will be compared to the medications that the patient received at discharge

5. Genetic Testing N/A ☒
   A. Describe
      i. the types of future research to be conducted using the materials, specifying if immortalization of cell lines, whole exome or genome sequencing, genome wide association studies, or animal studies are planned *Write here*
      ii. the plan for the collection of material or the conditions under which material will be received *Write here*
      iii. the types of information about the donor/individual contributors that will be entered into a database *Write here*
      iv. the methods to uphold confidentiality *Write here*

   B. What are the conditions or procedures for sharing of materials and/or distributing for future research projects? *Write here*
   C. Is widespread sharing of materials planned? *Write here*
   D. When and under what conditions will materials be stripped of all identifiers? *Write here*
   E. Can donor-subjects withdraw their materials at any time, and/or withdraw the identifiers that connect them to their materials? *Write here*
      i. How will requests to withdraw materials be handled (e.g., material no longer identified: that is, anonymized) or material destroyed)? *Write here*
   F. Describe the provisions for protection of participant privacy *Write here*
   G. Describe the methods for the security of storage and sharing of materials *Write here*

6. Subject Population: Provide a detailed description of the types of human subjects who will be recruited into this study.

   We will recruit a total of 30 study participants undergoing their procedure at Yale New Haven Hospital. Yale New Haven Hospital in New Haven, CT sees over 79,000 patients a year with approximately 65,000 adult patients. Fifteen patients will be recruited after seeing Dr. Kurt Roberts at Yale Bariatric/Gastrointestinal Practice in New Haven, with the other 15 patients recruited after seeing Dr. Joseph Akar at the Yale New Haven Hospital Heart & Vascular Center.

7. Subject classification: Check off all classifications of subjects that will be specifically recruited for enrollment in the research project. Will subjects who may require additional safeguards or other considerations be enrolled in the study? If so, identify the population of subjects requiring special safeguards and provide a justification for their involvement.

   Pregnant women or females of childbearing potential have the potential of being enrolled in this study but will not be specifically recruited for enrollment preferentially over other patients. We anticipate that this study presents minimal risk to pregnant women.

☐Children ☐ Healthy ☐Fetal material, placenta, or dead fetus
☐Non-English Speaking ☐ Prisoners ☐Economically disadvantaged persons
☐Decisionally Impaired ☐ Employees ☐Pregnant women and/or fetuses
☐Yale Students ☐ Females of childbearing potential

NOTE: Is this research proposal designed to enroll children who are wards of the state as potential subjects?
Yes ☐ No ☒

8. Inclusion/Exclusion Criteria: What are the criteria used to determine subject inclusion or exclusion?
   Inclusion criteria:
   - Age >18
   - English-speaking
   - Planned for either sleeve gastrectomy, gastric bypass, or catheter-based atrial fibrillation ablation
   - Participant is willing and able to read and sign consent and participate in study
   - Participant has an email account and a smartphone able to download the necessary applications
   - Participant is willing to use the mobile health platform and syncable devices (e.g. Fitbit Charge 2)
   - Attending bariatric surgeon or cardiac electrophysiologist (as appropriate) concurs that patient is a candidate for enrollment

9. How will eligibility be determined, and by whom? Write here

   To be eligible, patients must meet the inclusion criteria listed above. A patient's eligibility will first be determined by the implanting physician who will be performing the catheter-based atrial fibrillation ablation or bariatric surgical procedure (either sleeve gastrectomy or gastric bypass). The criterion used will simply be the cardiac electrophysiologist stating that the patient is being seen pre-procedurally for catheter ablation of atrial fibrillation or the bariatric surgeon stating that the patient is being seen pre-operatively for sleeve gastrectomy or gastric bypass. Once deemed eligible by the physician, patients will be contacted through their treating/implanting physician's office via phone around the same time that their final pre-operative appointment is confirmed by an automated system (2 days prior). At this time the office staff will inform eligible patients that if they are interested, a research associate (RA) will be onsite the day of their appointment to discuss participating in a study looking to monitor post-procedure safety and effectiveness. If a patient has been deemed eligible by their treating physician but is not scheduled to be seen in office again prior to their procedure, the RA may reach out directly via phone to ask if the patient would be interested in learning more and if so, schedule time for the patient to come in and discuss the project further. In clinic, patients who assent will then be introduced to the RA by the physician after the conclusion of their appointment. The RA will then confirm the patient meets all the eligibility requirements and discuss the specifics of the study described above.

10. Risks: Describe the reasonably foreseeable risks, including risks to subject privacy, discomforts, or inconveniences associated with subjects participating in the research.

    The risk to patient privacy is no different with this study than it is with any other study that securely collects and appropriately stores personally identifiable information or protected health information.
    The Hugo application, like many other personal health records, is not a covered entity; therefore, the HIPAA privacy rule does not apply to this platform. The Hugo platform does take all necessary precautions, including industry-standard encryption, to minimize privacy and security risks to personally identifiable information stored on behalf of study participants. Hugo makes publicly available its Security Statement

(http://hugophr.com/security), its Privacy Notice (http://hugophr.com/privacy-notice), and Terms of Service (http://hugophr.com/terms-of-service/)

Participants will undergo the possible inconvenience of filling out electronic patient-reported outcome measure surveys, which should take approximately 60 minutes for the longer surveys (at baseline, 1 week, 4 weeks, and 8 weeks) and 15 minutes for the short surveys every Monday and Thursday a total of 10 times. Participants will also experience the possible inconvenience of wearing a Fitbit for extended periods of time as well as the possible inconvenience of utilizing and syncing the Kardia Mobile or Nokia Body Scale once a week. The estimated time required to sync the weight scale weekly for 8 weeks is 30 minutes, to sync the AliveCor weekly for 8 weeks is 30 minutes, and to sync the Fitbit weekly for 8 weeks is 15 minutes.

Although the Fitbit has been deemed a 'Low-Risk Device' by the FDA[7] and is therefore not deemed medical grade[8], there is the risk of inaccuracy in Heart Rate measurements. According to the Fitbit terms of service, found at www.fitbit.com/legal/terms-of-service, "The accuracy of the data collected and presented through the Fitbit Service is not intended to match that of medical devices or scientific measurement devices." The AliveCor Kardia Mobile device has been approved by the FDA as a 510k device since January 2015. In one published study of patients post-atrial fibrillation ablation that tested use of the AliveCor, only 2% of patients found it difficult to use[9]. However, as noted above, we will clearly state to the patients that this study should in no way impact their regular care plans.

11. Minimizing Risks: Describe the manner in which the above-mentioned risks will be minimized.

    All patient data will be collected, handled, and stored according the most rigorous accepted standards. Staff involved in the study will be appropriately trained to maximize data security and technical systems will meet or exceed requirements imposed by HIPAA. Sensitive information will always be encrypted in transit (using secure file transfer protocols when data is obtained at Yale from the Mayo Clinic team that is cleaning and curating the data) and at rest. Paper documents at YNHH/CORE will be scanned into and saved onto a secure server. Once documents are scanned, the original documents will be shredded using a secure document destruction service.

    The risk of inaccurate heart rate readings by Fitbit or ECG readings by AliveCor may occur by wearing or using the device improperly; the RA will show participants the best way to use these devices to minimize this risk.

12. Data and Safety Monitoring Plan: Include an appropriate Data and Safety Monitoring Plan (DSMP) based on the investigator's risk assessment stated below. (Note: the HIC will make the final determination of the risk to subjects.)
    a. What is the investigator's assessment of the overall risk level for subjects participating in this study? Minimal risk to patients
    b. If children are involved, what is the investigator's assessment of the overall risk level for the children participating in this study? No children will be involved in this study
    c. Include an appropriate Data and Safety Monitoring Plan. Examples of DSMPs are available here http://your.yale.edu/policies-procedures/forms/420-fr-01-data-and-safety-monitoring-plans-templates for
        i. Minimal risk
        ii. Greater than minimal

The principal investigators (PI) are responsible for monitoring the data, assuring protocol compliance, and conducting the safety reviews at the specified frequency regularly. During the review process the PIs will evaluate whether the study should continue unchanged, require modification/amendment, or close to enrollment.

The PIs or the Institutional Review Board (IRB) have the authority to stop or suspend the study or require modifications.

This protocol presents minimal risks to the subjects and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), including adverse events, are not anticipated. In the unlikely event that such events occur, we will follow FDA reporting guidelines (see below), followed by a written report within 5 calendar days of the PIs becoming aware of the event to the IRB (using the appropriate forms from the website) and any appropriate funding and regulatory agencies. The investigators will apprise fellow investigators and study personnel of all UPIRSOs and adverse events that occur during the conduct of this research project via email as they are reviewed by the PIs. The protocol's research monitor(s), e.g. study sponsors, funding and regulatory agencies, and regulatory and decision-making bodies, will be informed of a data breach within 5 days of the event becoming known to the PI.

We will follow the below FDA reporting guidelines, which are consistent with FDA's Medical Device Report (MDR) program.

"The reportable AEs are outlined and related to patient deaths, serious injuries and malfunctions.

(1) Submit reports of individual adverse events no later than 30 calendar days after the day that they become aware of a reportable death, serious injury, or malfunction.

(2) Submit reports of individual adverse events no later than 5 work days after the day that they become aware of:

(i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health, or

(ii) A reportable event for which FDA made a written request.

(3) Submit supplemental reports if they obtain information that they did not submit in an initial report.
MDR reportable event (or reportable event) means:
(1) An event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury or
(2) An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices:
(i) May have caused or contributed to a death or serious injury, or
(ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Serious injury means an injury or illness that:
(1) Is life-threatening,
(2) Results in permanent impairment of a body function or permanent damage to a body structure, or

(3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage."

During this study, potential device/product complaints may be identified. Thus, any potential combinations of a Johnson & Johnson device and outcome (e.g. complications, adverse events) or product complaints (any alleged deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device) will be forwarded to the appropriate company Complaint Handling Unit for standard follow up within 48 hours of the PI being made aware of the event pair. For non-Johnson & Johnson products, potential combinations of specific device brand and outcome will be reported to the product manufacturer.

PROMs and syncable data received will not be reviewed by researchers, and this fact will be made clear to study participants at enrollment. Patients will be provided with an emergency contact card at the time of enrollment (see Appendix) and informed that symptoms reported in this study are not being monitored or evaluated in real-time and that any adverse or severe symptoms should be reported directly to their implanting physician, PCP, or emergency room physicians as they would have in the normal course of their care.

d. For multi-site studies for which the Yale PI serves as the lead investigator:
   i. How will adverse events and unanticipated problems involving risks to subjects or others be reported, reviewed and managed? *Write here*
   ii. What provisions are in place for management of interim results? *Write here*
   iii. What will the multi-site process be for protocol modifications? *Write here*

13. **Statistical Considerations:** Describe the statistical analyses that support the study design.
N/A. This is a pilot study to understand feasibility of using this novel method for data collection, without any specific clinical primary outcome.

SECTION II: RESEARCH INVOLVING DRUGS, BIOLOGICS, RADIOTRACERS, PLACEBOS AND DEVICES

If this section (or one of its parts, A or B) is not applicable, check off N/A and delete the rest of the section.

A. RADIOTRACERS ☒N/A

1. Name of the radiotracer: *Write here*

2. Is the radiotracer FDA approved? ☐YES ☐NO

If NO, an FDA issued IND is required for the investigational use unless RDRC assumes oversight.

3. Check one: ☐IND# *Write here* or ☐RDRC oversight (RDRC approval will be required prior to use)

B. DRUGS/BIOLOGICS ☒N/A

1. If an **exemption from IND filing requirements is** sought for a clinical investigation of a drug product that is lawfully marketed in the United States, review the following categories and complete the category that applies (*and delete the inapplicable categories)*:

Exempt Category 1: The clinical investigation of a drug product that is lawfully marketed in the United States can be exempt from IND regulations if all of the following are yes:	
1. The intention of the investigation is NOT to report to the FDA as a well-controlled study in support of a new indication for use or to be used to support any other significant change in the labeling for the drug.	☐
2. The drug that is undergoing investigation is lawfully marketed as a prescription drug product, and the intention of the investigation is NOT to support a significant change in the advertising for the product.	☐
3. The investigation does NOT involve a route of administration or dosage level or use in populations or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product	☐
4. The investigation will be conducted in compliance with the requirements for institutional (HIC) review and with the requirements for informed consent of the FDA regulations (21 CFR Part 50 and 21 CFR Part 56).	☐
5. The investigation will be conducted in compliance with the requirements regarding promotion and charging for investigational drugs.	☐

Exempt Category 2 (all items i, ii, and iii must be checked to grant a category 2 exemption)

☐i. The clinical investigation is for an *in vitro* diagnostic biological product that involves one or more of the following (check all that apply):

- ☐ Blood grouping serum
- ☐ Reagent red blood cells
- ☐ Anti-human globulin

☐ii. The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure; and

☐iii. The diagnostic test is shipped in compliance with 21 CFR §312.160.

Exempt Category 3

☐ The drug is intended solely for tests in vitro or in laboratory research animals if shipped in accordance with 21 CFR 312.60

Exempt Category 4

☐ A clinical investigation involving use of a placebo if the investigation does not otherwise require submission of an IND.

2. **Background Information:** Provide a description of previous human use, known risks, and data addressing dosage(s), interval(s), route(s) of administration, and any other factors that might influence risks. If this is the first time this drug is being administered to humans, include relevant data on animal models.
Write here

3. **Source:** Identify the source of the drug or biologic to be used. *Write here*

a) Is the drug provided free of charge to subjects? ☐YES ☐NO
If yes, by whom? *Write here*

1. **Storage, Preparation and Use:** Describe the method of storage, preparation, stability information, and for parenteral products, method of sterilization and method of testing sterility and pyrogenicity.
Write here

Check applicable Investigational Drug Service utilized:

☐ YNHH IDS ☐ CMHC Pharmacy ☐ West Haven VA
☐ PET Center ☐ None
☐ Other:

Note: *If the YNHH IDS (or comparable service at CMHC or WHVA) will not be utilized, explain in detail how the PI will oversee these aspects of drug accountability, storage, and preparation*.

2. Use of Placebo: ☐Not applicable to this research project

If use of a placebo is planned, provide a justification which addresses the following:

a) Describe the safety and efficacy of other available therapies. If there are no other available therapies, state this. *Write here*

b) State the maximum total length of time a participant may receive placebo while on the study.
Write here
c) Address the greatest potential harm that may come to a participant as a result of receiving placebo.
Write here
d) Describe the procedures that are in place to safeguard participants receiving placebo.
Write here

3. Continuation of Drug Therapy After Study Closure ☐Not applicable to this project

Are subjects provided the opportunity to continue to receive the study drug(s) after the study has ended?

☐ Yes If yes, describe the conditions under which continued access to study drug(s) may apply as well as conditions for termination of such access. *Write here*

☐ NO If no, explain why this is acceptable. *Write here*

B. DEVICES ☒N/A

1. Are there any investigational devices used or investigational procedures performed at Yale-New Haven Hospital (YNHH) (e.g., in the YNHH Operating Room or YNHH Heart and Vascular Center)? ☐Yes ☐No

If Yes, please be aware of the following requirements:

A YNHH New Product/Trial Request Form must be completed via EPIC: Pull down the Tools tab in the EPIC Banner, Click on Lawson, Click on "Add new" under the New Technology Request Summary and fill out the forms requested including the "Initial Request Form," "Clinical Evidence Summary", and attach any other pertinent documents. Then select "save and submit" to submit your request; AND

Your request must be reviewed and approved in writing by the appropriate YNHH committee before patients/subjects may be scheduled to receive the investigational device or investigational procedure.

2. Background Information: Provide a description of previous human use, known risks, and any other factors that might influence risks. If this is the first time this device is being used in humans, include relevant data on animal models.
   Write here
3. Source:
   a) Identify the source of the device to be used. *Write here*
   b) Is the device provided free of charge to subjects? ☐Yes ☐No

4. Investigational device accountability: State how the PI, or named designee, ensures that an investigational device is used only in accordance with the research protocol approved by the HIC, and maintains control of the investigational device as follows:

   a) Maintains appropriate records, including receipt of shipment, inventory at the site, dispensation or use by each participant, and final disposition and/or the return of the investigational device (or other disposal if applicable): *Write here*

   b) Documents pertinent information assigned to the investigational device (e.g., date, quantity, batch or serial number, expiration date if applicable, and unique code number): *Write here*

   c) Stores the investigational device according to the manufacturer's recommendations with respect to temperature, humidity, lighting, and other environmental considerations: *Write here*

   d) Ensures that the device is stored in a secure area with limited access in accordance with applicable regulatory requirements: *Write here*

e) Distributes the investigational device to subjects enrolled in the IRB-approved protocol: *Write here*

SECTION III: RECRUITMENT/CONSENT AND ASSENT PROCEDURES

1. **Targeted Enrollment: Give the number of subjects:**
   a. Targeted for enrollment at Yale for this protocol: 30 Participants
   b. If this is a multi-site study, give the total number of subjects targeted across all sites: 60 Participants

2. **Indicate recruitment methods below.** Attach copies of any recruitment materials that will be used.

☐ Flyers	☐ Internet/web postings	☐ Radio
☐ Posters	☐ Mass email solicitation	☐ Telephone
☐ Letter	☐ Departmental/Center website	☐ Television
☐ Medical record review*	☐ Departmental/Center research boards	☐ Newspaper
☐ Departmental/Center newsletters	☐ Web-based clinical trial registries	☐ Clinicaltrails.gov
☐ YCCI Recruitment database	☐ Social Media (Twitter/Facebook):	
☒ Other: Attending Physician identifies that the patient is a candidate prior to the patient's final pre-operative appointment for catheter ablation of atrial fibrillation, sleeve gastrectomy, or gastric bypass.		

* Requests for medical records should be made through JDAT as described at
http://medicine.yale.edu/ycci/oncore/availableservices/datarequests/datarequests.aspx

3. **Recruitment Procedures:**

a. Describe how potential subjects will be identified.

Patients will be identified by their bariatric surgeon or electrophysiologist prior to their final pre-operative appointment. Eligible patients must be 18 years of age older, English speaking, and must be scheduled to undergo a catheter-based atrial fibrillation ablation or a bariatric surgical procedure (either sleeve gastrectomy or gastric bypass). The physician's office will then alert the RA of the potential patient the week prior to their final pre-operative clinic appointment.

b. Describe how potential subjects are contacted.

Patients will be contacted through their treating/implanting physician's office via phone around the same time that their final pre-operative appointment is confirmed by an automated system (2 days prior). At this time, the office staff will inform eligible patients that if they are interested, a research associate (RA) will be onsite the day of their appointment to discuss participating in a study looking to monitor post-procedure safety and effectiveness. Eligibility will be determined by the cardiac electrophysiologist stating that the patient is being seen pre-procedurally for catheter ablation of atrial fibrillation or the bariatric surgeon stating that the patient is being seen pre-operatively for sleeve gastrectomy or gastric bypass. On the phone call, patients will be informed that participation is optional but if they would like to learn more that they should plan to be at the office for additional time and to bring their smartphone and MyChart login information, any phone account passwords, and a recent prescription if possible (please see Appendix for script). Patients not reached will have a message left stating the same. If a patient has been deemed eligible by their treating physician but is not scheduled to be seen in office again prior to their procedure, the RA may reach out directly via phone to ask if the patient would be interested in learning more and if so, schedule time for the patient to come in and discuss the project further. In clinic, patients who assent will then be introduced to the RA by the physician after the conclusion of their appointment.

c. Who is recruiting potential subjects?
Research Associate Laura Ciaccio will recruit potential participants at YNHH. No person with any potential conflicts of interest will enroll subjects

4. Assessment of Current Health Provider Relationship for HIPAA Consideration:
Does the Investigator or any member of the research team have a direct existing clinical relationship with any potential subject?
☒Yes, all subjects
☐Yes, some of the subjects
☐No

If yes, describe the nature of this relationship.
It is possible that Dr. Akar or Dr. Roberts may have treated the patients prior to their procedure. They would only suggest that a potential patient be considered a research study participant – neither of them would recruit the patient in that circumstance to the study and care would not be impacted in any way if a patient consents or does not consent to participation in the study.

5. Request for waiver of HIPAA authorization: (When requesting a waiver of HIPAA Authorization for either the entire study, or for recruitment purposes only. Note: if you are collecting PHI as part of a phone or email screen, you must request a HIPAA waiver for recruitment purposes.)
Choose one:
☐ For entire study
☐ For recruitment/screening purposes only
☐ For inclusion of non-English speaking subject if short form is being used and there is no translated HIPAA research authorization form available on the University's HIPAA website at hipaa.yale.edu.

i. Describe why it would be impracticable to obtain the subject's authorization for use/disclosure of this data:

ii. If requesting a waiver of signed authorization, describe why it would be impracticable to obtain the subject's signed authorization for use/disclosure of this data: *Write here*

The investigator assures that the protected health information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.

Researchers are reminded that unauthorized disclosures of PHI to individuals outside of the Yale HIPAA-Covered entity must be accounted for in the "accounting for disclosures log", by subject name, purpose, date, recipients, and a description of information provided. Logs are to be forwarded to the Deputy HIPAA Privacy Officer.

6. Process of Consent/Assent: Describe the setting and conditions under which consent/assent will be obtained, including parental permission or surrogate permission and the steps taken to ensure subjects' independent decision-making.

Two days prior to the patient's final pre-operative appointment, the physician's office staff will let the patient know that their doctor has identified them as a potential participant for a research study, and that if they are

interested, a RA will be onsite the day of their appointment to discuss this research opportunity and to plan for additional time at the office. After their appointment, if the patient chooses to learn more about the study, the implanting physician will introduce the patient to the RA who will take them to a separate private area to review the consent form and discuss the participation requirements. If a patient has been deemed eligible by their treating physician but is not scheduled to be seen in office again prior to their procedure, the RA may reach out directly via phone to ask if the patient would be interested in learning more and if so, schedule time for the patient to come in and discuss the project further and, if the patient is amenable, enroll the patient into the study. The RA will then confirm that the patient meets all the eligibility criteria and is able to consent for themselves. After verbally reviewing the consent form the RA will provide the patient with a printed copy as well. They will be given the opportunity to ask any additional questions or discuss any concerns they might have and will then be ask if they would like to participate in the study. If they confirm they would like to become a study participant the patient will be asked to sign two copies of the printed consent form, one for the RA to keep on file and one for the patient to take with them. At this time, the RA collecting consent will sign both copies as well. Contact information will be highlighted on the consent in case patients have additional questions at any time. The RA will then collect the appropriate contact information from the participant including phone number, email address, planned date of procedure for in-hospital follow up and address for location to send stipend gift card (see Appendix). An enrollment note will then be completed and signed by both the RA and study participant to confirm that all aspects of enrollment and consent collection have been completed (see Appendix).

Should a potential study participant decline to enroll in the study, the RA will ask if the patient would be willing to complete a short questionnaire to collect basic demographic information and better understand why they have declined participation (see Appendix).

7. Evaluation of Subject(s) Capacity to Provide Informed Consent/Assent: Indicate how the personnel obtaining consent will assess the potential subject's ability and capacity to consent to the research being proposed.

   All consenting participants must be capable of providing informed consent in order to participate in the study. Participants who are cognitively impaired will not be eligible for the study. To participate in this study, subjects must be alert and oriented to person, time and place, and able to consent for themselves. No surrogate consents will be accepted.

8. Non-English Speaking Subjects: Explain provisions in place to ensure comprehension for research involving non-English speaking subjects. If enrollment of these subjects is anticipated, translated copies of all consent materials must be submitted for approval prior to use.

   N/A as non-English speaking people will not be asked to participate in this pilot study

As a limited alternative to the above requirement, will you use the short form* for consenting process if you unexpectedly encounter a non-English speaking individual interested in study participation and the translation of the long form is not possible prior to intended enrollment? YES ☐ NO ☐

Note* If more than 2 study participants are enrolled using a short form translated into the same language, then the full consent form should be translated into that language for use the next time a subject speaking that language is to be enrolled.

Several translated short form templates are available on the HRPP website (yale.edu/hrpp) and translated HIPAA Research Authorization Forms are available on the HIPAA website (hipaa.yale.edu). If the translation of the short

form is not available on our website, then the translated short form needs to be submitted to the IRB office for approval via modification prior to enrolling the subject. *Please review the guidance and presentation on use of the short form available on the HRPP website.*

If using a short form without a translated HIPAA Research Authorization Form, please request a HIPAA waiver in the section above.

9. Consent Waiver: In certain circumstances, the HIC may grant a waiver of signed consent, or a full waiver of consent, depending on the study. If you will request either a waiver of consent, or a waiver of signed consent for this study, complete the appropriate section below.

☒Not Requesting any consent waivers

☐Requesting a waiver of signed consent:

☐ Recruitment/Screening only *(if for recruitment, the questions in the box below will apply to recruitment activities only)*

☐ Entire Study (Note that an information sheet may be required.)

For a waiver of signed consent, address the following:

- Would the signed consent form be the only record linking the subject and the research? YES ☐ NO ☐
- Does a breach of confidentiality constitute the principal risk to subjects? YES ☐ NO ☐

OR

- Does the research pose greater than minimal risk? YES ☐ NO☐
- Does the research include any activities that would require signed consent in a non-research context? YES ☐ NO ☐

☐ Requesting a waiver of consent:

☐ Recruitment/Screening only *(if for recruitment, the questions in the box below will apply to recruitment activities only)*

☐ Entire Study

For a full waiver of consent, please address all of the following:

- Does the research pose greater than minimal risk to subjects?
  ☐ Yes *If you answered yes, stop. A waiver cannot be granted.*
  ☐ No
- Will the waiver adversely affect subjects' rights and welfare? YES ☐ NO☐
- Why would the research be impracticable to conduct without the waiver? *Write here*
- Where appropriate, how will pertinent information be returned to, or shared with subjects at a later date? *Write here*

SECTION IV: PROTECTION OF RESEARCH SUBJECTS

Confidentiality & Security of Data:

1. What protected health information (medical information along with the HIPAA identifiers) about subjects will be collected and used for the research?

   Age, gender, date of birth and several categories of health information (provider encounters, notes, medication lists, problem lists, family history, allergies, laboratory findings, procedures, immunizations, vital signs, and medical record numbers) will be collected via the Hugo application. We will also be collecting data provided and synced to the Hugo application from the wearable devices including the Fitbit Charge 2 (heart rate ambulation and sleep), Nokia Body scale (weight), and the Kardia Mobile EKG (heart rhythm). In addition, we will obtain medication data from 2 major pharmacies.

   The research associate will also access the patient's full medical record, with read-only access, within the YNHH Epic electronic medical record (EMR) system. This data will not leave the Epic EMR system in any way, and is only being used to verify certain categories of patient events to confirm that they have been included in the Hugo application. Data access to the YNHH Epic EMR will only be granted after all necessary trainings are complete and sign off is received from the Yale IRB and YNHH medical records department using the Yale New Haven Health System's Research Request for Medical Records Access form.

2. How will the research data be collected, recorded and stored?
   After obtaining consent, patients will be requested to submit data from their Hugo personal health records to the study over SSL with a minimum of 128 bit encryption. This data will initially be transferred to Mayo Clinic to a data analyst associated with this project for cleaning. All YNHH patient data will then be shared using Signiant's Media Exchange Managed File Transfer (MFT). This platform is a web-based application used to share data packages over the internet through a secure channel. When being shared, the data will be encrypted using https secure protocol (Appendix). Access to this data will only by available to study personnel at Yale and Mayo Clinic, with collaborators at the Mayo Clinic receiving their own IRB approval.

3. How will the digital data be stored? ☐CD ☐DVD ☐Flash Drive ☐Portable Hard Drive ☒Secured Server ☐Laptop Computer ☐Desktop Computer ☐Other

4. What methods and procedures will be used to safeguard the confidentiality and security of the identifiable study data and the storage media indicated above during and after the subject's participation in the study?

   All data used at Yale will be provided by the Mayo Clinic over secure channels and encrypted during sending. Data will be stored on 3-lock compliant servers within Yale or on secure, Yale-issued IronKey devices. Only study personnel directly involved in data analysis with a need to access PHI will have access to these data. Any access to de-identified data will be completed via the Yale secure network or accessed via a secure connection to the Yale VPN. Please also see the Hugo Security Statement (Appendix). The sync for science platform is a personal health record that follows the Federal Trade Commission requirements for notification.

All portable devices must contain encryption software, per University Policy 5100. If there is a technical reason a device cannot be encrypted please submit an exception request to the Information Security, Policy and Compliance Office by clicking on url http://its.yale.edu/egrc or email it.compliance@yale.edu

5. What will be done with the data when the research is completed? Are there plans to destroy the identifiable data? If yes, describe how, by whom and when identifiers will be destroyed. If no, describe how the data and/or identifiers will be secured.

   Data will be maintained on secure, encrypted servers at Yale Center for Outcomes Research and Evaluation after completion of the research study for a minimum of 5 years after publication of our findings in a peer-reviewed journal (in such case as there is a need to return to the original data source to validate a finding or respond to a question).

   After data is collected, deidentified data will be shared with collaborators, listed on the research protocol, from Johnson & Johnson. HIPAA identifiers will be removed prior to share and patients will be made aware via the consent process.

   Study participants will always have access to their health data and the ability to download their personalized health record and take it with them. They will be given access to updates of the sync for science platform. After the completion of the study, we will also make summary level findings available to participants, without any identifiable personal health information.

6. If appropriate, has a Certificate of Confidentiality been obtained*?*
Since the data obtained are from broad health characteristics from personal health records that do not target any particular sensitive research areas, a CoC has not been obtained.

SECTION V: POTENTIAL BENEFITS

Potential Benefits: Identify any benefits that may be reasonably expected to result from the research, either to the subject(s) or to society at large. (Payment of subjects is not considered a benefit in this context of the risk benefit assessment.)

Individuals who participate in this study will have access to their health data along with the choice and ability to share it with researchers. Those who choose to share their information will help create a more robust research database, will pioneer a new method for data collection that will enable researchers to continue to strive for better health outcomes, and advance the understanding of health and disease. Participants will also have the option of continuing access to their data at the end of the study, if they so wish, and receive updates to the sync for science platform. Using the provided syncable devices, participants may also gain additional awareness and information regarding their health and fitness.

SECTION VI: RESEARCH ALTERNATIVES AND ECONOMIC CONSIDERATIONS

1. Alternatives: What other alternatives are available to the study subjects outside of the research?

   The alternative to participating in the proposed study is to not participate. Participation and non-participation will have no impact on the course of treatment that the patient will receive.

2. Payments for Participation (Economic Considerations): Describe any payments that will be made to subjects, the amount and schedule of payments, and the conditions for receiving this compensation.

Patients will receive a stipend for their time contributed as part of this study. Estimated hourly stipend based on the average minimum wage in Connecticut ($10) will be provided. This stipend will cover the consent process, initial set up and baseline questionnaire (4 hrs), longer questionnaires provided at, 1-, 4-, and 8-weeks (1 hour each), short questionnaires provided every Monday and Thursday a total of 10 times (15 minutes each), along with the time it takes to sync and use the provided devices (0.5 hrs per week for AliveCor and weight scale; 0.25 hrs per week for Fitbit). The total estimated maximum time is 15.5 hours.

These payments will be made to a refillable Bank of America gift card issued and mailed to the patients via OnCore. Payments will be processed once initial set up is complete and then as each of the longer 1, 4, and 8 week questionnaires is received in conjunction with data being synced. Payments will be processed after all ten occurrences for the short questionnaires. Patients will be alerted that their name, telephone number and address will be shared with Bank of America in order to issue their card as well as be provided with the OnCore Bank of America Participant Instructions (Appendix). Patients will also be made aware that if after activation their card is lost or stolen, Bank of America will charge participants a $5 replacement fee.

Patients will be given the necessary syncable devices to keep as well. Fair market value of these devices are: Fitbit Charge 2 at $149.99; the Kardia Mobile at $99; and the Nokia Body scale at $59.99.

3. Costs for Participation (Economic Considerations): Clearly describe the subject's costs associated with participation in the research, and the interventions or procedures of the study that will be provided at no cost to subjects.

   The platform, technology, devices and apps used in this study will be provided to participants free of cost. Updates to the platform will also be provided free of cost for the duration of the study.
   Participants will still be responsible for any costs associated with routine follow ups or doctor's visits, as they would be in the normal processes of care. Participants will still be responsible for any co-pay required by their insurance company for standard treatments. Participants are responsible for data charges that may be incurred for utilizing online features of the Hugo, Fitbit, Alivecor or Nokia Health Mate mobile applications when not connected to Wi-Fi.

4. In Case of Injury: This section is required for any research involving more than minimal risk, and for minimal risk research that presents the potential for physical harm (e.g., research involving blood draws).

   a. Will medical treatment be available if research-related injury occurs? *Write here*

   b. Where and from whom may treatment be obtained? *Write here*
   c. Are there any limits to the treatment being provided? *Write here*
   d. Who will pay for this treatment? *Write here*
   e. How will the medical treatment be accessed by subjects? *Write here*

IMPORTANT REMINDERS

Will this study have a billable service? Yes ☐ No☒

A billable service is defined as any service rendered to a study subject that, if he/she was not on a study, would normally generate a bill from either Yale-New Haven Hospital or Yale Medical Group to the patient or the patient's

insurer. The service may or may not be performed by the research staff on your study, but may be provided by professionals within either Yale-New Haven Hospital or Yale Medical Group (examples include x-rays, MRIs, CT scans, specimens sent to central labs, or specimens sent to pathology). Notes: 1. There is no distinction made whether the service is paid for by the subject or their insurance (Standard of Care) or by the study's funding mechanism (Research Sponsored). 2. This generally includes new services or orders placed in EPIC for research subjects.

If answered, "yes", this study will need to be set up in OnCore, Yale's clinical research management system, for Epic to appropriately route research related charges. Please contact oncore.support@yale.edu

Are there any procedures involved in this protocol that will be performed at YNHH or one of its affiliated entities? Yes ☒ No ☐

If Yes, please answer questions a through c and note instructions below.

a. Does your YNHH privilege delineation currently include the specific procedure that you will perform? Yes ☒ No ☐

b. Will you be using any new equipment or equipment that you have not used in the past for this procedure? Yes ☐ No ☒

c. Will a novel approach using existing equipment be applied? Yes ☐ No ☒

If you answered "no" to question 4a, or "yes" to question 4b or c, please contact the YNHH Department of Physician Services (688-2615) for prior approval before commencing with your research protocol.

IMPORTANT REMINDER ABOUT RESEARCH AT YNHH

Please note that if this protocol includes Yale-New Haven Hospital patients, including patients at the HRU, the Principal Investigator and any co-investigators who are physicians or mid-level practitioners (includes PAs, APRNs, psychologists and speech pathologists) who may have direct patient contact with patients on YNHH premises must have medical staff appointment and appropriate clinical privileges at YNHH. If you are uncertain whether the study personnel meet the criteria, please telephone the Physician Services Department at 203-688-2615. By submitting this protocol as a PI, you attest that you and any co-investigator who may have patient contact has a medical staff appointment and appropriate clinical privileges at YNHH.

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9. Tarakji KG, Wazni OM, Callahan T, et al. Using a Novel Wireless System for Monitoring Patients After the Atrial Fibrillation Ablation Procedure: The iTransmit Study. Heart rhythm 2015;**12**(3):554-59.