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

Protocol Revisions

Contents

Introduction

Any change to the protocol document or model consent form for ETCTN studies must be reviewed and approved by CTEP and the CIRB prior to implementation. The documents must follow the electronic submission (eSubmission) guidelines provided by CTEP (refer to the link below for additional details). The purpose of this document is to provide guidance for ETCTN study revisions where the DF/HCC physician is the Protocol Chair.

A revision is defined by CTEP as a change to the protocol or consent prior to full CTEP approval of the protocol. Revisions are required when 1) CTEP provides comments in the form of a Consensus Review and subsequent conference call summary, 2) CTEP provides a Follow-up Review, 3) the CIRB requests modifications, 4) the FDA requests modifications or 5) the Protocol Chair identifies modifications required prior to study approval. Changes made to the protocol and model consent after CTEP approval are submitted to CTEP as an amendment. Refer to the DF/HCC ETCTN Amendments to CTEP Guide for details.

Procedure

1) The Protocol Chair prepares the revision submission with assistance from the study team.
   a) The summary of change must address each comment from the CTEP Conference Call Summary (for the first CTEP requested revision), Follow-up Review(s) (subsequent CTEP requested revisions), CIRB requested modifications, or FDA requested modifications. If the Protocol Chair is making additional edits, those need to be clearly detailed in the summary of change.
   b) The documents must follow the CTEP electronic submission (eSubmission) guidelines provided by CTEP. Refer to the DF/HCC ETCTN CTEP Submission Requirements Guide for detailed instructions on how to format the revision documents and specific submission requirements.
   c) The documents must be sent directly to the CTEP Protocol and Information Office (PIO) via email at pio@ctep.nci.nih.gov.

2) The PIO acknowledges receipt of the submission and notifies the submitter if information is missing or if corrections are required that will result in CTEP placing the submission on hold.
3) CTEP reviews the revision and either issues a Follow-up Review with comments requiring a response (i.e., another revision is required) or provides approval on hold. The approval could be placed on hold for a number of reasons; the most common reasons are for FDA review, CIRB review/approval, and completion of the Medidata RAVE build.
4) Refer to the DF/HCC ETCTN Initial NCI CIRB Review and Approval and DF/HCC ETCTN Medidata Rave and OPEN Eligibility Forms Build for the next steps.

Links

CTEP Investigator Handbook (section 8):
http://ctep.cancer.gov/investigatorResources/investigators_handbook.htm

Step by Step Guide for Submitting eSubmission Ready Documents to CTEP:
http://ctep.cancer.gov/protocolDevelopment/amendments.htm

Protocol Revision and Amendment Process Information Sheet:
http://ctep.cancer.gov/initiativesPrograms/etctn_information_checklists.htm