

eISCRO User Guide:

How to Submit a Renewal

Last Update	June 21, 2012
Intended Audience	Principal Investigator/Study Team
Purpose	To provide the user with step-by-step instructions on how to submit a renewal.

⇒ Refer to the [eISCRO Getting Starting Guide](#) before getting started.

Follow the steps below to submit a renewal:

- STEP 1. Close all open web browsers.
- STEP 2. Open a new browser and go to: <http://eISCRO.jhu.edu>
- STEP 3. Login using your JHEDID and password
 - The **My ISCRO Studies** workspace should appear, if not, select it from left side.
- STEP 4. Select the “All My Studies” tab, and then select the approved ISCRO Application for which you need to submit a renewal.

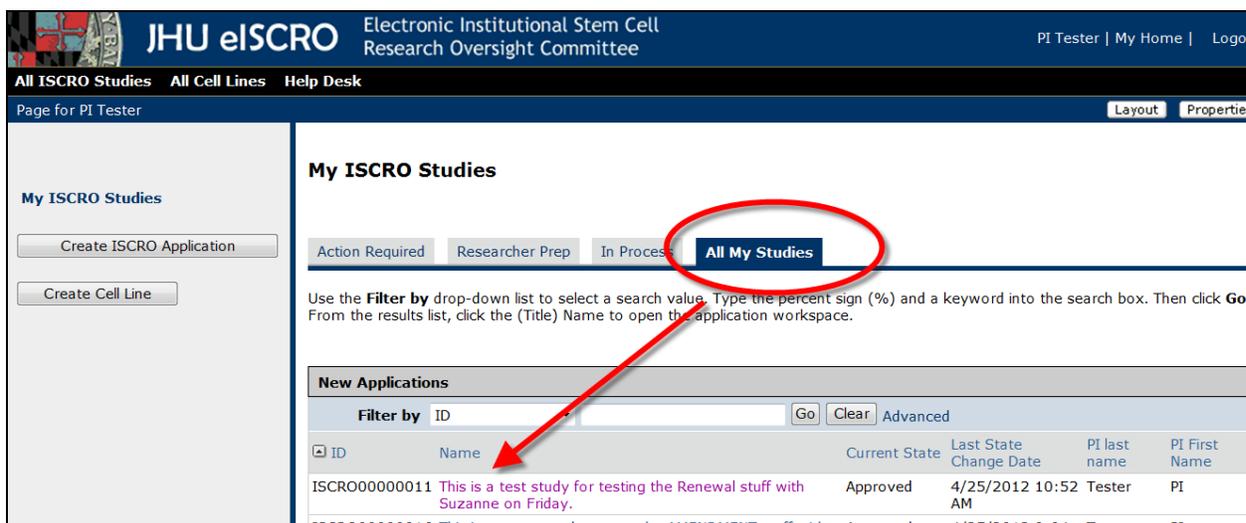


Figure 1

- STEP 5. Select the “Create Future Study Action” button, and the SmartForm appears.

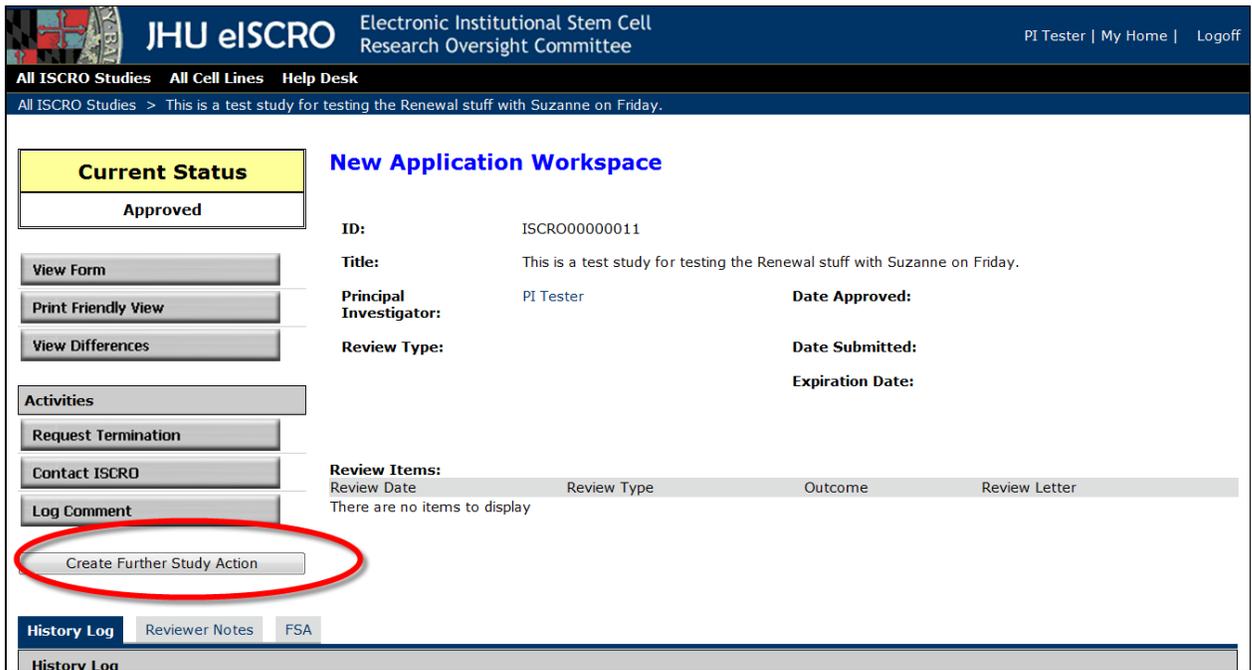


Figure 2

STEP 6. Select the "Renewal" check box.

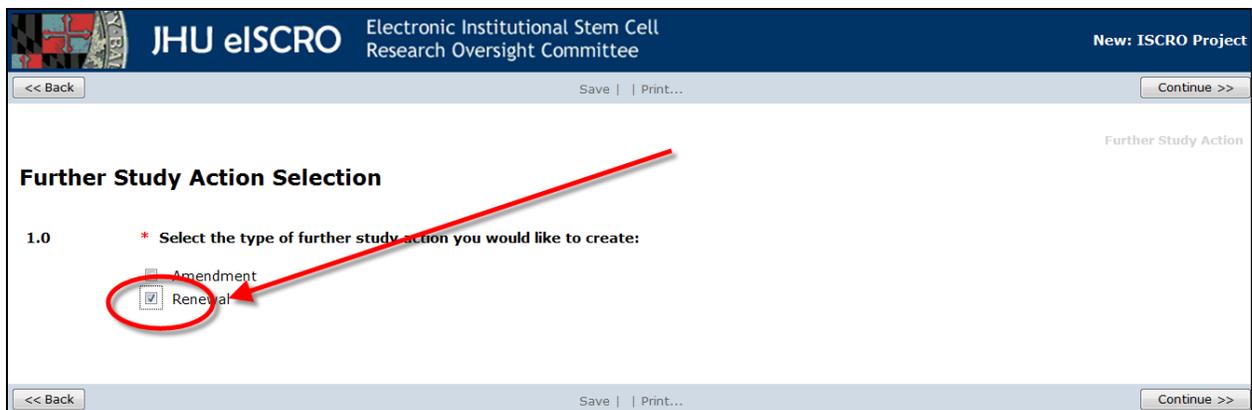


Figure 3

STEP 7. Select "Continue" to save the application and proceed to the next section.

- The system will save the renewal and generate an ISCRO ID number which will appear in the right corner of the form.



Figure 3

STEP 8. Complete Section 1 – General Information.

- Required fields are indicated with a red asterisk. *

JHU eISCRO Electronic Institutional Stem Cell Research Oversight Committee Edit: ISCRO Project - RN00000113

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: 1 - General Information Continue >>

Renewal

1 - General Information

1.0 Please review your ISCRO protocol application, using the link below, to confirm that its contents remain accurate. Once you have read the entire form, you may close the window and return to this renewal form.
ISCRO00000011

2.0 * Is all of the information in the above application accurate?
 YES. All the information in the above application remains accurate.
 NO. Changes are needed to the application to bring it up to date and I will submit an amendment to ISCRO to request these changes.
 Please remember that amendments (such as cell lines, animal species, procedures, funding) must be reviewed and approved by the JHU ISCRO Committee and by any other required JHU review committees prior to the implementation of the changes, except when a deviation is necessary to prevent imminent harm.

3.0 * Do you intend to continue this research?
 Yes No Clear

3.1 * Explain:

4.0 * Describe the research that was conducted and the interim and/or final results of that research:

Figure 4

- STEP 9. Select “Continue”** to complete the remaining sections using the blue navigation bar (Figure 4, above).
- The navigation bar can be found at the bottom and top of the form.
 - You can select **“Continue”** to proceed through each page of the application SmartForm.
 - When **“Continue”** is selected the system automatically saves the form.
 - You can select **“Save”** at any time and **“Exit”** the form. If needed, you can come back later and finish the form.
 - Select **“Exit”** to close the SmartForm. The system will confirm that the form will be saved.
 - You can skip to a specific section of the form by choosing a page name from the **“Jump To”** drop-down menu located on the blue navigation bar.
 - **NOTE:** If the **“Back”** button is selected the system will not automatically save the information entered on that page of the form. Be sure to select **“Save”** before the **“Back”** button is selected.
- STEP 10. Make sure required questions are answered.** The system will not allow the renewal to be submitted to the ISCRO until all required items are completed on the renewal SmartForm.
- To assess completeness of the form, you can **Turn on** the **Hide/Show Errors** feature, from the blue navigation bar, to provide a list of validation errors that the system finds along the way.
 - As required questions are answered in each section, the error/warning messages will disappear from the list.
 - The hide/show errors feature is optional and can be turned on/off at any time from the blue navigation bar.

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<< Back Save | Exit | **Hide/Show Errors** | Print... | Jump To: 1 - General Information Continue >>

Renewal

1 - General Information

1.0 Please review your ISCRO protocol application, using the link below, to confirm that its contents remain accurate. Once you have read the entire form, you may close the window and return to this renewal form.

ISCRO00000011

2.0 * Is all of the information in the above application accurate?

YES. All the information in the above application remains accurate.

Message	Field Name	Jump To
⊖ This is a required field; therefore, you must provide the required information.	Continue Research	1 - General Information
⊖ This is a required field; therefore, you must provide the required information.	Explain Continue	1 - General Information
⊖ This is a required field; therefore, you must provide the required information.	Explain Research	1 - General Information

Figure 6

STEP 11. Once you have completed the form, Select the “Finish” button on the last section of the SmartForm entitled “Finalize Application”.

- **NOTE:** You are not done yet.
- The SmartForm will close and you will be taken to the application workspace where you will be able to finally “Submit” the application to the ISCRO.
- The application is NOT sent to the ISCRO until the “Submit” activity on the workspace is run. **NOTE:** ONLY THE PI CAN SUBMIT THE RENEWAL.

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<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: 2 - Final Page **Finish**

Renewal

2 - Final Page

Thank you for completing the Renewal form.

- Click 'Hide/Show Errors' above or below to check for any errors and omissions in your Renewal form. All required fields must be completed in order to submit this form.
- Click 'Finish' below to exit and return to the Renewal workspace for the study.
- Finally, click the 'Submit' button on the left side of Renewal workspace. Follow the instructions in the activity window that pops up and click OK.

NOTE: Only the PI can submit the Renewal.

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: 2 - Final Page **Finish**

Figure 7

STEP 12. From the application workspace, select the “Submit” activity, located on the left side of the workspace.

- If additional changes are need on the SmartForm before the renewal is submitted, select the “View/Edit Form” activity to open up the form and resume completing it.
- **NOTE:** The PI cannot edit the form after submission, unless the ISCRO sends it back with questions.

JHU eISCRO Electronic Institutional Stem Cell Research Oversight Committee

PI Tester | My Home | Logoff

All ISCRO Studies All Cell Lines Help Desk

All ISCRO Studies > This is a test study for testing the Renewal stuff with Suzanne on Friday. > Renewal: RN00000113 For: ISCRO00000011 Layout

Current Status
Pre Submission

Renewal Workspace

ID: RN00000113
Title: Renewal: RN00000113 For: ISCRO00000011
Principal Investigator: PI Tester
Review Type:
Date Approved:
Date Submitted:
Expiration Date:

Activities
Submit
Study Team Withdraw
Contact ISCRO
Log Comment

Review Items:
Review Date Review Type Outcome Review Letter
There are no items to display

History Log Reviewer Notes

History Log
Filter by ID [] Go Clear Advanced
No data to display.

Figure 8

- If the system finds error/warning messages they will be displayed.

STEP 13. To correct error/warning message, select the errors in the list and the system will take you directly to the page where the answer can be corrected, repeat this until all error messages have disappeared from the list.

Error/Warning Messages Refresh

Message	Field Name	Jump To
⊖ This is a required field; therefore, you must provide the required information.	Student Research	3 - Research Personnel
⊖ This is a required field; therefore, you must provide the required information.	Non Hopkins Entity	5 - Research Sites

Figure 9

STEP 14. After all error/warning messages are resolved, select the “Submit” activity again, the PI certification appears.

STEP 15. Read the PI Certification text, and then select “OK”.

Submit New Application

Submit

Clicking "OK" below is the electronic equivalent of your signature.

UPON SUBMITTING THIS FORM I CERTIFY THAT I HAVE REVIEWED IT IN ITS ENTIRETY, AND I AM FULLY COGNIZANT OF, AND IN AGREEMENT WITH ALL SUBMITTED STATEMENTS. I ENSURE, OR WILL ENSURE THE FOLLOWING:

1. All questions on this application are answered truthfully and with appropriate completeness.
2. Adequate resources and facilities are available to carry out the proposed research.
3. Adherence to the current state and federal regulations and with the Johns Hopkins University Institutional Stem Cell Research Oversight Committee requirements governing this research will be ensured.
4. Before beginning research described in this application, all persons working on this project will complete the human pluripotent stem cell ethics education training module.
5. Before beginning research described in this application, all persons working on this project will read the JHU ISCR0 Committee's Policies and Procedures.
6. All persons working on this project have the appropriate training to conduct the portion of the research in which they are involved.
7. The Office of the Vice Dean for Research will be notified if there is a change in sources of funding in the lab, whether or not such a change is related to this application.
8. A formal tracking system, (including users and locations) will be implemented and maintained for use of all hPSCs for which I have an MTA.
9. A security system will be implemented and maintained for all hPSCs for which I have an MTA, so that only authorized personnel will have access to those lines.
10. No person working on this project will encourage infertility treatment teams to generate more oocytes than clinically necessary.
11. No person working on this project will perform experiments for human reproductive cloning.
12. No person working on this project will perform experiments involving *in vitro* culture of any intact human embryo for longer than 14 days or until formation of the primitive streak begins, whichever occurs first. Day 14 embryos will be destroyed.
13. No person working on this project will introduce any type of hPSCs into human or non-human primate blastocysts.
14. No person working on this project will allow an animal to breed if hPSCs have been intentionally introduced into the germ line of this animal.
15. Prompt response will be given to all requests for information or materials solicited by the JHU ISCR0 committee.
16. Cooperation with committees/organizations that have the right to perform audits of laboratories involved with hPSC research will be ensured.
17. All persons working on this project have been provided a copy of the entire current version of the research protocol and are fully informed of the current (a) study procedures (including procedure modifications), (b) potential risks associated with the conduct of this study and the steps to be taken to prevent or minimize these potential risks; (c) data and record-keeping requirements; and (d) the current approval status of the research study.
18. If applicable, the attached consent forms are those used to consent donors of all materials used in this project, and that the original forms are available for inspection/verification.
19. Adequate, current, and accurate research data, records, outcomes, and problems/events (if applicable) will be maintained in order to permit an ongoing assessment of this research project.
20. The JHU ISCR0 Committee will be notified upon termination of this JHU ISCR0 Committee approved research.

Click OK below to complete this activity.

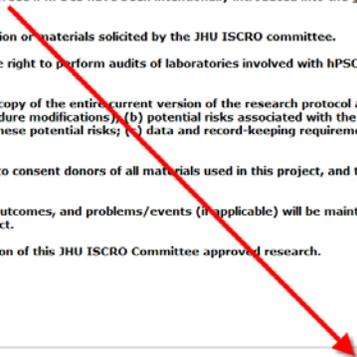


Figure 10

- STEP 16.** After submission, select **"My Home"** located on the top left corner to return to your Inbox.
- The system will send an email notification confirming the submission of the renewal.
 - The ISCR0 office will receive the submission and begin reviewing the application.
 - The renewal can no longer be edited at this time, unless the ISCR0 office sends it back for clarification and/or changes.
- STEP 17.** To view the renewal that was just submitted, select the **"In Process"** tab located on the **My ISCR0 Studies** workspace.

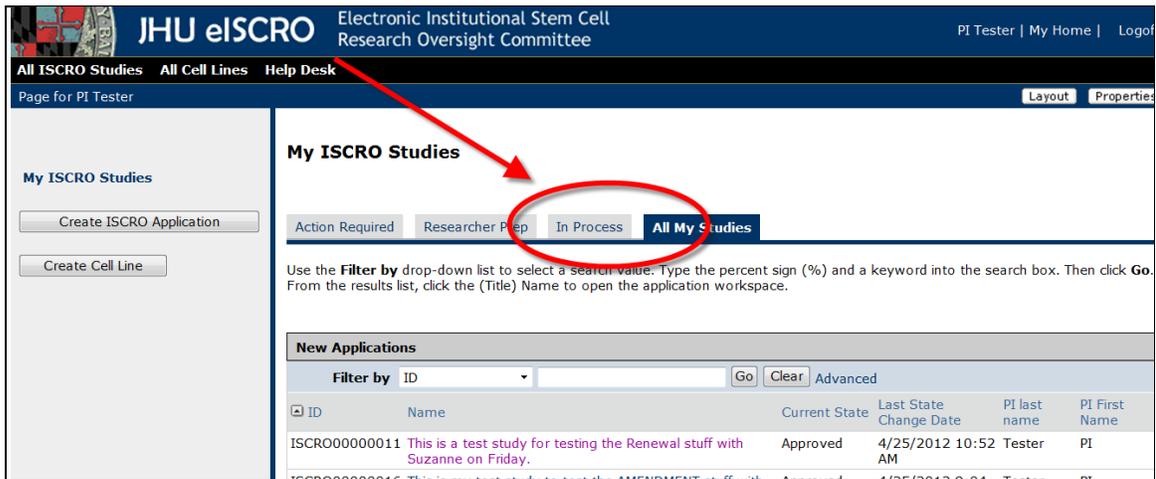


Figure 11

- You can find out the status of the ISCRO review by looking at the “Current Status” on the application workspace. For additional questions about the status of an application, **contact** the ISCRO by selecting the “**Contact ISCRO**” activity on the application workspace. This sends the ISCRO Office an email notification containing your question through the eISCRO system.

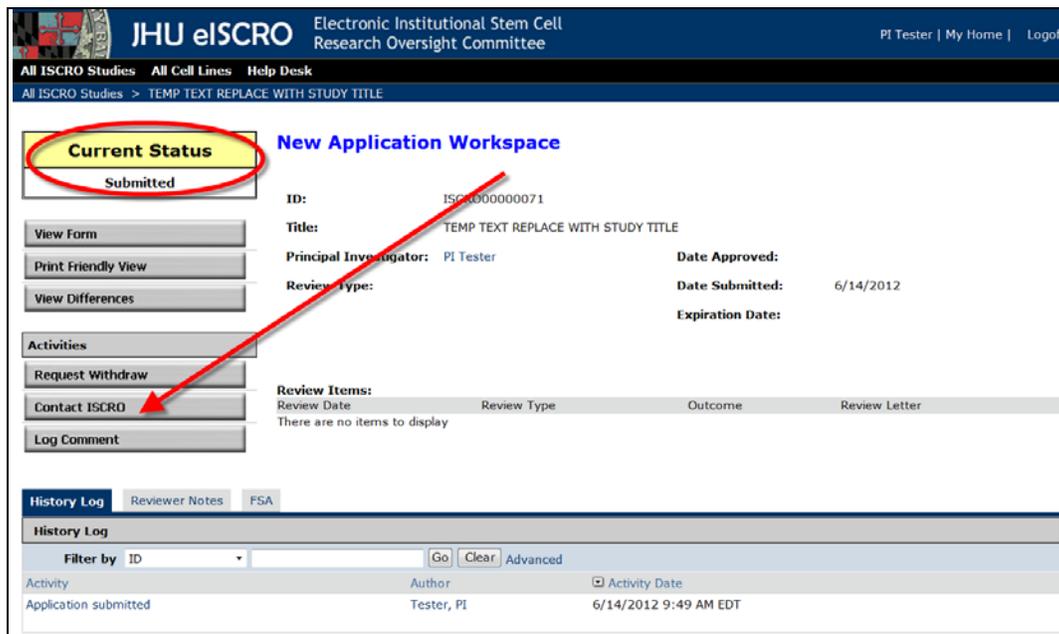


Figure 12

STEP 18. To close out of eISCRO, Select “Logoff”, located on the top left corner.

- **NOTE:** It is **very important** to **CLOSE** your browser window if you are finished using the system to ensure that you are completely logged out of eISCRO. This is because the system uses a Single Sign-On login process and will retain a user’s browser session until it is ended (by closing out the browser session, or the system times out).



Figure 13