DF/HCC Investigator-Sponsored Multi-Center Trials: Review and Approval Process and Requirements

This document outlines the process for review and approval of investigator-sponsored, multi-center research (as defined in MULTI-100: Investigator-Sponsored Multi-Center Research), and the related requirements.

1. Submitting a New Multi-Center Protocol

There are 3 key multi-center specific requirements that must be met at the time a new multi-center protocol is submitted. These requirements also apply to existing investigator-sponsored research that is being amended to become a multi-center protocol.

- Signed Institutional Multi-Center Approval Form included in submission (see below)
  - Must be requested according to the specific process defined by the sponsor-investigator's home institution. Only the designated institutional signatories may sign the Institutional Multi-Center Approval Form.
  - The form will indicate that a study is approved for multi-center research. However, the form may or may not indicate approval to add specific sites or a specific number of sites. In some cases, a new approval may be required to expand a study beyond what was initially approved.

- The protocol must contain appropriate multi-center language and, when required, a formal Multi-Center Data Safety Monitoring Plan (DSMP).
  - The submitted protocol should include language, as appropriate, to describe how research activities will occur at external participating sites, and how the sponsor team will coordinate and oversee these activities.
  - All interventional multi-center trials must include a formal DSMP following the required DF/HCC DSMP template.

- The sponsor-investigator must complete or have previously completed the DF/HCC Multi-Center Sponsor Training.
  - Please find instructions for completing this training on the Training & Education Page under Additional Required Trainings for PIs.

2. How to Obtain an Institutional Multi-Center Approval Form

A signed institutional approval form must be submitted with the new study application and/or amendment requesting to expand a study to multi-center. This process varies by institution. The Sponsor-investigator must follow their home institution's process to request the approval, as indicated below:

BIDMC:

Contact BIDMCCCTOQualityManagement@bidmc.harvard.edu

DFCI:

Requests must be submitted through the DFCI CTO SharePoint Workflow.

- For questions or guidance, please contact the Regulatory Affairs Partner assigned to your Disease Group or email DFCI_clinicaltrials@dfci.harvard.edu

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- For more information:
  - DFCI Clinical Trials Office SOPs: http://dfcionline.org/clinical/clinicalresearch/clinical-trials-office/sops/

MGB (includes MGH and BWH):

For studies managed by the MGH Cancer Center Protocol Office (CCPO):

- For new submissions, updates to current approval form, or other questions, please first contact Lisa Raeke, CCPO Associate Director at lraeke@mgh.harvard.edu.
- The CCPO will facilitate the review and approval process. Approval by Martha Jones, VP Human Research Affairs, is required.

For BWH and any MGH studies not managed by the CCPO:

- Please pre-fill the first two sections of this form and email it to Martha Jones, VP Human Research Affairs, for approval (mjones44@partners.edu).

3. Adding External Sites

The DF/HCC-sponsored multi-center protocol must be approved and active at the DF/HCC Core Site before external sites can be added and opened to accrual. If the protocol is being converted to a multi-center trial via amendment, that amendment must be approved and activated before adding sites.

External Sites Relying on a local or commercial IRB:

- Sponsor-investigators must work with the appropriate contracts office at their institution to ensure the necessary agreements are in place prior to adding external sites.
- Review the external site's proposed consent form prior to their submission to the IRB.
  - The approved DF/HCC consent form should be used as the model consent.
  - If the external site requires changes to the consent language, please ensure that any changes comply with the DF/HCC Guidance: Model Consent Language for DF/HCC Multi-Center Investigator-Sponsored Trials.
- The external site must submit and obtain IRB approval for the current protocol and the sponsor-approved consent.
- When ready to activate a new external site, the DF/HCC sponsor-investigator (or designee) must submit the **Sponsor-Investigator Add/Open/Complete External Site** form in iRIS. The following attachments must be provided:
  - Signed institutional multi-center approval form demonstrating approval to add the site.
  - IRB approval memo for the external site from the IRB of record
- The DF/HCC core site will receive a notification from IRIS once the add external site request is processed. This notification must be received before notifying the external site that research activities may begin.

External Sites Relying on the DFCI IRB:

- The DFCI IRB may agree to act as the IRB of record for non-DF/HCC sites if required under federal regulations or if the DF/HCC investigator will serve as the lead site in collaborative research for a limited number of other participating sites, and requests that the DF/HCC IRB serve as the IRB of record. Please contact the OHRS office (OHRS@dfci.harvard.edu) for guidance on submitting a request for outside sites to rely on the DFCI IRB.

- External sites relying on the DFCI IRB are added by submitting an **Amendment** form in iRIS.
- Both IRB approval and activation of the amendment are required. The DF/HCC core site will receive the IRB approval memo first, and a separate notification from IRIS upon activation of the amendment. The amendment must be activated prior to notifying the external site that research activities may begin.

4. Institutional Approval Form Signatories

Below is the list of individuals at each institution who may provide multi-center approval. The institutional multi-center approval form will only be accepted when signed by one of the individuals below. However, please follow the instructions listed above to initiate the review and approval process at your institution.

BIDMC
Michele Vincitore
Emma Logan

BCH
August Cervini
Tatiana Koretskaia

MGB
Martha Jones

DFCI
Michele Copersino
Brittney Delsesto
Kiley Knapp
Peyton Spencer
Kathleen Lee