

ETCTN NCI CIRB Initiative Information Page

1. Introduction

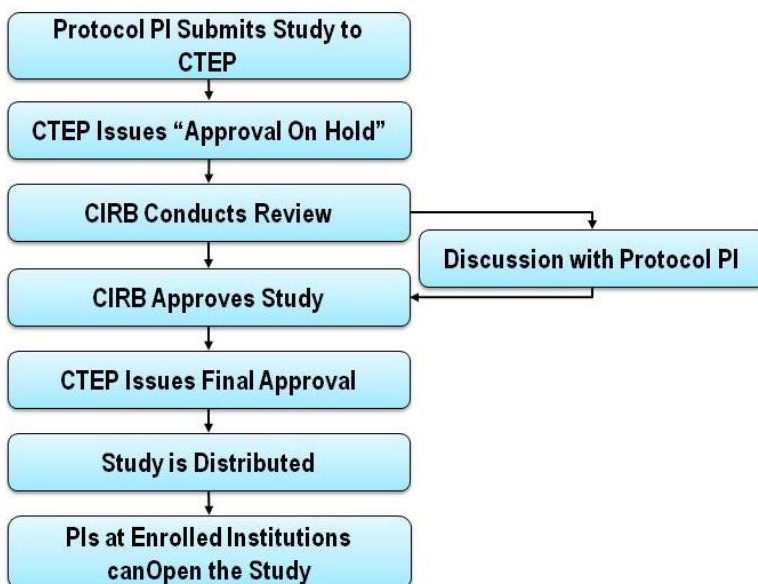
The NCI Central Institutional Review Board (CIRB) Initiative includes four CIRBs that conduct Institutional Review Board (IRB) review of select Adult and Pediatric trials. Studies developed in the ETCTN will be reviewed by the Adult CIRB – Early Phase Emphasis. The membership of the Early Phase Emphasis CIRB includes physicians, patient advocates, nurses, pharmacists, and statisticians who are knowledgeable about the design and conduct of early phase oncology trials.

It is expected that all trials opened under the ETCTN will be reviewed by the NCI CIRB.

2. How Does the CIRB Work?

2.1 CIRB Study Review

The CIRB conducts the IRB review of a study before it receives final Cancer Therapy Evaluation Program (CTEP) approval. The Protocol Principal Investigator (PI) is responsible for addressing any concerns the CIRB may have during the IRB review process. After completion of the IRB review (and assuming all other necessary reviews are complete, e.g., Food and Drug Administration), CTEP grants final approval of the study and the study is made available to the network.



2.2 Participation in the CIRB

2.2.1 Enrollment and Opening a Study

To enroll in the CIRB Initiative, potential Signatory Institutions must complete an application, an Authorization Agreement, and electronic worksheets describing institutional practices, state and local laws governing research, and institutional PIs. More information about enrolling in the program can be obtained by visiting the [NCI CIRB website](#) or by contacting the CIRB Help Desk by email at support@ncicirbcontact.zendesk.com or by phone at 888-657-3711 (Monday-Friday, 8:00 am-4:00 pm ET).

Once in the program, Signatory Institutions indicate their intention to open a study by completing a Study Specific Worksheet (SSW) and submitting it for approval via IRBManager. CIRB approval of a Signatory's SSW will be communicated directly to the CTSU and will be applied to the CIRB Signatory's affiliates and components according to the preferences set up by the Signatory. See more information on CIRB site preferences in the [Help Topics on the Regulatory page](#) of the CTSU website (login required). Once a Signatory has CIRB approval for a study, amendment and continuing reviews will be automatically applied to the associated sites included in the CIRB preferences.

2.2.2 NCICIRB Roster

Each Signatory organization will have an institution and person roster, but this is separate from the institution and person rosters covered in the [Rosters and Roles for ETCTN/EDDOP-Participants \(Institution Rosters and Person Rosters\) Information Page](#). Signatory and site staff must be on the NCI CIRB roster to access IRB Manager and carry out other tasks with respect to the CIRB. Like other rosters, the NCICIRB roster can be maintained by signatory staff using the Roster Update Management System (RUMS) on the CTSU website.

3. For Questions and Support

More information about the NCI CIRB Initiative is available on the [NCI CIRB website](#).

For questions about the NCI CIRB, please contact the CIRB Help Desk:

- CIRB Help Desk: 888-657-3711 or support@ncicirbcontact.zendesk.com.