



Experimental Therapeutics Clinical Trials Network

Team Driven. Cancer Therapy Focused.

National Cancer Institute at the National Institutes of Health

TRIAL DEVELOPMENT
Intended for those involved with the development of ETCTN trials

TRIAL CONDUCT
Intended for those at clinical sites conducting ETCTN trials

ETCTN NCI CIRB Initiative Information Sheet

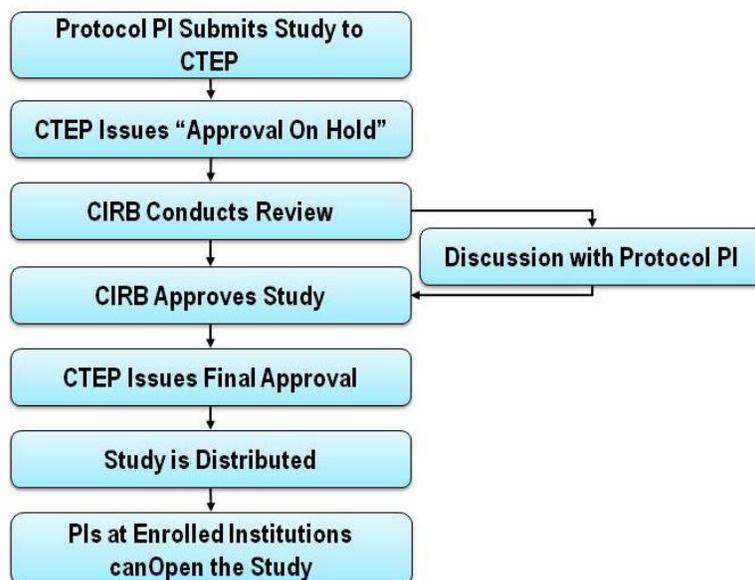
1. Introduction

The NCI Central Institutional Review Board (CIRB) Initiative includes four CIRBs that conduct 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?

The CIRB conducts the IRB review of a study before it receives final CTEP approval. The Protocol 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., FDA), CTEP grants final approval of the study and the study is made available to the network. PIs at institutions that are enrolled in the CIRB Initiative complete a study-specific electronic form for approval by the CIRB and then can open the study.





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In order to enroll in the CIRB Initiative, the CIRB requires institutions to 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 contacting the CIRB Helpdesk by email at ncicirbcontact@emmes.com or by phone at 888-657-3711 (M-F, 8am-4pm Eastern)

3. For Questions and Support

More information about the NCI CIRB Initiative is available on the CIRB's website at www.ncicirb.org.

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

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