

Framingham Heart Study

Manual of Procedures

MOP-version 1.0

November 14, 2018

Offsite Visit

Generation 3, Omni 2, NOS Cohorts Examination 3

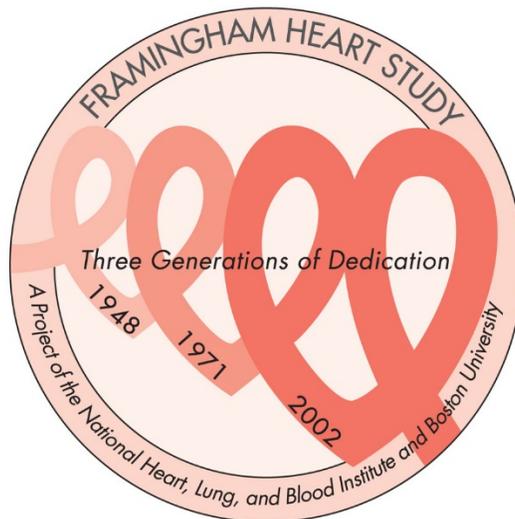


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1.0 Gen 3 Exam 3 Components-Offsite

Section I: Informed Consent & Tracking Procedures

- 1) Consent
- 2) HIPPA - Release of Health Information for Research Purposes
- 3) Admitting Form
- 4) Research Proxy

Section II: Lab

Section III: Clinical Measurements & Procedures

- 1) **Anthropometrics**
 - a. Weight
 - b. Waist
 - c. Hip
- 2) **ECG**
 - a. ECG
- 3) **Observed Physical Performance**
 - a. Hand Grip Test

Section IV: Tech-Administered Questionnaires

- 1) **Cognitive Function**
 - a. Cerad/Stroop
 - b. AD8
 - c. Moca
- 2) **Physical Function**
 - a. PAI
 - b. Rosow-Breslau
 - c. Physical Activities
 - d. Respiratory Questionnaire
- 3) **Depressive Symptoms**
 - a. CES-D

Section V: NP-Administered Medical History and Physical Exam

- 1) Medical History
- 2) Resting Blood Pressure

Section VI: Self-Administered Questionnaires

- 1) Socio-demographics
- 2) SF12 Health Survey
- 3) Bleeding Questionnaire

Section VII: Ancillary Studies

- 1) Physical Activity Monitor
- 2) Microbiome Study
- 3) eFHS

Section VIII: Exam Completeness

- 1) Check MD and Tech Completeness
- 2) Exit Interview

1.1 Exam Consent Form

A copy of the electronic informed consent form administered by REDCap follows this page.

A03 - Exam Consent Form

FHS_IDTYPE_ID _____

Name: [firstname] [lastname] FHS ID: [fhs_idtype_id]

Framingham Heart Study

Group 3 Exam 3

RESEARCH CONSENT FORM

Welcome back to the Framingham Heart Study

Together we are helping to fight heart disease and other major diseases and health conditions through research.

Why is the research study being done?

The Framingham Heart Study is a long term research study. The purpose of the study is:

- (1) To help understand how heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other major diseases and health conditions develop; and
- (2) To examine DNA and its relationship to the risks of developing these diseases and other health conditions.

The research examination that will be conducted as part of this study is not clinical care. The tests are for research purposes only. We do not provide medical services. This research examination does not take the place of medical care by your own health care provider.

About your consent

Please read this research consent form carefully. It tells you important information about the research study. Taking part in a research study is voluntary. The decision whether or not to take part in all or any part of the research exam is entirely up to you. If you choose to take part, you can decide to stop at any time. Your decision will be honored and respected. There will be no penalty to you if you decide to stop or not to take part.

If I have questions or concerns about this research study, whom can I call?

If you have any questions about the research or about this form, please ask us. You can call us with your questions or concerns. You can ask questions as often as you want.

You can call a study staff member directly at (508) 872-6562, or you can send an email to FHS@bu.edu.

The Framingham Heart Study is led by investigators from Boston University and the National, Heart, Lung, and Blood Institute at the National Institutes of Health. Dr. Vasan S Ramachandran and Dr. Daniel Levy are in charge of the research study. You can contact Dr. Ramachandran at (617) 638-8090 Monday to Friday between 9am and 5pm or by email at vasan@bu.edu and Dr. Levy at (508) 935-3400 Monday to Friday between 9am and 5pm or by email at levyd@nih.gov.

If you want to speak to someone not directly involved in the research study, please contact the Boston University Medical Campus (BUMC) Institutional Review Board at (617) 638-7207.

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Name: [firstname] [lastname] FHS ID: [fhs_idtype_id]

What will happen in this research exam?

You will need to fast for 12 hours before you come to the study appointment for the blood draw. You can take your usual morning medication and drink water on the morning of your visit.

Your research examination will take place at the FHS Research Center at 73 Mount Wayte Avenue, Framingham, MA, or in your home or other residence. The onsite research exam will take around 4 hours to complete.

As before, we will

- draw a sample of blood for genetic and laboratory tests to better understand risk factors for heart disease and other diseases under investigation (for example, the amount and function of different types of cholesterol in your blood). The total blood draw will be around 120 mL, which is about 8 tablespoons. The blood draw will occur in two stages. The first blood draw soon after your arrival and the second blood draw after the Cardiopulmonary Fitness Evaluation.
- collect a urine sample
- measure your height and weight
- complete an electrocardiogram (ECG)
- record your blood pressure
- update your medical history information
- complete a test of vascular function that tests blood vessel (artery) stiffness by recording the blood pressure waveform
- ask you to sign a form to allow FHS to obtain copies of medical records, including Medicare records. The release form is valid to obtain these records unless canceled by you.
- contact you later by mail, email, or by phone to obtain additional information or to invite you to participate in further FHS related studies. You may also be invited to return for another examination in the future.

Surveys

We will also be asking you to complete questionnaires such as physical function, diet, exercise, memory and mood, and your lifestyle habits, including whether you smoke or use alcohol. Some of the questionnaires you will have seen before and others will be new to you.

Some of your responses will be recorded using a digital audio recorder. Recordings will be analyzed in conjunction with other study information. We will also use recordings to make sure that your responses are accurately documented.

There are some new research activities.

1. **Cardiopulmonary Fitness Evaluation:** The Cardiopulmonary Fitness Evaluation is designed to find out the efficiency of your heart, lungs, and circulation of blood. We will ask you to exercise on a stationary cycle while you are attached to machines that will record your breathing and heart function. We will ask you to pedal the cycle for as long as you are able. While you are pedaling you will breathe into a tube that will collect and measure the air you breathe in and out. Your heart rate and blood pressure will be watched throughout this activity. We will monitor your heart rate using an electrocardiogram (ECG) by placing small stick-on pads to your skin. This test will take about 30 minutes in total, with about 10-15 minutes spent actually exercising. At the end of this test, a blood sample of around 25 mL, or 2 tablespoons, will be drawn.

What risks can I expect? As with any moderate exercise you will become tired and short of breath; this is normal. It is likely that your heart rate and blood pressure will increase. In rare instances, abnormal changes may occur such as fainting, irregular heart beat and low blood pressure. In very rare instances heart attack may occur as in any other strenuous activity. Every effort will be made to minimize any possible problem by constant surveillance during testing as well as the ability to stop the tests at any time. Equipment and trained personnel are available to deal with unusual situations, should they arise.

Minimal bruising, pain, bleeding, or in rare circumstances, infection may occur, as a result of the blood draw. Also, although rare, some people feel lightheaded or faint when their blood is drawn.

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2. Bone Study: High Resolution-Peripheral Quantitative Computed Tomography bone scan of the forearm and lower leg: While seated, we will place your forearm on a support and then place it inside the machine to take the scan. When we have completed the scan of your arm, we will do the same with your lower leg. It is important that you remain as still as possible for this scan. Dual-energy x-ray absorptiometry scan of the hip and the whole body: This scan involves lying on a padded table and having the machine pass over and scan your hip and your entire body.

What risks can I expect? Having bone density tests involve the use of X-rays, which are a form of radiation. However, the radiation that you will be exposed to as part of this study is so small that there is no significant risk to your health.

Due to potential risk to the fetus, pregnant women, as determined by self-report or by a positive pregnancy test, will be excluded from this test.

3. Desktop AGE Reader (Skin Test): This test measures the amount of a special type of collagen in the skin of your forearm that can be affected by levels of blood sugar. The amount of the special type of collagen in the skin is related to the amount in the bone. We will clean your arm with a wet wipe. You will then place your bare forearm on the reader and it will shine a light on your skin to perform the measurement.

What risks can I expect? There are no known risks associated with the skin reader.

4. Fibroscan: The fibroscan is a test to measure the presence of fat or scarring in the liver. A painless pulse is generated on your skin that travels to the liver and measures how stiff your liver is.

What risks can I expect? There may be minor discomfort from the application of lubricating jelly and pressure on the skin from the fibroscan probe. However, there are no known risks associated with the fibroscan.

There are some conditions that may interfere with the ability of the device to obtain valid measures. They include being pregnant, having fluid in the abdominal cavity (ascites), and having implanted medical devices, such as a heart pacemaker. We will ask, but please let us know if you have any of these conditions and we will not complete the fibroscan.

5. Additional Medical Record Release for Medicare Using Social Security Numbers :

You will be asked if investigators and their research collaborators at other institutions, including Duke University, may link your Social Security Number to the Center for Medicare & Medicaid Services data to obtain Medicare information. Social Security Numbers will not be released to outside institutions for purposes not related to the study except with consent or as required by law.

What risks can I expect? We do our best to protect your study information (see below). However there is still a risk of loss of confidentiality.

Take home tests:

6. Electronic FHS (eFHS) Study: If you live in the US, have an email account with access to a daily Internet connection or have a smartphone, we will invite you to take part in the eFHS study. Taking part requires that you download apps and use wireless devices. The apps will require you to complete surveys regarding lifestyle and health, and the devices will measure heart rate, blood pressure, weight, and physical activity.

What risks can I expect? There are no known risks to taking part in this study.

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7. Stool Sample Collection: We will ask you if you would like to use a kit to collect a stool sample at home and then to send the sample by mail to a laboratory. The purpose of this study is to better understand the causes of cardiovascular disease and diabetes, by studying what bacteria are present in your gut, and what biological functions they are performing. The take home kit contains instructions and supplies for the stool collection. The kit also contains a sheet with a few questions about how you have been feeling recently, the foods you have been recently eating and the appearance of your stool.

What risks can I expect? The stool sample collection is inconvenient and might make you feel uncomfortable. You may also be uncomfortable answering some of the questions we ask you in the questionnaire that goes with your stool collection kit. You may choose to not answer any questions that you do not feel comfortable answering. Your answers will be kept confidential and will not be associated with your name or personal identifying information.

8. Accelerometer: You will be asked to wear a physical activity monitor on a belt for a week and to return it to FHS. It measures how active you are throughout the day.

What risks can I expect? There are no known risks to taking part in this study.

General Risks: The research exam is time consuming and repetitive. Other discomforts include headaches, feeling hungry due to fasting, fatigue and chill during the visit. We do not expect any risk of injury as a result of your participation in the study. However, first aid will be available.

Unknown Risks: There may also be some risks that we are unable to determine at this time.

Genetic Studies

We plan to do genetic research on the DNA from your biological samples. The biological samples include blood cells, tissue cells, stool samples, etc. DNA is the material that makes up your genes. Genes are passed from parent to child. All living things are made of cells. Genes are the part of cells that contain the instructions which tell our bodies how to grow and work and determine physical characteristics such as hair and eye color.

Also, if you agree, we will process white blood cells from a sample of your blood to become stem cells in the laboratory. The resulting cells are known as Induced Pluripotent Stem Cells (iPS cells), and they will be used in the laboratory to act like cells from other organs, such as liver cells, fat cells, heart cells, lung cells, vascular cells, gut cells, nerve cells, different types of blood cells, and many other engineered or naturally occurring cell types. These cells and the cell products that can be obtained from them such as RNA, proteins, and metabolites may be studied in laboratories to learn more about the causes of health and diseases of these organs.

Your cells will be stored indefinitely in a stem cell repository at Boston University. Your cells may also be stored in a central repository or bank.

If you agree, your stored tissues, cells and any resulting iPS cell lines or their derivatives could be used in future related and unrelated research studies including:

- Injecting or transplanting the stem cells or their derivatives into animals for research purposes. Your samples may be used in research that involves genetic manipulation but they will not be used to clone or to otherwise create an entire human being.
- Testing for genetic and DNA composition. Genes may be analyzed and/or manipulated to study normal function or development, and some of the DNA in the stem cells or their derivatives may be altered.
- Other uses involving research or development of commercial products for the diagnosis, prevention, or treatment of various diseases.
- Samples (blood cells, the iPS cells, or their derivatives) obtained from you in this study may be used in the development of one or more diagnostic or therapeutic products which could be patented and licensed by those involved in the research or development of such products. There are no plans to provide financial compensation to you should this occur.

How will I learn the results of this study?

The main way results of research from this study are reported is in scientific publications and presentations at scientific meetings. Summary findings are also sometimes described in our newsletters.

We will also report some routine research test measurements to you and/or your health care provider at the time of the exam or after your visit. These may include, for example, blood pressure and cholesterol.

In some cases, if we determine it to be appropriate, we may report to you and/or your health care provider research findings as they relate to you, if you give your permission. This information, if it is reported, might be reported long after your visit for a number of reasons. As an example, it might take years of work to analyze information and arrive at research findings, possibly using newly developed scientific methods.

Name: [firstname] [lastname] FHS ID: [fhs_idtype_id]

Our genetic research might generate findings that could be relevant to you and possibly your family members, such as information about a particular genetic variant that might put you at risk of a serious health condition. At this time, we believe that most of the genetic research findings do not have medical importance to individuals, but the field of genetics is changing rapidly.

We currently do not have specific plans to contact you or your health care provider about genetic or non-genetic research findings other than some routine research test measurements. In general, we cannot commit to providing any other research findings to you. In determining whether we share additional research information with you, we will take into account a number of considerations on a case-by-case basis. These might include whether the findings were based on tests that are clinically acceptable, accurate and reliable, whether the findings reveal a significant risk of a serious health condition, whether there is at the relevant time a recognized treatment or prevention intervention or other available actions that have the potential to change the clinical course of the health condition, whether reporting or not reporting the results is likely to increase the risk of harm to you, and other relevant factors that we might not be able to predict at this time.

Research test measurements and findings are not the same as clinical test results. As such, our research examination is not necessarily performed by individuals with clinical training and qualifications, and many parts of the examination do not meet the standards for certified clinical testing. For these reasons, our research tests should not be relied on to make any diagnosis, treatment, or health planning decisions. We do not provide health care or give medical advice or genetic testing or provide counseling. If you or your health care provider decides that follow-up tests or treatments are necessary, then you (or a third party such as a health insurance carrier or Medicare) will be responsible for the cost.

How are my samples and information shared with other researchers?

Samples and information will be kept indefinitely. If you agree, your data and donated blood, blood cells, resulting iPS cells or their derivatives, urine, nose cells, and any other specimens may be shared with other researchers. These include other academic, non-profit, and for-profit entities, including but not limited to hospitals, universities, cell/tissue storage banks and repositories, databanks and data repositories, and businesses, whether for related or unrelated research studies. They will not be labeled with your name or other direct personal identifiers, only a code.

Coded audio recording information will be analyzed by qualifying collaborators inside and outside of BUMC. Your name and other direct personal identifiers will not be shared with these entities.

You have the right to refuse to allow your data and samples to be used or shared for further research. Please check the appropriate box in the selection below.

If you give your permission to allow your data and biological samples to be used or shared for further research, you may withdraw your permission at any time by contacting the FHS investigators. However, if your data or samples have already been released to other researchers, we will not be able to instruct the other researchers to stop using them, to destroy them or products made from them. Your data and samples will not include your name or other direct identifiers.

What risks can I expect?

Participating in genetic research could have a negative impact on you, your family, and your loved ones. The genetic studies might result in research findings that relate to your risk of a serious health condition or other genetic information that we might consider to be appropriate to report to you and your health care provider, if you wish us to report them (see below). This could present you with some difficult decisions regarding the available information and the disease risks you and your family members might face. Knowledge of genetic research findings can provoke anxiety and influence decisions regarding marriage, family planning, and other matters.

How is my information protected?

We take steps to make sure that the personal information we collect about you is kept private and secure. We label your samples and information with a code, and we keep the key to the code in a password protected database. Only approved staff is given the password. We use other safeguards at our facilities and for our information technology and systems to protect the privacy and security of your information. We do not sell, rent, or lease your contact information.

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Name: [firstname] [lastname] FHS ID: [fhs_idtype_id]

If information from this study is published or presented at scientific meetings, and when your samples and information are shared with other researchers and deposited in data and specimen banks and repositories, your name and other direct personal identifiers will not be used.

However, we cannot guarantee total privacy. We may give access to your information in order to do the study and to make sure we do the study according to certain standards set by ethics, law, and quality groups. Information may be made available to researchers that are part of this study, the Institutional Review Board that oversees this research, research and non-research staff and organizations who need the information to do their jobs for the conduct and oversight of the study, people or groups that we hire to do work for us (such as data or biosample storage companies, insurers, and lawyers), and Federal and state agencies as required by law or if they are involved in the research or its oversight. In most cases, any information that is given out to others is identified by code and not with your name or other direct personal identifiers. Once information is given to outside parties, we cannot promise that it will be kept private. Please be aware that your personal information may be given out if required by law (e.g., to prevent possible injury to yourself or others).

To help us further protect your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer or employer learns of your participation, and obtains your consent to receive research information, then FHS is not allowed to use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the Certificate of Confidentiality does not prevent the investigators from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Patenting Discoveries

Research from this study may, one day, result in new tests to diagnose or predict diseases. It may also lead to the development of new ways to prevent or treat diseases. As is true of all federally-funded research, researchers and their employers are permitted by Federal law to patent discoveries from which they may gain financially. You and your heirs will not benefit financially.

What are the possible benefits from being in this research study?

You will not be paid for your participation in this study, and you will not receive any personal health benefits as a result of your participation in this study. We hope that this study will help us better understand what causes heart disease and other diseases and conditions and how to better prevent and treat them.

What are the costs of taking part in the study?

Costs that you may incur on the day of your participation include, but are not limited to, loss of work and transportation costs (gas, tolls, etc.).

No special arrangement will be made by the Framingham Heart Study for compensation or payment solely because of your participation in this study. If you think you have been injured by being in this study, please let the investigators know right away. Boston University and the sponsors do not offer a program to provide compensation for the cost of care for research related injury or other expenses such as lost wages, disability, pain, or discomfort. You will be sent a bill for the medical care you receive for research injury if your medical insurance does not pay for your medical care. This does not waive any of your legal rights.

How long will I be in the study?

FHS is a long term study.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

The investigator may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

Name: [firstname] [lastname] FHS ID: [fhs_idtype_id]

Please check the appropriate box for each of the following statements:

1) I agree to participate in the FHS examination, including the collection of data, blood, urine samples, and various research tests and measurements. I agree to the use of all data, samples, and research materials for studies of the factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other diseases and health conditions.
(code0)

Yes No

2) I agree to allow Induced Pluripotent Stem Cells (iPS cells) to be made from my blood and altered so that they function like cells from other organs.

(code13)

Yes No

3) I agree to allow my data, blood, DNA and other genetic material, iPS cells and their derivatives, urine samples, and any other specimens to be used in genetic research, of factors contributing to heart and blood vessel diseases, lung and blood diseases, stroke, memory loss, cancer, and other diseases and health conditions.

(code3)

Yes No

4) I agree to allow researchers from commercial companies to have access to my data, blood, DNA and other genetic material, iPS cells and their derivatives, urine samples, and any other specimens for research. I understand that my data and specimens will be shared without my name or direct personal identifiers.

(code4)

Yes No

5) I agree to allow the FHS to release the findings of non-genetic research tests and examinations to me and/or my physician, clinic, hospital, or other health care provider.

(code30)

Yes No

6) I agree to allow the FHS to provide me, and with my permission, my physician, clinic, hospital, or other health care provider information relating to genetic research findings as they may relate to me.

(code31)

Yes No

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Name: [firstname] [lastname] FHS ID: [fhs_idtype_id]

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Participants Signature

(Participants Signature)

Consent date

Legally Authorized Representative (LAR)s Signature

(LAR Signature)

Consent date (LAR)

Person Obtaining Consent Signature

- 19 - Emily Manders 556 - Patrice Sutherland
 - 701 - Maureen Valentino
 - 718 - Barbara Inglese
 - 725 - Paulina Drummond
 - 778 - Mary Hogan 788 - Christine Hess
 - 794 - Deb McCoin 857 - Maria Barry
 - 865 - Ayesha Chowhan
 - 866 - Danette Carroll
 - 867 - Donna Magnanti
 - 868 - Miyoshi Holden
 - 869 - Melissa Poplaski
 - 870 - Caitlin Vachon
 - 871 - Amy Curry 886 - Lindsay Clayson
 - 908 - Tarikwa Leveille
 - 916 - Jared Zucker 924 - Christopher McDonough
- (Use dropdown for your Tech ID)

Consent date (Witness)

Comments for consents

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2.0 Scheduling Offsite Visits

Before making a call, check the roster.

- On the main screen, check the comment line and Consent Status and date.
- Check the Referral screen (F14) for additional comments.
- Check the Booking screen for scheduled exams and exam history; check the roster screen for the participant's age.

The core exam takes priority over ancillary study appointments and should be scheduled first. If, however, a participant has been seen recently or is scheduled for another appointment, wait several months before trying to schedule the appointment.

After an appointment has been scheduled, the Coordinator will update the roster, email the schedule to the offsite email list (changes depending on cohort).

Staff may call a participant directly to schedule an offsite appointment if:

- (1) There is no notation of cognitive impairment (*COG IMP* on the comment line or the referral screen)
- (2) Consent Status is less than 3
- (3) There are no comments regarding severe hearing loss or speech difficulties

A. Home Visits

If the Coordinator calls the participant directly because these conditions do not apply, but then has questions about the participant's cognitive status, the Coordinator should call the designated proxy or family member before scheduling. If the contact person denies any problems and says the participant is capable of answering questions and signing consent forms, ask the contact if he or she would be willing to provide additional information if necessary after the exam.

If any of the above cognitive issues are noted, call the participant's designated FHS Proxy or family member first to determine if a Home Visit is feasible. If unable to reach any contacts (telephones disconnected, etc.), check the participant's admitting/interview form from previous exams and/or any recent medical records in the chart to see who is listed as the responsible party or next of kin.

B. Nursing Home Visits

If there is no cognitive impairment noted in the roster, the Coordinator may call the nursing home, identifying herself as a Framingham Heart Study staff member, and ask to speak to the nurse in charge of the care of the participant. When speaking with the nurse, explain why you are calling, what the visit will entail, determine what the best time to visit would be, and then schedule an appointment. As a courtesy, call the participant's proxy or a listed contact, starting with the spouse (unless there are instructions to the contrary on the roster) to inform her/him that we will be going to the nursing home; this person or another family member may wish to be present at the exam.

If the nursing home staff member says the participant is too ill for a visit and/or has had serious medical events since our last visit or health update, the Coordinator may call a family member for details concerning the participant's condition and ask again about visiting. If the contact also refuses, ask if he/she will complete a telephone health update, using the Medical History Update form.

If a recruiter is told by the nursing home that the participant has died since the Heart Study's last visit or health update, she/he will complete a Death Information Form for the Participant Coordinator, who will immediately update the Roster, and give copies to the relevant staff members. If the nursing home can't or won't provide the information needed and the death occurred at least several months ago, the Coordinator may call the proxy or family member for information.

2.1 SCHEDULING OFFSITE APPOINTMENTS

1. Schedule appointment with a participant.
2. Put appointment into a) Roster, b) Referral, c) Booking screens.

ROSTER SCREEN

1. Change survival date to the date participant is contacted.
2. Indicate on comment line the month/year the appointment is booked, the date of the appointment and HV or NHV (home visit or nursing home visit), i.e. 7/18 scd 9/23 HV
3. If the appointment is canceled these fields should be updated. (Survival date is ONLY changed if you speak with participant.) The comment line should indicate (cx) i.e. 7/18scd9/23cx HV
At the time the appointment is rescheduled, this should be added to the comment line.

REFERRAL SCREEN

The appropriate referral code should be indicated (see the drop down menu), i.e. 61=home visit, 69=nursing home visit.

BOOKING SCREEN

1. Click on new record at the bottom of booking screen.
2. **EDATE/TIME:** Put in Full Date 12/20/2013 space then time (military time) 13:30 (1:30pm).
3. **EXAM:** Put in current exam #, i.e. 9, etc.
4. **EXAM TYPE:** =11 Nursing Home/Home visit.
5. **EXAM STAT:** is either current or canceled.
6. **EXAM LOCATION:** e.g. home or nursing home.
7. **CONFIDENTIAL COMMENT:** can be removed if not pertaining to current exam. These comments are carried over from previous exams.
8. **RESCHEDULED:** Number of cancellations. If an appointment is a reschedule it should also be written on the comment line, as well as the number of reschedules, i.e. resched x3.
9. **COMMENT LINES:** This area is where you can put comments that are important to person doing the home visit, such as speech issues, wheel chair, etc. Be sensitive to the fact that these comments will print on the schedule and they carry over from previous exams. If there is a different address than the one indicated in their PTS, it should be indicated here.
10. **BOOKER:** Put scheduler initials and then click on update at bottom of screen. If the initials are not entered it will not save, and you will not be able to print appointment letter.

PRINTING SCHEDULES - CRYSTAL REPORTS

1. Under PTS - Recruiting.
2. Click on book_off.rpt.
3. Put in Date, click OK twice.
4. Print from printer icon on side.
5. Be sure to **log off** when finished.

CRYSTAL REPORT TO PRINT CALL BACK LIST

1. Click on ccallbackrpt.
2. Enter ID type, e.g. 1 for Offspring, and also Referral Code you are requesting, i.e. 39 or 31.
3. Then click OK and print.
4. Again, **log off** when finished.

3.0 Preparation for an Off-site Examination

A. Supplies

The following supplies should be brought with you on an offsite visit:

Android Tablet and Charger

1 Portable EKG machine

1 Portable EKG acquisition module

2 Packs of EKG electrodes

1 Heart square

1 Cosmetic Pencil

Alcohol wipes

Gauze

Adhesive remover pads

3 Blood pressure cuffs; large adult, adult and pediatric (Latex Free)

1 Pocket Aneroid Sphygmomanometer

1 Littman Classic II Stethoscope

1 Portable scale

Response sheets for participant

1 JAMAR dynamometer

1 Stopwatch

1 Tape measure

B. Preparation

On the day of the scheduled Heart Study visit it is best to call the participant to confirm the appointment. Instruct the participant that he/she should wear a top that easily opens in the front to facilitate the ECG and remind them to have any available medications they take. With their confirmation letter, a form is included that helps to summarize their medical history since their last exam. Ask them to have this form ready.

Take only current exam paperwork to the exam and leave the last exam folder and all of the originals at FHS. Originals should never leave the FHS building. Photocopies are made of all of the forms needed and will put them in the chart.

C. Refer to Checklists before, during and after the exam.

4.0 Medical History

The date of the participant's last exam and the date of the participant's last health history update will be pre-printed at the top of the medical history form. A health status page will be attached to the medical history form listing medical encounters reported by the participant on the health history update form. The forms from the participant's last examination are also provided in a folder behind the current medical history form. The medical history taken from the participant is an update from the Heart Study's last contact with the participant (based on the date of the last Health History Update or last examination). The examiner should also refer to the Summary of Findings form in the participant's chart to verify whether a medical encounter is new or has already been identified. This form records the outcome of all Endpoint reviews and therefore documents all cardiovascular disease events adjudicated by the study.

The health status page may have incomplete data on medical encounters. Be sure to clarify any missing information and record it under medical encounters on the first page of the medical history form.

Medical History Form

1st Examiner Prefix

(0=MD, 1=Tech, for OFFSITE visit)

Note: zero is in as a default, for OFFSITE visits, slash the zero out and write in 1 for Tech

Hospitalization in interim

A hospitalization is considered an overnight stay.

If the participant was in the Emergency Room (E.R.) and then admitted, the event would be considered only for hospitalization and not as E.R. visit.

E.R. visit in interim

An emergency room visit is when the person is both admitted to and discharged from the emergency room the same day.

Day surgery in interim

Day surgery is a surgical procedure performed on an out-patient basis either in an ambulatory surgery department of a hospital or in a physician's office.

The person is in and out the same day.

Major illness with visit to the doctor in interim

Illness with visit to physician is defined as a visit outside of a regular check-up. It can be further clarified by defining it as a visit to the doctor for a specific reason. It is imperative that the reason for the visit be documented.

Check-up in interim by doctor

A check-up is considered to be a routine visit.

Details of all hospitalizations, ER visits, day surgery, and physician visits must be provided as follows:

- A. Medical Encounter
Write the details about the medical event. If the participant cannot provide a “medical condition”, symptoms leading to the medical encounter should be listed (for example, chest pain, shortness of breath).
- B. Month/Year
Record the date of the medical encounter. People often cannot recall the exact month or even the year. Trying to couple the event with a season or holiday sometimes helps.
- C. Site of the hospital or office
The hospital and the city and state are most important.
- D. Doctor
Record the name of the physician seen. If the participant sees a physician’s assistant or a nurse practitioner in the physician’s office, obtain both names.

Note: If FHS needs outside hospital records, please obtain details: mo/yr, hospital site.

Medical History – Prescription and Non-Prescription Medication

On home visits, the participant is asked to show the medical technician his/her medication bottles including over-the counter preparations. In the case of a nursing home visit, the technician should record the medications from the participant's medication orders in their nursing home chart.

Copy the name of the medication, the strength including units, and the total number of doses per day/week/month. Include pills, skin patches, eye drops, creams, salves, injections. Include herbal, alternative, and soy-based preparations.

Print the medication name, strength, number per day/week/month, and if taken PRN.

*****List ONLY medications taken regularly in the past month/ongoing medications*****

Medical History

The physician or off-site medical technician will obtain an interim medical history using the standardized exam 9 form. The questions should be asked exactly as written on the form and the participant's response recorded according to the response choices provided on the form. In addition a comment area is provided on the form to record a narrative account of cardiovascular symptoms including chest pain, shortness of breath, syncope, exertional leg discomfort and cerebrovascular symptoms. It is critical that a narrative be provided to clarify the symptoms for investigators adjudicating events in Endpoint Review.

It is also critical to record all health care visits (physician, ER, hospital) the participant has had for the symptom. Outside medical records will be obtained to verify the participant's account of their medical condition.

Additional instructions for obtaining the medical history and properly coding the participant's responses are as follows.

Chest pain (screen MD13)

When the participant states that they have not experienced any chest discomfort, clarify further using the terms *chest pain*, *chest tightness*, *chest pressure*.

If the participant states that they never used Nitroglycerin as a way to relieve the discomfort be sure to code as 8= not tried, rather than 0= no relief.

Alcohol Consumption (screen MD09)

Code number of alcoholic beverages as EITHER weekly **OR** monthly as appropriate.

Cerebrovascular, Neurological and Venous Diseases (screen MD15)

It is important to stress that these CVA symptoms are **sudden**, not a gradual progression of a symptom.

1. Sudden Muscular Weakness
*Since (date of last FHS exam) until today, have you experienced any **sudden** muscular weakness? For example, face drooping or weakness, particularly on one side of your body.*
2. Sudden Speech Difficulty
*Since (date of last FHS exam) until today, have you experienced any **sudden** difficulty with your speech such as understanding spoken words or trouble speaking?*
3. Sudden Visual Defect
*Since (date of last FHS exam) until today, have you experienced any **sudden** visual defect?*
4. Sudden Double Vision

Since (date of last FHS exam) until today, have you experienced any double vision?

5. Sudden Loss of Vision in One Eye

*Since (date of last FHS exam) until today, have you experienced any **sudden** loss of vision in one eye, like a shade coming down over your eye?*

6. Sudden Numbness, Tingling

Since (date of last FHS exam) until today, have you experienced any numbness or tingling on one side of your face or one side of your body?

If the participant answers yes, ask is numbness and tingling positional?

CVD Procedures (screen MD17)

The participant is queried regarding CVD procedures since the last Heart Study contact.

If the participant has had more than one procedure of a particular type code only the first procedure and list all other procedures in the comment section.

Clarify the procedure list for the participant as follows:

Heart valvular surgery

Have you had surgery on your heart valves?

Exercise tolerance test

Have you had an exercise stress test or a treadmill test of your heart?

Coronary Arteriogram

This test is an invasive test done in the hospital. An x-ray is taken of your arteries after you receive an injection of a dye that outlines the blood vessels of your heart.

Coronary artery angioplasty/stent/PCI

Angioplasty is a procedure in which a balloon is used to open a narrowed or blocked artery in your heart. (This is also known as Percutaneous Coronary Intervention (PCI)).

A stent is a wire mesh tube that is placed in the artery to hold it open. The stent is usually placed in the artery during angioplasty.

Coronary bypass surgery

Have you had bypass surgery also known as CABG (coronary artery bypass grafting)? During bypass surgery the diseased section of your coronary arteries are bypassed with a healthy artery or a vein in order to increase blood flow to your heart muscle.

Permanent pacemaker insertion

Have you had a pacemaker inserted? A pacemaker is used to replace the function of the natural pacemaker in your heart when your heart is beating too slowly. Permanent pacemakers are surgically placed into the chest through a small incision.

AICD

This stands for Automatic Implantable Cardiac Defibrillator (AICD) and is a device that is implanted under the skin of the chest to analyze the rhythm of your heart and discharges an electrical shock if a serious irregularity is detected.

Carotid artery surgery/stent

The carotid artery is located in your neck and carries blood and oxygen to your brain. Carotid artery surgery is a surgical procedure to restore adequate blood flow to your brain. A stent is inserted into the carotid artery to open a narrowed or blocked area of the artery to help maintain an adequate blood flow to the brain.

Thoracic aorta surgery

Have you had surgery on your aorta- the large blood vessel coming from your heart? This surgery is done to repair the aorta for example when there is an aneurysm (a weakening or bulge in the wall of the aorta) .

Abdominal aorta surgery/stent

Have you had surgery on the large blood vessel in your abdomen (belly) called the aorta? This surgery would be done to repair a problem such as an aneurysm (weakening or bulge in the wall of the artery) or blockage in the aorta.

Femoral or lower extremity surgery/stent/angioplasty

Have you had any surgery to improve the circulation in your legs such as bypass surgery or angioplasty?

Lower extremity amputation

Have you had an amputation of part of your leg or foot?

Other cardiovascular procedures (write in)

Have you had any other tests or procedures on your heart or blood vessels?

For Offsite visits a technician will complete the physician medical history portion of the exam. The form will then be reviewed and completed by a physician. ALL physicians will be asked to share in this responsibility during their assigned clinic time. The physician chart review includes the following:

1. Review the physician exam form and complete all physician opinions regarding endpoints (AP, MI, CI, CHF, stroke, syncope, and IC) based upon the coded and written narratives the technician obtained at the time of the visit.
2. Code the ECG. The MD ECG reading should be added to the letter to the personal physician.
3. Complete the "clinical diagnostic impression"
3. Review the letter to the personal physician making any deletions/additions/changes in medical terminology that are required.
4. Return the chart the SAME day to the technician or the clinic tech at the board in clinic.

NOTE: The area entitled "Examiner's Opinion" at the bottom of every page is not to be completed by the medical technician but by the physician reviewing the chart in clinic. The medical technician does not perform a physical exam. Therefore, the physical exam portion of the medical history form will be left blank on offsite visit.

5.0 Blood Pressure Measurement & Maximum Inflation Level

A. Equipment:

1. One standard Litman stethoscope tubing and earpieces with bell: Classic II 3M
2. One standard mercury column sphygmomanometer: Baumanometer (clinic)
3. Aneroid sphygmomanometer (offsite)
4. BP cuffs in four sizes (all Latex free)
 - Thigh adult cuff
 - Large adult cuff
 - Regular adult cuff
 - Pediatric cuff

B. Blood Pressure Cuff Placement:

1. Bare participant's left arm to above the point of the shoulder.
2. Determine correct cuff size using guidelines inside the cuff.
3. Palpate the brachial artery.
4. With participant seated, place the appropriate cuff around the upper left arm. The midpoint of the length of the bladder should lie over the brachial artery. Each cuff has an artery marker. The mid-height of the cuff should be at heart level.
5. Place the lower edge of the cuff, with its tubing connections, about one inch (1") above the natural crease across the inner aspect of the elbow.
6. Wrap the cuff snugly about the arm, with the palm of the participant's hand turned upward.
7. If the subject has had a left-sided mastectomy, the right arm may be used for blood pressure measurement. If right arm is used, note it on the form.

C. Determination of Maximal Inflation Level

For each participant, determine the maximal inflation level, or the pressure to which the cuff is to be inflated for blood pressure measurement. This assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and thus allows the first Kortokoff sound to be heard.

1. Attach the cuff tubing to the sphygmomanometer.
2. Palpate the radial pulse.
3. Inflate the cuff rapidly until the radial pulse is no longer felt (palpated systolic pressure) by inflating rapidly to 70 mmHg, then inflating by 10mmHg increments.
4. Deflate the cuff quickly and completely.
5. The maximal inflation level is 30 mmHg **above** the palpated systolic pressure.

D. Guidelines for Accurate Blood Pressure Readings:

1. The participant should be in a seated position for at least 5 minutes before the blood pressure is measured with both feet remaining flat on the floor.
2. All readings are made to the nearest even digit.
3. Any reading which appears to fall exactly between marking on the mercury column should be read to the next higher marking (i.e. 2, 4, 6, 8, or 0).
4. All readings are made to the top of the meniscus, the rounded surface of the mercury column.
5. When the pressure is released quickly from a high level, a vacuum is formed above the mercury and the meniscus is distorted. Allow a few moments for it to reappear before reading the manometer.

For offsite Blood Pressures: Check that the needle is at the zero mark at the start and the end of the measurement. Place the manometer in direct line of sight with the eye on a line perpendicular to the center of the face of the gauge.

E. Blood Pressure Readings:

1. Following any previous inflation, wait at least 30 seconds after the cuff has completely deflated.
2. By closing the thumb valve and squeezing the bulb, inflate the cuff at a rapid but smooth continuous rate to the maximal inflation level (30 mmHg above palpated systolic pressure).
3. The examiner's eyes should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.
4. Open the thumb valve slightly. Allow the cuff to deflate, maintaining a constant rate of deflation at approximately 2 mmHg per second.
5. Using the bell of the stethoscope, listen throughout the entire range of deflation, from the maximum pressure past the systolic reading (the pressure where the FIRST regular sound is heard), until 10 mmHg BELOW the level of the diastolic reading (that is, 10 mmHg below the level at which the LAST regular sound is heard).
6. Deflate the cuff fully by opening the thumb valve.
7. Remove the stethoscope. Neatly enter systolic and diastolic readings in the spaces provided on the form.

5.1 Elevated Blood Pressure

If, during a home visit the blood pressure is:

> **200/110** a call is made to a FHS NP who will notify the participant's personal physician. The chart will be marked "expedite" so that the letter to the personal physician is sent out ASAP.

> **180/100** the chart is expedited

-The Referral sheet is completed to note that contact was made to an FHS MD during the exam.

-If a phone contact was made by an FHS NP to the participant's personal physician, the FHS NP is to complete a "Record of Telephone Encounter" form.

If, during a nursing home visit the blood pressure is:

> **140/90** inform the nurse caring for the participant or the charge nurse

> **180/100** inform the nurse caring for the participant or the charge nurse. The chart will be marked "expedite" so that the letter to the personal physician is sent out ASAP.

6.0 Weight Offsite Visits

1. The participant should remove slippers or shoes.
2. Prior to asking participant to step on the scale, turn scale on, check to make sure it reads 0.0. The scale should be on a flat, hard surface.
3. Ask the participant to step onto the scale.
4. Instruct the participant to stand in the middle of the scale platform with head erect and eyes looking straight ahead. Weight should be equally distributed on both feet, and participant should not touch or support himself/herself.
5. Read the digital display while participant is on the scale.
6. Have the participant step off the scale.
7. Record the weight to the nearest pound; round up if ≥ 0.5 , round down if < 0.5 .
9. If participant is unable to stand for weight measurement at a nursing home, record the last weight in nursing home chart and the date the weight was obtained. If the participant is unable to stand on a scale during a home visit, record the weight measurement as 999.
10. Calibrate the scale monthly with 50lb weight

7.0 Visiting the Cognitively Impaired

The physical component of the exam requires the cooperation of the participant. The following are some suggestions to be able to effectively communicate with those with dementia.

Effective Communication Suggestions:

1. Be patient
2. Do not try to reason
3. Keep information simple
4. Use given names
5. Use eye contact
6. Give one direction at a time
7. Give clear instructions instead of asking questions
8. Keep communication in the present
9. Use sensitive touch when possible
10. Give frequent acknowledgment and encouragement
11. Ignore misinformation and simply acknowledge the communication

8.0 Nursing Home Chart Review Protocol

When visiting a participant in a Nursing Home most of the necessary information may be obtained through the review of the participants Nursing Home chart. When calling to confirm the offsite visit to the Nursing Home, inform the nurse taking care of the participant that you will need to look through his or her chart. Most nurses will ensure that the chart will be available upon your arrival.

1. Updating Sociodemographic Data and Family History
Upon opening the nursing home chart, one should see a face sheet. This sheet contains all the personal demographic data on their patient, including their next of kin. If the name(s) vary from the most recent ones on the Personal and Family History it should be documented, along with their addresses and phone numbers.
At the bottom of the face sheet it often lists the admission diagnosis of the patient. This is extremely important, especially if this is their first Nursing Home offsite visit.
2. Medications
Most charts contain an up-to-date list of the patient's medications. Some facilities keep the medications in a separate chart. If the patient's medications are not listed in their chart, ask for the medication book. Many times the medication sheets for months prior may also still be in the chart, make sure you use the most recent medication list (the dates will be at the bottom of the form).
3. Interim Medical History
The two sections that are most helpful in locating medical history information are "Consults" and "Medical History". Some nursing homes keep copies of all hospitalization records in a clear sleeve. The "Physician's Notes" and "Nurses Notes" sections are also helpful.

NOTE: Since all facilities have their own chart organization system it is best to thoroughly examine the whole chart. Some facilities thin their charts more frequently and if only the last month's information is present, then ask to see the whole interim period. This will ensure that nothing is missed.
4. Activities of Daily Living
To update a participant's activities of daily living the best reference is the MDI or minimum data sheet. This is a computer sheet, usually at the front of the chart, and it is updated about every 4 to 6 months. This sheet lists activities of daily living, hospitalizations, etc. Always refer back to notes and daily documented information to corroborate data, but this gives a nice head start. To truly confirm the current level of functioning of the patient consult with his or her nurse and list nurse as the Proxy.
5. Weight

If you are unable to obtain the participants weight using the FHS protocol you can use their nursing home chart records. Weight is typically done weekly at nursing home facilities. If you can't find a list of their current weight you can reference their physical exam report. Check to see if the nursing home keeps a separate weight book first before using the physical, we want to use the most recent measurement. Record the weight on file and the date it was obtained.

9.0 Offsite Visit Chart Completion

After returning to the Heart Study the following procedure is used to ensure that the chart is processed in an efficient manner.

9.1 ECG Physician Review

The full size tracing of the ECG and the ECG from the participant's previous exam should be presented to a FHS physician within 24 hours of the visit or within 24 hours of the tech returning to the FHS. This is done for comparison and reading. Should there be any marked ECG changes; the FHS physician should inform the participant's personal physician immediately.

After a contact is made with the PCP, the physician should complete a phone encounter sheet or the referral tracking form to document his/her actions.

The field visit tech will complete the chart the day of the visit or the next day if the visit occurred late in the day or was out of the Metrowest area.

Field visit charts will be processed within 1-2 days of the visit and the tracking sheet will be returned to the offsite tech for confirmation of completion.

9.2 Chart Review Protocol

1. Review all forms to ensure that all areas are completed. This includes the participant's letter and the physician summary sheet. On the summary sheet, document the medical findings that are new since the last exam and any other significant medical conditions carried over from previous exams.
2. If the participant had a stroke or has shown marked cognitive changes in the interim, a referral is made to the Stroke and/or Dementia study. After completing the referral forms, attach to the front of the chart.
3. A checklist is used to ensure that the NP, the Cohort Participant Coordinator, the Offsite Technician and Data technician receive the participant's information and daily sheet.
4. The chart should then be given to the Cohort Participant Coordinator. The Cohort Participant Coordinator will update the roster and give the chart to the data technician to type the MD letter.

10.0 Security Measures

Participant Chart

- No original participant chart content will leave FHS
- Participant information that is needed will be copied and placed in a folder
- When the participant folder is returned to FHS, copied information will be shredded
- Once NP and Tech have collected all the data from the Offsite participant, the data will be uploaded to server and data deleted from tablet

Offsite Visit

- Participant information and equipment will be in the trunk of the car, not left on seats that can be seen through the windows
- Do not leave participant information and equipment overnight in the car; bring it into your house or hotel
- Check and make sure everything (participant chart, tablet, equipment) is brought back to FHS (refer to Exam and Post exam checklist)

11.0 Using the REDCap Mobile App

Before using the REDCap Mobile App you must be given access to the device and a REDCap user must be created for you. The project you intend to use must have been downloaded onto the device. If it is your project, you must have Mobile App. checked on the rights page before you can download the project onto the device.

Before going into the field you must download preloaded participant information onto the device. If the information is not downloaded, it will not show in the headers, DOB calculations will not be performed and medical information collection dates will not appear in questions.

**The name, DOB, last exam date, last MHU date and last medical information date (the later of exam and MHU) can be keyed after creating a new record on the first instrument of the G3E3 project. However, for the sake of accuracy this information should be downloaded. The only reasons for keying this information are if you are unable to upload previously collected data or are unable to download participant information.

Before downloading the participant information, selecting Refresh Setup & Data will delete any records that has been previously collected on the device. If for any reason the data on the device has not been uploaded to the server, the project should not be refreshed.

Tech id is stored in the G3E3 project as a number. In the center the name is displayed with that number. While in the field, key tech id (number only) into box. If later reviewed on the server, it will display properly.

There is no way to connect to the database containing the medications. They must be collected on paper and entered once data has been uploaded to the server.

You can logout from the Main Menu. If you are on another page, you need to back-up through the menus to the Main Menu. Otherwise, the session remains live and the next time the app is opened one needs to logout or resume? The Instrument menu precedes the Record menu. Therefore, you need to use the back arrow to go to an instrument for the same participant other than the next (save data and go to next instrument is always a choice at bottom of each instrument). One can't go directly from the Cell Line Consent Form to the Completeness Checks. You must go back through 'Select Record' to 'Collect Data' and then 'Select Instrument' and 'Select Record'.

On the Select Instrument and Select Record pages, my device didn't load properly in Landscape. The items to select were hidden behind the heading. I had to turn device to portrait (which is what the designers may have intended).

Initial Set Up –

Before downloading a project to the Mobile App, you must be given rights to the to the project, including Mobile App.

REDCap Admin on the device must create a user with same name as individual uses for REDCap on the server.

User logs into REDCap **on the server** and selects that project. Click on 'REDCap Mobile App' in menu to the left of the page.

Go to 'Set Up Project' tab and select 'Request Token'.

Once granted a token, open 'Set Up Project' tab **on the server**. Make sure the QR code is visible on the monitor. Then, open Mobile App **on the device**. Select 'Set Up Project', select 'Scan QR code' and scan the QR code that is on the monitor.

If the QR code doesn't work:

On the server click the link below the QR code "Can't get the QR code to work?". You will be presented an initialization code. This code is only valid for ten minutes. **On the device** key this code into the box under 'The Alternative Method' and select 'Submit Code'.

Set up should be automatic. After successfully downloading the project you will be presented with a menu.

Select '**Do Not Download Records**'.

After set up is complete, you may logout or select 'Collect Data'.

Below are step by step instructions for using the REDCap Mobile App.

Before going on visit:

Select REDCap Mobile App on the device's Home Screen.



T-Mobile Wi-Fi 11:18 AM 93%

Log In

Username: knieto

PIN:

Log In

[Trouble logging in?](#)

Done

1	2 ABC	3 DEF
4 GHI	5 JKL	6 MNO
7 PQRS	8 TUV	9 WXYZ
	0	<input type="text"/>

T-Mobile Wi-Fi 1:56 PM 80%

Logout REDCap Mobile App Connected knieto (v2.50.1)

- My Projects
- Set Up Mobile Project
- Change My Password
- About the REDCap Mobile App
- Frequently Asked Questions
- Translate the Interface (Translate)
- Report a Bug
- Purpose

From Main Menu, Select 'My Projects':

Login Page:

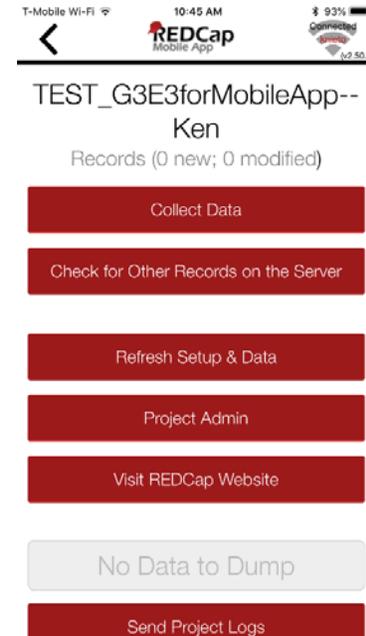
Select username and enter your six digit pin, then click 'Log In':

Select your project from the menu:



(participants). For a participant that has not had their exam only the preloaded information will be downloaded onto the device.

Before downloading the participant information Refresh Setup & Data will delete any data that has been previously collected on the device. If for any reason the data on the device has not been uploaded to the server, the project should not be refreshed.



If you are ready to proceed select 'Refresh Setup & Data':

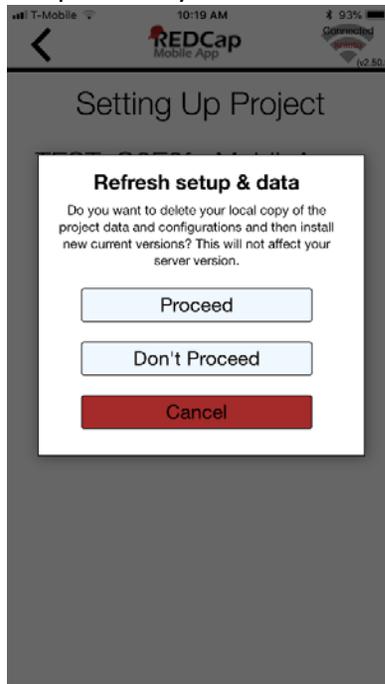
Refresh Setup & Data:

Refresh Setup & Data allows you to sync any updates that may have been made to the project since the previous download. You may also download data for all or selected records

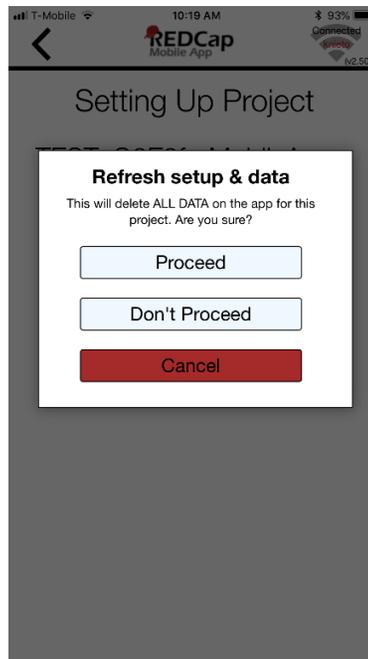
Update Metadata:

First warning lets you know that you are deleting and replacing the project on the device. You are also deleting

the previously collected data:



Again you are warned that you will be deleting previously collected data on the device and if you wish to proceed:



Please be patient...:



Select records for which you want to download participant information. You should only download a partial set:



TEST_G3E3forMobileApp--
Ken

Set Up Complete

Do you want to download all 4491 records from the project, or do you want to leave the project blank in the app?

- Download All 4491 Records
- Download by Form Status
- Get a Partial Set of Data
- Do NOT Download Records

Check to select records to download:



Download Checked Records

Choose Records (Total 0 Selected)

Search:

- All Displayed Records
- Record 1-1234
- Record 2-3456
- Record 2-6536
- Record 2-7038
- Record 2-7120
- Record 2-7121
- Record 2-8025
- Record 2-8027
- Record 2-8065
- Record 2-8129
- Record 2-8133
- Record 2-8313
- Record 2-8326
- Record 2-8372
- Record 2-8382
- Record 2-8428

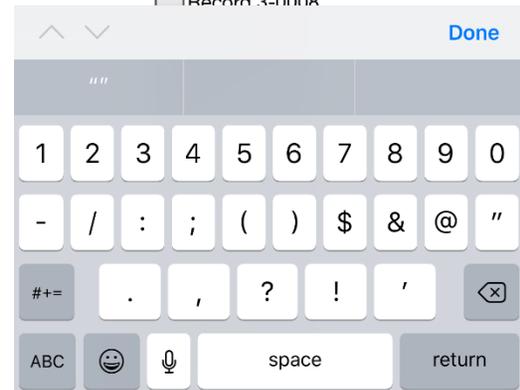


Download Checked Records

Choose Records (Total 0 Selected)

Search:

- All Displayed Records
- Record 3-0001
- Record 3-0002
- Record 3-0004
- Record 3-0005
- Record 3-0007
- Record 3-0008



You may type id into search box. You still must check the desired record:

Check to select:



Download Checked Records

Choose Records (Total 1 Selected)

Search:

- All Displayed Records
- Record 3-0001
- Record 3-0002
- Record 3-0004
- Record 3-0005
- Record 3-0007
- Record 3-0008
- Record 3-0013
- Record 3-0016
- Record 3-0019
- Record 3-0022
- Record 3-0027
- Record 3-0028
- Record 3-0030
- Record 3-0032
- Record 3-0035
- Record 3-0036
- Record 3-0038
- Record 3-0039



Download Checked Records

Choose Records (Total 2 Selected)

Search:

- All Displayed Records
- Record 3-5000
- Record 3-5001
- Record 3-5003
- Record 3-5004
- Record 3-5017
- Record 3-5018
- Record 3-5020
- Record 3-5021
- Record 3-5022
- Record 3-5025
- Record 3-5026
- Record 3-5037
- Record 3-5038
- Record 3-5039
- Record 3-5042
- Record 3-5044
- Record 3-5045
- Record 3-5046

Patience:



Downloading Data
TEST_G3E3forMobileApp--
Ken



Downloading data from server and
processing...

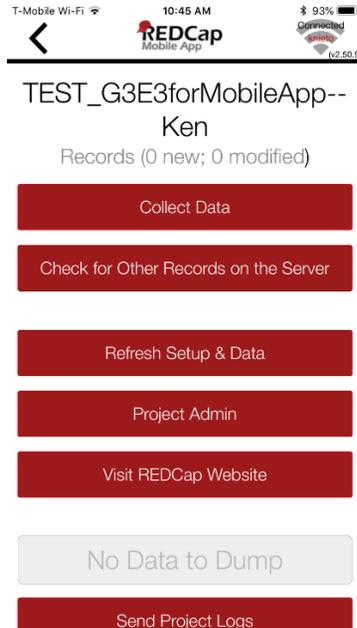


Stop the Download

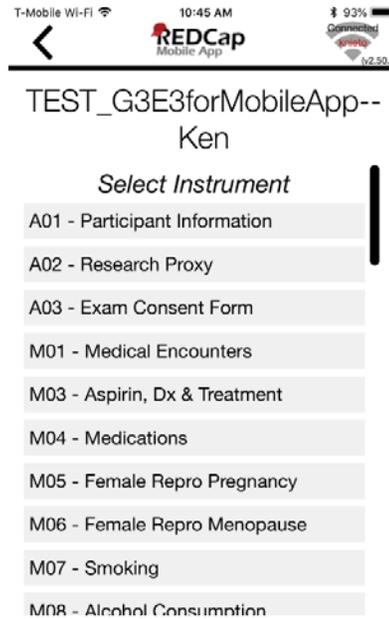
In the field—

Select REDCap Mobile App., login,
Select 'My Projects' and select G3E3...

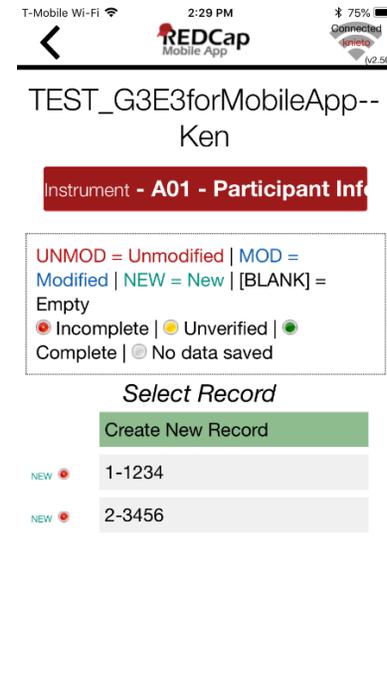
Select 'Collect Data':



Select Instrument from Menu:



Select Record (or create new record):



Data entry should proceed as it would on the laptops in the center.
**If not using external keyboard, when landing on numeric field, keyboard will automatically go to number mode. Again, you don't have links on left of instrument that allow you to select another instrument. You must go back to instrument menu.

Instrument Controls:

If, while on an instrument, you click 'Show instrument controls' (above FHS_IDTYPE_ID) ...

TEST_G3E3forMobileApp--Ken
M14 - Venous, PAD & IC Opinion

[Show instrument controls](#)

FHS_IDTYPE_ID	9-9999
Name: Nieto, Ken DOB: 02-08-1960	
Age: 58	Last Exam: 01-01-1990
Sex: Male	Last Medical Health Update: 01-01-2000
Exam date: 08-02-2018	
Venous and Peripheral Arterial Disease and Intermittent Claudication Opinion	

It's small, but in the next figure you can see the font size in the lower right corner. You can increase or decrease the font size. You can also 'Secure the Instrument'. This will lock the device on this instrument and only allow the user to save:

TEST_G3E3forMobileApp--Ken
M14 - Venous, PAD & IC Opinion

[Hide instrument controls](#)

Cancel	Size +
Secure the Instrument	Size -
Current Font-Size: 17px	

FHS IDTYPE ID **9-9999**

If locked, the instrument can be unlocked by clicking 'Release the Instrument' in lower right corner. You will be prompted for your PIN.

Aspirin, Diagnoses and Treatment Questions

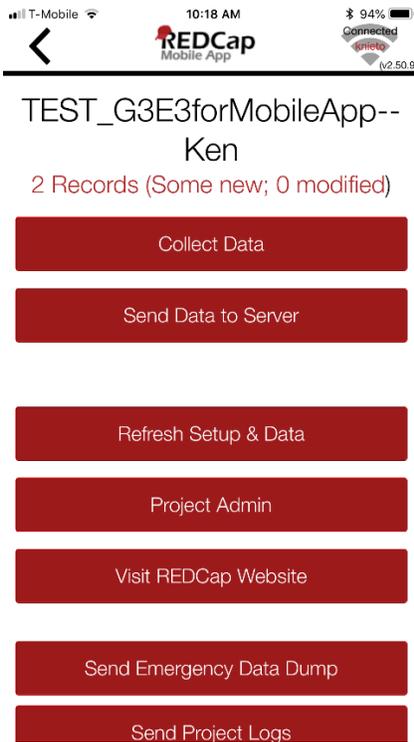
Save Record

Release the Instrument

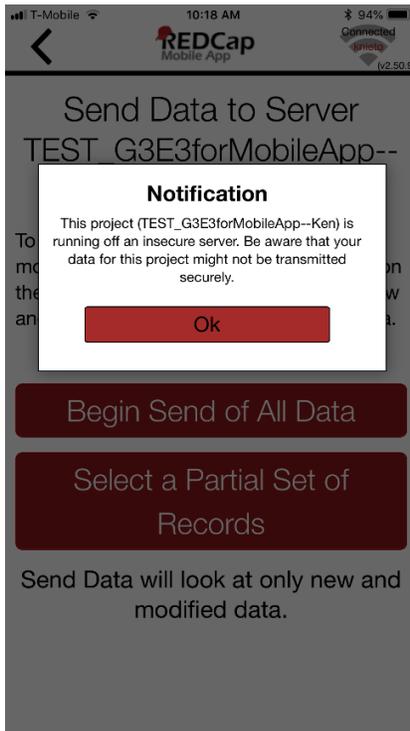
Upon return—

Select REDCap Mobile App., login, Select ‘My Projects’ and select G3E3...

To upload/sync data to server,
Select ‘Send Data to Server’:



The entire process of syncing data is done on the domain, behind the firewall. Click ‘Ok’:



You should be notified that sync was successful. From here you may return to the project or refresh the project and begin download of the participant information for the next visit:

Sync Report

Sync successfully completed

Project Title: TEST_G3E3forMobileApp--
Ken

Sync time: 7/31/2018 - 10:18:45 [Sync history](#)

New records to upload: 0

New records to upload: 0

Records Uploaded: 2 [Detailed Info](#)

Records Renamed: 0

Back to Project

Refresh Setup & Data (Recommended)

12.0 Checklists

12.1 PRE OFFSITE VISIT Checklist

Labels go here

- Call to confirm appointment (1-2 days before)
 - ✓ Ask about Ancillary Studies. If interested:
 - Ask Height and Weight (Actual)
 - Type of cell phone and current email (eFHS)
- Tablet Charged; take Charger
- Upload Participant Information
- Participant Notes/Copies
 - ✓ Consent Form
 - ✓ Authorization to Release Med Records
 - ✓ SSN Tracking Form
 - ✓ Summary of Findings
 - ✓ Latest MHU
 - ✓ Medical Records
- NP Equipment: BP monitor, cuffs, stethoscope
- Tech Equipment
 - ✓ Tablet: charged and participant information uploaded, charger
 - ✓ Admitting Form
 - ✓ ECG machine and supplies (include Heart Square)
 - ✓ Tape Measure
 - ✓ Scale
 - ✓ Hand Grip
 - ✓ Cog books: Cerad/Stroop, purple or green pen
 - ✓ Ancillary Studies
 - ✓ Red recycle bags

** Paper form of RC kept in NP bag and Tech bag

12.2 DURING OFFSITE VISIT Checklist

Labels go here

Consent Form, Health Proxy, Medical Release Form

NP

- ✓ Take picture of medications
- ✓ Administer medical history on RedCap
- ✓ Take Blood Pressures

Tech

- ✓ Weight
- ✓ Hips/Waist Measurement
- ✓ ECG
- ✓ Hand Grip
- ✓ Questionnaires on RedCap
- ✓ Cognitive battery
- ✓ Self-Administered Questionnaire
- ✓ Ancillary Studies (if possible)
- ✓ Exit Interview
- ✓ Give red bag

12.3 POST OFFSITE VISIT Checklist

Labels go here

- Upload Data
- Shred copies of participant records
- NP
 - ✓ Review ECG
 - ✓ Complete participant letter in RedCap
 - ✓ Give chart to Barbara
- Tech
 - ✓ Take pictures of meds (computer in Research Center Float Desk); delete pictures from tablet
 - ✓ Transmit ECG to MUSE
 - ✓ Put ECG in Chart
 - ✓ Give chart to NP
 - ✓ Put tablet on charger
 - ✓ Restock bag, if needed
 - ✓ Inform Data when everything complete in RC
 - ✓ Put Admit form in chart
 - ✓ Give Daily Sheets to:
 - Room 130- 2 daily sheets
 - Pocket on wall in Room 212
 - Chart
 - Pocket outside Room 204
 - Ancillary Studies: Actical, Tonometry, Exercise, Fibroscan, Microbiome, eFHS