

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

# NCI Central Institutional Review Board (CIRB) Annual Principal Investigator (PI) Worksheet (ETCTN Trials Only)

---

## Contents

Introduction .....	1
Procedure (Completing/Submitting Annual PI worksheet at DFCI and BWH).....	1
Procedure (Completing/Submitting Annual PI worksheet at MGH).....	2
Procedure (Completing/Submitting Annual PI Worksheet at BIDMC) .....	2
Links .....	2

## Introduction

At DF/HCC, all ETCTN-sponsored research will use the NCI CIRB. In addition to NCI CIRB Rostering, the Site Principal Investigator at each participating DF/HCC location for the ETCTN study must submit an Annual Principal Investigator Worksheet about Local Context to the NCI CIRB.

The Site Principal Investigator at each participating DF/HCC location must also submit a Study-Specific Worksheet about Local Context before an ETCTN study is activated at DF/HCC. The Annual PI Worksheet can be submitted with the Study-Specific Worksheet; however, the NCI CIRB will not review the Study-Specific Worksheet until the Annual PI Worksheet is approved. For additional information, refer to the [DF/HCC ETCTN NCI CIRB Study-Specific Worksheet Guide](#).

## Procedure (Completing/Submitting Annual PI worksheet at DFCI and BWH)

- 1) The study team must inform Sharon Atkinson ([Sharon\\_Atkinson@dfci.harvard.edu](mailto:Sharon_Atkinson@dfci.harvard.edu)) and Shelby Watterworth ([Shelbya\\_Watterworth@dfci.harvard.edu](mailto:Shelbya_Watterworth@dfci.harvard.edu)) when an investigator in their group is going to be the lead DF/HCC Investigator for an ETCTN study.
- 2) Sharon or Shelby will work with the study team and investigator to complete the Annual PI Worksheet.
- 3) The Annual PI Worksheet will be submitted on the investigator's behalf through [NCI CIRB IRBManager](#).
- 4) The NCI CIRB will typically provide approval within a month of submission. The NCI CIRB will notify the investigator and the submitter of the approval via email.

## **Procedure (Completing/Submitting Annual PI worksheet at MGH)**

- 1) Contact Patrick Mostyn ([pmostyn@partners.org](mailto:pmostyn@partners.org))

## **Procedure (Completing/Submitting Annual PI Worksheet at BIDMC)**

- 1) Contact Jai Penner-Hahn ([jpennerh@bidmc.harvard.edu](mailto:jpennerh@bidmc.harvard.edu))

## **Links**

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