

Creating a Continuing Review

Important Information

- Study teams receive an email reminder that their research application is due for a continuing review 30, 60, and 90 days prior to the study expiration date.

eResearch Home Workspace

ID	Name	Date Modified	Type	Owner	State	Last State Change	PI
HUM00005441	Test study for eResearch PI new application	11/29/2006 9:06 AM	Application	Cindango, Mary	Approved	11/29/2006 8:55 AM	Investigator
HUM00005467	Test Study for Core Staff Expedited Review	11/11/2006 2:15 AM	Application	Cindango, Mary	Approved	11/10/2006 3:11 PM	Investigator

1. Click the **Approved Studies** tab to display approved studies.
2. Click the **Name** of the study to view more detail.

eResearch Study Workspace

Activity	Author	Activity Date
Approved	Mary Cindango	11/29/2006 8:55 AM EST
See Approval Letter	Ingrid Investigator	11/28/2006 10:29 AM EST
Submitted Changes to Core Staff	Mary Cindango	11/28/2006 10:13 AM EST
Changes Requested by Core Committee Staff	Ingrid Investigator	11/28/2006 9:56 AM EST
Changes Requested by Core Committee Staff	Mary Cindango	11/28/2006 9:55 AM EST
Update Issues	Ingrid Investigator	11/28/2006 9:21 AM EST
Changes Requested by Core Committee Staff	Mary Cindango	11/27/2006 1:05 PM EST
Submitted Application	Ingrid Investigator	11/27/2006 11:44 AM EST

3. Click **New Continuing Review**.

Continuing Review Form

5

Scheduled Continuing Review (SCR) or Termination

Important Information

- The SCR or Termination is only for renewing or terminating an already approved study.
- Changes to the study must be made via an Amendment.
- Submit Adverse Events or OIRs before continuing with this SCR.

1.1.1 SCR or Termination Title:
HUM0005441_Continuing Review - Wed Nov 29 09:36:51 EST 2006

4

This SCR or Termination report is being submitted for the following application:

Study Title: Test study for eResearch PI new application
PI: Ingrid Investigator
Expiration Date: 12/6/2007
eResearch ID: HUM0005441
GCRC ID:

* Required

5

4. Enter a title for the continuing review.

Note: To make tracking the continuing review easier, include the name of the original study in the title.

5. Click **Continue**.

Continuing Review Form

6

7

1.0 Study Activity Status

1.1 Characterize the ongoing study activity.

Select one:

- Renewal - study activity continues to include ongoing or future research interaction/intervention with subjects or collection of identifiable private information.
- Renewal - activity limited to subject follow-up and analysis of identifiable data. All research intervention has been completed. Interaction is limited to follow-up activities only. Data continues to contain subject identifiers or links.
- Renewal - activity limited to analysis of identifiable data. All research interaction and intervention has been completed. Data continues to contain subject identifiers or links.
- Renewal - activity limited to analysis of de-identified data. All research interaction and intervention with subjects or collection of identifiable private information has been completed. The subject identifiers held by the study team (including links and lists) have been destroyed.
- Renewal - umbrella project. The study lacks immediate plans for involvement of human subjects, their data, or their specimens.
- Termination Report. The study is completed; there is no further subject recruitment, follow-up, or data analysis.

1.1.1 If study activity continues to include research interaction/intervention with subjects, has subject enrollment concluded?
 Yes No Clear

* Required

7

6. Complete the required information on each page.

7. Click **Continue** to move to the next page of the study.

Submit SCR

8

The SCR or Termination is almost complete . . .

Two additional steps are required to submit this SCR or Termination for review:

- Click "Finish" to save the application and return to the Study Workspace.
- The PI must then click the "Submit" button.

After these steps are completed, the SCR will be sent to the IRB for review.

8

8. Click **Finish** at the end of the continuing review.

Continuing Review Workspace

- Click **Submit Scheduled Continuing Review**.

Submit Scheduled Continuing Review Window

- Click **OK**.

Note: Track the progress of a continuing review in the Home Workspace under the **In Progress** tab. Once the continuing review is approved, it is viewed under the **Approved** tab.