Subject Identification

<Note: all items in "<>" are instructions/guidance. All headings must be included in the consent form. Recommended language is given as a guideline and may be altered based on the specifics of the protocol.>

Protocol Title: < The Protocol Title must be consistent throughout the protocol submission and should include the Newton-Wellesley Hospital HRIC study number.>

Principal Investigator: < Must be on staff at the Institution, not an Intern, Resident, or Fellow.>

Description of Subject Population: < If there are different sub-populations in a given protocol you, you must differentiate that subpopulation in Parenthesis after the Description of Subject Population in each of the consent forms. i.e. females with hypertension (group A), females with hypertension (group B).>

Protocol Version: **Consent Form Revision Date:**

ABOUT THIS CONSENT FORM

< Must include a statement that the study involves research. It should be clear that consent is for explanatory purposes, that participation is voluntary, and their decision should be made only after they have received sufficient information to understand what is being asked of them>.

Recommended Language:

We are asking you to take part in a research study. The title of the study is _____ . It is being funded by _____.

You have been asked to take part in this research because you have_____ (Give a statement as to why this particular person is asked to participate as a research subject)

This is a study of an investigational <drug/device/biologic> called _____. Investigational means that the <drug/device/biologic> is not approved by the Food and Drug Administration.

This form was created to help explain the research study. If you choose to take part, it will be used to document that you want to be part of this research study.

This form includes information that you may need to help you decide whether to take part in this research study. It also tells you whom to contact if you have questions at any time. This form tells why this research is being done. It tells what you will be asked to do if you choose to take part. It tells you about any possible risks, inconveniences, costs, or discomforts you may face. It tells you how your privacy will be protected. You can use this form to help you talk with the investigator. You can also use this form as a reference.

You are urged to discuss any questions you have about this study with members of the research team.

Your doctor is an investigator in this research study. Because of this, he or she is interested in both your welfare and in the conduct or this study. Before entering this study or at anytime, you may ask for a second opinion about your care from another doctor who is not part of this study. You are not required to participate in any research offered by your doctor. If you decide you do not want to participate, your doctor will continue to provide you medical care.

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STUDY CONTACTS

<Include the name and telephone number of the responsible investigator. If the study treatment is invasive, include a 24 hour telephone number>

SPONSOR

<Start typing here>

NUMBER OF SUBJECTS TO BE ENROLLED

<Start typing here>

WHY IS THIS RESEARCH STUDY BEING DONE?

<Give a clear explanation of the reason for the research study. The objectives stated here must match the research protocol. Include relevant background information regarding the investigational intervention and/or disease, as it pertains to the rationale for conducting this study. Include a basic description of the condition/disease under study. Include a basic description of the intervention (s) under study. It should be made clear which of the agents/devices/survey instruments are investigational (experimental) and why each was chosen for the study>

HOW LONG WILL I TAKE PART IN THIS RESEARCH STUDY?

<Specify the minimum amount of time a subject is expected to participate. If the study includes long term follow-up, state what that will entail. If you plan on reviewing medial records, make it clear for how long. Make it clear that subjects have the right to withdraw from the study at any time. When appropriate describe any risks/consequences of sudden withdrawal from the study. Must describe anticipated circumstances under which the subject's participation may be terminated by the investigator without the subject's consent. >

Recommended Language:

We will ask that you stay in this research study for _____ to complete the procedures.

After that, we will ask you to stay on the study so we can collect more information about your health. For example, any treatments you get in the future and whether your disease stays the same or gets better or worse. If you take part in this research, we will collect this information from your medical records. We will store it in a research record.

The investigator or sponsor may stop your participation in this study for several reasons. <List any applicable circumstances>

WHAT WILL HAPPEN IN THIS RESEARCH STUDY?
<Give a clear detailed account of the participant's activity in and contribution to the study. Must include a description of procedures to be followed, and the identification of any procedures that are experimental. Be clear about what procedures are part of this person's routine care and which are protocol-specific. Provide and reference a schema or calendar if there are numerous procedures or visits. Explain what type of information is being collected. Describe any biological specimens that will be collected, specify the amount, describe the collection method, what samples will be used for, and intentions for their disposal or storage. Describe randomization process and use of placebo if applicable.>

Study Information Included in Your Electronic Medical Record
[Statement 1: Use this statement for most studies.]
A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs).

[Statement 2: Use this statement if you consider the study topic to be highly sensitive (for example, studies of sexual practice; sexual victimization; illegal behaviors; alcohol, drugs or other addictive products; or stigmatizing illnesses) such that the study title should <u>not</u> appear in the subject's medical record.]
A notation that you are taking part in this research study may be made in your electronic medical record. **For this study, only a study number, and NOT the title of the study, will be in your record: for example Study #123.** Information from the research that relates to your general medical care may be included in the record (for example: list of allergies, results of standard blood tests done at the hospital labs).

Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

WHAT ARE THE RISKS OF THE STUDY?
<Must include a description of any reasonably foreseeable risks or discomforts to the subject. Must include a statement that the treatment of procedure may involve risks to the subject (or embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable. List all physical and nonphysical risks and discomforts of participating in the study, be explicit about severity and reversibility. Make the likelihood of experiencing each side effect clear. Use language that is understandable to a lay reader. It is preferred to list risks in bulleted format so it is easier to read and understand. List any medications that will be used to prevent certain side effects. If multiple drugs/agents are being used in the study, list the potential side effects for each drug separately. If placebo is used, state the risk that the condition under study may not improve or may become worse.

The information in this section should be limited to the risks and discomforts related to the procedures being done for research purposes, and should not include those related to the participant's routine medical care.>

Recommended Language:

While on this study, you are at risk for side effects described below. Since this drug [or device/procedure/combination of drugs] is so new, there may also be other side effects that we cannot predict. Also side effects may be worse or more frequent than expected.

A big risk to taking part in this study is the drug or dose of a drug may not help you. This means that you may spend time and have side effects taking a drug that does not help you.

For your safety, please tell the doctor all of your present and past diseases and allergies that you know. Since the study drug is new, taking other drugs may increase side effects, or may cause unknown side effects. It is important, therefore, that you tell the study doctor if you are taking any prescription and over-the counter drugs, herbal preparations and nutritional supplements.

If you enroll on this study and have a side effect you are concerned about, you can call the investigator or another study doctor any time of day or night by paging_____.

For Oncology Studies:

Because the drugs in this study can affect an unborn baby, you should not become pregnant or father a child while on this study. You should not breast feed your baby while on this study. Ask about counseling and more information about preventing pregnancy.

Or

Many drugs used to treat cancer including [list study drugs] are highly likely to cause damage to sperms, oocytes (eggs), and developing fetuses (unborn babies). Although there is not enough medical information to know the exact risks, the known effects of these drugs on dividing cells makes it likely that they would cause miscarriages or birth defects if given to expectant mothers. It is therefore imperative that you not become pregnant or father a child while on this study. You should not breast feed your baby while on this study. Ask about counseling and more information about preventing pregnancy.

For Other Studies:

This [treatment/drug/procedure] may involve risks to an unborn child that are currently unforeseeable. Therefore you should avoid becoming pregnant or fathering a child while on this study. If you do become pregnant, you should tell the study doctor right away. You should not breast feed your baby while on this study. Ask for more information about preventing pregnancy.

WHAT ARE THE BENEFITS OF THE STUDY?
<Must include a description of any benefits to the subject or to others which may reasonably be expected from the research. It is acceptable to indicate the specific hopes of the study, however, it must be clear that the effectiveness of the study intervention is unknown. It is not acceptable to be overly optimistic or pass judgment on the relative benefits of this study versus another intervention. Do not include **compensation as a benefit**.>

Recommended Language:

If you agree to take part in this study, there [may or may not be/will not be/will likely be no] direct medical benefit to you. We hope the information learned from this study will benefit other people with _____ in the future.

Or

Based on previous studies, we expect that this study will provide benefits that are at least comparable to [the current standard of care for _____]. These benefits may include [ ]. It is possible that [the new treatment being studied] may be safer and/or more effective than [the standard treatment]. We do not know this yet, however, which is the main reason for performing this study.

WHAT OTHER TREATMENTS OR PROCEDURES ARE AVAILABLE FOR MY CONDITION?
<Disclose appropriate alternative procedures or courses of treatment, if any that might be advantageous to the subject. Include a statement that participation is voluntary. Include palliative care, other investigational agents/trials (general statement, do not need to list specifics), indicate if subjects can get same treatment off study. If study does not include a treatment intervention, clearly state that the alternative is to not enroll in this study. Note: This section may not be relevant for all studies. You may delete this section if the study involves healthy volunteers. **This section must be included when research is designed to test the safety and/or effectiveness of a treatment or procedure**.>

Recommended Language:

Taking part in this research study is voluntary. Instead of being in this study, you have these options:
<list>
You should discuss these and other options with your doctor so that you can make a good decision about taking part in this research study.

CAN I STILL GET MEDICAL CARE WITHIN PARTNERS IF I DON'T TAKE PART IN THIS RESEARCH STUDY, OR IF I STOP TAKING PART?

Recommended Language -

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 or have the 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.

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?
<Include any money or other forms of compensation or reimbursement, include how the amount is calculated if participant does not complete entire study for any reason. Use "compensation" or "reimbursement" rather than "paid." This section may not be relevant for every study. The study heading may be deleted if subjects will not receive any compensation for the study. If there is compensation, include the second paragraph regarding the IRS and taxable income. >

Recommended Language -

The compensation for <state what expenses are covered> while participating in this study will be <$ amount> at the completion of the study <or other time>. If you withdraw early from the study for any reason, you will be compensated for <state what expenses are covered> related to the study visits you have already completed as follows: <state $ amount per visit or other time frame>.

The IRS requires Newton-Wellesley Hospital to report this amount on a Form 1099. In order to do this, you will be asked to give us your Social Security Number and a valid U.S. address. These payments are considered taxable income. If you have any questions regarding this you should consult with a person who can advise you on these matters.

WHAT WILL I HAVE TO PAY FOR IF I TAKE PART IN THIS RESEARCH STUDY?

<Include information about what procedures will be provided at no cost, what procedures will be billed to the participant and his/her health insurance, and when applicable, include a statement indicating that the cost of the participant's routine medical care will be billed to the participant or his/her health insurance company in the usual way. Must include any additional costs to the subject that may result from participation in the research.>

WHAT HAPPENS IF I AM INJURED AS A RESULT OF TAKING PART IN THIS RESEARCH?

<Must include an explanation as to whether any compensation and any medical treatments are available if injury occurs, and if so, what they consist of, or where further information may be obtained. Include a statement specifying whether or not treatment for an injury or illness caused by participation in this study will be covered by the sponsor or institution.>

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 the. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

INSTRUCTIONS: the sponsor may request to include a statement about the injury coverage the sponsor will offer. When the sponsor requests to include such a treatment, the statement may be entered below, after the institution's commitment to provide care for the injury. For example: "In this study, [Sponsor] will pay for medical treatment for any injury that is not paid for by your health insurer if the injury is a direct result of your taking part in the study."

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you may 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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

There are several people available to you if you have questions:

Type of question	Role	Person	Contact
About the study, procedures, risks, benefits, alternatives and rights	Investigator		
About changing the appointment or parking or further discussion about the study.	Study Coordinator		
About questions or complaints you don't want to discuss with the investigator or to obtain information or offer input.	Institutional Review Board	Office of Research	617-243-6493 617-243-6211

PUBLICATION OF RESULTS OR USE FOR TEACHING PURPOSES

Recommended Language:

The results of this study may be published in a medical book or journal or used for teaching purposes. However, your name or other identifiers will not be used in any publication or teaching materials without your specific permission.

If I take part in this research study, how will you protect my privacy?
During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

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.

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.

YOUR PRIVACY RIGHTS

You have the right not to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take 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. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

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. You may only get such information after the research is finished.

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

Subject Identification

Study Doctor or Person Obtaining Consent _____ Date/Time _____

Statement of Person Giving Information 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.

GENERAL INSTRUCTIONS: Include signature line(s) as appropriate to the subject population and consent process described in the protocol document. Delete those signature lines that are not applicable.

Instructions: Include the following signature line when informed consent and authorization for participation of some or all subjects will be obtained directly from the subjects.

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 shard as described above.

Subject _____ Date/Time _____

INSTRUCTIONS: Include the following signature line when informed consent and authorization for participation of some or all child subjects will be obtained from parents/guardian.

Signature of Parent(s)/Guardian for Child:

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

Parent(s)/Guardian for Child _____ Date/Time _____

Subject Identification

INSTRUCTIONS: Include the following signature line when informed consent and authorization for participation of some or all adult subjects will be obtained from a guardian, health care proxy, durable power of attorney, or family member/next of kin.

Signature of Guardian or Authorized Representative for Adult:

I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her health information to be used and shared as described above.

_____
Print Name (check applicable box below)

- ☐ Court-appointed Guardian
- ☐ Health Care Proxy
- ☐ Durable Power of Attorney
- ☐ Family Member/Next-of-Kin

_____ _____
Signature Date/Time

INSTRUCTIONS: Include a line for relationship to adult subject when informed consent and authorization for participation of some or all adult subjects will be obtained from a family member/ next-to-kin.

Relationship to Subjects: _____

Instructions: Include this section when assent of children ages 14-17 or of decisionally-impaired adult subjects will be obtained. Do not include this section for assent of children ages 7-13. For assent of children ages 7-13, use the separate Child Assent 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, and my questions have been answered.
-

Subject Identification

INSTRUCTIONS: Include signature line(s) for children ages 14-17 or decisionally-impaired adult subjects as appropriate to the subject population and assent process described in the protocol documents. Delete those signature lines that are not applicable. When assent of subjects will be obtained, always include at least one of the following signature lines.

Signature of Child:

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

_____ _____

Child, Ages 14-17 Date/Time

Signature of Adult:

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

_____ _____

Adult Date/Time

INSTRUCTIONS: The HRIC does not routinely require a subject advocate be involved in the consent process; therefore, delete this section unless the sponsor requires a subject advocate, or you plan to use a subject advocate. Should the HRIC require a subject advocate, they will instruct you to add the following signature line to the consent form.

Subject Advocate

In certain situations, the Partners Human Research committee (PHRC) will require that a subject advocate also be involved in the consent process. The subject advocate is a person who looks out for the interests of the study subject. This person is not directly involved in carrying out the research. By signing the dating below, the subject advocate represent (or "says") that the subject has given meaningful consent to take part in the research study.

Statement of Subject Advocate

I represent that the subject or authorized individual signing above has given meaningful consent.

Subject Identification

Subject Advocate (when required by HRIC or sponsor _____ Date/Time _____

Instructions: Include the following signature line when you anticipate using the "short form" consent process to obtain and document informed consent of subjects who do not speak English. For more information, refer to http://healthcare.partners.org/phsirb/nonengco.htm.

Consent of Non-English Speaking Subjects Using the "Short Form" in the subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter _____ Date/Time _____

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name _____ Date/Time _____

INSTRUCTIONS: include the following signature line when you anticipate enrolling subjects who cannot read or write in any language.

Subject Identification

Witness to Consent of Subjects who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/ her consent and authorization for participation by (check one box as applicable):

☐ Making his/her mark above

☐ Other means _____
(fill in above)

_____ _____
Witness Date/Time

I have received a copy of this consent form. (Patient's Initials) _____