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

Protocol and Consent Development

Contents

Introduction

Within 60 days of the Cancer Therapy Evaluation Program (CTEP) granting approval for the Letter of Intent (LOI), the Protocol Chair must submit the protocol, model consent form, and Protocol Submission Worksheet (PSW) to the CTEP Protocol and Information Office (PIO).

Procedure

1) The Protocol Chair prepares the protocol document with assistance from the study team
   a) Download the CTEP Generic Protocol Template from CTEP website.
   b) Complete the protocol according to the CTEP generic protocol template and any agent-specific templates provided with the LOI approval letter.
      i) The content can be modified to meet the scientific portion of the study however formatting should not be changed unless necessary.
      ii) Phase I studies must be open at DF/HCC and at least two other LAOs. Phase 2 studies must be open to all ETCTN LAOs. Details regarding expected participation may be provided by CTEP during the LOI review and approval.
      iii) Carefully follow the DF/HCC ETCTN CTEP Submission Requirements Guide. Submissions to CTEP that do not comply with the requirements outlined in the guidance document will not be accepted by the CTEP PIO.
2) The Protocol Chair prepares the model consent form with assistance from the study team
   a) Download the NCI Informed Consent Template from CTEP website.
   b) Complete the model consent according to consent template. Follow all directions within the model consent form. **No DF/HCC specific language can be included in the model consent form** (e.g., do not insert the names of DF/HCC study doctors or contact information).
   c) The initial consent submission to the CTEP PIO must include a Microsoft Word version of the consent form.

3) The Protocol Chair or study team member submits the completed protocol and consent along with the CTEP Protocol Submission Worksheet to CTEP PIO (pio@ctep.nci.nih.gov). If a response to the CTEP LOI consensus review and/or conference call summary has not already been provided to CTEP, it should be included with the protocol submission.
4) The CTEP Protocol Review Committee (PRC) reviews the study documents and provides a consensus review.
5) A conference call between the CTEP reviewers and Protocol Chair to discuss the comments in the consensus review is scheduled by the PIO.
6) After the conference call summary is received, the comments in the call summary must be used by the Study Chair to prepare the first protocol revision. Refer to the DF/HCC ETCTN Protocol Revisions to CTEP Guide for details.

Links

CTEP Protocol Development Website: http://ctep.cancer.gov/protocolDevelopment/default.htm

CTEP Protocol Templates and Guidelines:
https://ctep.cancer.gov/protocolDevelopment/templates_applications.htm

NCI Informed Consent Template and Supplemental Documents:
https://ctep.cancer.gov/protocolDevelopment/informed_consent.htm