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

Initial NCI Central Institutional Review Board (CIRB) Approval

Contents

Introduction

All ETCTN studies conducted at DF/HCC utilize the NCI CIRB as the IRB of record. After the Cancer Therapy Evaluation Program (CTEP) completes their review of the protocol and model consent document, the NCI CIRB conducts their review. The Protocol Chair, with assistance from the study team, must provide the necessary paperwork, address all review comments, and update study documents as requested by the NCI CIRB.

Procedure

1) The NCI CTEP Protocol and Information Office (PIO) automatically notifies the NCI CIRB once the CTEP review of the protocol and model consent form is complete. The Protocol Chair is copied on this email communication.
2) A member of the NCI CIRB Operations Office provides the Protocol Chair a copy of the NCI CIRB Application with instructions and a due date for submitting the completed application and other required documents.
3) The Protocol Chair, with assistance from study staff, completes the application.
   a) The application pertains to the overall trial activity meaning information specific to DF/HCC only cannot be included. An application that contains DF/HCC-specific information will not be accepted and will result in a delay of the NCI CIRB review.
   b) It is strongly recommended that all scientific and modality related questions be completed by the Protocol Chair and not the study staff.
4) The NCI CIRB notifies the Protocol Chair when the review has been scheduled and provides instructions for the Protocol Chair to participate in the meeting. Protocol Chair participation is expected.

5) The NCI CIRB conducts their review and notifies the Protocol Chair of the review decision. The NCI CIRB may request modifications be made to the protocol and/or model consent document.
   a) The Protocol Chair, with assistance from the study staff, addresses each of the NCI CIRB comments and follows the instructions provided by the NCI CIRB Operations Office regarding how to format and resubmit the requested documents.
6) The NCI CIRB notifies the Protocol Chair, NCI CTEP, Theradex, and the NCI Cancer Trials Support Unit (CTSU) once the study has been approved.
7) Refer to the DF/HCC ETCTN Medidata Rave Build Guide for next steps.

Links

NCI Central Institutional Review Board (CIRB) Initiative Information Sheet:
https://ctep.cancer.gov/initiativesPrograms/etctn_information_checklists.htm