Guidance on Single IRB Review Process

This document outlines how the DFCI IRB may rely on an external IRB to serve as the IRB of record for a DF/HCC site or Investigator.

The Dana-Farber Cancer Institute (DFCI) IRB has established various IRB Authorization agreements to allow an external IRB to serve as the IRB of record for a DF/HCC site or Investigator. These agreements outline the responsibilities of each organization in the IRB review, reporting and research oversight. Additionally, this information sheet outlines the process for establishing new IRB Authorization Agreements

In June 2016, the NIH issued a policy requiring the use of a single Institutional Review Board for NIH-funded multi-site studies.
http://osp.od.nih.gov/sites/default/files/NIH_sIRB_Policy_Multi_site_Research_UPDATED2016.pdf

A. Definitions

1. **Central IRB:** An IRB that provides IRB review services for multiple research studies.
2. **Single IRB (sIRB)**: An IRB that has been selected to carry out the IRB review of research studies for all sites participating in a multi-site study.
3. **External IRB:** An IRB being utilized other than the DFCI IRB where a DF/HCC investigator or site is engaged in research.
4. **Independent (or commercial) IRB:** An IRB that is not affiliated with an institution engaged in research.
5. **IRB Authorization Agreement:** A formal written agreement between organizations collaborating in non-exempt human subjects' research that outlines each organization's responsibilities in the oversight of research and identifies which IRB will serve as the IRB of record for the project.

B. Reliance Agreements

The DFCI IRB has made specific arrangements for use of the following IRBs for review of DF/HCC conducted research:

1. The DFCI IRB is the designated Single IRB of record for oncology protocols conducted by the five clinical institutions that comprise the Dana-Farber/Harvard Cancer Center (DF/HCC) Consortium.
    - Beth Israel Deaconess Medical Center (BIDMC)
    - Boston Children's Hospital (BCH)
    - Dana-Farber Cancer Institute (DFCI)
    - Brigham and Women's Hospital (BWH)
    - Massachusetts General Hospital (MGH)

    ⇨ Partners Healthcare Inc.

    ***The DFCI IRB is currently unable to serve as the Single IRB of record for outside sites.**

2. National Cancer Institute Central IRB (NCI CIRB)
3. National Marrow Donor Program (NMDP) IRB (on a protocol by protocol basis)
4. Fred Hutchinson Cancer Research Center (FHCRC) IRB (on a protocol by protocol basis)

C. Future Reliance Agreements

The following criteria will be considered when deciding to allow a study to rely on a new external IRB:

1. Current Approved FWA, IORG and IRB numbers with OHRP
2. Current AAHRPP Accreditation
3. Qualification and Experience in the review of oncology research, such as a designated NCI Comprehensive Cancer Center
4. Requirement by funding agent to use a single IRB
5. No FDA Warning Letters

For studies relying on a Single IRB other than the NCI CIRB, the following steps will be required:

1. Please submit the Notice of Request to Rely on an External Single IRB form via OHRS Submit as a New Project Application.
2. OHRS will then negotiate a Reliance Agreement with the outside IRB. Please note that this may take up to several weeks/months to be finalized. Whenever possible DFCI will use the SMART IRB common reliance agreement platform.
3. OHRS will also seek permission from the Partners, BIDMC and Boston Children's Hospital IRB Offices to rely on the outside IRB.

**Please note, requests for reliance are subject to OHRS and institutional review and may be denied for any reason including, but not limited to, the type of research, the risk of the research, the qualifications of the study staff, the resources required to conduct the research, etc.*

D. Initial Submission

1. Once a new protocol has received approval from the External IRB it can then be submitted to OHRS. The following documents must be submitted through OHRS Submit.

   Required Initial Submission Documents as applicable:

   - New Project Application Form – Single IRB
   - Research Funding Form
   - Statement of Investigator Form
   - Study Specific Research Team Update Form
   - Outside Interest Log Sheet (if applicable)
   - Research Nursing/Pharmacy Protocol Screening Form (if applicable)

- Radiation Safety Screening Form (if applicable)
- Alert Page (if applicable)
- Central/Single IRB Approval documentation for both the overall study and the local site
- Central/Single IRB Approved Consent Document
- Consent Document with local DF/HCC consent information included with the Central/Single IRB approved consent document
- Central/Single IRB Approved Protocol Document
- Central/Single IRB Approved Study Recruitment Materials (if applicable)
- Central/Single IRB Approved Data Collection Materials Given to Participants: Questionnaires, Surveys, etc. (if applicable)
- Investigator's Brochure (IB) (if applicable)
- Pharmacy Manual (if applicable)
- Laboratory Manual (if applicable)
- Participant Drug Diary (if applicable)
- DFCI Clinical Trials Request Form (if applicable)
- BIDMC Confirmation of Investigator Resources Form (if applicable)
- Eligibility Checklist (if applicable)

Note: Starting in 2015, all protocols that have been designated as using a Central/Single IRB will be numbered beginning with a 700 series protocol number, for example: 15-701.

E. OHRS Review:

1. OHRS will perform an administrative review of all Central/Single IRB submissions to ensure compliance with local institutional requirements.
2. During OHRS review it may be determined that the trial must be reviewed by the DFCI IRB. If this occurs you will be advised by OHRS as to next steps.

F. Scientific and Ancillary Reviews:

Upon completion of the OHRS review, the protocol will be routed for the following required Cancer Center and Ancillary reviews:

- Scientific Review
- Institutional and Faculty Conflict of Interest
- Radiation Safety Committee Review (if applicable)
- BioSafety Review (if applicable)

OHRS will provide the SRC approval memo and route the project for activation once the above reviews are completed.

G. Activation Requirements:

1. Protocols will be routed for required Institutional / Departmental review and activation sign-offs including (but not limited to):
    a. Nursing
    b. Pharmacy
    c. Pathology
    d. Clinical Trials Offices (e.g. DFCI CTO / BIDMC CCTO / MGH CCPO)
    e. DF/HCC Offices (e.g. CTRIO / ODQ / OHRS)
    f. EPIC related sign offs (e.g. RSA-RSH)
2. Once all Activation sign-offs are received, study teams will be sent a Central/Single IRB Activation Memo and the study documents will be posted to OncPro for use.

Research may not begin locally until the study team has been notified that the protocol has been activated.

Post Activation Reporting Requirements to OHRS and DFCI IRB:

Continuing Reviews: The study team maintains responsibility for providing OHRS documentation of continuing review approval from the Central IRB. If continuing review approval is not provided before the approval lapses, the study will expire and subjects 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 Single IRB approval documents as well as the **Application for Continuing Review of Single IRB Protocols**
- The Minor Deviation/ Violation Log will be reviewed.
- The study will also be routed for a Scientific Progress Review.

Amendments: The study team maintains responsibility for providing OHRS with all revised protocol documents approved by the Central/Single IRB. These documents will be posted on OncPro by OHRS. Revised documents must be provided to OHRS within 30 days of receipt from the sponsor and/or Central/Single IRB.

- The study team is responsible for submitting the Single IRB approval documents as well as the **Amendment Submission Form - Single IRB**
- A Review will be performed of the amendment submission
- The amendment will be routed for Activation as needed.

Adverse Events, Other Events and Unanticipated Problems: The DFCI IRB retains responsibility for the oversight of all events occurring at participating DF/HCC sites related to Adverse Events, Deviations, Violations, Exceptions and Unanticipated Problems. As a result, the study team is required to follow all DFCI IRB reporting policies related to Adverse Events, Deviations, Violations, Exceptions and Unanticipated Problems including the collection and reporting of minor deviations and violations at the time of External IRB annual approval submission.

- You may also be required to report to the sponsor, and the Central/Single IRB etc. as per the protocol and Central/Single IRB requirements.
- These submissions will be reviewed by the DFCI IRB per the DFCI IRB Policies and Procedures Manual.

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

Overview of Approval/Activation Notifications for Central/Single IRB Review Studies

Review Type	SRC Approval Memo	DFCI IRB Approval Memo	Central IRB Activation Memo	Email Notification Only	No Notification Sent
New Protocol Submission	**X**		**X**		
Continuing Review			**X**	***Email notification of Scientific Progress review**	
All Amendments			**X**		
Research Team Update					**X**
Administrative Update				**X**	
Document Request				**X**	
Other Events				**X**	
Adverse Events				**X**	
Report of Unanticipated Problem Involving Risk to Subjects or Others				**X**	