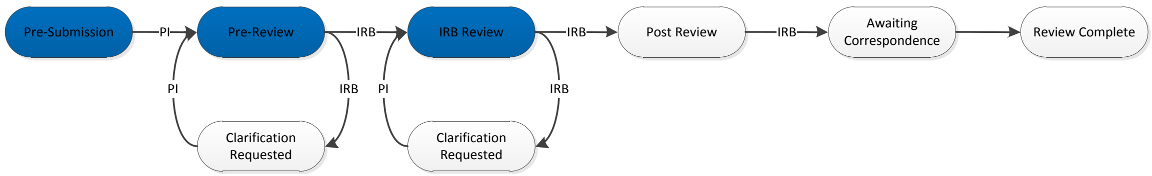
Job Aid Title	How to Create and Submit a New Research Study Submission
Relevant Users	All Users
Covered Topics	○ How to create a new research study submission ○ How to submit the research study to the IRB (PI ONLY)



! Note: If you are trying to locate an existing study, do <u>not</u> create a new study. Refer to the [How to Navigate to Find Existing Studies](#) Job Aid for instructions.

1. **Log into eIRB**
   - Log in using your assigned username and password.

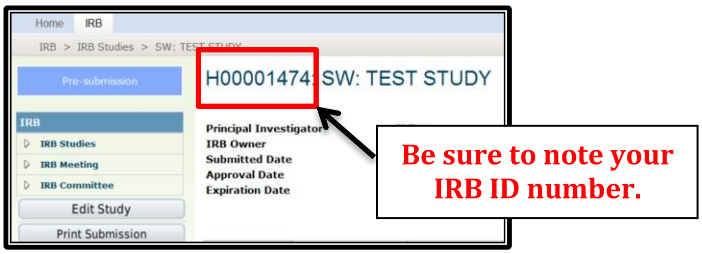
     ! Note: Refer to the [How to Log into eIRB / Forgot My User Name or Password](#) Job Aid for instructions on how to log into eIRB.
   - If you are the PI and are ready to **submit**, skip to Step 6 (Submit the study).
2. **Start a research study submission**
   - When you log into the system, you will be directed to your eIRB **Inbox**. Select Create New Study located under **My Current Actions** on the left side of your workspace. This opens the *electronic* "FORM: Initial Review (HRP-200)" within eIRB for the initial submission (also referred to as the "Parent" study).
3. **Fill in the Submission**
   - Answer the questions in each Section (e.g., Section 1.0 Study Information, Section 2.0 Funding Source). In Section 7.0 Attachments, you will upload the Investigator Study Plan and any additional study documents. Questions marked with * are required fields. You will not be able to proceed without completing those questions. Click **Continue** to go to the next page.

     !Note:

     - You may select 'Internal' for **Funding Source** and 'Departmental' for the **Internal Program** in Section 2.0 Funding Sources when the project does not have dedicated funding.
     - Should an external source (Sponsor) and/or drug not be in eIRB, you may request that they be added by visiting the [eIRB Data Request](#) page on the IRB's website.
     - It is strongly recommend that you review the [How to Manage Files in eIRB](#) Job Aid prior to uploading documents in Section 7.0 Attachments.

- Select **Finish** when you reach **8.0 Final Page**. If you need to leave the submission and continue working on it at a later time, click **Save** and then **Exit** at the top or bottom of the form to save your work.

- **Be sure to add yourself to the study before logging off (see Step 4 below).**
- Be sure to retrieve your IRB ID number (sometimes referred to as 'Study ID' or 'Docket Number'). The IRB ID number can be found at the top of the study workspace (see below).



! Note: eIRB generates the IRB ID number as soon as you create the study (H followed by 8 digits). Add the IRB ID number to any applicable study documents prior to uploading (e.g., informed consent form, HIPAA form, Advertisements, etc.).

4. Complete the additional required information

- You must **Edit Research Staff** and **Edit Consumer – Lay Summary** under My Current Actions in the study workspace. **You can also complete these two sections before completing step 3 above.** The PI will **not** be able to submit the study if these two sections have not been completed.
- **Edit Research Staff:**
  - On the left side of under **My Current Actions,** click the **Edit Research Staff** link.

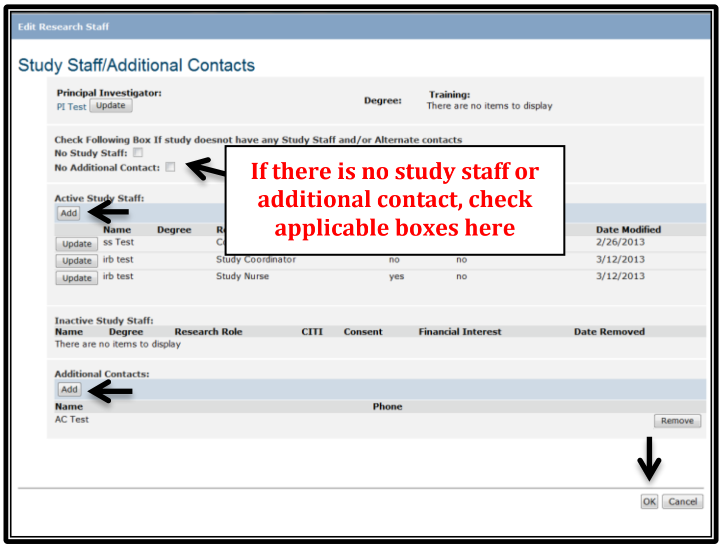
  - Use the **Add** button to open the **Study Staff/Additional Contacts** pop-up.

    !Note:

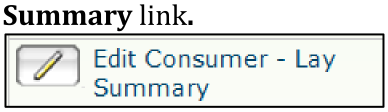
    - Refer to the How to Edit Research Staff Job Aid for detailed instructions on how to add/update project personnel in eIRB.
    - If you are not the PI but need access to the study and need to receive copies of eIRB correspondence, **add yourself as an Additional Contact before exiting the page. If you are Study Staff, add yourself as Study Staff.** In many cases, you may need to list yourself as both the Additional Contact and Study Staff to

ensure that you have the necessary editing and notification privileges in eIRB.

- Click **OK** at the bottom right to exit the page when done.



- **Edit Consumer – Lay Summary:**
  - On the left side under **My Current Actions,** click **Edit Consumer – Lay Summary** link.



  - Once you have entered a required brief lay summary of the study, click **OK** at the bottom right of the pop-up to close.
  - The lay summary will be posted to the UMass Worcester Conquering Diseases website **unless you uncheck the box** and prevent the summary from being published.

5. Ready for PI Review (Additional Contact, Study Staff):

- Select **Ready for PI Review** under **My Current Actions** to send a notification to the PI. **The PI is the only person who can submit a study.**

! Notes:

- You can continue editing the study in pre-submission until you are ready to submit.
- If you decide not to submit the study or want to place the submission on hold indefinitely, you can click **Place on Hold** under **My Current Actions**. This will retain your work but will move your study from pre-submission to ON HOLD. You can always click **Take off Hold** to move your application back to pre-submission and continue to work on it.

6. Submit the study (PI ONLY)

- Once the submission has been prepared and ready to submit, click the **Submit** link under **My Current Actions.** If you receive error/warning messages, then check to see that steps 3 and 4 above are completed.

- Read the investigator acknowledgement. Click **OK** on the bottom right when you are ready to confirm the statement; this will send your research study to the IRB office for pre-review.

  ! Note: The Investigator's Manual is available at the UMass Medical School IRB Web site.

- You will know that you have submitted successfully when the submission's "state" in the upper left-hand of the screen has changed from Pre-submission to Pre-Review.