

**MASS GENERAL BRIGHAM HUMAN RESEARCH
OFFICE
RESEARCH CONSENT FORM REVIEW
WORKSHEET**

This consent form review worksheet has been developed to assist members with review of research consent forms. Investigators are encouraged to use this tool in addition to the instructions, templates and worksheets for developing consent forms available in Research Navigator.

Federal regulations require that the following **BASIC ELEMENTS OF INFORMED CONSENT** shall be provided to each subject. When appropriate, the following **ADDITIONAL INFORMATION** shall be provided to each subject:

About this consent form

- A statement that the study involves research

Note: This is covered in the standard consent form language in the consent form template.

- When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A),** include the following statement required by FDA, “A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”

Why is this research study being done?

- An explanation of the purposes of the research
- When appropriate,** the approximate number of subjects involved in the study **(include whenever accrual goal for entire study/our sites is included in the protocol submission)**

How long will I take part in this research study?

- An explanation of the expected duration of the subject’s participation

What will happen in this research study?

- A description of the procedures to be followed
- Identification of any procedures which are experimental; for example: IND drugs; off-label use of FDA-approved drugs; investigational devices; off-label use of FDA-approved devices; experimental surgical techniques/approaches
- When appropriate,** anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent **(include this when the protocol mentions this possibility)**
- When appropriate,** the consequences of a subject’s decision to withdraw from the research; for example: stopping the study drug abruptly **(include this when withdrawal from the research may have adverse consequences)**
- When appropriate,** procedures for orderly termination of participation by the subject **(include this when the protocol includes procedures for early withdrawal/termination)**

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

- A description of any reasonably foreseeable risks or discomforts to the subject and, when applicable, the embryo or fetus; for example: physical, psychological, social, economic, or legal risks
- When appropriate,** a statement that the particular treatment or procedure may involve risks to the subject that are currently unforeseeable **(include this when research involves investigational drugs/devices, or other experimental procedures involving risk, or where a goal of the research is to define safety)**
- When appropriate,** a statement that the particular treatment or procedure may involve risks to the embryo or fetus, if the subject may become pregnant that are currently unforeseeable **(include this when the research involves pregnant women/women who can become pregnant, and the effect of the research procedures on pregnancy have not been evaluated or a goal of the research is to define safety in pregnancy)**

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

- A description of any benefits to the subject or to others which may reasonably be expected from the research

What other treatments or procedures are available for my condition?

- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject **(may not be applicable for all studies; e.g., studies of healthy volunteer or human physiology)**

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

- A statement that participation is voluntary
- A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
- A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
- When appropriate**, 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

Note: These are covered in the standard consent form language in the consent form template.

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

- A statement about the procedures for dropping out of the study, or being withdrawn from the study

Note: This is covered in the standard consent form language in the consent form template.

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

- When applicable**, the anticipated pro-rated payment, if any, to the subject for participating in the trial (amount and schedule of pro-rated payments)

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

- When appropriate**, any additional costs to the subject that may result from participation in the research **(include this when additional costs are expected)**

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

For research involving more than minimal risk,

- An explanation as to whether any compensation is available if injury occurs
- An explanation as to whether any medical treatments are available if injury occurs and,
- If so, what they consist of, or where further information [about compensation and available medical treatments] may be obtained
- Whom to contact in the event of a research-related injury to the subject

Note: These are covered in the standard consent form language in the consent form template.

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

- An explanation of whom to contact for answers to pertinent questions about the research
- An explanation of whom to contact for answers to questions about research subjects' rights, or to discuss concerns or complaints about the research

Note: These are covered in the standard consent form language in the consent form template.

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

- A statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained
- A statement that notes the possibility that the Food and Drug Administration may inspect the records

Note: These are covered in the standard consent form language in the consent form template.