Frequently Asked Questions & Answers

New Protocol Submissions

Question: Do I need to wait for the FDA to approve or respond to our IND application before submitting a new protocol to OHRS?

Answer: No, you can submit your new protocol application to OHRS and indicate that the FDA approval is pending. Some study teams prefer to wait until the FDA has responded when they anticipate that the FDA may require changes to the protocol as part of their review process.

Question: Now that nurses are being added as "co-investigators", how should they be answering the question about the number of trial on which they have participated?

Answer: The intent of the question is to identify which individuals should complete the New Investigator Training with CTEO. If a person has not been an "investigator" on a trial before, but has worked on other trials, then they should mark "No" and provide the date they completed the New Investigator training.

Question: We are still working out whether (and to what extent) reimbursement of expenses and/or coverage for reasonable costs for treating research-related injuries will be offered to participants. Can I still submit my new application while we continue to work out the details?

Answer: Yes. But an amendment should be submitted for IRB review and approval before offering any expense reimbursement to participants or advising them that the sponsor will be covering costs for treating research-related injuries. The amendment should be submitted as soon as possible, preferrably prior to activation. (Note: if your study is already active, you should still submit an amendment with a plan to reconsent participants).

Informed Consent

Question: Why do the OHRS Departmental Review Comments and/or the IRB Conditions for Approval ask that language about <u>how to prevent pregnancy</u> be removed from the Informed Consent Document and be provided to participants as a separate handout?

Answer: The most recent NCI Consent Form Template focuses on making consents more concise by eliminating repetition of information and moving instructional language from the informed consent document to a separate handout/attachment. Accordingly, under the NCI guidelines, the topic of contraception would be treated as follows:

- A statement that a participant should not become pregnant or father a child while on the study is important information that relates to a person's decision to participate in the study and so should be included in the consent.
- Information about how to prevent pregnancy is not required information and should not be included in the consent, but should be provided to the participant as a separate attachment or handout.

Question: Do participants have to sign the separate informational handouts/attachments?

Answer: No. There is no requirement under the human subject protection regulations that educational

handouts be signed by the participant. So from the IRB perspective, the participants need only sign the Informed Consent Document.

Question: The Industry Sponsor wants to add language to the research-related injury section of the informed consent document. Will the IRB allow this added language?

Answer: It depends. If the sponsor is willing to cover the reasonable costs of treating research-related injuries, the IRB will not approve any language that conditions such coverage on the following:

- Participant must follow the protocol, consent or instructions of the study team
- Study team was not negligent in the conduct of the study

Question: Can an investigator who sees patients at other locations, e.g., investigator at a DFCI has a clinic at DFCI satellite one day a week, consent patients to a study that is only being conducted at their primary institutions?

Answer: Yes. If you work at DFCI, you can consent someone anywhere at DFCI even if it is not approved for activation at all locations. For instance, you could consent at Faulkner even though the research will be conducted on the main campus.

Question: What is the difference between a waiver of consent and a waiver of documentation of consent?

Answer: Please refer to the OHRS Information Sheet (pages 2-3).

Question: If I revise the consent, do I need to submit a clean version?

Answer: No, just an underlined version. We will accept the changes and post to OncPro once it is approved.

Amendments

Question: Do I need to submit an underlined protocol?

Answer: You need to submit a clean version of the protocol and *either* an **underlined version** *or* a **summary of changes** of the revised protocol.

Deviations, Violations & Eligibility Exceptions

Question: Do I need to submit a separate Violation Form to report a violation for not reporting an adverse event on time?

Answer: The team should not be filling out a separate violation form for a late reporting of an Adverse Event. The late reporting is documented right in the Adverse Event Form, Part B, Question 2.

General Committee Issues

Question: Can OHRS provide a copy of the SRC or IRB Roster to send to the sponsor?

Answer: No. The DFCI IRBs do not post membership rosters or release names of the IRB members. Study team may provide the sponsor with a copy of the Open Letter to Sponsors which describes this policy and is available from our website.