Framingham Heart Study
Group 3 (Generation 3, Omni 2, NOS Cohorts)
Exam 4
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.

Basic Information

Title of Project: Framingham Heart Study

IRB Number: H-32132

Sponsor: National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH)

Principal Investigator(s): Joanne M. Murabito, MD, ScM
Framingham Heart Study
73 Mount Wayte Ave
Framingham, MA 01702

George O'Connor, MD, MS
Framingham Heart Study
73 Mount Wayte Ave
Framingham, MA 01702

Study Center Email: fhs@bu.edu

Study Center Phone Number: (508) 872-6562 or (800) 854-7582

Why is the research study being done? (Overview & Purpose)

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.

What Will Happen in This Research Study?

You will need to fast for 10 hours before you come to the study appointment for the blood draw. You can continue to drink water while fasting and take your usual medication on the morning of your visit. Most medication can be taken while fasting, but you should consult with your health care providers if you have any questions or concerns.

Your research examination will take place at the FHS Research Center at 73 Mount Wayte Avenue, Framingham, MA, by phone or video conference (also referred to as a televisit), or in your home or other residence.
The full onsite research exam will take around 4-5 hours to complete and we are offering several options for how participants may complete the exam. Participants may choose to participate in a full in-person exam; split in-person appointments; hybrid (televisit and shorter in-person exam); or offsite in home or other residence.

> **Notes for televisit and offsite exams:** Only exam components that may be completed remotely will be included during the televisit. Components that require in-person assessment may be conducted during visits to the Research Center or offsite appointments in which FHS staff visit you in your home or other residence.
>
> Some of the study components described in the later section, *"What will happen in this research study?*" may not be administered during televisits, due to the need to take certain measurements in person. Also, some of the study components may not be administered during televisit or offsite examinations taking place at your home or care facility, due to large equipment that cannot be transported outside of the FHS Research Center. For example, High Resolution-Peripheral Quantitative Computed Tomography (image scanning of your bones) will not be completed outside of the Research Center because that equipment may not be transported.

As before in previous FHS Exams for your cohorts, we will again:

- 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 up to 90 mL, which is about 6.1 tablespoons.
  - The blood draw will occur in two stages. The first blood draw soon after your arrival and the second blood draw after the Mixed Meal.
- Measure your height, weight, waist, and hips.
- Administer questionnaires related to your health and behaviors.
- Complete an electrocardiogram (ECG).
- Record your blood pressure.
- Complete two bone scans called "High Resolution-Peripheral Quantitative Computed Tomography (HR-pQCT)" to examine the bone structure in your lower leg and lower

arm bones. *Please note that eligibility screening for this activity may require that you complete a urine pregnancy test, if applicable.
- Provide you a kit to collect a stool sample at home and return to our researchers;
- Administer a bleeding questionnaire.
- Update your medical history information.
- Ask you to sign an authorization form to allow FHS to obtain copies of your **medical records, including Medicare**. The release form gives us permission to obtain these records unless you revoke permission in the future.
- Contact you later by mail, email, or by phone (call or text) to obtain additional information. You may also be invited to complete **annual medical history updates.**
- Contact you in person, by mail, email, or phone (call or text), to invite you to participate in **future additional FHS related studies.** You may also be invited to return for another examination in the future. As always your participation is always voluntary.

Surveys
We will also be asking you to complete questionnaires about your physical function, diet, exercise, memory and mood, and 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. We will use recordings to make sure that your responses are accurately documented for quality control purposes. 0

There are also research activities that will be NEW to your participant cohort:

1. **<u>Glucose Monitoring Study</u>:** We will ask you to wear a small device called a continuous glucose monitor on your upper arm or abdomen. The sensor is connected to a thin wire, the thickness of a horsehair, which will be inserted into your skin. The insertion process is almost painless, and the sensor is held in place by an adhesive sticker for up to 10 days. This monitor will measure your glucose levels every 5 minutes. We will also ask you to wear a fitness tracker on your wrist for 7 days. Upon conclusion of the 10-day monitoring period, we will ask that you mail the glucose monitor and fitness tracker back to FHS after you remove them.

   We will also ask you to log your sleep and wake times for 7 days and log your food intake for 3 days. You will be provided a paper form to record your sleep. You will log your dietary information through a website accessible via a unique passcode. You may also be asked to take pictures of your meals through a smartphone app. Any personally identifiable information accidentally captured in these images will be cropped out before being saved by our research team.

   The FHS study team will not provide any identifiers or identifiable information to the manufacturers of the devices (Dexcom, Fitbit) or to the ASA24 or Keenoa website/app.

   <u>What risks can I expect?</u> There is minimal risk that you will have an allergic reaction to the continuous glucose monitor sensor adhesive (a sticky tape that holds the sensor in place) or that the thin wire will break and/or cause an infection at the insertion site. If symptoms develop, we will ask you to contact a FHS technician, who can advise you on device removal. Most reactions will resolve on their own within one week of device removal.

2. **<u>Sensory Sensitivity Study</u>:** We are interested in learning about different types of

sensations people may experience in their daily lives, and to better understand why some people have pain, more pain, or pain in more parts of their body, than other people do. We will ask some questions about pain and other sensations and assess your sensitivity to pressure on your skin. To test your sensitivity to pressure, a small device will be pressed against a muscle on your shoulder to measure how much pressure is applied before you feel any discomfort.

What risks can I expect? Although rare, there is the potential for skin irritation and redness or bruising during testing. Bruising or discomfort could potentially result from application of the pressure meter during pressure pain threshold testing and/or blood pressure cuff inflation.

3. **Mixed Meal Challenge Study:** You will be provided a mixed meal drink and researchers are interested in assessing how blood markers of your metabolism change in response. The mixed meal drink (about the size of a can of soda, 350 milliliters) consists of a Boost Plus nutritional supplement drink with several nutritional additives. This drink consists of 600 calories (kcal) and is 75g (48%) carbohydrates, 21g (31%) fat, and 29g (21%) protein. It is designed to be similar to a typical American meal. You will consume the drink in approximately 5 minutes. Two (2) hours after you have finished the drink, we will perform a second blood draw so that changes in your blood can be evaluated.
The drink and additives are consumer-grade products that are intended for safe human consumption. The drink is not suitable for individuals with several conditions: (1) diabetes that requires insulin or that results in very high blood sugars; (2) allergy to milk protein (not including lactose intolerance), soy protein, or galactosemia; (3) any other potential allergies. A list of ingredients will be provided to you before participating.

   What risks can I expect? Some participants may experience digestive issues after consuming the mixed meal drink, including diarrhea, flatulence, abdominal cramping, and/or nausea. These symptoms occur in approximately 1 out of 50 people and are generally mild. You will also need a second blood draw as part of this study. As a result of blood draw, minimal bruising, pain, bleeding, lightheadedness/fainting, or in rare circumstances, infection may occur.

4. **Blood Pressure Resilience Study:** We are interested in observing how your heart and blood circulation system respond to various activities that you undertake during your daily life. We will have you perform a set of structured tasks while closely monitoring your heart rate and blood pressure. These tasks include sitting from a lying down position, gently squeezing a device with your hand, performing a mental activity, standing from a sitting position, and walking at your usual pace for three minutes. A compact device will be placed on your wrist with a small cuff on one of your fingers to continuously monitor your heart rate and blood pressure while you perform these tasks. We will also place a small clip on a fingertip to monitor your blood oxygen and a small patch on your chest to continuously monitor your ECG.

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

Overall Examination Risks and Discomforts

General Risks related to FHS: The FHS research exam is time consuming and repetitive. Other discomforts may include headache, feeling hungry due to fasting, fatigue and chill during the visit. Also as a result of blood draw(s), minimal bruising, pain, bleeding, lightheadedness/ fainting, or in rare circumstances, infection may occur

Risks related to Bone Study Imaging: "High Resolution-Peripheral Quantitative Computed Tomography (HR-pQCT)" bone scans involve exposure to radiation. Since the amount of radiation is so small, equivalent to 2-3 days of background radiation, there are no known long- term effects of this radiation on your health. However due to potential risk to a fetus, pregnant women, as determined by self-report or by a positive pregnancy test, will be excluded from this test.

Risks specific to new ancillary studies' activities are discussed in the sections above
Unknown Risks: There may also be some risks that we are unable to determine at this time.

We do not expect any risk of injury as a result of your participation in the study. However, first aid will be available.

Genetic Studies

You may have already provided consent in the past for the collection of biological samples for DNA research or the creation of Induced Pluripotent Stem Cells (iPS cells). We plan to continue to do genetic research on the DNA from your biological samples. The biological samples include blood cells, tissue cells, 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.

You may choose to participate in non-genetic FHS research without choosing to participate in genetic research. Later in the form you are asked to specifically indicate if you choose to participate in genetic research.

How will I learn the results of this study?

Core Framingham Heart 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 and on our study website.

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.
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. In the cases when genetic research findings are reported to you, a study investigator and genetic counselor will contact you to confirm your continued interest in hearing about genetic research results. If you confirm your interest, the study staff will inform you of the research results and recommend next steps such as obtaining confirmatory clinical testing and speaking with your personal healthcare provider.

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 decide 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.

Glucose Monitoring Study: Following completion of study activities, we will return a set of summary results to you from the "Ambulatory Glucose Profile" provided by Dexcom Clarity software. If study investigators further determine your results to be important for you to discuss with your healthcare provider, we will send a letter to you and your healthcare provider including the same Ambulatory Glucose Profile data. We will inform your healthcare provider of your results only if your glucose levels are significantly higher or lower than would be expected. It is important for you to also know that this Glucose Monitor is not used to diagnose diabetes or any other condition, but your healthcare provider may recommend further tests if very high or low glucose levels are observed.

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, 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. The cell/tissue storage banks and repositories, databanks and data repositories, include but are not limited to, NIH repositories dbGaP and BioLINCC. Internal and external researchers may request data and materials for research. The repositories have standard operating procedures to protect your confidentiality. Your data and samples will not be labeled with your name or other direct personal identifiers, only a code.

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? (Risks and Discomforts)

General risks and individual risks related to new activities are discussed above.

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. There is a potential risk that your genetic information could be used to your disadvantage. For example, if genetic research findings suggest a serious health problem, that could be used to make it harder for you to get or keep a job or insurance. Both Massachusetts state laws and federal laws, particularly the Genetic Information Nondiscrimination Act (GINA), generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. These laws will generally protect you in the following ways:

1. Health insurance companies and group health plans may not request your genetic information that we get from this research.

2. Health insurance companies and group health plans may not use your geneticinformation when making decisions regarding your eligibility or premiums.

3. Massachusetts employers with 6 or more employees (or 15 or more employees in other states, under GINA) may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that neither Massachusetts law nor GINA protects you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Thus, life insurance, disability insurance, and long-term care insurance companies may legally ask whether you have had genetic testing and deny coverage for refusal to answer this question.

What are the possible benefits from being in this research study? (Potential Benefits)

While you will not receive any direct benefit 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)

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.).

Payment

You will not be paid for your participation in this study.
The research may also lead to the development of drugs, tests, or procedures that might have commercial value. You will not get any money if products are developed from the research.

How is my information protected? (Confidentiality)

Data and Samples Storage: We will store your information in ways we think are secure. We will store biological samples taken from your body (such as urine, blood, or tissue). 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 will store paper files in locked filing cabinets and secured rooms. We will store electronic files in computer systems with password protection and encryption.
Only the people listed later in this section will be given access to your information. However, we cannot guarantee complete confidentiality.

Protection of information during research presentations: 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 cell/tissue storage banks, your name and other direct personal identifiers will not be used.

Use and Sharing of Your Health Information: We do not sell, rent, or lease your contact information.

We ask anyone who gets your information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private. When information or biological samples are shared for research purposes your information is identified by a code and not with your name or other direct personal identifiers.

Third-Party Involvement: For the purposes of the Glucose Monitoring Study research staff will set up profiles for participants for Dexcom, Fitbit, Keenoa, and ASA24 using coded IDs with no identifiable information. For participation in Glucose Monitoring participants will wear Dexcom and Fitbit device and enter data on the Keenoa app or ASA24 website/database. This data, which is not stored at Boston Medical Center or Boston University, is outside of our control. Dexcom and Keenoa have agreed not to use the data on their servers. Data collected via Fitbit or the ASA24 website/database may be used for other purposes that are not related to the study. Please carefully read and think about the Dexcom, Fitbit, Keenoa, and the ASA24 website/database Terms of Service and Privacy Policies before agreeing to give them any of your information.
If you do not want to share your data with Fitbit, Keenoa, or the ASA24 website/database, that is completely acceptable and you still may participate in the Glucose Monitoring Study, but your glucose data will be stored on Dexcom's servers, so if you do not want them to store your deidentified data then you cannot be in the Glucose Monitoring Study.

Communicating with participants: This study gives you the option of communicating using unsecure email and/or text for appointment reminders and satisfaction surveys. This is because some people like the option of communicating by email and/or text message. It is important for you to understand that regular email and text are convenient but are generally not secure. As a result, information about you could be intercepted by someone not involved with the study. We will give you the option of using secure email (Data Motion), non-secure email, and/or non- secure text.

Certificate of Confidentiality (CoC): This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information or biological samples are covered by a CoC. The CoC provides how we can share research information or biological samples. Because we have a CoC, we cannot give out research information or biological samples that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information or biological samples in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to be in the study and sign this form, we will share information and biological samples that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- Researchers for studies described in the section "*What will happen in this research study?"* These people are expected to protect your information and biological samples in the same way we protect it.
- Any people who you give us separate permission to share your information.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database
- Using research data in future studies, done by us or by other scientists.
- Using biological samples in future studies, done by us or by other scientists.

Sharing of Genetic Data and Samples: Samples that are collected from you in this study will be analyzed to find out information about your genetic makeup. Your genetics and health information, *without your name or other data that could easily identify you*, will be put in a database run by the National Institutes of Health (NIH). This may include your whole genome information. Other researchers can ask the NIH to get your information from the database. You should know that it is possible that your genetics information might be used to identify you or your family, though we believe it is not too likely that this will happen. Once your information is given to the NIH database, you can ask to have NIH stop sharing it, but NIH cannot take back information that was already shared.

You should know that we are required to report information about child abuse or neglect; elder abuse; specific reportable diseases; or harm to others.

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.

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

During this study, we may find out something that might make you not want to stay in the study. If this happens, we will tell you as soon as possible. You should also tell us if you ever have concerns about being in the study.

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

The FHS research team will try to answer all of your questions. You can ask questions as often as you want. If you have questions or concerns at any time, contact a study staff member directly at (508) 872-6562 or (800) 854-7582. You can also send an email to FHS@bu.edu. Also call if you need to report an injury while being in this research.

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. Joanne Murabito and Dr. George O'Connor (Boston University), and Dr. Daniel Levy (NHLBI) are in charge of the research study.

- You can contact Drs. Murabito or O' Connor at (508) 872-6562 or (800) 854-7582 Monday through Friday between 9am and 5pm or by email at fhs@bu.edu.
- You may contact Dr. Daniel Levy at (508) 935-3400 Monday to Friday between 9am and 5pm or by email at levyd@nih.gov.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Please read all of the following statements and make a selection for each item to indicate how FHS shares your data:

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.

   | _| YES | _| NO (*For Internal Use – Office Code 0)*

2) 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.

   | _| YES | _| NO (*For Internal Use – Office Code 3)*

3) 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.

   | _| YES | _| NO (*For Internal Use – Office Code 4)*

4) 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.

   | _| YES | _| NO (*For Internal Use - Office Code 30*)

5) 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.

   | _| YES | _| NO (*For Internal Use - Office Code 31*)

Subject: _____
Printed name of subject

By signing this consent form, you are indicating that:

- you have read this form (or it has been read to you)
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you permit the use and sharing of information that may identify you as described,

including your health information.

To be completed by subject if personally signing

_____ _____
Signature of subject Date

To be completed by LAR if subject does not personally sign
I am providing consent on behalf of the subject.

_____ _____
Printed name of Legally Authorized Representative (LAR) Relationship to Subject

_____ _____
Signature of Legally Authorized Representative Date

Researcher: _____
Printed name of person conducting consent discussion

To be completed by researcher if subject personally signs
I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

_____ _____
Signature of person conducting consent discussion Date

To be completed by researcher if subject does not personally sign
I have personally explained the research to the above-named subject's Legally Authorized Representative and answered all questions. I believe that the Legally Authorized Representative understands what is involved in the study and freely agrees to have the subject participate.

I consider that the above-named subject (check one):
- ☐ is capable of understanding what is involved in the study and freely agrees to participate.
- ☐ is not capable of understanding what is involved in the study.

_____ _____
Signature of Person conducting consent discussion Date