

National Cancer Institute (NCI)
Experimental Therapeutics Clinical Trials Network (ETCTN) Guidance

Single IRB New Project Application for OHRS

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Introduction

Following NCI Central Institutional Review Board (CIRB) approval and Cancer Therapy Evaluation Program (CTEP) activation, the lead DF/HCC investigator must follow all local institutional procedures and submit all required documents to OHRS for local activation prior to enrolling any subjects at DF/HCC. ETCTN studies are exempt from the DFCI institutional review of investigator-sponsored studies.

Procedure

- 1) Lead DF/HCC Investigator with assistance from study team members will complete any applicable institutional review requirements (i.e., any BIDMC-, DFCI-, or MGH-specific procedures).
- 2) Lead DF/HCC Investigator with assistance from study team members will complete the [Single IRB New Project Application](#) and will prepare all other applicable OHRS documents (see checklist within the Single IRB New Project Application).
 - a) Inform the institutional ETCTN contact that a new project application is being prepared:
 - i) **When the lead DF/HCC Investigator is from BIDMC:** staff must contact Christine Conley (Cconley@bidmc.harvard.edu) to obtain a copy of the NCI CIRB Approved Study-Specific Worksheet.
 - ii) **When the lead DF/HCC Investigator is from DFCI:** staff must contact Sharon Atkinson (Sharon_Atkinson@dfci.harvard.edu). Sharon will assist the study team with the NCI CIRB Approved Study-Specific Worksheet, Study Funding Form, and other submission documents, as needed.
 - iii) **When the lead DF/HCC Investigator is from MGH:** staff must contact Patrick Mostyn (pmostyn@partners.org) to obtain a copy of the NCI CIRB Approved Study-Specific Worksheet.
 - b) Retrieve the NCI CIRB Approved Documents (Protocol, Model Consent, NCI CIRB approval memo(s)) from the Cancer Trials Support Unit (CTSU) website. Refer to the [DF/HCC ETCTN Retrieving Documents from the CTSU Website Guide](#) for instructions.

- c) Create the local DF/HCC consent. Refer to the [DF/HCC ETCTN Local Consent Development Guide](#).
- 3) Lead DF/HCC investigator or study team member will submit the New Project Application along with all required documents to OHRS.
- 4) OHRS will review and route the documents for local activation sign off.
- 5) BIDMC, DFCl, and MGH are activated at the same time. Once local activation is completed, the lead DF/HCC study team will receive a local activation memo and study documents will be posted to OncPro.
 - a) At DF/HCC always use the documents (Protocol and ICF) posted on OncPro. If the protocol and/or model consent form are updated, it must first be reviewed and approved by CTEP and NCI CIRB. Then the updated protocol and DF/HCC consent are submitted to OHRS for review and posting on OncPro. Details regarding that process can be found in the [DF/HCC ETCTN Amendment Guide](#).
- 6) Subjects can now be enrolled at DF/HCC.

Links

CTSU Website: <https://www.ctsu.org/Public/Default.aspx>