ORS
Office of
Research & Scholarship

INTRODUCTION TO THE MENTOR GUIDE FOR IRB REVIEW

The purpose of this guide is to assist mentors with using IRBManager. Learners should be directed to the IRB Quick Guide for assistance.

How do I register for IRBManager?

Instructions on how to register in IRBManager are available here:
https://capella.libanswers.com/doctoralsupport/faq/132953

All IRB forms require learners to list their mentors on the form, using the email address that the mentor has used to register in IRBManager. Thus, learners will not be able to submit their IRB forms until you have registered for IRBManager. Therefore, if you have mentees that will soon be in IRB, register as soon as possible. We strongly advise that you use your Capella email address to register in IRBManager.

General Application Information

All IRB submission forms are located on the home page of IRBManager, under "Actions" in the upper left-hand corner of the screen. There are four forms for your mentees to choose from when submitting materials to the IRB for review:

- **New IRB Application:** This form is intended for use by learners who are in dissertation programs and who intend to conduct studies that will involve collection of new data (via interviews, surveys, focus groups, etc.). This form should not be completed by learners in professional capstone programs **unless** they are specifically directed to do so by the IRB Office.

- **Record-Based Research Application:** This form is intended for use by learners who are in dissertation programs and who intend to conduct studies that that will **exclusively** involve analysis of pre-existing data. If a learner will be collecting any **new** data (via interviews, surveys, focus groups, etc.) in addition to an analysis of pre-existing data, then they should not complete this form and should complete the New IRB Application instead.

- **Doctoral Capstone Screening Form:** All learners who are in professional capstone programs should complete and submit this form (unless they are in the PsyD program; see below). Learners who are in dissertation programs should

not complete and submit this form.

- **PsyD Screening Form:** Only learners in the PsyD program should complete and submit this form. No other learners should complete and submit this form.

The web-based form (called an xform in the system) allows learners to answer questions geared towards their particular study design.

Note the following:
- The IRB forms require the learner to answer all questions within a page or section of the form before proceeding onto the next page or section.

- To ensure learner accountability for their IRB forms, you should not edit the IRB form or attached documents for your learner. If you see that something is missing or incorrect on the IRB form, you should email the learner and provide them with guidance about the missing and/or incorrect information or on the Application or attached documents.

- Your mentee will submit the completed form directly to the IRB within the IRBManager system.

- There are a few ways for your mentees to share their IRB form with you prior to submission for IRB review. The first, and easiest, way is for them to add you as a Collaborator to the IRB form. This will enable you to view the form as they are working on it in IRBManager. Detailed instructions on how they can add you as a collaborator are available here: https://capella.libanswers.com/doctoralsupport/faq/132927

  Mentees can also create a PDF copy of the form and then email that PDF version of the form to you. They can create a PDF copy of any form by clicking on the "More" button at the bottom of any page within the form and then selecting "View as PDF" from the menu of options. This will save a PDF copy of the entire form to their computer.

- Mentees are also able to submit IRB Modification and Continuing Review Forms within IRBManager without mentor sign-off. If the modification request is significant in scope, the IRB may reach out to you to ensure you are aware of the modification. You will be able to view these forms within IRBManager, even though your review is not mandated prior to submission to the IRB.

What should I know if my learner is in a professional capstone program?

If you are a mentor advising learners in a professional capstone program, read below. If you are a mentor advising learners in a dissertation program, you may skip this section.

IRB review of professional capstone submissions is not the same as IRB review of other submissions. With professional capstone submissions, the IRB conducts a review of the information on the Doctoral Capstone Screening Form to make a human subjects research determination re: the project.

If the IRB determines that the project appears to qualify as human subjects research (as 45 CFR 46 define human subjects research), then the IRB will request that the learner complete and submit the New IRB Application and the project will undergo standard IRB review.

If the IRB determines that the project does **not** qualify as human subjects research (as human subjects research is defined by 45 CFR 46), then the IRB's review of the materials will generally be considered complete and the learner will be approved to move on to the next stage of their project. Note that the IRB may still require the learner to make minor changes to project materials or procedures in order for a learner's project to adhere to Capella institutional policies and/or ethical best practices.

More information about the IRB's process of determining whether a project constitutes human subjects research or not is available here: https://capella.libanswers.com/doctoralsupport/faq/357331

What information should learners provide on the Doctoral Capstone Screening Form?

- Learners should explain the purpose of their project, as well as the planned project procedures/activities.
- Learners should attach a copy of permission letters from the site(s) they will be working with for their project. Permission letters should be follow the guidance available here: https://campus.capella.edu/doctoral-programs/research-scholarship/institutional-review-board/site-permission
- If a project site has an IRB, the learner should consult with the site IRB to determine if it will need to review the project in addition to Capella IRB.
- Learners should provide a copy of their CITI completion report. The completion report contains a list of all completed CITI modules and is available for learners on the CITI website.
- Learners are advised to upload a copy of their school-approved Capstone Project Plan/Doctoral Project Prospectus/proposal/Project charter/Capstone form [DNP] in the Additional Documents section
- Learners should also attach copies of any data collection tools (surveys, interview guides, focus group questions, etc.) that they plan to use to collect data for their project

What happens during IRB review?

When a learner submits materials to the IRB for review, that submission first undergoes a process called **screening** by the IRB Office. During the screening process, the IRB looks at the materials to determine whether the submission is complete (i.e., are any needed documents missing or are sections of the form incomplete or unfinished) and coherent (i.e., do all responses on the form make sense and attempt to answer the appropriate question or prompt). If the IRB determines that a submission is incomplete or overly unclear, the submission form is returned to the learner with notes (in blue text boxes) placed directly on the form itself indicating what changes need to be made to the form (or attached materials, such as recruitment/consent documents). The turnaround time for this screening process is to 5 business days.

When the IRB has completed its screening of a learner's submission and determined that it should undergo IRB review, then the study is formally assigned for **IRB review**. Submissions at the minimal risk level (exempt or expedited) are assigned to one of the faculty reviewers on the IRB committee. The turnaround time for IRB reviews is 7 days after they have been assigned. (NOTE: this is not 7 days after documents have been submitted.)

Submissions that are determined to be greater than minimal risk are assigned to the full IRB committee, which is comprised of Capella faculty members as well as non-scientists and a community member. The full IRB committee meets once per week during the academic quarter to conduct reviews. Learner submissions will be assigned to the next available full IRB committee meeting once the IRB Office has determined that the submission is ready to be reviewed. The full IRB committee's decision is communicated via email to the learner and mentor within 7 days after the review of a study at the full IRB committee meeting.

Once a study has been assigned for IRB review, there are four potential review outcomes: **approval**, **approval with conditions**, **deferral**, and **disapproval**. Only the full IRB committee may disapprove a study. When an IRB review has been completed, the learner and mentor are notified via email of the outcome of the IRB review. The decision letter for that IRB review will always be attached to the email notification of the IRB review outcome. The decision letter contains the specific guidance about the IRB review.
- If the study has been deferred or approved with conditions, the decision letter will list the revisions that the learner must make to the form and/or accompanying materials.

- If the study has been disapproved, the decision letter will explain why the full IRB committee believes that the study is not able to be approved or move forward as presently designed.

- If the study has been approved, the decision letter will include next steps for the learner as they move ahead in the dissertation process.

Mentors should review the decision letters with their mentees to ensure that they understand what revisions are needed and how those revisions should be implemented. If you or your mentee have questions about the needed revisions on the decision letter, they should contact the IRB Office (irb@capella.edu) to request further clarification.

How will I know when my mentee has submitted materials for review?

You'll receive an email from the IRB stating that your mentee has submitted a new or revised form. Within that email there will be a link to the application.

Mentee's IRB Application Submitted to the IRB Office

CI Capella IRB Inbox <irb@capella.edu>
To

Your mentee,   , has submitted their IRB Application to the IRB Office and it is currently in queue for screening prior to formal review. You can access your mentee's IRB application via the link below:

IRB Application

As a reminder, you do also have access to your mentee's application in IRBManager once the application has been submitted. Please take a moment now to ensure you can access and view and application.

Please contact the IRB Office should you have any questions or concerns about the IRB review process or if the application was submitted prematurely without your review and approval.

Capella IRB Office

IRB@capella.edu

Should you delete or misplace the email (or if you prefer not to use email for workflow), you can also access your mentees' IRB forms via IRB Manager. You can access a list of the active forms listing you as mentor by clicking on the "[xx] active Projects" link or by clicking on the "[xx] xForms being processed…" link.

What other communications will I receive from the IRB and what do they mean?

Often the IRB will return a submission form (such as an IRB Application or Doctoral Capstone Screening Form) to the learner during the screening process. Forms are returned at this time to enable learners to address concerns noted by the IRB during the screening of the submission materials – i.e., that a necessary document was missing or incomplete or that information on the form was overly unclear. When the submission form is returned to the learner, you will receive an email like this:

IRB Application Returned - Revisions needed before form can be sent on for review

CI   Capella IRB Inbox <irb@capella.edu>
To

Dear

The IRB Office has completed the screening of your submission. Your form is being returned to you as additional information or corrections are needed before this form can be sent on for official IRB review. See the notes on the form to know what items need to be addressed before this form can be sent on for review.

To view notes, you must open the form in IRBManager and use the 'Next' button to click through. Notes have been added to the section(s) requiring additional information or correction. You can also select the 'View Questions with Notes' button to view where the notes have been added to your application.

Your mentor has also been copied on this message.

To access the IRB application, click this link: IRB Application

Sincerely,
The Capella IRB Office

Once the IRB has determined that a submission is ready to undergo formal IRB review, the study is assigned for review. When that happens, you will receive an email like this:

IRB application is with IRB for review

CI   Capella IRB Inbox <irb@capella.edu>
To

Dear

Researcher:
Study title:

This email is to notify you that the above study is currently with the IRB for review. You will receive an email from the IRB Office about the outcome of the review. This email will include a copy of the decision letter.

Note: The last day learners may submit for review this quarter is 5PM CST Friday of week ten of the quarter. Study materials received after that time will not be reviewed until the beginning of the next quarter. At that time, the reviewer will complete the review within 10 business days

If you do not receive notification of the IRB's decision within 10 business days (except during quarter break), contact the IRB Office at irb@capella.edu.

Sincerely,
The IRB Office

When the IRB review has been completed, you and your mentee will (usually) receive two emails. The first email indicates that the learner's form has been returned to them for revisions. This occurs when the outcome of the IRB review is a deferral or approval with conditions, meaning that the learner needs to make revisions or corrections to their materials before they can be approved by the IRB. That email will look like this:

IRB Application Returned - Revisions Required

Capella IRB Inbox <irb@capella.edu>
To

Dear

Your IRB application has been returned to you to make revisions following IRB review. Please make the requested revisions outlined in either the notes on the IRB Application or the decision letter that you received separately. As a reminder you may not collect data until you receive a Capella University IRB Approval Letter.

You can access the IRB application here: IRB Application

Sincerely,
The Capella IRB Office

The second email will indicate the outcome of the review (such as deferral or approval with conditions). It will also include the IRB decision letter as a PDF attachment. The IRB decision letter is the document that contains the actual revisions or corrections that the learner needs to make to their materials. The email indicating the outcome of the review will look like this:

(deferral)

IRB Decision Letter - Deferred

CI Capella IRB (irb @ capella.edu) <irb@capella.edu>
To
Cc
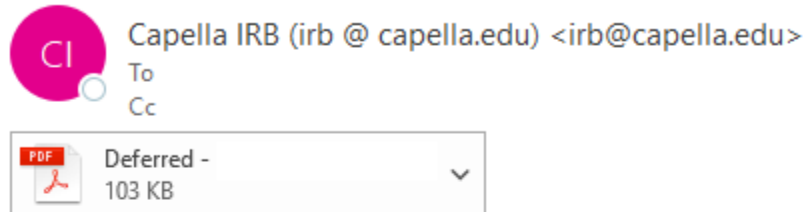
📄 PDF Deferred –
103 KB

The IRB has completed its review of your study. At this time, your study has been deferred by the IRB. The deferral means that changes to your study and/or additional information is needed in order to ensure that your study meets the requirements for IRB approval.

Attached to this email is the IRB Decision Letter. You and your mentor will need to review the decision letter carefully to ensure that you've provide all the necessary information to the IRB for the next review.
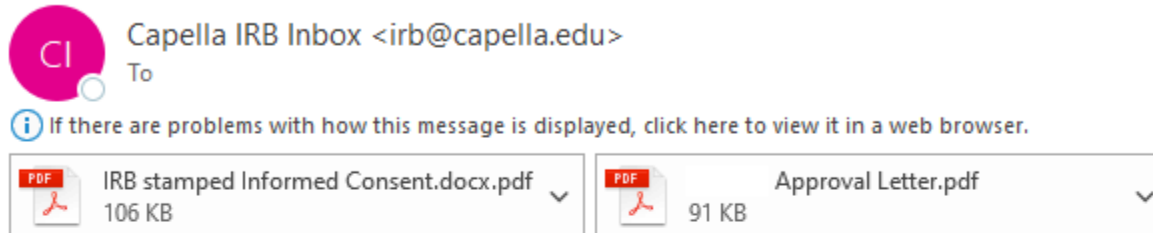
To make changes to your application:

- login to IRBManager and click '1 xForm awaiting your attention'.

- On the application, update the answers on your IRB application that are required based on the IRB review.

- If you need to provide information that does not have a corresponding application question, provide the information in the 'Additional Information' section located at the end of the application.

(approval with conditions)

IRB Decision Letter - Approved with Conditions (Information needed)

Capella IRB (irb @ capella.edu) <irb@capella.edu>
To
Cc

📄 Approved with Conditions -
98 KB
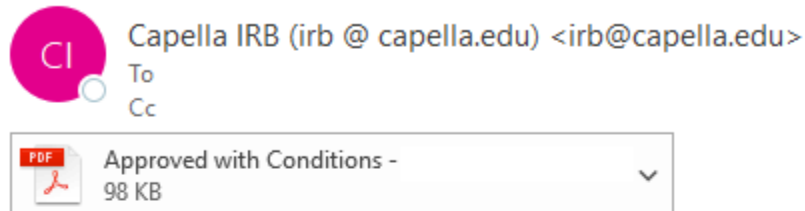
The IRB has completed its review of your study and has approved this study with conditions. Approved with conditions means that the proposed study meets the standards for ethical conduct, and requires only minor cosmetic or administrative changes to full approval.

You may not begin recruiting participants or collecting data until you have received full approval from the Capella IRB. Refer to the attached IRB Decision Letter to determine what additional information/changes are needed.

You will need to submit this documentation and receive by email your IRB approval letter before you may begin study procedures.

To make changes to your application:

- login to IRBManager and click '1 xForm awaiting your attention'.

- On the application, update the answers on your IRB application that are required based on the IRB review. **Do not** use the notes feature to make revisions.

Once the IRB has completed its review(s) and determined that the learner's procedures and materials are acceptable, the study will be approved by the IRB. The email indicating that a study has been approved will look like this:

IRB Decision Letter

Capella IRB Inbox <irb@capella.edu>
To

(i) If there are problems with how this message is displayed, click here to view it in a web browser.

| PDF IRB stamped Informed Consent.docx.pdf 106 KB | PDF Approval Letter.pdf 91 KB |

The IRB has approved your application. Attached is a copy of the IRB approval letter. Please note the following aspects regarding your approval. These items are also outlined in the attached approval letter which you should carefully review prior to data collection.

- You are required to follow your study procedures **exactly** as approved by the IRB including participant facing study materials (IRB approved stamped informed consent form attached to this email, recruitment materials, etc.). Should you need to make changes to study materials and/or procedures you must obtain IRB approval **prior** to implementation. For further information about compliance with your IRB approval review our Campus (iGuide) resources at: https://campus.capella.edu/web/doctoral-programs/research-scholarship/data-collection-compliance

- Per the Doctoral Learner policy, you are required to be enrolled during recruitment, data collection, and data analysis. If you are not enrolled, you must cease recruitment, data collection and analysis. The policy is available for review on Campus (iGuide) here: https://www.capella.edu/content/dam/capella/PDF/policies/3.01.10.pdf

Viewing the IRB form in IRBManager

If learners have shared the IRB form with you using the Collaborator feature (see page 2), you will be able to access the form prior to submission in IRBManager. You will also be able to access the IRB form after it has been submitted and it is under review, deferred, approved with conditions, or approved. There are different ways to do so.

1) Searching by learner name in the upper right hand corner of the IRB Manager screen enter the learner's last name and hit enter. This will display the learner's study:

Home		Find Project
Search Results		Help Test's Settings Sign o

Projects matching 'test' (2 Total)

Project Code ▲	Project Title ⇕	Expires ⇕	Learner ⇕	Status ⇕
2014-208-SoBT	TEST		Test, Learner	New from researcher
2014-406-PsyD	TEST		Test, Learner	Not Human Subject Research

2) Click on the project code (hint: if your learner's study hasn't yet been approved, this is also a good way to check on the status of the review at a glance) to bring up the study and click on Initial Submission (unless you want to check the learner's Modification Form or Continuing Review, then click on those events):

| Home | | | | | | | Find Project | 🔍 |

Project 2014-208-SoBT   Help Test's Settings Sign off

| Project Title: | TEST | | | | Year: | |
| Comments: | | | | | | |

Project-Site

Site:	SoBT - SoBT PhD		Learner:	Test, Learner
Status:	New from researcher		Additional:	N
Approval:			Expiration:	
Initial Approval:				
Comments:				

▼ **Contacts (1)**

Name	Role
Mentor, Test	Mentor

▼ **Attachments (1)**

Name	Type	Date	By
IRB Modification Form.pdf	Additional Information	03/28/14	testlearner

▼ **Events (2)**

Event	⬍	Att	FE	Instance/UED	⬍	Start	▼	Complete	⬍	Last Mtg	⬍
Amendment		0		Adding a research site Change in sample size Change in sampling procedures		03/11/14					
Initial Submission		4				02/11/14					

- Then click on 'xforms':

It will display a list of forms associated with the account. Click on the link to view. Note that the IRB Reviewer Evaluation Form may be listed but the feedback on that form is not visible to individuals outside the IRB Office. Refer to the learner's decision letter for IRB feedback on the study.

What if my learner needs to make changes to their materials?

Learners who need to make modifications, amendments, or other changes to their IRB-approved procedures or materials should submit those changes to the IRB using an IRB Modification Form. Information on how to access the IRB Modification Form is available here:

https://capella.libanswers.com/doctoralsupport/faq/132931

Note that learners must click on their Project ID first before clicking on "Start xForm" in order to be able to access an IRB Modification Form.

Additionally, only learners who have already received IRB approval should complete and submit an IRB Modification Form. Learners who are still undergoing IRB review and need to make changes to project procedures or materials should make those changes directly on the IRB Application (and/or their supplemental materials such as recruitment/informed consent materials).

When should learners notify the IRB of proposed changes/modifications?
- If the researcher is making any changes to
    - their recruitment strategy (such as adding new methods of recruitment)
    - their research/recruitment sites/organizations (such as adding new sites/organizations)
    - their sample population (this includes changes to inclusion/exclusion criteria)
    - data collection tools (such as adding new tools or revising questions on existing tools)
    - adding research assistants

- this is not a comprehensive list of potential changes; when in doubt, a learner and mentor should contact the IRB (irb@capella.edu) to discuss proposed changes to study procedures or materials

- all proposed changes must receive approval from the IRB before they may be implemented.

- The IRB does not need to approve corrections to grammar, contact information, or minor typos in recruitment materials or data collection tools. However, the researcher should provide updated contact information (if applicable) to the IRB.

IRB Modification Forms can be submitted by learners without mental approval. However, you will receive an email from the IRB that your mentee has submitted an IRB Modification Form. The email will contain a link to the form. If the modification request has not approved by you, contact the IRB immediately to have review halted, and follow up with the learner.

What if my learner needs to extend their IRB approval?

Learners who need to extend their IRB approval beyond the listed expiration date should complete and submit a Continuing Review form in IRB Manager. Information on how to access the Continuing Review form is available here:

https://capella.libanswers.com/doctoralsupport/faq/132957

- Length of IRB approval guidance:
  - studies approved at the exempt level: no expiration of IRB approval

  - studies approved at the expedited level: IRB approval generally lasts 12 months

  - studies reviewed at the greater than minimal risk level: IRB approval lasts less than 12 months (usually 6 months)

- Continuing review requirements:
  - studies approved at the exempt level: no continuing review required

  - studies reviewed at the expedited level: continuing review required after 12 months (or listed duration of IRB approval, if different) if researcher is still recruiting and/or collecting data from participants

  - studies reviewed at the greater than minimal risk level: continuing review required after 6 months (or listed duration of IRB approval, if different) if researcher is still recruiting and/or collecting data from participants, or analyzing identifiable data

  - Note that if IRB approval expires for a study reviewed at the expedited or greater than minimal risk levels, then all researcher activities (such as recruitment, informed consent, data collection, etc.) must cease immediately and may not resume until the IRB has approved the Continuing Review request and extended IRB approval

Continuing Review forms can be submitted by learners without mental approval. However, you will receive an email from the IRB that your mentee has submitted a Continuing Review form. The email will contain a link to the form. If the continuing review request has not been approved by you, contact the IRB immediately to have the review halted, and follow up with the learner.