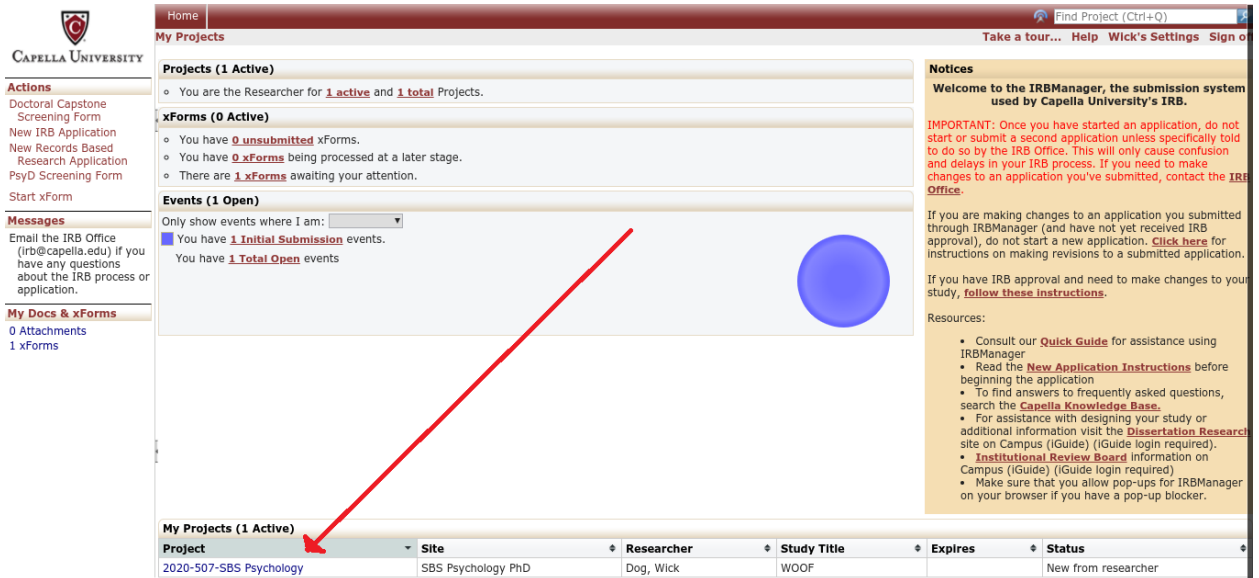
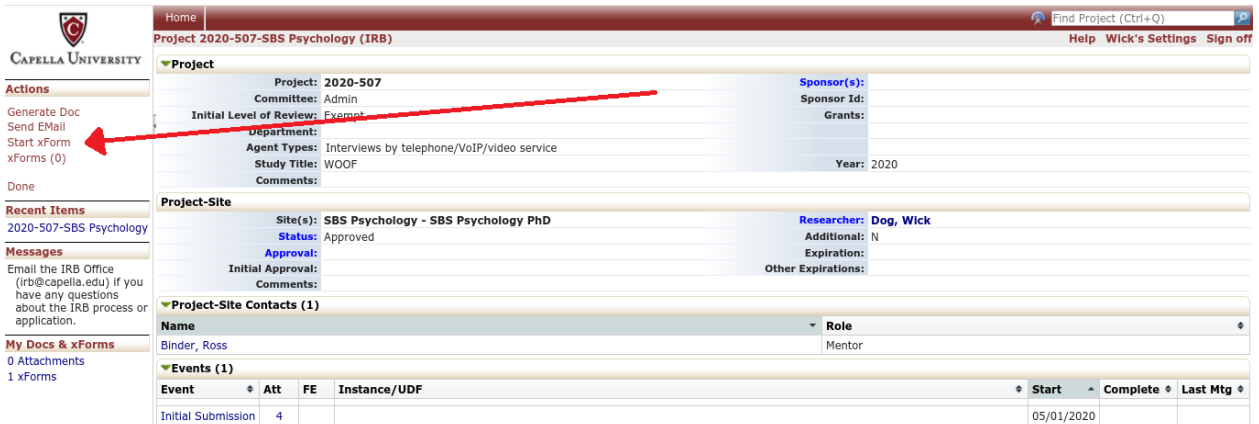


To submit a modification to your approved study in IRB Manager, please follow these steps:

- 1) Log in to IRB Manager. You will see your home page.
- 2) Click on your study ID:
 - a) Here is a sample image of the home page.
 - b) To click on your study ID, you will need to locate it on the home page. It will be located under My Projects, as identified by the red arrow in the image below. Click on the blue text.



- 3) When you click on your study, you will see a page similar to the one below:
 - a) On the left-hand side of the screen, you will see a list of options (under the title "Actions").
 - b) Select "Start xForm" from that list of options.



NOTE: You MUST click on your Project ID BEFORE you click on Start xForm. If you do not click on your Project ID first, you will NOT be able to access the IRB Modification Form.

- 4) You will see a list of xForms for you to choose from, as seen below:
 - a) Select “IRB Modification Form” from that list of xForms

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Start Form on Project 2020-507-SBS Psychology (IRB)

Filter:

Action	Form (Click to start)	Description
	Continuing Review	You must complete and submit this form at least three weeks before the expiration date of your original approval. If IRB approval of a project expires without renewal, you may not enroll any new participants and all research activities involving interaction with human participants or their records must be suspended.
	Doctoral Capstone IRB Screening Form	All learners conducting a Capstone project (and all DNP learners) should use this form to determine if your study requires IRB review and oversight.
	IRB Application	Researchers who will engage in any form of interaction or contact with participants need to complete this application. Researchers using existing records as part of their study and will not engage in any form of interaction or contact with participants should complete the Records Based Research Application. Capstone and DNP learners may NOT use this form unless specifically told to do so by the IRB Office. If you are making revisions to your current IRB application, do not complete this form.
	IRB Modification Form	Researchers who wish to make changes to their previously IRB approved study need to complete this form. Contact IRB@capella.edu with questions about modification requests and form.
	PsyD Screening Form	Learner enrolled in the Doctor of Psychology programme (PsyD not PhD) should use this form to determine if your study requires IRB review and oversight.
	Records Based Research Application	Researchers should complete this application if they are using already existing records for their study and if this is the only data that will be analyzed. Data collection that involves any form of interaction or intervention with participants requires the standard IRB Application.
	Study Closure Form	Submit this form if you are done recruiting participants and analyzing data.

- 5) You will then see the first page of the IRB Modification Form, as seen below:
 - a) Fill out the IRB Modification Form, using the guidance provided on the form itself.

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IRB Modification Form -- Amendment header

[Next](#)

NO CHANGES IN THE RESEARCH MAY BE INTRODUCED WITHOUT PRIOR IRB APPROVAL, UNLESS THE CHANGES ARE INTRODUCED TO ELIMINATE APPARENT IMMEDIATE HAZARDS TO THE PARTICIPANTS (46.103 [B] 4). IN THAT CASE, THIS MODIFICATION FORM MUST BE WITHIN 24 HOURS TO RECEIVE IRB APPROVAL FOR THE CHANGES. [Add Note](#)

Study Number [Add Note](#) [View Audit](#)
2014-208

Study Title [Add Note](#) [View Audit](#)
TEST

Initial IRB approval date of research [Add Note](#) [View Audit](#)
N/A

Researcher's name [Add Note](#) [View Audit](#)
Test, Learner
Email: irb@capella.edu Phone:

Research Supervisor's name [Add Note](#) [View Audit](#)
Mentor, Test
Email: research@scholarship@capella.edu Phone:

Study change type (Required) [Add Note](#)
 Adding a research assistant
 Adding a research site
 Change in data collection procedures
 Change in sample size
 Change in sampling procedures
 Change to informed consent documents
 Change to recruitment materials
 Changes in the inclusion/exclusion criteria
 Modification of data collection instruments
Please identify the proposed changes to your study below. Check all that apply.

[Previous](#) [Next](#) [Save for Later](#) [PDF](#)

- 6) It is recommended that you upload a copy of your revised research plan (DRP), or SMART form, or proposal (DPP) as an attachment to your IRB Modification Form. Your research plan, SMART form, or proposal (which form you are required to complete depends upon the program you are in) should be revised to align with the changes that you are proposing in the IRB Modification Form.
- 7) If you will need to revise any additional materials, such as your recruitment or informed consent materials or your interview questions, you should be sure to upload copies of those revised documents to your IRB Modification Form as well.
- 8) All documents should be attached under the item labeled “Upload revised documents required for this modification.” Click on “Add Attachments” to upload your revised materials.

Amendment details Page 2 of 2

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IRB Modification Form -- Amendment details

Provide more information on how the modification proposed could increase risks to participants. View Audit

Upload revised documents required for this modification. View Audit

Add Attachment

Examples of documents that you may need to submit based on your modification are:

- site permission letters
- revised Research Plan/SMR form if changes to your study required review by your school
- revised consent documents
- Confidentiality agreement for research assistants, transcriptionists, etc.
- new/revised instruments
- new/revised recruitment materials

- 9) Once you have completely filled out the IRB Modification Form, you will need to submit it for review in IRB Manager.
- a) The form is submitted by entering your IRB Manager password in the appropriate box and then clicking "Next"

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IRB Modification Form -- Amendment details

Modification description (Required) Add Note

(Limited to 2500 characters.) Provide a clear description of the proposed modification(s)

n/a

Provide a clear rationale for the requested changes (Required) Add Note

n/a

Will the proposed changes will increase the potential risks to participants or change the nature of the existing potential risks to participants? Add Note (Required)

No

Provide more information on how they modification proposed could increase risks to participants. Add Note

n/a

Upload documents required for this modification. Add Note

Add Attachment

Examples of documents that you may need to submit based on your modification are:

- site permission letters
- revised Research Plan/SMR form if changes to your study required review by your school
- revised consent documents
- Confidentiality agreement for research assistants, transcriptionists, etc.
- new/revised instruments
- new/revised recruitment materials

Researcher's signature (Required) Add Note

To sign, enter password for testlearner

By entering your password you are electronically signing this form and ensuring that all information provided in this form is correct. Additionally, you attest that your mentor and the school (if necessary) have approved this modification.

Previous Next Save for Later PDF

b) Then click “Submit” to formally submit your IRB Modification Form into IRB Manager.

A screenshot of a 'Form Completed' notification box. The box has a light blue header with the text 'Form Completed'. Below the header, the text reads: 'You've completed the form. You can now either save the form for later revision, or submit it.' At the bottom of the box, there are four buttons: 'Go Back', 'Save for Later', 'Print', and 'Submit'. A red arrow points from the top right of the box down to the 'Submit' button.

10) If you have additional questions about submitting a modification to your study, contact the IRB Office at irb@capella.edu