IRB Order of Operations Flowchart

This document includes the basic details regarding what human subjects research is and how the IRB submission and review process works. This document is meant to be used as guidance for researchers to assist in the thorough completion of an IRB submission from start to finish.

It is recommended that this document be consumed in full, as needed. Please utilize the search function for keywords or phrases to jump to specific information, as applicable.

If there is any question that is not answered within this document, please email IRB@gmu.edu

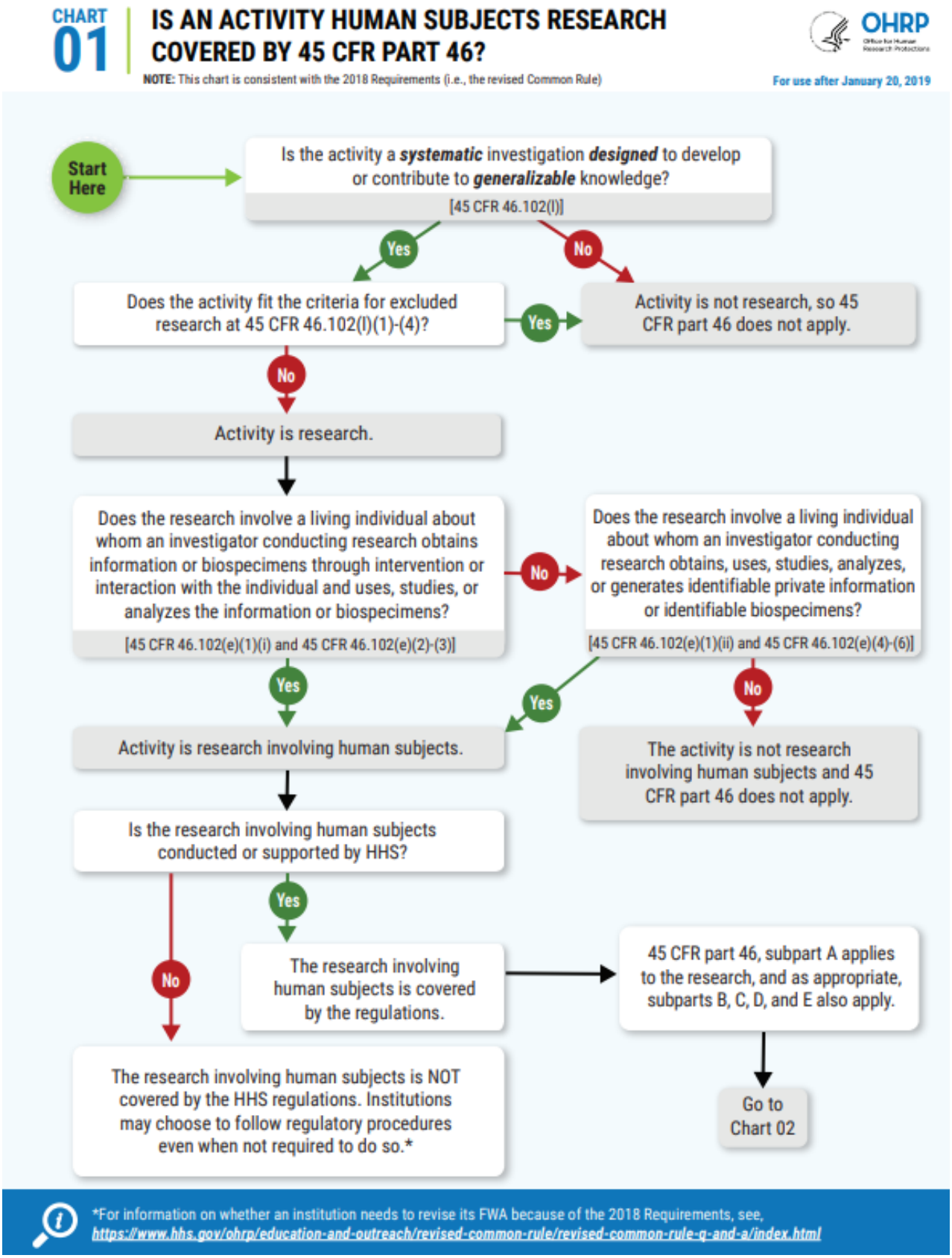
Is my project research?

Definition of **research**: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of the federal policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Classroom projects, quality improvement projects do **NOT** meet the definition of research

Classroom project SOP: SOP_1.3.5_Classroom-projects-1.pdf (gmu.edu)

Definition of **human subject**: a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information about whom includes a subject's opinion on a given topic.

BOTH of the above must be true for the project to be considered human subjects research



HHS decision charts: https://www.hhs.gov/ohrp/sites/default/files/human-subject-regulations-decision-charts-2018-requirements.pdf

My project is research…now what?

Required Training:

All researchers who will be involved in the research process, including the consent process, data collection, analysis of identifiable data, and/or will have access to identifiable data is required to complete the CITI Basic training course, either Group 1 for Social & Behavioral research or Group 2 for Biomedical research.

To complete CITI Basic training, follow the instructions on our website: Human Subjects Training - Office of Research Integrity and Assurance (gmu.edu)

To access the CITI website directly: Research, Ethics, and Compliance Training | CITI Program

If any researcher on the study team has already completed the Basic training at another institution, we can accept a copy of that report as long as it is current. Be sure to attach a copy of the training report to the IRBNet package.

Note: we do NOT accept the Responsible Conduct of Research (RCR) training.

Principal Investigator (PI):

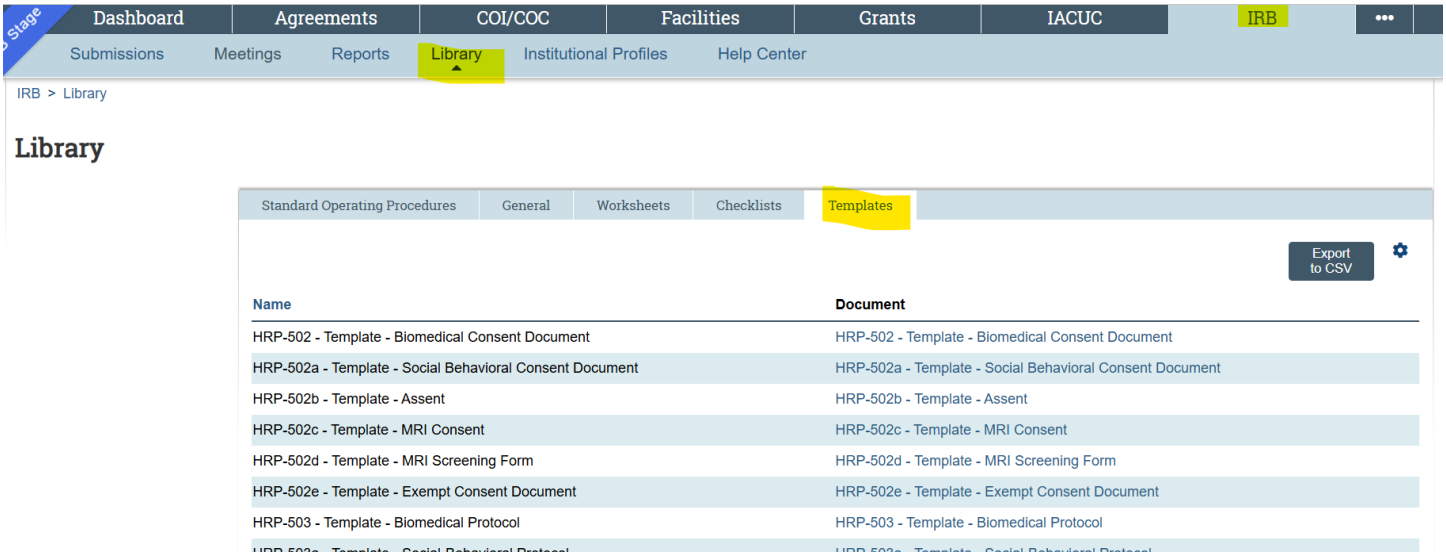
All human subjects research conducted at GMU requires a full-time faculty member to be serve in the role of Principal Investigator (PI). Please refer to the following link to review the university policy: https://universitypolicy.gmu.edu/policies/principal-investigators/

Review System: RAMP

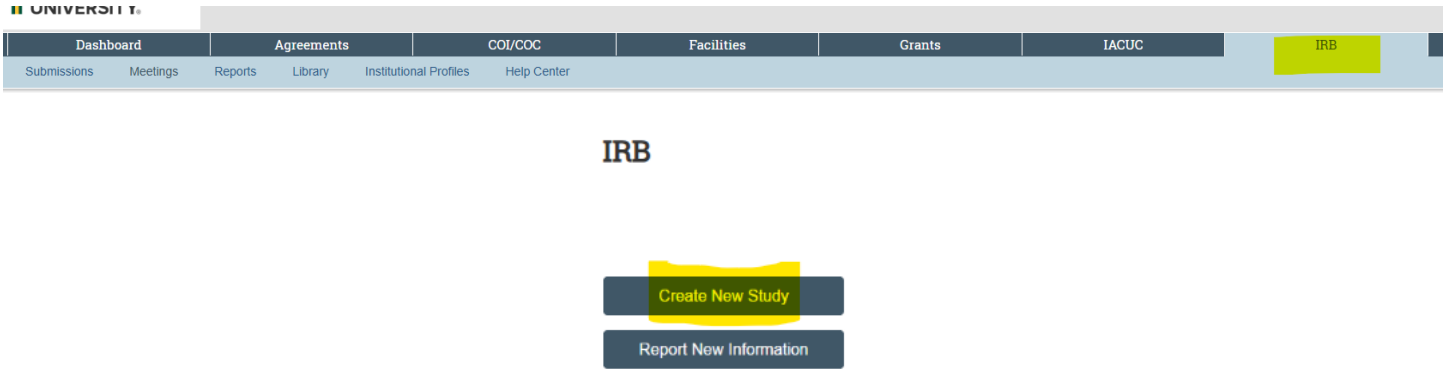
We review all studies through RAMP (https://ramp.gmu.edu/). This is where the protocol templates are located, the consent template, and other relevant documents that may be required during the application process. This is also how we communicate with researchers during the review process and where we publish approval letters.

As a GMU student, staff, or faculty member, you will already have a RAMP account. If you have not already done so, be sure to log in and activate your account. This includes submitting your COI disclosure within RAMP.

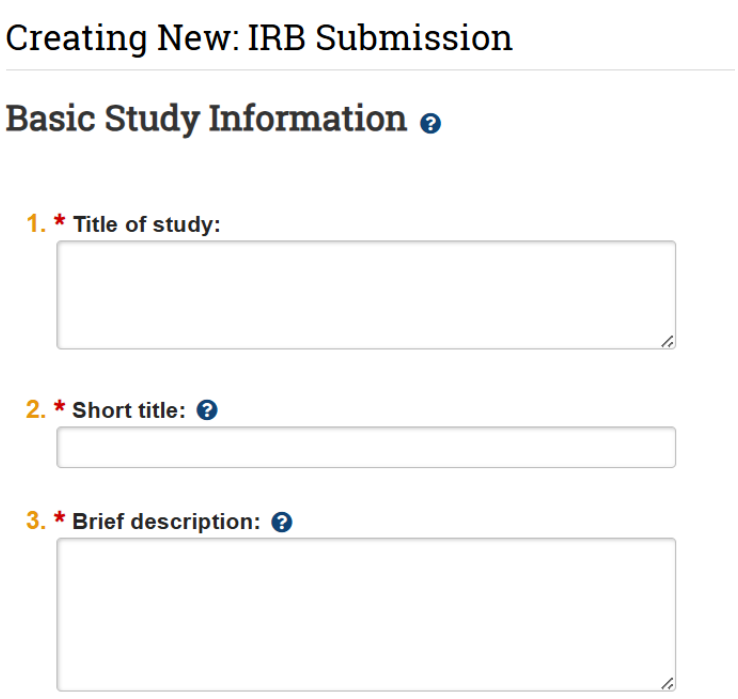
Download the applicable protocol template form from the RAMP IRB document library and complete it in full. Download the consent template that is available in the RAMP library to create your consent form. Be sure to remove the instructions and template language/prompts before attaching it to the package. The document that is attached for the IRB to review should only include the consent that will be given to participants.

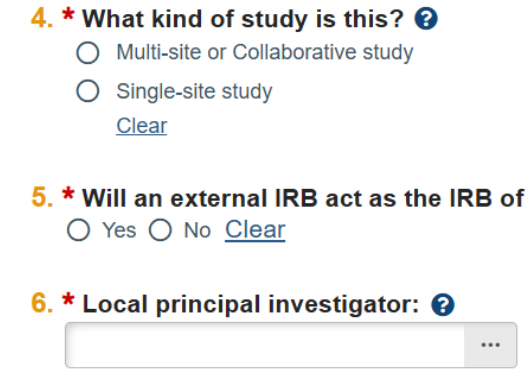


To create a new project, click on the IRB tab on the top right of the screen, then Create New Study from the left menu.

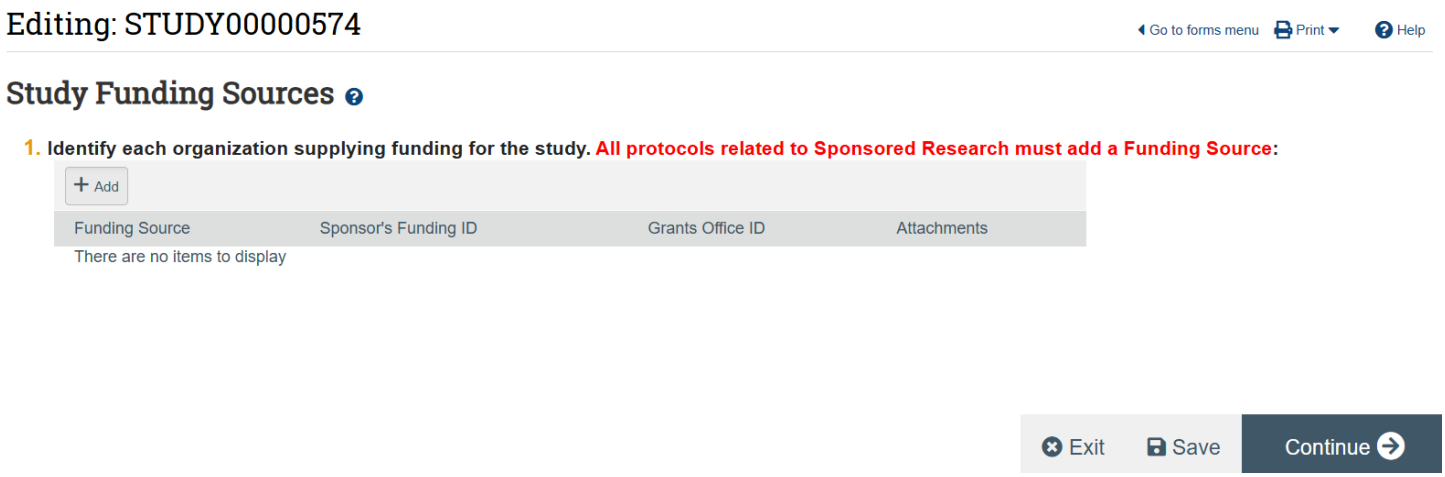


Answer each question in the Basic Study Information page in RAMP:



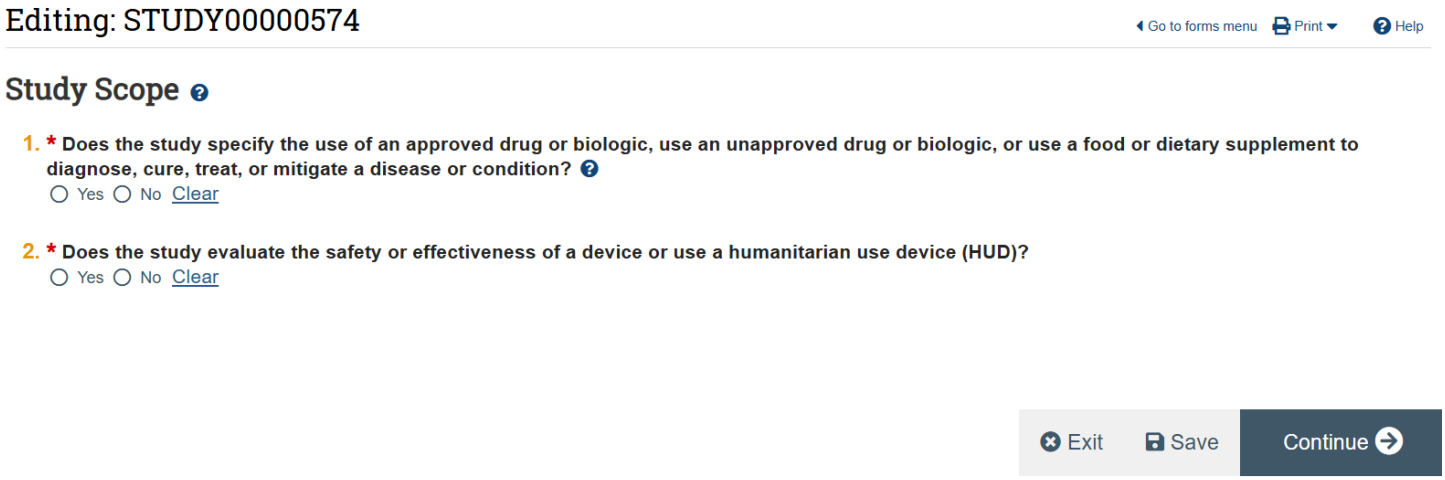


Click Continue to move to the next section, Funding Sources. Enter any funding sources, if applicable. If the study is not funded, you can click Continue to move to the next section.

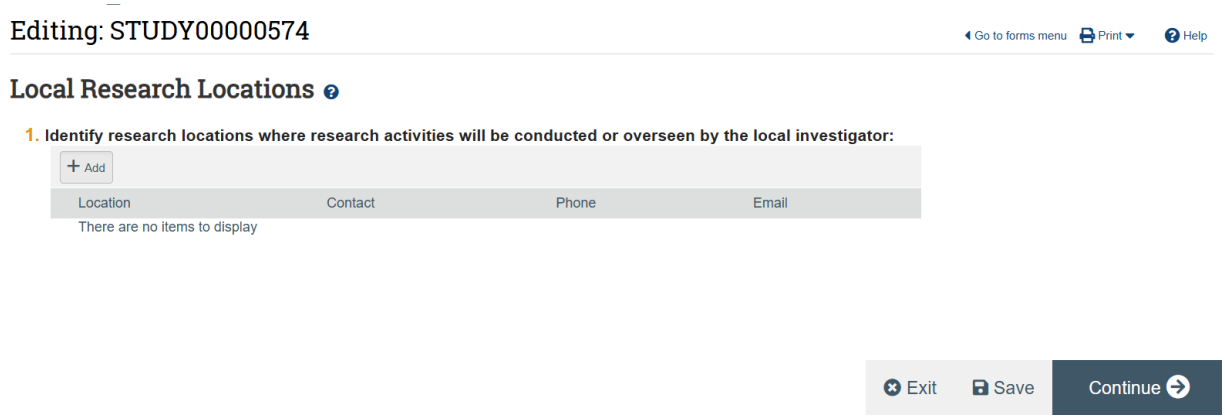


Next you will add all researchers that are involved in the study, both GMU-affiliated personnel and external members.

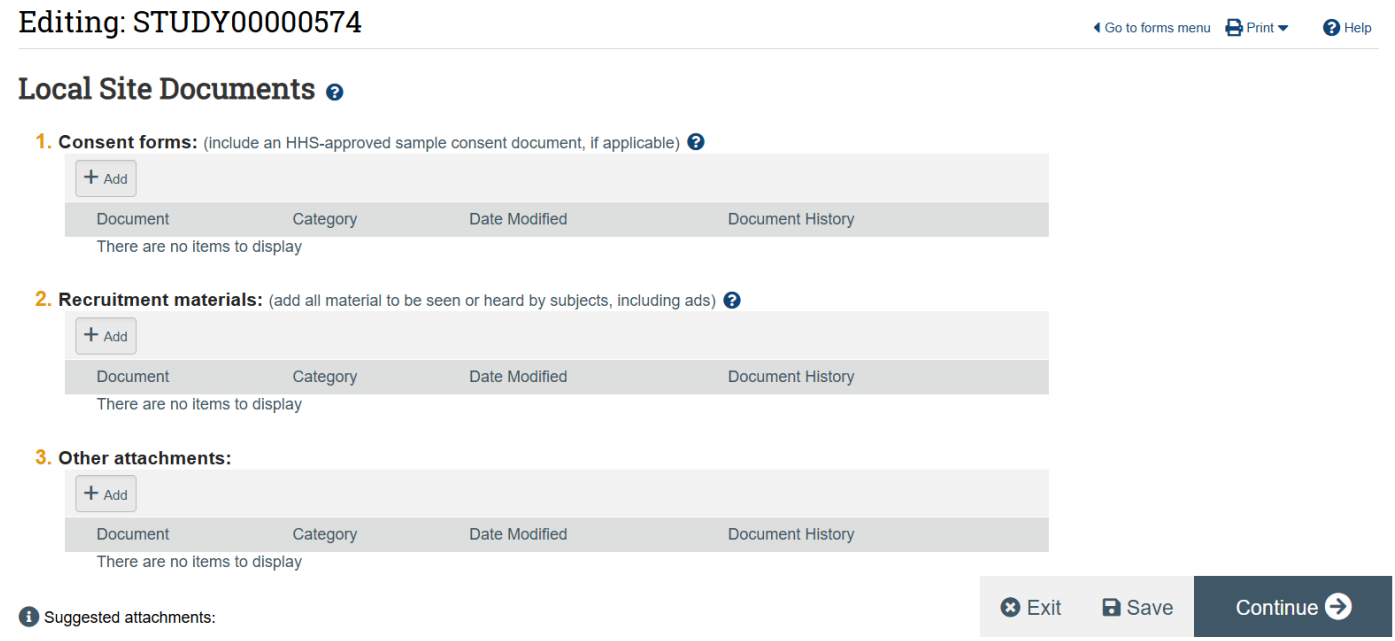
Next, answer the Study Scope prompts and click Continue when done.



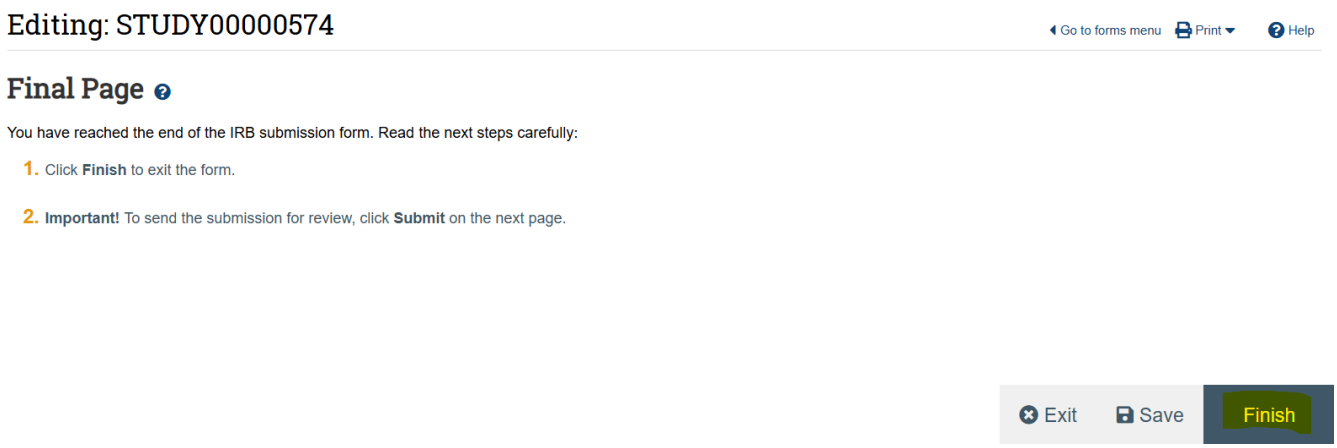
Add the research locations where procedures will occur (both physical locations or online platforms), and click Continue when done.



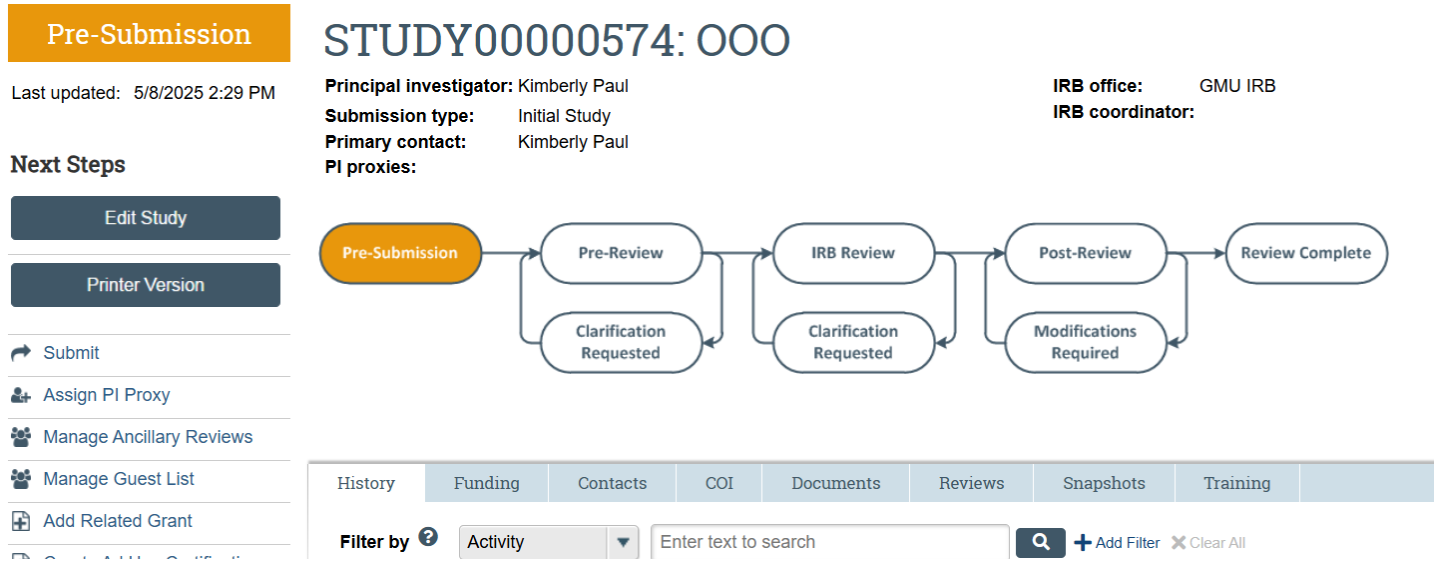
Attach the consent form(s), recruitment material, instrumentation that will be used, etc. to the package when prompted in the respective sections. Note: the instrumentation, stimuli, screenshots, videos, etc. should be attached in the Other documents section. When done, click Continue.



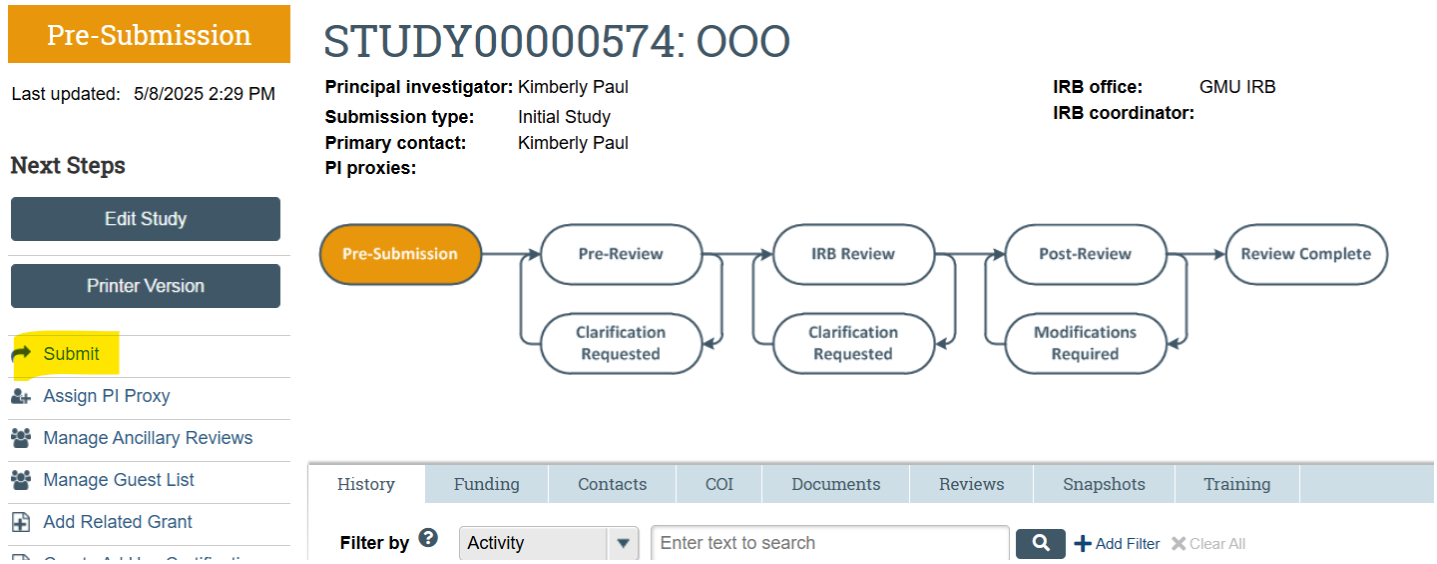
The final page will prompt you to click Finish. Clicking Finish will complete the study creation.



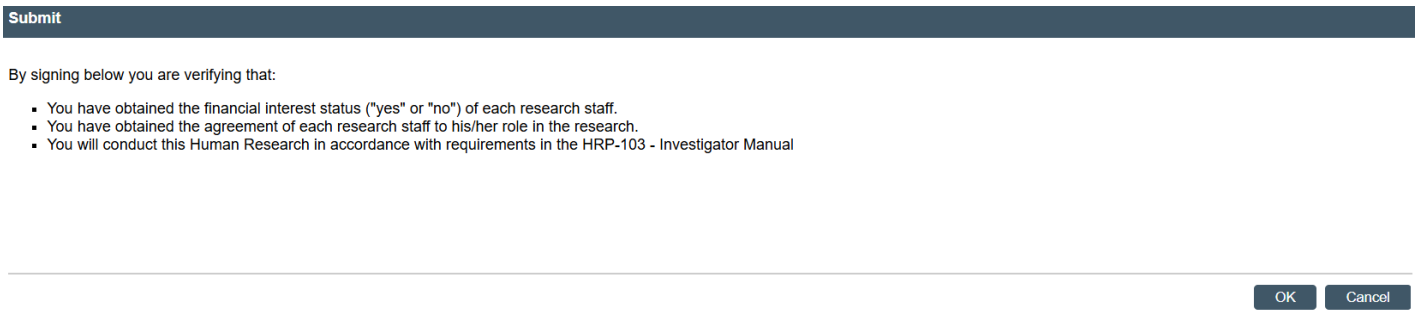
You will notice that the study status is currently in Pre-Submission – this means that **the study has not yet been submitted.**



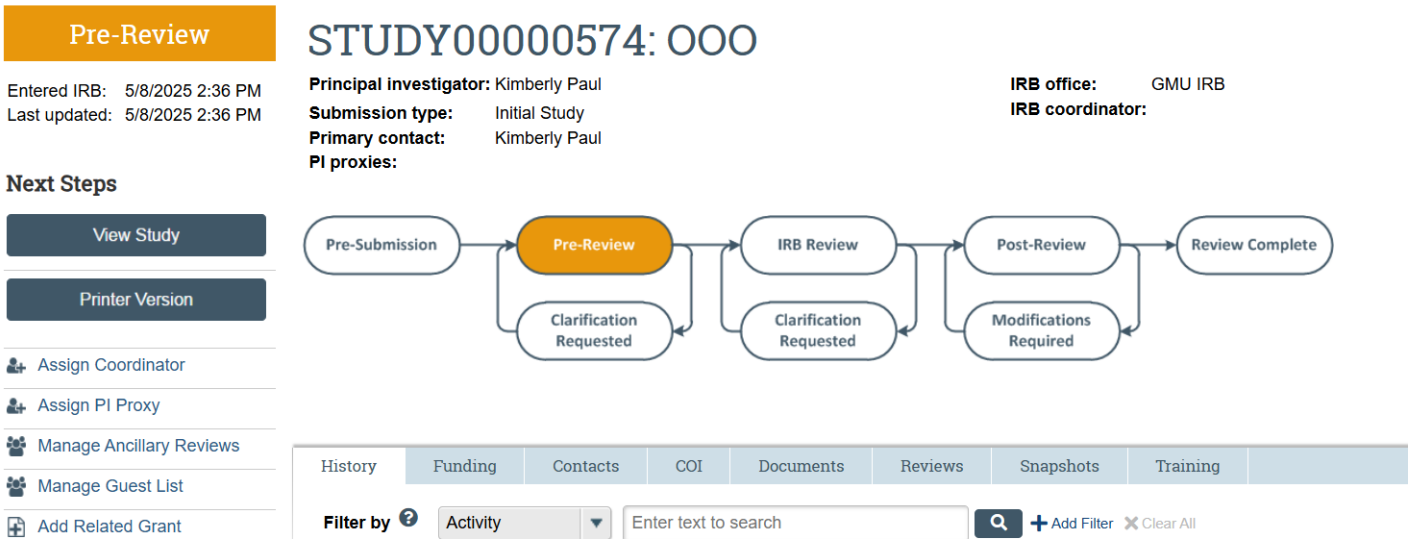
Only the person listed as the PI will have the ability to click Submit. The PI has to click the Submit button the left side menu.



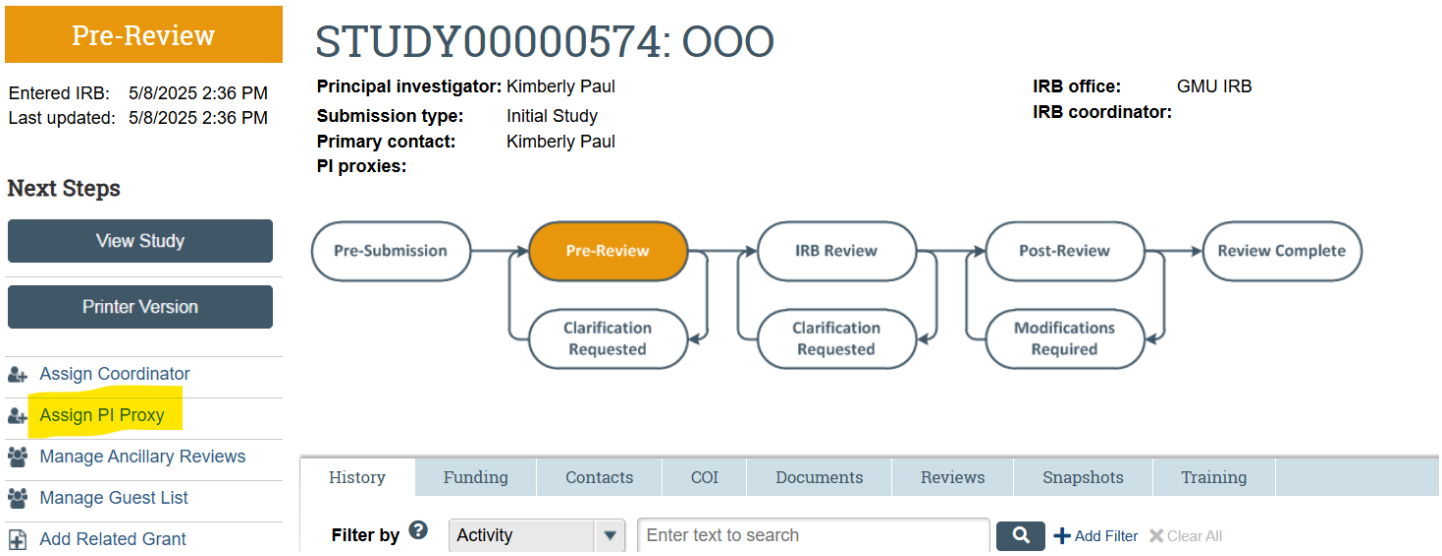
Once the Submit button is selected, there will be a pop-up screen displayed:

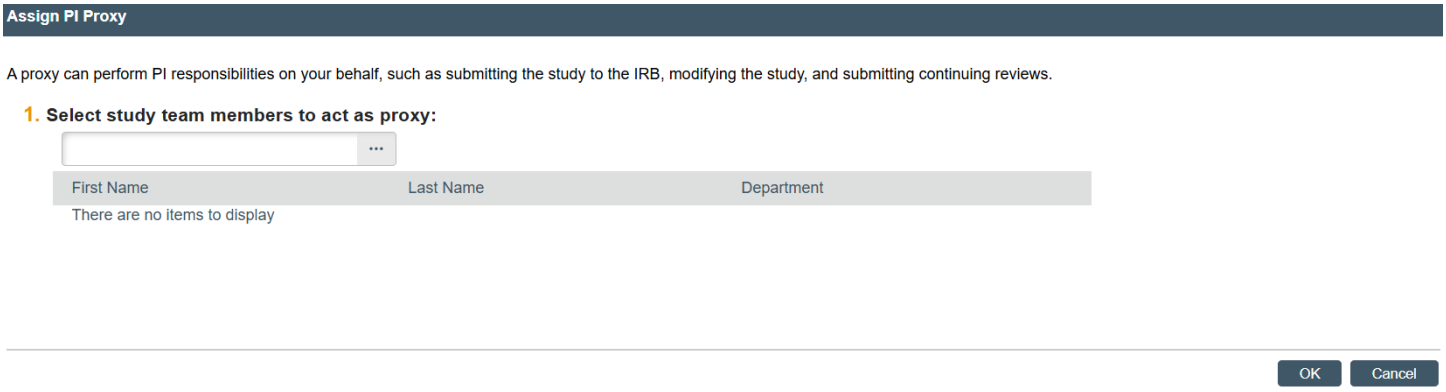


Clicking OK in the bottom right of the pop-up screen will submit the study to the IRB for review. You will know that the study has been successfully submitted when the orange status bar in the top left of the study home page says “Pre-Review.”



At this time, after the study has been submitted to the IRB by the PI, a PI proxy can be assigned, if desired. The PI can select Assign PI Proxy from the left menu to assign another person to act on behalf of the PI in RAMP for the submission, giving them the ability to make changes and submit future revisions, as needed.





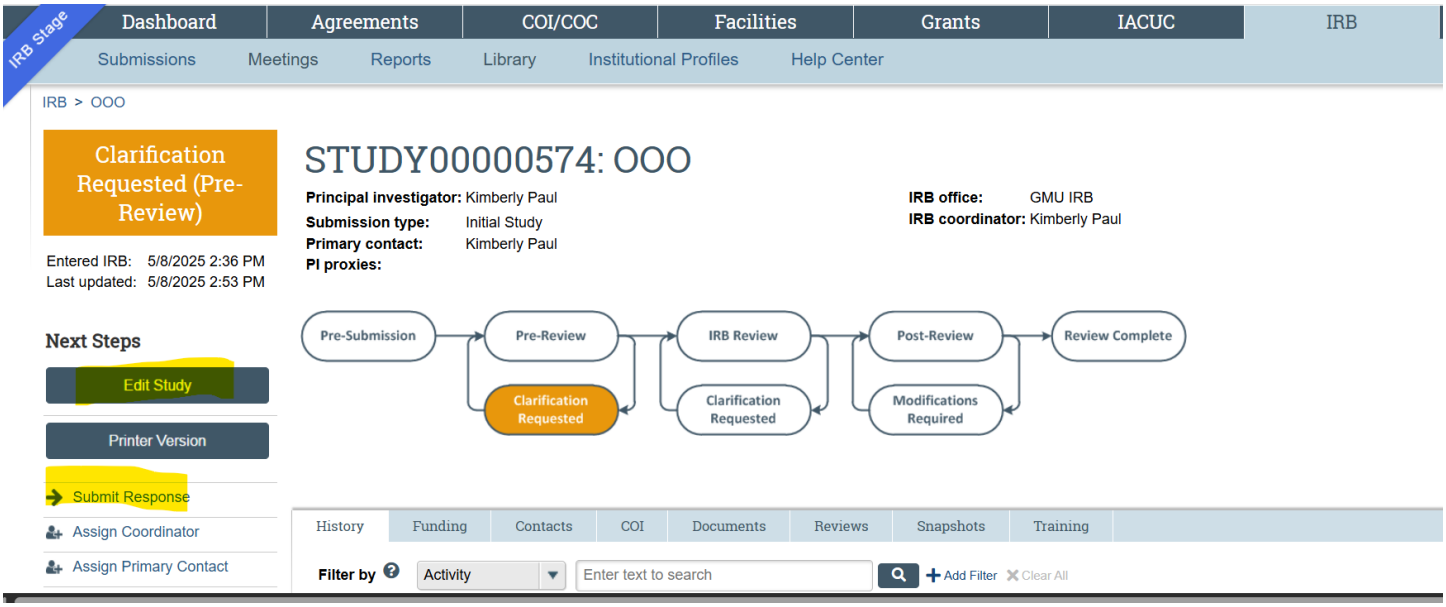
Note: only people who are listed as study team members in the original submission can be assigned to the role of a PI proxy.

Here is a tutorial video explaining how to submit a new project in RAMP:
https://vimeo.com/1001686992/d16f996f55?share=copy

Review Process

Once the project is submitted for review, the IRB Compliance Specialists will conduct a preliminary review of the submission within 10-15 business days. Once the project receives a preliminary review, the project will be kicked back to the researchers with requests for clarifications and/or additional information that is needed. The communication for these requests takes place via RAMP's messaging system. You will be notified via email that there has been requested clarifications/communications; however, you will need to login to RAMP to view the message. You will also note that the status of the submission will say Clarification Requested (Pre-Review) – this means that the study has been kicked back to the researchers for revisions.

Once modifications are made to required documents, you will click Update next to the document you are updating to attach the updated version. Once everything has been addressed, be sure to resubmit the changes by clicking Submit Response on the left side of the screen. Note: the PI will have this option and anyone who has been assigned as PI proxy.



When the package is re-submitted with the changes made, another review will be conducted to ensure that the revisions were made correctly, generally within 10 business days of submitting a response. During this time, the status of the study will go back to Pre-Review. There may also be additional requests following the preliminary review depending on the updated information received during the preliminary review. If there is another round of revisions needed, the same steps as above regarding the response submitting process should be followed.

Please note that there will be one IRB compliance specialist assigned to help facilitate the review of a RAMP submission. It is recommended that any specific questions during the review are directed toward the specialist on the project, as they will be most familiar with your submission.

To access approved documents with the IRB stamp and decision letters, click on your study and the documents will be available in the main communication page.

The submission deadline (https://oria.gmu.edu/topics/human-subjects/irb/meeting-schedule/) is for studies that may require review by the full board. We accept submissions on a rolling basis, and the majority of submissions do not require full board review (i.e., they can be submitted any time, regardless of the submission deadline posted on our website). However, if your study involves prisoners, FDA regulated drugs or devices, more than minimal risk to participants, the use of a DEXA scan, etc., then the submission deadline should be considered to ensure that your study is eligible for the next IRB meeting.

Generally, the entire review process takes between 4-6 weeks for an exempt or expedited study, 4-10 weeks for full board studies. The duration of the review process depends on the quality and completion of the application and materials submitted and how quickly / accurately revisions are addressed.

If there is a tight funding deadline, communicate that with us ahead of time. Submit a high-quality application/submission to reduce the amount of back and forth. We review submissions in the order that they are received.

Levels of Review

Not Research: The project does not meet the definition of either research or human subjects, therefore no IRB review is required. This does not mean that you cannot conduct the procedures; rather, this simply means that no IRB oversight is required so the IRB office will not review the protocol.

Exempt: The IRB office makes this determination. Exemptions (2018 Requirements) | HHS.gov

Expedited: At least one member of the IRB reviewed the submission and the protocol must fit into at least one of the expedited categories. OHRP Expedited Review Categories (1998) | HHS.gov

Full Board: The study was reviewed at one (or more) convened IRB meeting with its members voting on the approval of the protocol.

My project has been approved but I need to make changes…how do I do this?

Modification Process

If there are any changes to the study design, instrumentation, consent and/or recruitment language, funding, study personnel, etc., an amendment will need to be submitted for review and approval before implementation of those changes. All full board and expedited studies need to submit modifications for any change. Exempt studies may need to submit a modification depending on what the change(s) are.**

To submit a modification, click on the study in question in RAMP. Select "Create Modification" and answer the prompts. The process for submitting and reviewing a modification are similar to the original process to submit a new project.

Please refer to the amendment instruction document for step-wise instructions on submitting an amendment.

For a tutorial on submitting a modification to an exempt study, please review the following video: https://vimeo.com/1001301285?share=copy

**Note: please review the following chart before submitting a modification for an exempt study:

PROJECT REVISIONS FOR EXEMPT STUDIES

Please review the Project Revision the following to confirm if a modification needs to be submitted:	**Do Submit**	**Don't Submit**	**No Longer Exempt**
1. Adding vulnerable populations, such as prisoners; children; pregnant women; non-English speakers; GMU Students or employees; individuals with diminished capacity to consent; prisoners; people living in poverty; people who are illiterate; and/or international populations, as participants.	X		It depends
2. Adding a survey or interview that involves children (i.e. individuals under the age of 18)	X		X
3. Revising survey/interview questions to make substantive changes, adding items, or revising content	X		It depends
4. Revising surveys/interviews to make minor edits that do not alter the nature of the questions being asked (fixing typos/grammatical errors, restating the same questions for clarity, reordering the questions, splitting one question into multiple questions)		X	
5. Revising interview/focus group questions to include additional planned initial or follow-up questions (i.e. any question that is known in advance to the researcher is a planned question).	X		It depends
6. Revising interview/focus group questions to include follow-up clarifying questions (i.e. questions that cannot be known to the researcher in advance because they are based on the individual responses of the participants).		X	
7. Adding observational research with children that involves participation by the researchers. For example: changing procedures from observing children playing with toys to add researchers entering the room and leading the activity.	X		X
8. Add research procedures that are subject to the FDA Regulations	X		X
9. Revising study procedures such that data samples will be individually identifiable when previously, they were not	X		It depends
10. Adding a new cohort of participants that are similar in age and type as the previously acknowledged cohort (i.e. adding a new group of students to existing pool of students)	X		
11. Increasing the enrollment number		X	

12. Replacing the Principal Investigator	X		
13. Adding External Collaborators	X		
14. Adding a student researcher, if this research will be used for their thesis or dissertation	X		
15. Adding or removing study personnel, not otherwise listed in # 12, 13, or 14 above. Note: Only listed personnel can/will be copied on correspondence with the IRB. The PI is responsible for ensuring that all study staff have completed the appropriate online ethics training, which can be found here: https://oria.gmu.edu/topics/human-subjects/training/		X	
16. Adding research activities that change the risk to participants	X		
17. Adding or removing funding	X		It depends
18. Adding additional types or varieties of food for tasting or consumer preference tests	X		It depends
19. Revising recruitment materials so long as the 6 required elements are still present and they conform to the GMU policy: https://oria.gmu.edu//wp-content/uploads/SOP_2.3.1-Recruitment_Final-1.pdf		X	
20. Adding compensation for participants (unless compensation is $600+ per participant in a year and/or compensation will now be paid via check)	Only if $600+ or check	X	
21. Adding extra credit as compensation in a manner that conforms to the GMU policy: https://mason.gmu.edu/~apatte17/Sona/Researchers%20Responsibilities.pdf		X	
22. Revisions to the consent/assent/parental consent form or process. These documents are stamped so even minor revisions must be submitted to a new stamped version can be submitted.	X		It depends
23. Revisions involving changes to, or additions of, conflicts of interest declarations or disclosures for study team members (including those not listed on the application).	X		

Contact Us

We host virtual drop in office hours on Mondays and Thursdays between 2:00pm-3:30pm for quicker questions (up to 10 minutes): https://gmu.zoom.us/j/98436967347

Note: June-August 2025 office hours will be limited to Thursdays between 2:00-3:30pm

We are available for questions and/or meeting requests via email at irb@gmu.edu

Contact Us - Office of Research Integrity and Assurance (gmu.edu)

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