ETCTN Protocol Revision Process Information Page for Studies not Authored by the Centralized Protocol Writing Support

1. Introduction

A revision is defined by CTEP as a change to the protocol **before** full Cancer Therapy Evaluation Program (CTEP) approval of the protocol. For most ETCTN studies, the protocol will be authored by CTEP's Central Protocol Writing Support (CPWS). The study team must follow the directions given by the CPWS. The information contained in this page is only for the rare study that is **not** authored by CPWS, and the study team must interact directly with CTEP for development of the protocol.

2. Requirements

Revisions require submission of the following.

- Protocol Document
    - Include a summary of changes (SOC) as the first section of the document with hyperlinks to the relevant section of the protocol.
    - Cut and paste the changes requested by CTEP as part of the consensus review as the SOC; the generic protocol template available on the CTEP Protocol Templates and Guidelines page provides an example.
    - Additional changes outside of CTEP comments must first be discussed with the lead reviewer as it may require extra revision and could delay study activation. Any additional changes must be included in the SOC.
    - Every submission must have a new version date for proper version control.
        - If this is different from institutional policies regarding version dating, a CTEP Version Date should be added to the protocol's cover page to comply with CTEP requirements for version dates.

- Informed Consent Document (ICD)
    - The ICD must be separate from the protocol document to comply with FDA electronic submission requirements.
    - Include an SOC as the first section of the ICD.
    - If there are no changes to the ICD from the previous CTEP approved version, it must still be submitted with a new CTEP version date that matches the protocol version date and a SOC that states that there are no changes to the ICD other than the change in version date.

3. Submission Process

Revisions must be submitted to the CTEP Protocol Information Office (PIO) via email at PIO@ctep.nci.nih.gov. All submissions must

- Comply with current electronic submission guidelines and be in Microsoft (MS) Word format; the CTEP Preparing Protocol Documents for eCTD Submissions to the FDA or the generic protocol template available on the Protocol Templates and Guidelines pages for MS Word format requirements contains more information.
- Be built on the most recent CTEP approved version of the protocol.
- Include track changes so that reviewers can easily see the changes from the last CTEP approved version of the protocol.
- SOC must clearly describe the changes made and include hyperlinks to the relevant section(s) of the document(s).

4. Approval Process

Approve as is or with recommendations.

- Upon CTEP's decision to approve as is or with recommendations, PIO will submit the revision to CIRB and Theradex for potential modifications to the study database in Medidata Rave on the study team's behalf.
- The study team must submit a CIRB application to CIRB so that CIRB can review the revision.
- PIO will send an outcome letter **or** *i*ssue final approval after all internal requirements have been verified once
    - The CIRB approves the revision (and notifies the study team and CTEP PIO of the decision)
    - CTEP concurs with any CIRB stipulations
    - FDA confirms receipt of the amendment
    - Theradex confirms that any Medidata Rave updates are complete

5. For Questions and Support

Contact CTEP PIO Help Desk via email at PIO@ctep.nci.nih.gov for questions about submitting protocol revisions.