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

Continuing Reviews

Contents

Introduction

The NCI Central Institutional Review Board (CIRB) conducts continuing reviews of all approved ETCTN protocols. The frequency of continuing review for each study is determined by the NCI CIRB at the time of initial review and subsequent continuing reviews. If the study does not receive approval to continue before the end of the approval period, approval expires and all research activity must stop.

The DF/HCC study team is responsible for providing the DF/HCC Office for Human Research Studies (OHRS) documentation of continuing review approval from the NCI CIRB at least 30 days prior to the study expiration date. If continuing review approval is not provided before the approval lapses, the study will expire and subjects will not be able to start and/or continue the research at DF/HCC until current continuing review approval is provided. The study will also be routed for a Scientific Progress Review (if applicable). The DFCI IRB will issue a Central IRB Continuing Review Activation Memo and the updated documents posted to OncPro.

Procedure

1) NCI CIRB Continuing Review

   If DF/HCC is not the lead organization for the study, skip to Step 2: Continuing Review to OHRS.

   a) Approximately four months prior to the expiration of the current study approval, the NCI CIRB Operations Office contacts the Protocol Chair
      i) The Operations Office notifies the Protocol Chair of:
         (1) Date of the last review
         (2) Expiration date of NCI CIRB approval
         (3) Protocol version date upon which to base the application
         (4) Submission deadline for documents to be returned to the NCI CIRB

ii) The NCI CIRB Operations Office provides a copy of the current NCI CIRB Application for Continuing Review

b) The Protocol Chair completes the NCI CIRB Application for Continuing Review

c) The Protocol Chair returns the completed application with any required supporting documents to the NCI CIRB Operations Office by the deadline

d) The NCI CIRB completes the continuing review

e) The NCI CIRB Operations Office notifies the Protocol Chair of the continuing review approval or if additional information is needed.

f) Once the NCI CIRB continuing review is complete, the NCI CIRB notifies the Cancer Trials Support Unit (CTSU) and the continuing review documents are posted to the CTSU Member website.

g) OHRS must now be notified of the continuing review approval as outlined in Step 2 below.

2) Continuing Review to OHRS

The steps below apply when DF/HCC is the lead organization (i.e., the Lead DF/HCC Investigator is the Protocol Chair) AND when DF/HCC is participating on an ETCTN study led by another institution.

a) The Lead DF/HCC Investigator or designated study team member must track when NCI CIRB Continuing Review approval is expected. The NCI CIRB notifies the Protocol Chair of continuing review approval but at this time there is no standard method of notifying participating sites of the approval.

b) The Lead DF/HCC Investigator or designated study team member checks the CTSU website to see if the NCI CIRB Continuing Review approval is available.

i) From the CTSU Homepage, click the NCI CIRB Updates tab, and select the appropriate protocol from the drop-down menu.

c) The Lead DF/HCC Investigator or designated study team member downloads the NCI CIRB Approval Documentation from the CTSU website

i) From the CTSU Homepage, click the NCI CIRB Updates tab, and select the appropriate protocol from the drop-down menu, click the link next to the protocol number to retrieve the continuing review documents.

1. OR

ii) From the CTSU homepage, click the Protocols tab, select the appropriate protocol number from the Protocols folders, click the Documents tab, and then select the Continuing Reviews tab. Refer to the DF/HCC ETCTN Retrieving Documents from the CTSU Website Guidance Document for details.

d) The Lead DF/HCC Investigator notifies OHRS of NCI CIRB continuing review approval

i) Complete the Application for Continuing Review – Single IRB from the OHRS website.

ii) Submit the completed application with any required supporting documents to OHRS

iii) The DFCI IRB will issue an NCI IRB Continuing Review Activation Memo and the footer of the consent document posted to OncPro will be updated to reflect the new expiration date.

Links

CTSU Member Website: https://www.ctsu.org/Public/Default.aspx