Reliance on the National Cancer Institute Central IRB
Investigator and DFCI IRB Responsibilities

This document outlines the procedures for utilizing the National Cancer Institute Central IRB (NCI CIRB) for studies conducted by investigators at Dana-Farber/Harvard Cancer Center (DF/HCC).

The NCI CIRB Initiative is a cooperative venture with FWA institutions that is intended to create a more effective and efficient mechanism for IRB oversight of NCI-sponsored Cooperative Group clinical trials and certain Cancer Therapy Evaluation Program (CTEP) trials.

Specifically, the NCI CIRB is designed to:

- improve access to certain NIH research by enabling rapid approval of clinical trials using the NCI CIRB review process;
- enhance the protection of study participants by providing consistent expert IRB review at the national level; and
- reduce the administrative burden for local IRBs and research staff.

Below is information about how to work with the NCI CIRB as well as research team responsibilities for any research that is overseen by the NCI CIRB.

A. Guidelines for the Consent Document and Process

The NCI uses a template consent form for all of its research. The only changes that DF/HCC teams are able to make to this template are to add local context information which has been pre-approved by the NCI CIRB.

1. **NCI CIRB Reviewed Research Consent Document:** The research team is responsible for merging the DF/HCC NCI CIRB local context language with the NCI CIRB approved model consent form which will then be used to consent participants. The DF/HCC boilerplate is required for these submissions to communicate the specific local language utilized by the DF/HCC to research participants. The DFCI IRB acknowledgment date will be reflected in the footer of the NCI CIRB approved consent document and will be posted to OncPro.

2. **Consenting Non-English-Speaking Participants in NCI CIRB Approved Research:** The NCI CIRB has approved the use of the DF/HCC short form consent documents and addendums to be utilized in all NCI CIRB approved research studies. Research teams should follow the current DF/HCC process for consenting Non-English-speaking participants.

3. **Translated Consent Documents:** Any translated informed consent documents must be approved by the NCI CIRB and then submitted to DFCI as an amendment with the

certificate of translation to OHRS before they can be utilized. When submitting amendments to the DFCI IRB when the NCI CIRB is the IRB of record, please make sure to use the specific CTEP amendment form.

4. **Formatting:** The consent document should not include the following DF/HCC Biomedical templated language:
    - **HIPAA Authorization**
    - **Participant Injury**
    - **DF/HCC Signature Blocks** *(e.g., signature blocks that are not included in the NCI CIRB Boilerplate Template Language document)*

B. Submissions to the DFCI IRB

1. New Project Application

When an investigator wishes to submit a research protocol that has been approved by the NCI CIRB, the following items must be submitted:

- NCI CIRB approved protocol document
- NCI CIRB approved consent document that contains the approved DF/HCC NCI CIRB local context language.
- NCI CIRB Approval Memos or Correspondence, which may include:
    - CTSU Email Correspondence
    - NCI CIRB New Project Application
    - Principal-Investigator Worksheet
    - Study-Specific Worksheet
- Alert Page (if applicable)
    - **Adult Studies**: Study-Chair Approval
    - **Pediatric Studies**: Core Principal Investigator Approval
- Recruitment Materials (if applicable)
- Imaging, Laboratory, or Pharmacy Manual (if applicable)
- Participant Drug Diary (if applicable)
- Investigators Brochure / Instructions for Use (if applicable)

Note: If the study is approaching the IRB expiration date and the NCI CIRB continuing review has been conducted, the research team may also include the NCI CIRB Continuing Review Approval Memo.

Once the NCI CIRB protocol is submitted to OHRS, OHRS will route the protocol for the following reviews:

- Expedited SRC Review. This review is conducted scientific prioritization only
- Review by the appropriate ancillary departments

Note: NCI CIRB research must complete ODQ activation prior to enrolling any subjects onto the research.

2. **Adverse Events, Other Events and Unanticipated Problems:** The DFCI IRB retains responsibility for the oversight of all events occurring at participating DF/HCC sites for cancer-related research. The research team is required to follow all DFCI IRB reporting policies related to Adverse Events, Deviations, Violations, Exceptions, and Unanticipated Problems per the DFCI IRB Policies and Procedures Manual including the collection and reporting of minor deviations and violations at the time of the Progress Report submission.

   In addition to the above, research teams must also comply with the NCI CIRB reporting requirements. This may lead to teams double-reporting to both DFCI and NCI.

3. **Conflicts of Interest**: The DFCI IRB maintains responsibility for reviewing financial and institutional Conflicts of Interest. All outside interests should be submitted using the Administrative Modification application.

4. **Amendments**: The research team is responsible for providing OHRS with all revised study-specific documents approved by the NCI CIRB. These documents will be posted on OncPro. Revised documents must be provided to OHRS within 30 calendar days of receipt from the sponsor and/or CIRB.

   In order to ensure the NCI CIRB review timeline is met, amendments to NCI CIRB studies should be submitted via the CTEP Amendment form.

   - The research team is responsible for submitting the NCI CIRB approval memo
   - A review will be performed of the CTEP amendment submission
   - If a CTEP amendment requires DFCI IRB review for local changes (e.g., a change in non-core principal investigator) a DFCI IRB approval memo will be issued.

5. **Progress Reports:** The research team is responsible for providing OHRS documentation of continuing review approval from the NCI IRB at least 15 days prior to the study expiration date. If continuing review approval is not provided before the approval lapses, the study will expire, and participants will not be able to start and/or continue the research at DF/HCC until current continuing review approval is provided. The study team is responsible for submitting:

   - The NCI CIRB Continuing Review Approval Memo
   - The Minor Deviation/Violation Log
   - The DFCI IRB will issue an Acknowledgment Memo.

Note: The study will also be routed for a Scientific Progress Review (if applicable)

C. Guidelines for the HIPAA Authorization

OHRS will create the HIPAA Authorization form for the study at the time of the New Project Application review, or if and when a new consent form is created and approved by the NCI CIRB.

When the research team submits a CTEP Amendment, OHRS will upload the previously created HIPAA Authorization form to the submission. The research team is not required to upload the HIPAA Authorization form. If there is a change in title, core or non-core principal investigator, or sponsor, OHRS will revise the HIPAA Authorization form to reflect the changes.

It is highly recommended that if there is a change to whom the participant's protected health information will be shared, it is appropriately reflected in the amendment summary section of the CTEP Amendment. This will assist OHRS by indicating which section of the HIPAA Authorization form needs to be revised to reflect the proposed changes.

If the research team requires a translated HIPAA Authorization form, they should reach out to the OHRS Central IRB inbox and include the study number and the requested language. If the HIPAA Authorization form has already been translated into the specified language, then this process may take up to one (1) business hour to complete. However, if OHRS does not have the specified language then this process may take up to five (5) business days to complete.

D. DFCI IRB Responsibilities

1. The DFCI IRB maintains responsibility for local oversight of the performance of CIRB-approved studies. These responsibilities include, but are not limited to:
    - Ensuring the initial and ongoing qualifications of investigators and research staff;
    - Overseeing the conduct of the research;
    - Monitoring protocol compliance;
    - Maintaining compliance with state, local, or institutional requirements related to the protection of human subjects;
    - Providing a means of communication to receive and address concerns from local study participants, and others, regarding the conduct of research;
    - Investigating, managing, and providing notification to the NCI CIRB of any study-specific incidents, experiences, or outcomes that seem to signify the instance of an unanticipated problem and/or serious or continuing noncompliance.
        - When notifying the NCI CIRB of a potential unanticipated problem and/or serious or continuing noncompliance, the DFCI IRB must provide a management plan to correct the incident, experience, or outcome. This plan must also document measures to prevent the reoccurrence of the potential unanticipated problem and/or serious or continuing noncompliance.
2. The DFCI IRB has the ultimate authority to observe any aspect of the research process; including the consent process.
    - The CIRB also retains the authority to direct the DFCI IRB to perform such inspections as necessary to assure adequate regulatory compliance.
3. The DFCI IRB will notify the NCI CIRB when a regulatory deficiency has been cited on an audit that occurred during the time that the NCI CIRB was responsible for study review.
4. The DFCI IRB will maintain a shadow file for each study under the NCI CIRB.
5. The DFCI IRB will conduct a full board review of any study enrolling prisoners.

- It should be noted that the NCI CIRB is not constituted to review studies enrolling prisoners. Studies assigned to DFCI IRB full board review must follow the procedures outlined in the DFCI SOPs.

Questions regarding Central IRB review process should be directed to OHRS at: (617) 632-3029 or OHRSCentral_IRB@dfci.harvard.edu