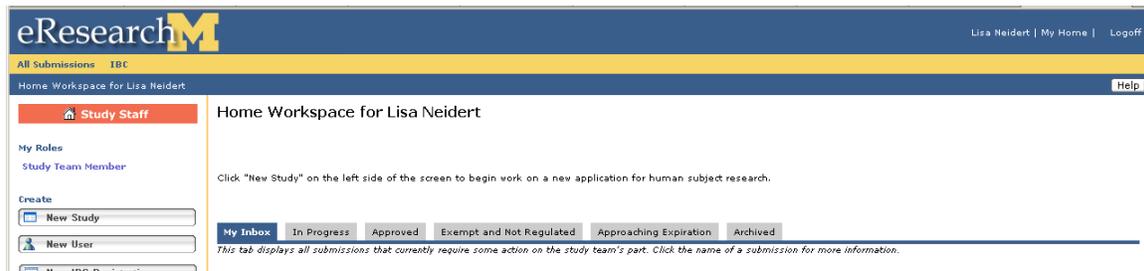


IRB SCHEDULED CONTINUING REVIEW (SCR)
Instructions for researchers using restricted data
January 2009

Overview

Initial approval for restricted data IRBs is for one year. Once the IRB is approved, it will move from the “*In Progress*” folder to the “*Approved*” folder. At the 9 month point in the approval year, you will be sent a reminder e-mail about renewing the IRB. At that point, the IRB is listed under two folders “*Approaching Expiration*” and “*Approved.*” To prevent “*Expiration*” status, one must perform an SCR. This memo describes how to do this.



All of your restricted data IRBs should be in the “*Approved*” folder from your e-Research Home Workspace. No restricted data IRB should be in the “*Exempt and Not Regulated*” folder.¹ [See the following memo for instructions on correcting this.]

Process

Go to “*Approaching Expiration*” folder

Click on study

Before opening an SCR,

click the “View Study” button

(located in the top left corner of the web page)

Towards the end of the continuing review you will be asked for the total number of subjects to date that are represented in the data. If you are using secondary data, you should use the number reported in the original IRB application so look this up before you begin the SCR. [Question 5.2.1].

If you are collecting data, report the current number of subjects.

If this is the second SCR (or more) for an IRB, you can skip this step as the total number of subjects as of the last SCR, are reported on the SCR form.

¹ The IRB has a [demonstration project](#) that allows an exemption for restricted data (Exemption 7). However, researchers still need to make the choices described in this document. The IRB staff will make the determination about whether your project is eligible or not. The IRB staff is not likely to know about contractual restrictions so be careful about accepting this exemption. Check with us if you are uncertain about your contract language.

Once you have noted the number of subjects

click the back button on your browser twice

You are now ready to start your New Continuing Review

Click on "New Continuing Review" in the left navigation area

Schedule Continuing Review (SCR) or Termination [Section Heading]

Review page – requires no action on your part

1.0 Subject Activity Status [Section Heading]

There are 6 choices for activity status. If you are doing secondary analysis of restricted data, choose the choice highlighted in the red font. If you are collecting data, select one of the first two choices, depending on the status of the project.



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.

1.2 This is secondary analysis of data; we are not involved in the collection of data.
[Answer]

1-1 Study Risk Level [Section Heading]

1-1.1 Keep risk level at previous choice, most likely “*No more than minimal risk*”

1-1.2 Choose No

1.0 Approved Study Summary [Section Heading]

No action required.

2-1 Existing Subject Data Status [Section Heading]

Type in number of subjects in the study [from section 5.2.1 in original IRB application]
If this is the second or later SCR, the number is reported on the form; repeat previous number:

2-1.1 * What is the total number of subjects to date that are represented in the data (e.g., databases, data sets, medical records, specimens from bank or repository) already analyzed?

	Total as of Last SCR	Total as of this SCR	Change for this Reporting Period
Subject Data	12000	12000 <i>(do not enter commas, dots, or special characters)</i>	0

* Required

2-4 AE and ORIO Summary [Section Heading]

Report number of withdrawals from the study. Users of secondary data should report "0" as you have no control over subject withdrawals.

4.0 End of Continuing Review [Section Heading]

Click on Error Check

The error check report should come back without errors

Click on OK

Click on Move to Ready to Submit Inbox

Check the box by the PI's name so that they get notification to submit the SCR. Click OK in the bottom right corner.

Click Finish

Only the PI can submit the SCR. Go back to the main page of the specific IRB. If you do not end up at the main page, go back to:

<http://eresearch.edu>

Go to "In Progress" folder

Click on the study that has an open SCR

In the left navigation bar of that page, will be a ready to submit button.

Click on the submit button.

You will hear back from the IRB review committee within two weeks.