Protocol Title: Lifestyle Validation Study

Principal Investigator: Walter Willett, MD, DrPH

Site Principal Investigator:

Description of Subject Population: Nurses' Health Studies I and II participants

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Why is this research study being done?

We are doing this research study to determine the best way to measure and analyze diet and physical activity in large cohorts, such as the Nurses' Health Studies I and II. Improving measurement of these factors will ultimately help the scientific community study how they relate to health.

We are asking you to take part in this study because you participated in our 1986 validation study and/or have previously provided a blood sample, filled out our most recent food frequency questionnaire, and have not had any major illness.

About 750 women from the Nurses' Health Studies I and II will take part in this research study.

The National Institutes of Health-National Cancer Institute is paying for this research to be done.

How long will I take part in this research study?

It will take you one year to 15 months to complete the study. Over the course of the study, it will take you about thirty hours to complete all of the study procedures.

What will happen in this research study?

If you choose to take part in this research study, we request that during the time you take part that you do not make major changes to your usual diet or physical activity. Examples of major changes include, but are not limited to, changing from walking to running for exercise or vice versa, beginning/ending a vegetarian diet, and changing from driving to biking or vice versa for transportation. If that is acceptable, and if you are eligible, and interested to participate, we will ask you to read this consent form. After speaking with a Study Coordinator on the telephone, we will ask you to sign and return the consent form to us in the pre-paid, pre-addressed envelope we provided with the form.

Once you are enrolled in the study by the Study Contact, you will have access to the study website, which you will use throughout your participation. The website will have study instructions and links to other websites where you will enter some of your data. The website will also allow you to track your progress throughout the study and to let us know you have received study materials. You will also use the website to specify acceptable date ranges for conducting certain tasks and indicate when they are completed. If we do not hear from you online by expected times, you will be contacted by an automated telephone calling system. This system will also be used for parts of the study that are time critical. If we are not able to reach you via the automated telephone calling system, one of our study staff members will contact you.

While taking part in this research study, you will use several diet and physical activity measurement tools. Soon after you agree to participate, you will receive detailed study instructions in the mail. The instructions will also be available online. You will also receive a DVD with instructions on how to complete your 7-day diet records.

The following sections describe all of the measurement tools you will use and how often you will use them:

Food Frequency Questionnaire (FFQ) and Physical Activity Questionnaire (PAQ)
You will complete the FFQ three times during the study. You will complete a paper version at the beginning and end of the year. You will also complete a version online at the end of the year.

You will complete two different PAQs. One PAQ will be completed twice during the study, and the other will be completed once.

The FFQ and the PAQ that you will complete twice during the study will be similar to the questionnaires you have filled out previously for the Nurses' Health Study I or II. The PAQ you will complete once is from the World Health Organization. While we hope that you will answer all of the questions, you can skip any questions you do not want to answer.

It will take you about 1 hour and 30 minutes to complete the three FFQs. It will take you about 15 minutes to complete the three PAQs.

7-Day Diet Record

You will keep two, 7-day diet records during the study. There will be about a six month interval between the first record and the second. Prior to keeping your diet record, you will receive a food scale, diet record booklet, ruler, pre-paid and pre-addressed return envelope, printed instructions, and a DVD. The DVD and printed instructions will explain how to keep a detailed diet record, how to use the food scale, and how to measure and record the types and amounts of foods you eat. After viewing the DVD, you will schedule a telephone instruction session with a research dietitian who will review the concepts in the DVD. While keeping your diet record, you will receive at least one telephone call to monitor your progress and answer your questions.

You will return the completed diet record to the Nutrition Coordinating Center (NCC) in a pre-paid, pre-addressed envelope. Once you return your diet record, staff at the NCC will analyze it to determine your reported nutrient intake. You may receive phone calls from the NCC with questions about your record or requests for further detail.

It will take you about 14 hours to complete the two 7-day diet records.

Automated Self-Administered 24-hour recall (ASA24)

Each season, you will complete a 24-hour dietary recall on-line using the ASA24. You will complete 4 in total. The ASA24 is an online computer program that will collect information on only the foods you consumed the previous day. It will guide you through the recall process and will also prompt you with questions about possible forgotten foods, cooking methods, and other aspects of your diet that day.

It will take you about 2 hours to complete the 4 ASA24s.

Activities Completed over Time in 24-hours (ACT24)
Each season, you will complete a 24-hour physical activity recall on-line using the ACT24. You will complete 4 in total. The ACT24 is similar to the ASA24 but asks about your physical activity during the previous day, instead of your diet.

It will take you about 2 hours to complete the 4 ACT24s.

Physical Activity Monitor
You will use a physical activity monitor twice during the study. There will be about a six month interval between the first and second use. The physical activity monitor is like a sophisticated pedometer that measures your movement while you wear it. Both times that you use the physical activity monitor, you will wear it on an elastic belt around your waist during waking hours for one week. You will enter data on a physical activity log sheet during this period. You will be asked to return the physical activity monitor to us after each use. You will ship the physical activity monitor to us by FedEx using materials we will provide.

It will take you about 30 minutes to put on and take off the physical activity monitor and to enter information on the physical activity log sheet every day for 7 days, twice.

Body Measurements
Each season, you will provide measurements of your body size and resting pulse rate. You will provide these measurements 4 times during the study. The first time you provide this information, you will record your height, weight, the circumferences of your waist and hips, and your resting pulse rate. We will provide a measuring tape for you to take the circumference measurements. On the three subsequent measurements, we will only ask you to record your weight and resting pulse rate.

It will take you about 15 minutes to complete the 4 body measurements.

Saliva Sample
You will collect two saliva samples. There will be approximately six months between the first and second sample. Fisher BioServices, Inc. will mail the supplies necessary for you to collect your saliva sample along with instructions. Once you have finished each saliva collection, you will ship the sample to Fisher BioServices, Inc. by FedEx using materials we will provide.

It will take you about 10 minutes to complete the two saliva samples.

24-Hour Urine Sample
Each season, you will provide a 24-hour urine sample. You will collect 4 samples in total. Fisher BioServices, Inc. will mail you the supplies necessary to collect your urine sample along with instructions and a questionnaire. If you are not allergic to para amino benzoic acid (PABA), you will take PABA tablets each day you collect urine so that we can make sure you collected all of your urine. PABA is a safe ingredient found in many dietary and vitamin supplements and topical sunscreens. Because PABA is eliminated from your body at a constant rate, we can measure it to verify that you have collected a complete 24-hour urine collection. This will help us know our laboratory measurements are correct. Once you have finished the urine collection, you will ship the sample and completed questionnaire to Fisher BioServices, Inc. by FedEx using materials we will provide.

It will take you about 4 hours to complete the 4 24-hour urine samples.

Fasting Blood Sample
You will collect two fasting blood samples. There will be about a six month interval between the first and second sample. Fisher BioServices, Inc. will mail you the supplies needed to take your blood sample. They will also send you instructions and a questionnaire. Prior to taking your blood sample, you will fast overnight. This means you will not consume any food or beverage (other than plain water) from midnight until you have taken your blood sample the following morning. Once you have taken your blood sample, you will ship it to Fisher BioServices, Inc. by FedEx using materials we will provide.

A total of 5 tablespoons of blood will be drawn during the entire course of this research study.

It will take you about 30 minutes to complete the two fasting blood samples.

Doubly Labeled Water (DLW)
Most subjects will complete the DLW procedure one time. About 100 subjects will be randomly selected to complete the procedure twice. If you are asked to complete the procedure twice, there will be a nine to fifteen month interval between the first and second time that you perform the procedure. Therefore if you are asked to complete the DLW procedure twice, the study will last longer than one year.

DLW is a special type of water with heavy atoms that you will drink. The heavy atoms are nonradioactive and naturally found in your body. The dose of water will slightly raise your body's level of these atoms. We will use urine samples to measure the heavy atoms as they are

eliminated from your body. The rate of elimination depends on your calorie use, so measuring it in your urine tells us how many calories your body uses.

One week before and about two weeks after you drink the DLW (about 3 weeks total), you will need to stay within one hundred miles of your home. Remaining in the same area is important because water in other areas may have different levels of the naturally-occurring heavy atoms. Those different levels could affect our test results.

Prior to each DLW dose, you will be asked to provide two urine samples. You will then drink a small amount of the DLW. Later that day, you will provide two more urine samples. You will then provide another two urine samples ten to fourteen days later. Altogether, the DLW procedure will involve the collection of six urine samples. You will record some information related to the DLW procedure, such as the times you perform each of the steps. The entire procedure will be supported by text message or telephone call reminders and thorough instructions.

The DLW will be provided to you by the Harvard School of Public Health. All other supplies will be sent to you by FisherBioServices, Inc. You will send your urine samples by FedEx to the Pennington Biomedical Research Center where they will be analyzed.

It will take you about 2 hours to complete the DLW procedure (or 4 hours if you asked to complete the DLW procedure twice).

When will I use each diet and physical activity assessment tool?

We will randomly place you into one of four groups. All groups will use the same tools but will use them in different orders. The table below shows an example timeline for one of the four groups. The timeline that you will be assigned to may be slightly different. Your timeline will be available to you on the study website where you will select ranges of time within the timeline to perform certain tasks. Adhering to your timeline as closely as possible is very important. Therefore, you will need to inform us when you will be away on vacation, or otherwise unavailable, as soon as you know. This information will allow us to adjust your schedule accordingly.

<table>
<tr><th colspan="12">Example timeline by month
(numbers are not necessarily specific months, so 1 may not be January)</th></tr>
<tr><th>1</th><th>2</th><th>3</th><th>4</th><th>5</th><th>6</th><th>7</th><th>8</th><th>9</th><th>10</th><th>11</th><th>12</th></tr>
<tr><td>FFQ, PAQ</td><td></td><td>DLW</td><td colspan="3" rowspan="2">ASA24, ACT24, 24-hr urine, body measurements/resting pulse rate</td><td colspan="2"></td><td>DLW repeat for some subjects</td><td>PAQ</td><td>Web-based FFQ</td><td>FFQ, PAQ</td></tr>
<tr><td colspan="3">ASA24, ACT24, 24-hr urine, body measurements/resting pulse rate, 7-day diet record, physical activity monitor, fasting blood, saliva sample</td><td colspan="3">ASA24, ACT24, 24-hr urine, body measurements/resting pulse rate, 7-day diet record, physical activity monitor, fasting blood, saliva sample</td><td colspan="4">ASA24, ACT24, 24-hr urine, body measurements/resting pulse rate</td></tr>
</table>

At the end of the study, we will provide you with the results of biochemical tests that are routinely used clinically. However, these may not be analyzed or provided until a year or two after you have completed the study. We will also provide you with results from your dietary analyses but, again, not until the study is complete.

What will happen to my biological samples?

The biological samples you will collect and send to us during this research study include blood, urine, and saliva. Samples sent to Fisher BioServices, Inc. will be processed and stored there temporarily. Samples will be stored permanently by the Channing Laboratory (part of Partners HealthCare System) and the National Institutes of Health National Cancer Institute (NCI). Samples will be analyzed by a number of laboratories for markers of your dietary intake.

To further protect your privacy, your samples will be labeled with an ID number that is different from your Nurses' Health Study ID number (alias ID). This alias ID number will be linked to your Nurses' Health Study ID number only at Channing Laboratory. Fisher and NCI will only have access to the alias ID.

Your samples may also be used in future research projects. For example, possible hormonal analyses may be performed on your samples to see how those hormones relate to disease. It is not possible to list every research project. Also, we cannot predict all of the research questions that will be important over the next years. As we learn more, new types of research and new research questions may arise. As always, any information you provide and the results of your analyses are considered strictly confidential and are used for medical statistical purposes only.

We plan to do genetic research on the DNA in your blood sample. DNA is the material that makes up your genes. 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. Genes are passed from parent to child. The genetic research we plan to do involves analyzing your DNA for patterns that might be related to the way your diet affects the level of nutrients and other factors in your blood.

We may also perform a whole genome analysis on your DNA sample. Usually researchers study just a few areas of your genetic code that are linked to a disease or condition. In whole genome studies, all or most of your genes are analyzed and used by researchers to study links to many diseases or conditions.

In order to allow researchers to share test results, the National Institutes of Health (NIH) and other central repositories have developed special data (information) banks that analyze data and collect the results of whole genome studies. These banks may also analyze and store DNA samples as well. These central banks will store your genetic information and samples and give them to other researchers to do more studies. We do not think that there will be further risks to your privacy and confidentiality by sharing your samples and whole genome information with these banks. However, we cannot predict how genetic information will be used in the future. The samples and data will be sent with only your ID number attached. Your name or other identifiable information will never be given to central banks. There are many safeguards in place to protect your information and samples while they are stored in repositories and used for research.

Research using your samples and whole genome information is important for the study of virtually all diseases and conditions. Therefore, the sample/data banks will provide study data for researchers working on any disease, which could include conditions such as HIV/AIDS, cancer, mental illness, and others.

Do you agree to allow your samples and information to be used for genetic research?

CHECK ONE BOX, and INITIAL: ☐ YES ☐ NO INITIALS _____

There is no scheduled date on which your samples and information in the bank will be destroyed. Your samples may be stored for research until they are "used up."

The code linking your samples to your medical record may be kept indefinitely so that your samples and updated health information may be used for research in the future.

Can I stop allowing my samples and information to be stored and used for research?

Yes. You have a right to withdraw your permission at any time. If you do, your samples and your information will be destroyed. However, it will not be possible to destroy samples and information that have already been given to researchers or collaborators or that have already had all codes that could be linked to you removed. If you decide to withdraw your permission, you should contact Junaidah Barnett, PhD, MCH(N), or our Study Contacts, at Lifestyle Validation Study, The Channing Laboratory, 181, Longwood Avenue, Boston, MA 02115-5804.

What are the risks and possible discomforts from being in this research study?

There are no known risks associated with consuming DLW.

The risks associated with blood collection are expected to be small given the detailed instructions we will provide and your experience as a health professional. You may develop a bruise or pain where the blood sample is taken. There is also a small risk of infection, lightheadedness, and/or fainting.

Some people are allergic to PABA. Oral use or skin application of PABA may lead to itching or a skin rash following sun exposure. You should not take the PABA tablets for this study if you are allergic to PABA or chemicals similar to PABA such as antidiabetic medicine (such as Diabenese, Tolinase, Orinase), thiazide diuretics, ester-type anesthetics, and dyes such as aniline or paraphenylenediamine (used in old hair dyes). You may still participate in this study if you are allergic to PABA.

Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record.

Taking part in a genetic study may also have a negative impact on family or other relationships. If you do not share information about taking part in this study, you will reduce this risk.

Breach of confidentiality regarding information you report is a possible risk. This information will not be particularly sensitive as it primarily involves diet and physical activity data, recent illness, and medication use. To track the progress of subjects through our study, we will have a password-protected website that contains your ID number, name, date of birth, contact information, and details on your study schedule and progress. To maintain confidentiality, only the Principal Investigator, Project Director (or designated assistants), and designated individuals in the groups listed below will have access to this website and/or the information it contains.

Online data will be provided via secure websites. The ACT24 and ASA24 will be hosted by the NCI or its collaborators. For other information, the system we will employ is the same system used for online questionnaires completed by nearly 40,000 participants in ongoing Channing Laboratory cohorts. This system has been used for many years without any incidents of security or confidentiality breach. All data transferred between respondents' computers and our server is protected by 128-bit SSL data encryption which protects the respondents' answers as they travel over the internet from their computer to our web server. This level of data security is the same as that used for online banking and credit card transactions.

As previously mentioned, several groups outside of the Channing Laboratory and the Harvard School of Public Health are helping conduct this study. Excluding the NCI, they will have your name, date of birth, and contact information. They will also have access to any data or samples you provide to them. These groups will be bound to a strict confidentiality clause written into their contracts. The groups are listed below:

Pennington Biomedical Research Center
You will mail your urine samples from the DLW procedure directly to Dr. Jennifer Rood's Mass Spectrometry Laboratory at Pennington Biomedical Research Center. Your samples will be analyzed there.

Fisher BioServices, Inc.
Kits for blood, urine, and saliva collections will be sent to you by Fisher BioServices, Inc., and you will return your samples to this company where they will be stored temporarily.

Nutrition Coordinating Center (NCC)
You will mail your completed diet records directly to the NCC. You may be contacted by staff members of the NCC by telephone regarding your diet records.

Aumtech and Inspeech
Aumtech and Inspeech are the companies we are working with to facilitate subject communication. This communication includes occasional text message and/or telephone prompts that you will receive from our automated telephone calling system. This company will also have access to our subject tracking website where all information on your progress and activities throughout the study will be monitored.

Other Investigators
The data from this study will be shared with other investigators according to National Institutes of Health policy. In particular, we are working with the NCI to include the data from this study as part of a much larger study of diet and physical activity measurement. The NCI will also be provided with a portion of your biological samples for future use. Data and samples shared with investigators at the NCI and beyond will be made anonymous and will lack detail that would be required to identify you.

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

You will not benefit from taking part in this study. Information gathered in this study will help researchers improve diet and physical activity measurement, which will ultimately improve research on those lifestyle factors as they relate to health.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

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.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

It is possible that we will have to ask you to drop out before you finish the study. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

You will be paid $600 for participating in this study. You will receive $200 once you have completed the first six months of the study, and you will receive the remaining $400 upon completion of the entire study. If you do not complete the study, you will be paid $200 if at least the first six months are completed.

What will I have to pay for if I take part in this research study?

Study funds will cover the costs of all the tests and supplies used during the study.

Costs for any ongoing or routine medical care you may receive apart from this study will be billed to you or to your insurance company in the usual way. You will be responsible for any deductibles or co-payments required by your insurer.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them.

Giving you care does not mean that Partners hospitals or researchers are at fault, or that there was any wrongdoing. There are no plans for Partners to pay you or give you other compensation for the injury. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

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

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Walter Willett, MD is the person in charge of this study. You can call him at 1-617-432-4680, M-F between 9am to 5pm. If you have any questions about this study, you may call our Project Director, Junaidah Barnett, PhD, MCH(N), or our Study Contacts at 1-877-NHS-2010 (1-877-647-2010) anytime (7 days a week, 24 hours a day). If you do not reach us, please leave a message and we will get back to you as soon as possible.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

Federal law requires Partners (Partners HealthCare System and its hospitals, health care providers and researchers) to protect the privacy of health information that identifies you. This information is called Protected Health Information. In the rest of this section, we refer to this simply as "health information."

If you decide to take part in this research study, your health information may be used within Partners and may be shared with others outside of Partners, as explained below.

We have marked with a ☒ how we plan to use and share your health information. If a box is not checked ☐, it means that type of use or sharing is not planned for in this research study.

We will also give you the **Partners Notice for Use and Sharing of Protected Health Information.** The Notice gives more details about how we use and share your health information.

- **Health Information About You That Might be Used or Shared During This Research**

  ☐ Information from your hospital or office health records within Partners or elsewhere, that may be reasonably related to the conduct and oversight of the research study. This may include information about hospital admissions or visits during this study, so that we know about any possible problems or side effects. If health information is needed from your doctors or hospitals outside Partners, you will be asked to give permission for these records to be sent to researchers within Partners.

  ☒ New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study

- **Why Health Information About You Might be Used or Shared with Others**

  The reasons we might use or share your health information are:

  - To do the research described above
  - To make sure we do the research according to certain standards - standards set by ethics and law, and by quality groups
  - For public health, and safety - for example, if we learn information that could mean harm to you or others, we may need to report this to a public health or public safety authority, or to specific individuals as required by law
  - For treatment, payment, or health care operations

- **People and Groups That May Use or Share Your Health Information**

  1. People or groups within Partners

  ☒ Researchers and the staff involved in this research study

  ☒ The Partners review board that oversees the research

  ☒ Staff within Partners who need the information to do their jobs (such as billing, or for overseeing quality of care or research)

  2. People or groups outside Partners

- ☒ People or groups that we hire to do certain work for us, such as data storage companies, our insurers, or our lawyers
- ☒ Federal and state agencies (such as the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections) and other U.S. or foreign government bodies, if required by law or involved in overseeing the research
- ☒ Organizations that make sure hospital standards are met
- ☒ The sponsor(s) of the research study, and people or groups it hires to help perform this research study
- ☒ Other researchers and medical centers that are part of this research study
- ☒ A group that oversees the data (study information) and safety of this research study
- ☐ Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside Partners, we cannot promise that it will remain private.

- **Time Period During Which Your Health Information Might be Used or Shared With Others**
  - Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

- **Your Privacy Rights**
  - You have the right **not** to sign this form permitting us to use and share your health information for research. If you don't sign this form, you can't take part in this research study. This is because we need to use the health information of everyone who takes part in this research study.
  - You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. This includes information used or shared to carry out the research study or to be sure the research is safe and of high quality.

If you withdraw your permission, you cannot continue to take part in this research study.

- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study.

  In this research study, you may only get such health information after the research is finished.

- **If Research Results Are Published or Used to Teach Others**

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Informed Consent and Authorization

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____ _____

Study Doctor or Person Obtaining Consent Date/Time

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.

- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject _____ Date/Time _____

Please use the pre-addressed and pre-stamped envelop and mail the signed consent form to:

Lifestyle Validation Study
The Channing Laboratory
181, Longwood Avenue
Boston, MA 02115-5804

Consent Form Version Date: 2-17-10