

**PARTNERS HUMAN RESEARCH COMMITTEE
INFORMED CONSENT DOCUMENT CHECKLIST**

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:

Why is this research study being done?

- (1) A statement that the study **involves research**,
 an explanation of the **purposes** of the research

How long will I take part in this research study?

- the **expected duration** of the subject's participation,

What will happen in this research study?

- a description of the **procedures** to be followed, and
 identification of any procedures which are **experimental**;

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

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

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

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

What other treatments or procedures are available for my condition?

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

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

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

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

- (6) For research involving **more than minimal risk**,
 an explanation as to whether any **compensation [for injury]** 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 [about compensation and available medical treatments]** may be obtained;

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

- (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;

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

- (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)]:

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

- (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**;

What will happen in this research study?

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

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

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

What will happen in this research study?

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

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

- (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

Why is this research study being done?

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