DFCI Policy on Pregnant Partner Consent Documents

Pregnant Partner Consent forms *should not* be submitted as part of the New Project Application. A Pregnant Partner Consent Form should only be submitted via amendment when a known pregnant partner has been identified. OHRS will review these documents via the expedited procedure, as necessary.

DF/HCC Process:

Prior to the Collection of Pregnant Partner Data:

- The Principal Investigator must ensure the protocol includes the following information:
  - A short but specific research plan/objective regarding the collection of data on consenting pregnant partners;
  - Specific data points to be collected and/or submission of the data collection forms to be used
  - Reporting time frame requirements (e.g. 24 hours of notification)
  - A supplemental instruction sheet for male participants and pregnant partners should be drafted with the applicable trial/research study information. Once IRB approved, this information sheet should be handed out at the time of initial consent and as needed during the study.
- The consent form should include basic information about what a male participant should do if they impregnate a partner. Please see DFHCC Consent Template – Common Rule for templated language.
- Detailed information for the participant and pregnant partners should be provided via a supplemental instruction sheet using the OHRS provided template (see above).
- A pregnant partner consent must also be submitted using the Pregnant Partner Consent Template.

During the Consent Process:

- During the ongoing consent process with a male participant, the treating investigator must discuss the responsibilities for reporting any partner pregnancies to the treating investigator/study team.
- The treating investigator may also provide the participant the supplemental information sheet with instructions to provide the document to any partners who may become pregnant.

Identification and Consent of a Pregnant Partner:

- When a participant informs the investigator of the partner's pregnancy, the treating investigator must:
  - Explain in detail the steps to follow in order to obtain consent from the pregnant partner; and
  - Notify the IRB of the pregnant partner information via the Other Event Reporting form.
  - At this time, the pregnant partner consent form should be submitted to OHRS via amendment for review.

- The treating investigator will ask the participant to give their pregnant partner a copy of the study-specific "Participant Instruction Sheet on Partners who become Pregnant" and the study-specific "Research Consent Form for Pregnant Partner of a Male Study Participant," once approved by the IRB.
- The participant will inform the pregnant partner that they have the option to contact the treating investigator and/or study team member to discuss the consent form, the clinical trial and the information that the researchers would like to obtain. The male participant can also provide general information about any potential fetal risks as a result of the male participant's study treatments.
- If the pregnant partner agrees to provide information to the treating investigator and study sponsor about their pregnancy, the partner should sign and return the provided pregnant partner consent to the male participant and/or the treating investigator.
    - **Please Note:** The pregnant partner will **not** be registered with the ODQ.
- If the study participant refuses to give the information sheet and/or consent document to the pregnant partner, or if the pregnant partner refuses to sign the consent form, no further contact will be attempted. This refusal must be documented in the study records.
- If the partner signs the consent, the consent process should be documented in the study participant's medical record. The treating investigator/study team will then report the pregnancy to the sponsor per the protocol. A pregnant partner's PHI will be protected in accordance with the protections provided to study subjects.