PARTNERS HUMAN RESEARCH COMMITTEE
INSTRUCTIONS FOR PREPARING RESEARCH CONSENT FORMS

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SECTION 1: General Instructions

CONSENT FORM (CF) TEMPLATES: Always use the current version of the Consent Form template (version date is in the header on each page). Go to the PHRC website [http://healthcare.partners.org/phsirb] and download the form(s) that you need. The following consent form templates are available on the website:

1. **General Consent Form Template**: Use this template when the study plan is to enroll **ONLY ADULTS** or **BOTH ADULTS AND CHILDREN** (age less than 18 years). When children age 14-17 are to be enrolled, consent of the parent and assent of the child are documented on this form. When children age 13 or less are to be enrolled, consent of the parent(s) is documented on this form and assent of the child (age 7-13) is documented on the separate Youth Assent Form (see below).

2. **Parental Consent Form Template**: Use this template when the study plan is to enroll **ONLY CHILDREN** (age less than 18 years). When children age 14-17 are to be enrolled, consent of the parent(s) and assent of the child are documented on this form. When children age 13 or less are to be enrolled, consent of the parent is documented on this form and assent of the child (age 7-13) is documented on the separate Youth Assent Form (see below).

3. **Youth Assent Form Template**: Use this template to document assent of children between the ages of 7 and 13. **Note**: Assent of children between the ages of 14 and 17 may be documented on the General or on the Parental Consent Form, as described above.

4. **Certificate of Confidentiality Consent Form Template**: Use this template when you have obtained a Certificate of Confidentiality for the study.

5. **Blood Draw (with identifiable health/medical information) Consent Form Template**: Use this template when the study involves only the withdrawal of a limited amount of blood for research purposes and collection of identifiable health/medical information.

6. **Blood Draw (with no identifiable health/medical information) Consent Form Template**: Use this template when the study involves only the withdrawal of a limited amount of blood for research purposes with **NO** identifiable health/medical information.

Note: Please contact us in advance if you wish to use any consent template other than the current PHRC template on the website. We may approve exceptions on a case-by-case basis.

CONSENT FORM FORMAT: Type all documents using **12 point, Times New Roman** font.

- Single space between lines of text; double space between paragraphs; and triple space before each informational heading.
- Place informational headings right above the relevant text. Headings should not "float" at the bottom of the page, either alone or with only part of a sentence attached.
- Before submitting the CF, print and check for printing process errors in the formatting, e.g., changed fonts, indentations, and floating headings.

SECTION 2: Creating Plainly Written Consent Forms

PLAIN LANGUAGE: Consent forms must be easy to read and understand, as research subjects have varying backgrounds and educational levels. Potential subjects may also be under physical and/or emotional stress when approached about participation in a research study. **CFs should be written at an 8th-grade reading level, or lower.** Common strategies for writing CF's that are easy to read and understand are as follows:

1. **Speak directly to the reader.** Use "you" when referring to the subject. For example, "You will take the study drug…," not "I will…" or "Subjects will…."

2. **Use the active voice to make it clear who will do what.** For example, write, "You must give consent" rather than the passive voice, "Consent must be given."

3. **Use words with the fewest number of syllables.** For example, use "drug" rather than "medication," "take part" rather than "participate."

4. **Use short, declarative sentences to deliver a clear message.** Break long sentences into several shorter ones. Express only one major idea in each sentence. Avoid complex sentences loaded with dependent clauses and exceptions.

5. **Break lengthy paragraphs or passages into multiple, shorter paragraphs.** Whenever possible, use a separate, short paragraph for each topic. Express only one major idea in each paragraph.

6. **Avoid unfamiliar or confusing words and phrases.** Avoid jargon. Use lay (non-technical) language in place of medical terminology, e.g., "bruise" rather than "hematoma." If it is necessary to use a technical term, explain it in lay language.
    - Use the same term consistently to identify a specific concept or object, e.g., use "research study" throughout, not a variety of terms such as "study," "investigation," "clinical trial," etc.
    - Use common household measures, i.e., teaspoon, tablespoon, cup, etc. (Note that 5 cc = 5 ml = approximately 1 teaspoon; 3 teaspoons = 1 tablespoon; 16 tablespoons = 1 cup).
    - Define an abbreviation the first time you use it, e.g., MRI (magnetic resonance imaging); then use the abbreviation alone. Limit use of unfamiliar abbreviations.
    - Don't use Latin abbreviations, such as i.e., e.g., and b.i.d, or symbols such as $\leq$ or $\geq$. Instead, use words ("less than or equal to").
    - Use "subjects," rather than "patients," when referring to research subjects, in order to avoid confusion between treatment and research.
    - Use the terms, "your own doctor" and "the study doctor" or "the researcher" to distinguish between the subject's treating physician and the study doctor/researcher.
    - Describe sample or object size in comparison to everyday objects, e.g., "A punch biopsy removes a skin sample about the size of the top of a pencil eraser."

7. **Avoid misinterpretations.** Place words carefully to avoid misinterpretations or muddied meanings.
    - Keep subjects and objects close to their verbs.
    - Make sure pronouns clearly refer to specific nouns.
    - Put conditionals, such as "only" and other modifiers, next to the words they modify, whenever possible.
    - Use contractions when appropriate. For example, write "don't take" rather than "do not take." Some readers may see the "do" and skip over the "not."

8. **Use vertical lists ("bullets") to highlight important information.**
   Use vertical lists of points/items to help your reader focus on important information in a visually clear way. Always use a lead-in sentence or phrase to explain your list of points or items.

   For example, vertical lists are useful for:
   - highlighting levels of importance;
   - helping the reader understand the order in which things happen;
   - making it easy for the reader to identify all necessary steps in a process;
   - setting apart items in a long list for easier reading.

   It's easy to over-use vertical lists. Use them to highlight important information, not to over-emphasize trivial matters. Limit vertical lists to 10 items or less. Be sure they make sense grammatically and are punctuated consistently.

9. **Don't use "You understand…."**
   Beginning a sentence with "You understand…" assumes that the individual reading the consent form understands what is being written, but this may not be the case. Many prospective subjects won't "understand" the scientific and medical significance of all of the statements and will require further explanation.

10. **Always print and proofread** the CF for grammatical, typographical, and formatting errors, and for readability, before submission to the PHRC.

Section 3: Instructions For Consent Form Header

THE HEADER

Add study-specific information by tabbing to (or clicking on) highlighted text fields.

1. **Protocol Title:** In most cases, this should be **identical** to the protocol submission.

2. **Principal/Overall Investigator:** The Principal Investigator (PI) must be a staff member of a Partners Institution, not a trainee, e.g., not a Fellow, Resident, or House Officer. There can be only **one** overall Principal Investigator.

3. **Site-Responsible Investigator(s)/Institution:** Add names in this space **ONLY** when one consent form is used for enrollment of subjects at multiple Partners' sites.

   - **DON'T** list the name of the overall principal investigator on this line.

   - **DON'T** list Overall PI, **non-Partners** Site-Responsible Investigators, Partners Co-investigators, or Study Staff on this line.

   - **DO** list **one** Site-Responsible Investigator for each participating Partners site when the consent form is used to enroll subjects at multiple Partners sites (i.e., BWH, MGH, NSMC, NWH, PCHI, SRH).

4. **Description of Subject Population:** Describe study population, e.g., "adults with diabetes," "healthy adults," etc. Do not include multiple inclusion criteria here, (for

example, “women with osteoporosis taking Fosamax”). The purpose of this line is to provide a brief description of the study population.

- **Don’t use the term “patients**,**”** as this document specifically refers to research subjects. Instead, use “adults,” “children,” “adolescents,” etc.

- **For multiple CFs**, label each one with the name of the study subpart and/or intended signers in parentheses, e.g., “Women with Endometriosis (Screening Phase)” or “Women with Endometriosis (Study Phase).”

5. **Subject Identification Box:** When a subject has given consent to take part, his/her identification information must be recorded on **all** pages of the CF as follows:

   Imprint the subject’s hospital ID card in the subject identification box on each page

   OR

   Print the subject’s name, address, and date of birth in the box on each page.

Section 4: Instructions For Each Section

REQUIRED ELEMENTS OF INFORMED CONSENT. The Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) require that certain information be provided to subjects when seeking their informed consent to participate in research. These basic and additional elements of informed consent have been incorporated into the instructions that follow. Whenever language is taken directly from the regulations, it is italicized in quotation marks. Section 5 of this document outlines the federal requirements for informed consent, as set forth in 45 CFR 46.116(a)(b) and 21 CFR 50.25(a)(b).

About This Consent Form

The text provided in the first paragraph of this section of the template cannot be changed.

The General Consent Form Template includes suggested language for use when the study plan is to enroll **BOTH ADULTS AND CHILDREN** (age less than 18 years). **Note**: For studies that involve **ONLY CHILDREN**, use the Parental Consent Form Template.

The General Consent Form Template also includes suggested language for use when the study plan is to enroll subjects who have impaired decision-making capacity requiring that permission for their participation be obtained from an authorized representative.

Why is this research study being done?

Include the following information under this heading:

1. **Purpose:** Provide *“an explanation of the **purposes of the research**”* [45 CFR 46.116(a)(1) and 21 CFR 50.25(a)(1)]. The purpose of the research study derives from, and must be consistent with, the specific aims of the protocol.

   For example, if the study is being done to test the efficacy and safety of an

investigational drug, state as follows: “The purpose of this research study is to find out whether [name of study drug] can help people with [disease/condition] and whether it is safe for them to take.”

When a **placebo** is used, mention that the study drug(s) will be compared to placebo. Explain placebo as follows:

“This study uses a placebo. A placebo looks exactly like the study drug, but it contains no active drug. We use placebos in research studies to learn if the effects seen in research subjects are truly from the study drug or from other reasons.”

If the study is a pilot study, include: “This is a pilot study. We do pilot studies on a small group of subjects to learn if a larger study would be useful.”

2. **Reason for Asking Individual to Take Part:** State explicitly why this particular person is being asked to take part.

   For example, “We are asking you to take part in this research study because you have adult onset diabetes but do not require insulin or other drugs to treat your condition.” **Don’t** use the term “invite.”

3. **Information on Drugs/Devices/Procedures Being Studied:** Identify *“any **procedures which are experimental**”* [45 CFR 46.116(a)(1) and 21 CFR 50.25(a)(1)]. Specify the FDA status of all drugs/devices under study, including whether the FDA has approved the drugs/devices for the indication/use being studied. If prior use in humans is limited, this should be stated.

   For example, “The [insert name of study drug/device] is/is not approved by the U.S. Food and Drug Administration (FDA) to treat [insert indication/use being studied].”

   For drugs approved by the FDA for another indication, but used off label in the study, use the following statement, “The FDA has approved [drug name] to treat [disease XYZ], but the FDA has not approved [drug name] to treat [disease ABC].”

   When the drug/device is <u>not</u> approved by the FDA for sale for any indication/use, include the following statement, “This means that [study drug/device] is available only for use in research studies.”

4. **Name of Corporate Sponsor(s):** Name corporate sponsor(s) and, when applicable, state that the sponsor is the company that makes the drug/device. Naming corporate sponsors informs subjects of entities with financial interests in the outcome of the study.

   For example, “[Sponsor name], the company that makes [drug/device], is paying us to do the study.”

   If the sponsor is only supplying the study drug, include the following: [Sponsor name], the company that makes the study drug [drug name] is supplying the drug for this study.

   Don’t name non-corporate sponsors (NIH or other) here. A subject may interpret government sponsorship of the research to be reassurance of the study’s safety or scientific merit.

5. **Expected Enrollment:** State *"the approximate **number of subjects** involved in the study"* [45 CFR 46.116(b)(6) and 21 CFR 50.25(b)(6)]. Indicate the approximate number to be enrolled at all sites, and at Partners site(s).

   For example, "About 100 people will take part in this research study. We expect to enroll about 20 subjects at Brigham and Women's Hospital (BWH)."

How long will I take part in this research study?

Describe *"the **expected duration of the subject's participation**"* [45 CFR 46.116(a)(1) and 21 CFR 50.25(a)(1)]. The expected duration of the subject's participation is the length of time from the subject's enrollment (signing the consent form) to the subject's completion of the final study visit or other follow-up study contact.

For example, "It will take you about [Insert duration of participation in hours, days, weeks, months, or years] to complete the study. During this time we will ask you to make [Insert Number] study visits."

What will happen in this research study?

Describe *"the **procedures to be followed,"*** [45 CFR 46.116(a)(1) and 21 CFR 50.25(a)(1)]. Organize this information chronologically by study visit, whenever possible. Include how much time it will take to complete each study visit and, in some cases, how long the study procedures will take.

The following must be included in the description of the procedures, when applicable to the study:

1. **Study design, including randomization, use of placebo, and blinding**. These details usually belong in the description of the randomization visit.

   When **randomization** is used, state the following:

   "We will assign you by chance (like a coin toss) to [describe the study groups, for example, drug, dose, route, schedule of administration]. You and the study doctor cannot choose your study group. You will have a [insert chance of being assigned to each group, for example 1 out of 3, an equal chance, etc.] of being assigned to [insert study groups]." Avoid using percentages, such as 50% chance.

   When a **double blind** design is used, state the following:

   "You and the study doctor will not know which study group you are in, but we can find out that information if we need it."

2. **Medical history and physical exams.** For example, questions about health history, past and current medications, height, weight, temperature, blood pressure, and heart rate. **Note**: Consider mentioning study-related elements of the physical exam that subjects may not expect to be part of a routine office physical for a healthy adult, e.g., a rectal or pelvic exam.

3. **Blood and urine tests** (including pregnancy tests, drug screens and other sensitive testing, such as HIV and hepatitis). For **blood draws**, include the total amount of blood withdrawn over the course of the study. Use household measures (teaspoons, tablespoons, cups, pints, etc.) to describe the amounts. When the total amount of blood is relatively large, use 2 cups (a standard blood donation) as a comparison.

   Pregnancy testing in minors: Add a statement, such as the following: "If your daughter has begun her periods (menstruation), we will ask her for a urine sample to test for pregnancy. If the test shows your daughter is pregnant, we will tell her. Your daughter cannot take part in this study if she is pregnant. We will tell you the results if your daughter agrees to let us tell you. Even if she does not agree, the study doctor may decide to tell you based on your daughter's age and maturity."

4. **Imaging tests.** For example, X-rays, MRIs, PET scans, ultrasound.

5. **Surgical and nonsurgical procedures.** For example, endoscopies, biopsies.

6. **Questionnaires or interviews.** Include a brief description of the types of questions included in the questionnaires or interviews. Include an estimate of how much time it will take to complete the questionnaires or interviews, and add the following statement: "While we hope that you will answer all of the questions, you can skip any questions you don't want to answer."

7. **Special study requirements.** For example, provide instructions for stopping current medications or, if any study tests or procedures require fasting before a study visit, give specific instructions on fasting, including length of fast before study visit and permissible fluids (e.g., water, no water).

8. **Off-site testing.** When the study requires off-site procedures, an explanation of where the visits, tests, or procedures will take place. Include details about transportation to and from the other site, when appropriate.

9. **Investigational diagnostic testing.** Explain that the findings will not be used to make clinical decisions.

10. **Research procedures added to routine clinical care.** Explain which procedures are done only for research and which would be done regardless of the individual's participation in the research. In general, describe in detail only research procedures. Description of research procedures should be included even when the subject is required to sign a separate clinical consent form, as in the case of lumbar punctures, biopsies, cardiac catheterization, etc.

11. **Sending data/specimens to research collaborators outside Partners.** Explain what information/specimens will be sent, to whom it will be sent, for what purpose, and how confidentiality will be maintained, such as details on how samples will be coded, etc.

12. **Storage of data/specimens for future use.** When data/specimens will be maintained at Partners or non-Partners sites for **future use**, be as specific as possible when describing the future use.

For example, state, “Some of your samples and study information will be used for research on bipolar disorder.” Describe where data/specimens will be stored and for how long, how confidentiality will be maintained, how data/specimens will be identified, and whether data/specimens can be withdrawn by the subject at a later time. When applicable, describe what the subject must do to have his/her data/specimens withdrawn.

13. **Use of Specimens.** When cells, tissues, blood or other specimens are collected during the course of the study, include the following statement:

    “We may use your samples and information to develop a new product or medical test to be sold. The sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples and information are used for this purpose.”

14. **Optional Procedures.** When a subject can participate in the study without agreeing to undergo certain study procedures, provide a space for subjects to indicate their choice and initial their selection. First, state that the procedures are not required for study participation. **Double space** before and after the optional items, so they stand out from the rest of the text. Use **bold type** for any consent items requiring initials or signatures.

    For example, “This procedure is optional (not required). You do not have to agree to have this procedure to take part in the study. The choice is yours.”

    Do you agree to have one additional biopsy? Yes___ No ___ Initials ___

15. **Sponsor Use of Identifiable Study Information for Additional Research.** When the research is corporate sponsored, use the following language when the corporate sponsor requests to use identifiable study information for additional research related to the study. The PHRC will allow only the following language on sponsor use of identifiable study information for this purpose:

    “[Company name], the sponsor of this research study, may use study information that identifies you to do the research described in this form and to do related research. This means research related to [insert name of drug or device being studied], alone or in combination with other drugs/devices; [insert medical condition being studied, e.g., glioblastoma, osteoporosis], or [insert general field, e.g., cancer, vascular disease (problems with the heart and blood vessels), asthma and inflammation], which is the same disease area being studied in this research.”

The following information must be included, when appropriate:

16. *“Anticipated circumstances under which the **subject’s participation may be terminated by the investigator** without regard to the subject’s consent”* [45 CFR 46.116(b)(2) and 21 CFR 50.25(b)(2)]. This requirement would be applicable to most interventional or treatment studies. Anticipated circumstances may include: (1) health reasons (e.g., serious adverse events, pregnancy); (2) issues of study compliance, (e.g., failure to make study visits or to take study drug as directed); (3) sponsor’s decision to stop the study; and (4) administrative reasons, among others.

17. *"Procedures for orderly **termination of participation by the subject**"* [45 CFR 46.116(b)(4) and 21 CFR 50.25(b)(4)]. This requirement would be applicable to most interventional or treatment studies. Procedures for orderly discontinuation of a subject might include telling the subject to taper the study drug and/or asking the subject to make a final study visit, and in some cases, asking for the return of any unused study drug, medical devices, diaries, or questionnaires. The final study visit may include a physical exam, laboratory tests, questionnaires, or other procedures. These should be specified, along with how long the end-of-study visit might last.

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

Describe *"any **reasonably foreseeable risks or discomforts** to the subject"* that might result from participation in the study [45 CFR 46.116(a)(2) and 21 CFR 50.25(a)(2)]. Be careful not to minimize risks or discomforts. Avoid use of reassuring terms such as "only a few," "generally safe," or "minimal risk." Use facts and figures, if available, to accurately state risks. Don't use percentages, instead explain occurrence of risks as XX out of 100. When appropriate for your study, we suggest the following introductory statement:

> "You may have side effects while taking part in this study. We will watch you carefully for any side effects. Side effects may or may not be serious. Many side effects will go away soon after you stop [insert taking the study drug, using the study device, or the study procedures]. **If you have any side effects during the study, you should tell the researchers right away.**"

The following must be included in the description of the reasonably foreseeable risks, when applicable to the study.

1. **Risks from drugs/devices/procedures performed solely for research purposes.** Include risks from baseline/screening procedures and ancillary/supportive care performed for research purposes.

   For example: (1) ancillary/supportive care **drugs**, such as lidocaine for research biopsies; gadolinium administration for a research contrast CT scan; (2) ancillary **procedures**, such as placement of an arterial line for research PET scans, or placement of an IV catheter for frequent blood sampling for pharmacokinetic research.

   Don't include these risks if the ancillary/supportive care would be done whether or not the subject takes part in the study.

   List separately for each drug/device/procedure the risks and discomforts in four categories, whenever possible. (1) **very common**; (2), **common**; (3) **less common;** and (4) **rare, but serious**.

   The categories of expected frequencies of **adverse drug reactions** are based on recommended guidelines for preparing clinical safety information from the Council for International Organizations of Medical Sciences (CIOMS), as described below:

Category	Range

Very common	≥ 10%
Common	≥ 1% and < 10%
Uncommon	≥ 0.1% and < 1%
Rare	≥ 0.01% and < 0.1%
Very rare	< 0.01%

In the "**very common,**" "**common**" and "**uncommon**" categories, identify those side effects that may be "serious." "Serious" side effects are those that:

- may result in death;
- may be potentially life threatening;
- may require inpatient hospitalization or prolongation of existing hospitalization;
- may result in a persistent or significant disability/incapacity;
- may result in a congenital anomaly/birth defect; or
- may require medical or surgical intervention to prevent serious outcomes.

"**Rare and very rare**" side effects do not have to be listed unless they are "serious," and then they should appear in the "rare but serious" category.

Whenever possible, describe side effects by how they make the subject feel.

For example, "Anemia (loss of red blood cells) – which can cause people to feel tired, weak, and short of breath."

When appropriate, add **risk of allergic reaction**, describe symptoms, and tell subjects what they should do if they experience these symptoms.

2. **Risks to an embryo or fetus or nursing infant.** Address the possibility of harm to an embryo or fetus.

   - Describe the **known** risks to an embryo, fetus, or nursing infant.
   - Include any requirements for use of birth control (by women and, when appropriate, by men) during the study and for whatever period thereafter. Using lay language (such as "birth control pill" for oral contraceptives), include a list of acceptable birth control methods. If a subject will be withdrawn from the study if she becomes pregnant, this must be stated.
   - If the investigators would like to follow the outcome of the pregnancy and the child after the birth, this must be requested. Describe the nature of the follow-up.

3. **Risks from drug interactions.** When applicable, remind the subject to contact the investigator before taking any new prescription or over-the-counter drugs, including nutritional or herbal supplements, or before making any changes in currently used prescription or over-the-counter drugs.

   For example: "It may be dangerous to take the study drug with other drugs. Contact the study doctor or study staff before you take any new drug or medication or change any drug or medication you are currently taking. This includes prescription drugs, over-the-counter medications, and dietary (vitamins) or herbal supplements."

4. **Risks from research-related exposure to radiation.** Describe the risks associated with only the research-related exposure(s) to radiation. The Radiation Safety

Committee will review this statement.

5. **Risks from incidental findings of unknown clinical significance.** When applicable, include risks of incidental findings of unknown clinical significance discovered during the study.

   When, for example, PET scans or MRI scans are done for research only, include an explanation of how incidental findings of possible clinical significance discovered during the study will be shared with the subject and/or the subject's own doctor.

   For example, "The MRI being done for this study is designed to answer research questions, not to examine your brain medically. This MRI is not a substitute for one a doctor would order. It may not show problems that would be picked up by a medical MRI. However, if we believe that there is something unusual in your MRI, we will ask a doctor trained to read MRIs to look at your MRI. If the specialist thinks that there may be something unusual in your MRI, we will contact you and refer you to another doctor for follow-up. If you have a primary care doctor, we can also contact your doctor (with your permission) and help get the right care for you. The results of your research MRI will not routinely become part of your hospital record. If we think there might be a problem but do not actually find one, you might be worried unnecessarily."

6. **Risks associated with daily activities.** Routine daily activities may become hazardous as a result of study participation.

   For example, when a drug that has sedative properties will be given, subjects should be told that the study drug might impair judgment. Include how long this impairment might last (e.g., "during the first week of treatment," "as long as you are taking the study drug and for two weeks after stopping the drug," etc.). Mention that the degree and duration of impairment will vary from person to person.

   For example, "The study drug can make you feel sleepy. However, it does not have the same effect on everyone taking it. To be on the safe side, you should not drink alcoholic beverages, drive a car, or operate machinery until you know how the study drug affects you."

7. **Risks to privacy/confidentiality of information.** Include risks related to disclosure of sensitive information, e.g., genetic testing, substance abuse, illegal activity, mental health diagnosis, sexual behavior, etc.

8. **Risks of disclosure of reportable information.** Include, when applicable, the requirement for investigators to report to legal authorities suspected child abuse, elder abuse, or intent of the subject to harm self or others.

9. **Discomforts.** Include, for example:
   - local reaction (pain associated with needle stick or bruising in area where needle was inserted) from blood withdrawal;
   - staying in one position during a lengthy procedure;
   - being enclosed in a confined space;
   - breathing through a mask;
   - completing lengthy questionnaires, etc.;
   - embarrassment or emotional discomfort when answering questions of a personal nature. Indicate that the subject can always choose not to answer

the question.

10. **Opportunity costs.** Participating in a research study may mean that a subject must forego other treatment options. Include, for example, the risk of stopping current therapy and possibly receiving less effective treatment as a subject in a research study. When applicable, mention the delay (due to study participation) in receiving standard therapy, such as when the subject is newly diagnosed.

11. **Non-medical risks of genetic studies:** Include, for example, risks to insurability and employment, potential psychological risks to the subject or family members who receive information about genetic findings, etc.

    For example, "Genetic information that results from this study does not have medical or treatment importance at this time. However, information about taking part in a genetic study may influence insurance and/or employers regarding your health status. If you do not share information about taking part in this study with others, you will reduce these risks. We will not place information about your participation in the study or the results of study tests in your medical record."

The following information must be included, when appropriate:

12. *"A statement that the particular treatment or procedure may involve **risks** to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently **unforeseeable**"* [45 CFR 46.116(b)(1) and 21.CFR 50.25(b)(1)]**.**

    For example, "There may be other side effects that are not known at this time."

    For women who can become pregnant: "The effect of the study [drug/device/procedure] on an embryo or fetus is unknown and may be harmful. You cannot take part in this study if you are pregnant or trying to get pregnant.

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

Describe *"any **benefits to the subject or to others** which may reasonably be expected from the research"* [45 CFR 46.116(a)(3) and 21 CFR 50.25(a)(3)]. Provide an accurate statement of possible benefits to the subject. **Do not include compensation as a benefit.**

1. **Possible benefit to individual subjects:** The first sentence, typically, should be: "You may not benefit from taking part in this study. However, we hope that [describe possible benefits]."

2. **No benefit to individual subjects:** The first sentence of this section, typically, should be: "You will not benefit from taking part in this study."

3. **Benefits to future patients:** Describe any future benefits to others that may reasonably be expected from the research. Avoid either understating or overstating the benefits to general scientific knowledge or to future patients.

   For example, "Others with [insert disease or condition being studied] may benefit in the future from what we learn in this study."

What other treatments or procedures are available for my condition?

Provide information on *"**appropriate alternative procedures or courses of treatment**, if any, that might be advantageous to the subject"* [45 CFR 46.116(a)(4) and 21 CFR 50.25(a)(4)]. Explicitly and concisely list the alternative procedures or courses of treatment. Be specific and name at least some other drugs, tests or procedures; this is required by federal guidelines. **It is not sufficient to state that alternative procedures or courses of treatments will be discussed with the subject.**

Include the following, when appropriate:

- Palliative care or no treatment;
- Taking part in other research studies;
- Availability of the study drug or device off-study (include this only when the drug/device is routinely used for this purpose at BWH/MGH).

Note: This section may not be relevant for all studies. You may delete this section heading if the study involves healthy volunteers and/or is designed to study human physiology. This section should be included when the research is designed to test the safety and/or effectiveness of a procedure or course of treatment, or if the study tests or evaluations are also available outside the 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?

The text provided in the template cannot be changed. This section states that *"**participation is voluntary**, **refusal to participate will involve no penalty or loss of benefits** to which the subject is otherwise entitled, and the **subject may discontinue participation at any time** without penalty or loss of benefits to which the subject is otherwise entitled"* [45 CFR 46.116(a)(8) and 21 CFR 50.25(a)(8)].

Also, this section includes *"a statement that **significant new findings** developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject"* [45 CFR 46.116(b)(5) and 21 CFR 50.25(b)(5)].

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

Describe what, if anything, a subject will receive for participating (e.g., money, or other compensation or reimbursement, such as a gift certificate, meal voucher, parking voucher, travel expenses, babysitting expenses, etc.). Always pro-rate compensation for individuals who, for whatever reason, don't or can't complete the study. For guidelines on remuneration, refer to http://healthcare.partners.org/phsirb/remun.htm

Note: You may choose to delete this section heading if subjects will not be paid and will not receive other forms of compensation for participation. Alternatively, you may state, "We will not pay you for taking part in this research study."

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

Explain how the cost of research-related procedures will be covered. When appropriate, include *"any **additional costs** to the subject that may result from participation in the research"* [45 CFR 46.116(b)(3) and 21 CFR 50.25(b)(3)].

1. **Research Costs** are exams/visits, procedures, tests, medications, investigational drugs, etc. or anything that is done solely for the purposes of the study. Generally, research funds must cover these costs, and subjects or their health insurers are not to be billed for research-related procedures.

   Note: If a standard care procedure is performed for research purposes more often than clinically required, then the extra procedures should be covered by research funds. For example, if a diagnostic scan is repeated to determine study eligibility, or if follow-up scans are done every four weeks instead of the standard care every eight weeks, the extra scans should be covered by research funds.

2. **Standard Clinical Costs** are those procedures and tests that would be done even if the subject did not participate in the research study.

   Include a statement, such as "The cost of your routine medical care will be billed to you or to your health insurance company in the usual way. You may be responsible for co-pays or deductibles."

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

The text provided cannot be changed. This section provides *"an explanation as to whether any **compensation** and an explanation as to whether any **medical treatments** are available if **injury** occurs and, if so, what they consist of, or where further information may be obtained"* [45 CFR 46.116(a)(6) and 21 CFR 50.25(a)(6)].

Note: When the sponsor requests inclusion of a statement about the injury coverage the sponsor will offer, the sponsor statement may be included in a separate paragraph after the first paragraph of the Partners standard language. If the sponsor language repeats the Partners standard language, delete repetitive language.

For example, "[Sponsor] will pay for the cost of medical treatment for any injury that is not paid for by your insurance company if the injury is a direct result of your participation in the study as described in the protocol. [Sponsor] has no plans to offer additional compensation."

Don't use exculpatory language, by which a subject agrees to waive or appears to waive legal rights to compensation after injury.

For example, "The sponsor will not pay for your medical care or compensate you for any injuries you may receive by taking part in this research study."

An example of language that is not exculpatory is: "The sponsor has no plans to pay for your medical care or to pay you if you are injured as a result of taking part in this research study."

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

This section provides *"an explanation of **whom to contact** for answers to pertinent **questions** about the **research and research subjects' rights**, and whom to contact in the event of a **research-related injury** to the subject"* [45 CFR 46.116(a)(7) and 21 CFR 50.25(a)(7)].

Provide names, phone numbers, special instructions, email addresses, and other information, as appropriate. **Note**: Each name must be followed by academic degrees, e.g., Grace Smith, M.D., Michael James, Ph.D., etc., so that subjects know the credentials of the individual they are contacting. Designating contacts as the study nurse, study doctor, study psychologist, study staff, etc. is helpful.

1. The text in the **first paragraph** of this section cannot be changed.

2. In the **second paragraph**, list the name and telephone number(s) of the Principal Investigator as the person in charge. If you are using one consent form for **multiple Partners sites**, also list contact information for **each** site's principal investigator.

   If the research involves treatment or other study procedures that pose more than minimal risk, also list the physician on call for medical concerns (e.g., side effects, new medications, injury). **This person must be a licensed physician listed on the protocol.** A 24-hour telephone contact number for this person must be included in this paragraph.

3. In the **third paragraph,** list the person(s) to call for general, non-emergent questions (e.g., scheduling study visits, payment for participation). This may be another member of the study staff. If you are using one consent form for multiple Partners sites, list a contact person for **each** site.

4. The text of the **last three paragraphs** in this section cannot be changed.

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

The text provided in this section of the template cannot be changed. This section describes *"the extent, if any, to which **confidentiality of records identifying the subjects** will be maintained"* [45 CFR 46.116(a)(5) and 21 CFR 50.25(a)(5)]. Specifically, this section discloses how protected health information (PHI) that identifies subjects will be used within Partners and shared with others outside of Partners.

Some boxes have been checked and cannot be unchecked, as these items apply to every research study and are required by the IRB. Empty check boxes are included next to potential uses and disclosures of PHI. Click on the optional boxes that apply to your study. This will place an "X" in each one. **Delete Instructions in shaded text boxes**.

Generally, it is prudent to obtain authorization for **every potential use** within Partners and **every potential disclosure** outside of Partners. By using this approach, you may avoid having to re-contact subjects to obtain additional written authorization or having to obtain a waiver of authorization from the IRB.

You will need to check any of the following boxes that apply to your study:

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

  Check the following box if you will look at subjects' medical records at any time, e.g., for screening, follow-up, etc.

  ☐ Information from your hospital or office health care records, within Partners or elsewhere, that may be reasonably related to the conduct and oversight of the study. If health information is needed from your doctors or hospitals outside Partners, we will ask you to give permission for these records to be sent to the researchers within Partners.

  Check the following box if you will create new identifiable health information about the subject as a result of lab tests, exams, etc. Generally, all research requiring written informed consent will create new PHI; therefore, this box should usually be checked.

  ☐ New health information from tests, procedures, visits, interviews, or forms filled out as part of the research study.

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

  The text in this section cannot be changed.

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

  This section is divided into "within Partners" and "outside Partners." **Note**: The first six boxes are already checked. These boxes cannot be unchecked, as these items apply to every study. The boxes listed below may or may not apply to your study:

  Check the following box if a sponsor or its agents (including corporate as well as non-corporate sponsors) will ever have access to subjects' identifiable health information (for example, during monitoring, review of AEs, and quality assurance). **It is always advisable to check this box if a sponsor is involved**, as you may not always anticipate the sponsor's need to review research records.

  ☐ The sponsor(s) of the research study, and people or groups it hires to help do the research

  Check the following box if other researchers and medical centers will have access to subjects' identifiable health information. **It is always advisable to check this box if any information will be shared with researchers and medical centers outside of Partners, or if this is a multi-center trial.** You

may not anticipate their desire to obtain even a single identifier, such as a date of birth, or the date a blood sample was drawn.

☐ Other researchers and medical centers that are part of this research study.

Check the following box if an independent Data Safety Monitoring Board (DSMB) or other independent individual or group has been designated, or if you anticipate that one might be set up at any time in the future.

☐ A group that oversees the data (study information) and safety of this research study.

Check the following box and type the name of any other entities/parties with whom identifiable health information will be shared, but only if they are not covered in the preceding categories.

☐ Other: TYPE NAME HERE

- **Your Privacy Rights**

  The only text provided in this section that can be changed is the final sentence: "In this research study, you may only get such health information after the research is finished."

  Delete this sentence if you will allow subjects to see and get a copy of their health information used or shared for treatment or for payment at any time during the study.

  Leave this sentence in if allowing subjects to see their health information during the study would jeopardize the scientific integrity of the results (for example, because the study is blinded).

Consent to Take Part in This Research Study, and Authorization to Use or Share Your Health Information for Research

The text provided in the template cannot be changed.

Note: The Partners Research Consent Form includes a line next to the signature line for date/time. Although all consent forms must be signed and dated, documentation of the time the consent form is signed is not required. Time is included with date to accommodate sponsors that require the exact time the document is signed be recorded on the consent form.

Consent Form Version Date

A field for consent form version date has been provided at the end of the consent document so that the person creating/updating the document can indicate the date the document was created/last updated.

In addition, an unlocked area has been provided following the Consent Form Version Date so that study sites can add information that will be helpful to better manage consent documents and versions. The study site may use this unlocked area to type in the file name and location (path name) of the consent document. Alternatively, they may choose to use one of several tools available in Word that will automatically add the file name and location and/or the date the document was created, as specified by the user. **PLEASE NOTE: THE USE OF THIS UNLOCKED AREA IS OPTIONAL**.

To use Word tools to automatically add fields to the end of the document,

1. On the Word Toolbar, click on **Insert**
2. Select **Field**
3. Under Categories, select **Document Information**
4. Under Field Names, select desired fields, such as **FileName**
5. To add path (/p) to the FileName, click on **Options**
6. Select **Field Specific Switches**
7. Click on **Add to Field**
8. Click on **OK**, and **OK** again

To use Word to **manually update fields** added to the end of the document,

1. Click on the **field**
2. Press **F9** on your keyboard.

To use Word tools to **automatically update fields** added to the end of the document,

1. On the Word Toolbar, click on **Tools**
2. Select **Options**
3. Click on **Print**
4. Check the box **Update Fields**
5. Click on **OK**

IMPORTANT REMINDER: Automatic field updates will occur when anyone, including the IRB office staff, prints the consent document.

Consent Form Instructions Version Date: December 2005

SECTION 5: FEDERAL REQUIREMENTS FOR INFORMED CONSENT (45 CFR 46.116 and 21 CFR 50.25)

The Department of Health and Human Services (DHHS) regulations [45 CFR 46.116(1)(1-8)] and the Food and Drug Administration (FDA) regulations [21 CFR 50.25(a)(1-8)] require that the following basic elements of informed consent be provided to each subject:

(1) A statement that the study **involves research**, an explanation of the **purposes** of the research and the **expected duration** of the subject's participation, a description of the **procedures** to be followed, and identification of any procedures which are **experimental**;

(2) A description of any reasonably foreseeable **risks or discomforts** to the subject;

(3) A description of any **benefits** to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate **alternative procedures** or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which **confidentiality** of records identifying the subjects will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any **compensation** and an explanation as to whether any medical treatments are available if **injury** occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of **whom to contact** for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(8) A statement that participation is **voluntary**, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, one or more of the following elements of information shall also be provided to each subject [45 CFR 46.116(b)(1-6) and 21 CFR 50.25(b)(1-6)]:

(1) A statement that the particular treatment or procedure may involve **risks** to the subject (or to the embryo or fetus, if the subject may become pregnant) that are currently **unforeseeable**;

(2) Anticipated circumstances under which the subject's **participation** may be **terminated** by the investigator without regard to the subject's consent;

(3) Any **additional costs** to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research, and procedures for **orderly termination** of participation by the subject;

(5) A statement that significant **new findings** developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate **number of subjects** involved in the study.