Research Consent Form

Newton-Wellesley Hospital
2014 Washington Street
Newton, MA 02462

Subject Identification

Protocol Title:

Principal Investigator:

Description of Subject Population:

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

ABOUT THIS CONSENT FORM
<Start typing here>

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?
<Start Typing here>

HOW LONG WILL I TAKE PART IN THIS RESEARCH STUDY?
<Start typing here.>

WHAT WILL HAPPEN IN THIS RESEARCH STUDY?
<Start typing here.>

WHAT ARE THE RISKS OF THE STUDY?
< Start typing here.>

WHAT ARE THE BENEFITS OF THE STUDY?
<Start typing here.>

WHAT OTHER TREATMENTS OR PROCEDURES ARE AVAILABLE FOR MY CONDITION?
<Start typing here.>

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

WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?
<Start typing here>

WHAT WILL I HAVE TO PAY FOR IF I TAKE PART IN THIS RESEARCH STUDY?
<Start typing here>

WHAT HAPPENS IF I AM INJURED AS A RESULT OF TAKING PART IN THIS RESEARCH?
<Start typing here>

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

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.

Subject Identification

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

_____ _____

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.

Subject Identification

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

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.

Subject Identification

_____

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.

Assent

Statement of Person Giving Assent

- 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.
-

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 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.

Witness to Consent of Subjects who Cannot Read or Write

Statement of Witness

Subject Identification

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) _____