RAP IRB SUBMIT STUDY FOR REVIEW

Important: Only the Principal Investigator (PI) or a PI Proxy can see the "submit" button and submit a study for review. For information on how to assign a PI proxy, see our <u>quidance</u>.

Submit Application

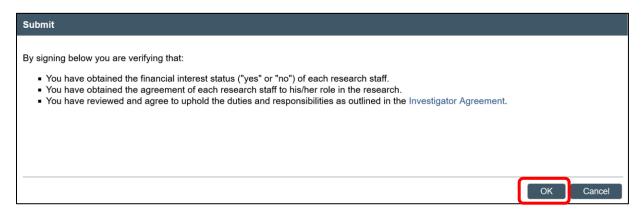
1. Once you have completed all the pages in Edit Study view, select "Finish" at the lower right side of the final page.



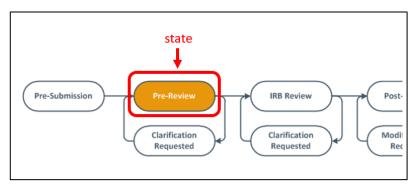
2. You will be taken to your study page in the pre-submission state. Select "Submit" from the choices at the left side of the screen.



3. If you have not entered required information on any page, you will be prompted to return to the incomplete page to edit it. Once all the required information is entered, you will see the submit screen. Once you have verified the information presented, click "OK" at the lower right corner of the screen (screenshot below).



Congratulations! Your protocol has been submitted for review. You can see that your study is now in the pre-review state. At this stage, you are no longer able to edit your study, but you do have some options listed below.



Post-submission options

Once your submission is in pre-review status, there are several options.

- Assign Primary Contact. The person who will act as the study's main point of contact for
 communications with the IRB. When the RCS communicates a decision or requires action by the study
 staff, the primary contact receives notifications in addition to the principal investigator and PI proxies
 if assigned. If the primary contact is also engaged in the research, this person must be listed as a
 team member within the study. There can only be one primary contact listed on each study.
- 2. Assign a PI Proxy. PI proxy(ies) may act on behalf of the PI of the study. PI proxy(ies) may submit a study for initial review, modify the study, and submit for continuing review. The PI may assign more than one proxy, but all proxies must be listed as a team member within the study.
- 3. Manage Ancillary Review. The PI may assign an ancillary review. For example, student led research requires an <u>ancillary review by their faculty advisor</u>. Contact RCS if the PI is unsure if ancillary reviews are required. RCS staff may also assign ancillary reviews.
- 4. *Manage Guest List*. If you would like individuals not listed on the protocol to view the details of the submission, you may add them to the guest list.
- 5. Add Comment. You may add additional information and supporting documentation to the submission by choosing "Add Comment". The comment will be visible to anyone with access to the submission.
- 6. *Copy Submission.* You may create a copy of the submission. You will remain the PI for the new submission.

- 7. Withdraw. If you would like to withdraw the submission for any reason, choose "withdraw". The submission will be reverted back to Pre-Submission status and you will be able to make edits. You may submit again when you are ready.
- 8. Discard. Choosing this action will permanently remove the submission.

Submitting changes to your submission

1. If the study is sent back to you with a request for clarifications or modifications, the "submit" button will change to "submit response." When you click "submit response," a window will open where you can add notes about the changes you made. Then please click "OK" in the lower right corner. Again, the state will shift to pre-review or post-review, meaning the study is no longer open for editing and has been submitted to our office. A notification will be sent automatically to the IRB coordinator assigned to your study.



2. For further help, please see our guidance on <u>Responding to clarification request or modifications</u> required. This guidance also contains screenshots to help you navigate the RAP.

Submitting participating sites

1. If your study has participating sites, the "submit" button for those sites will say "submit site materials."

