

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

NCI Central Institutional Review Board (CIRB) Change of PI Worksheets

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Introduction

A Change of PI worksheet must be completed when there is a change in the DF/HCC Site Principal Investigator of an existing ETCTN study. The Change of PI Worksheet should be submitted on behalf of the new Site Principal Investigator. The Site Principal Investigator assuming responsibility for the study at your institution must have an approved Annual PI Worksheet on file with the NCI CIRB; the Change of PI Worksheet will not be reviewed 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 DF/HCC sites)

- 1) The study team must inform Sharon Atkinson (Sharon_Atkinson@dfci.harvard.edu) and Shelby Watterworth (Shelby_Watterworth@dfci.harvard.edu) when the Site Principal Investigator for an ETCTN study is going to change.
- 2) Sharon or Shelby will confirm that the new Site Principal Investigator is appropriately rostered and has an approved PI Worksheet on file with the CIRB. If necessary, an [Annual PI Worksheet](#) will be submitted on the new investigator's behalf.
- 3) Sharon or Shelby will then work with the study team and the new Site Principal Investigator to complete the Change in PI Worksheet.
- 4) The Change in PI Worksheet will be submitted on the new investigator's behalf through [NCI CIRB IRBManager](#).
- 5) The investigator assuming responsibility for the study will receive an email from "Local Context Contact, CIRB" with a link directly to the Change in PI Worksheet. This email goes only to the new 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.

- 6) The NCI CIRB will typically provide approval within one week of PI signature and submission. The NCI CIRB will notify the investigator and 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>