

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

NCI Central Institutional Review Board (CIRB) Study-Specific Worksheets

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Introduction

At DF/HCC, all ETCTN-sponsored research will use the NCI CIRB. Along with the Annual Principal Investigator Worksheet About Local Context, each DF/HCC Site Principal Investigator must submit a separate Study-Specific Worksheet (SSW) About Local Context to the NCI CIRB (separate worksheets must be filed for BIDMC, DFCI, and MGH).

An SSW must be completed when an ETCTN study is going to be open at DF/HCC or when there is a change in the DF/HCC Site Principal Investigator of an existing ETCTN study. The SSW can be submitted along with the Annual PI Worksheet; however, the NCI CIRB will not review the SSW until the Annual PI Worksheet is approved. For additional information on the Annual PI Worksheet, refer to the [DF/HCC ETCTN NCI CIRB Annual PI Worksheet Guide](#).

Procedure (Completing/Submitting an SSW at all sites)

- 1) The study team must inform Sharon Atkinson (Sharon_Atkinson@dfci.harvard.edu) and Shelby Watterworth (Shelbya_Watterworth@dfci.harvard.edu) when an investigator in their group is going to be the Site Principal Investigator for an ETCTN study.
- 2) Sharon or Shelby will work with the study team and investigator to complete the SSW.
- 3) The SSW will be submitted on the investigator's behalf through [NCI CIRB IRBManager](#).
- 4) The investigator will receive an email from "Local Context Contact, CIRB" with a link directly to the SSW. This email goes only to the investigator because he or she must review each page of the worksheet, confirm their intent to comply by entering their CTEP-IAM credentials, then submit the worksheet in the system for review and approval by the CIRB.

- 5) The NCI CIRB will typically provide approval within one week of submission. The NCI CIRB will notify the investigator the submitter of the approval via email. The email includes the CIRB Approval letter as an Attachment.

Links

NCI CIRB IRBManager: <https://nci.my.irbmanager.com/Login.aspx>