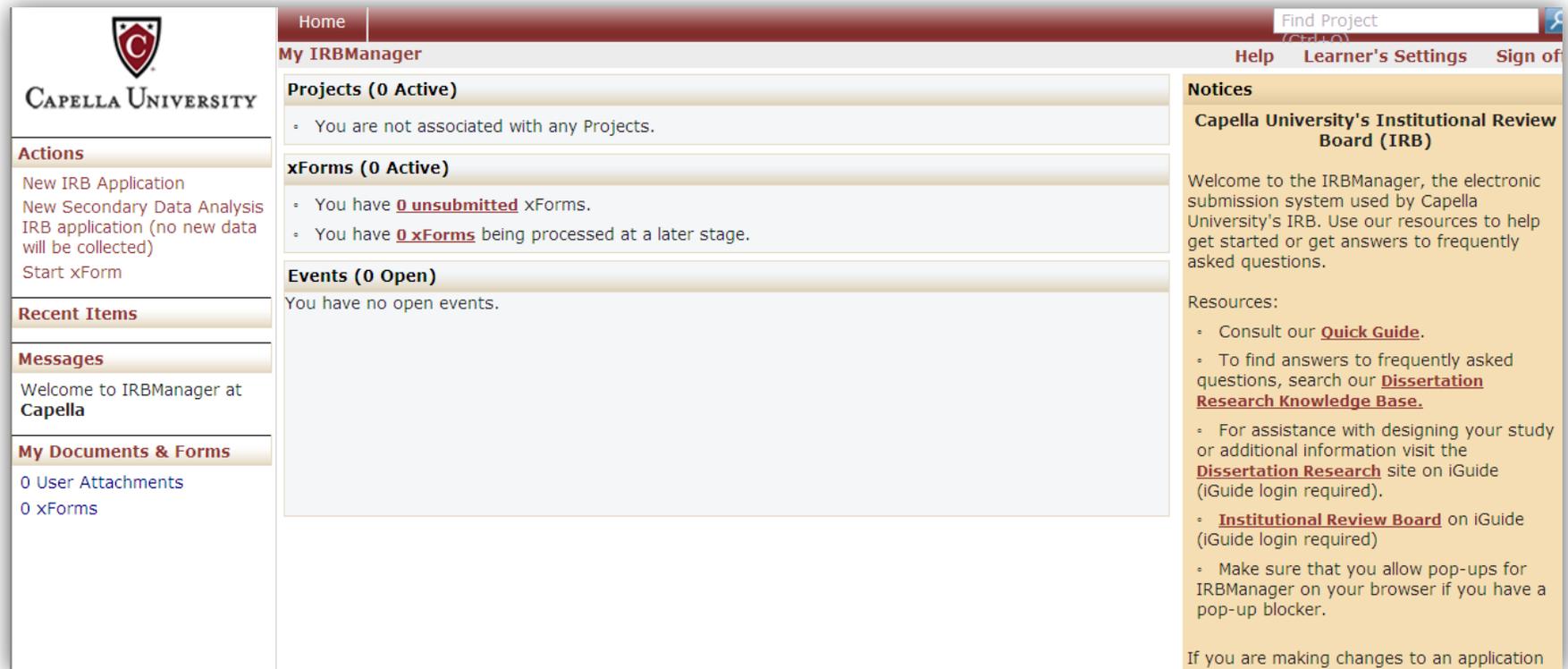


## STARTING A NEW APPLICATION IN IRBMANAGER

The purpose of this guide is to help you with the technical aspect of submitting your IRB application through IRBManager. This guide is not intended to walk you through filling out the application.

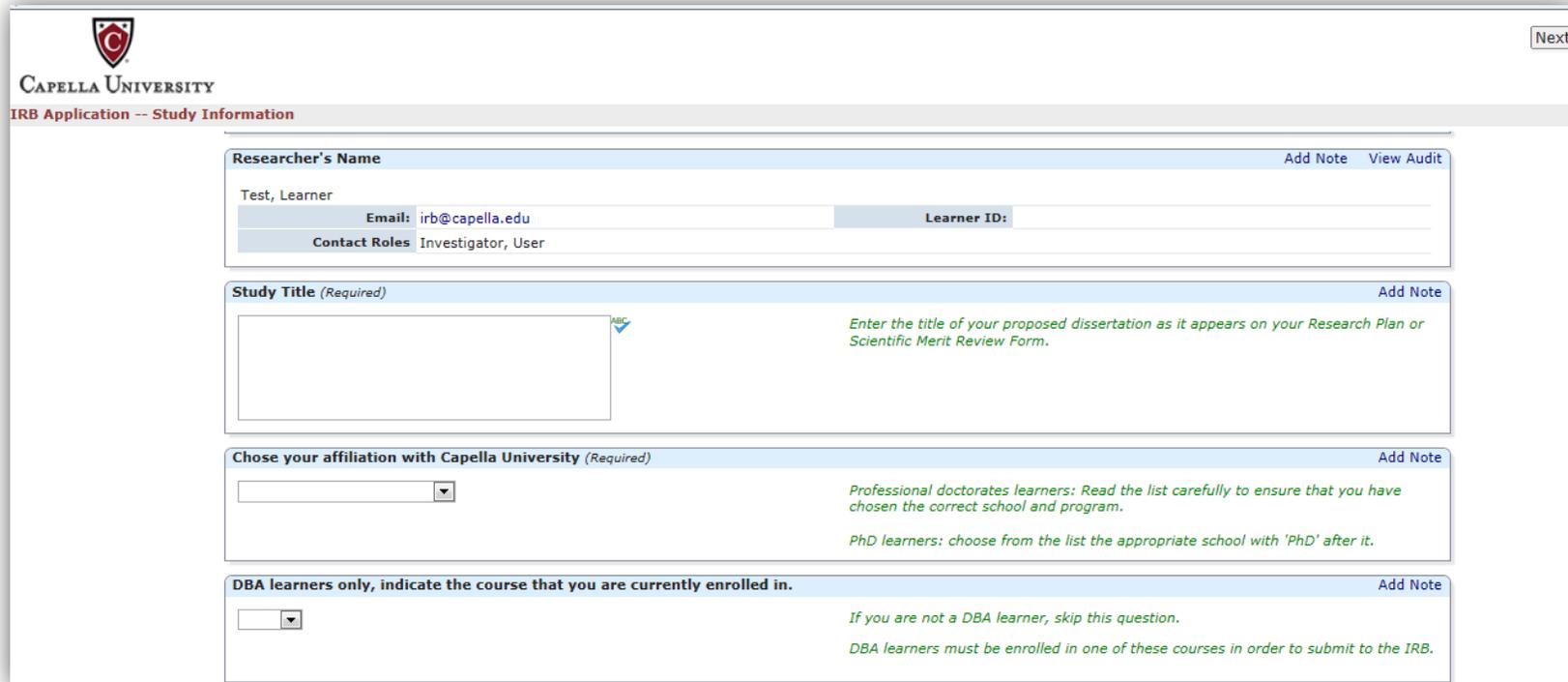
1. Ensure that you have registered with IRBManager
2. After you login to IRBManager you will see your home screen:



The screenshot shows the IRBManager home interface. On the left, the Capella University logo is at the top, followed by a navigation menu with sections: **Actions** (New IRB Application, New Secondary Data Analysis IRB application, Start xForm), **Recent Items**, **Messages** (Welcome to IRBManager at Capella), and **My Documents & Forms** (0 User Attachments, 0 xForms). The main content area is titled 'My IRBManager' and includes a search bar and navigation links (Home, Help, Learner's Settings, Sign of). Below this are three sections: **Projects (0 Active)** (You are not associated with any Projects), **xForms (0 Active)** (You have 0 unsubmitted xForms, 0 xForms being processed), and **Events (0 Open)** (You have no open events). On the right, a **Notices** section titled 'Capella University's Institutional Review Board (IRB)' contains a welcome message and a **Resources** section with links to a Quick Guide, Dissertation Research Knowledge Base, and Institutional Review Board.

3. Click on 'New IRB Application'

- a. Unless you are analysing existing data **only**. This means that all of the data you will be analysing for your study has been collected by others. If you are analysing existing data choose 'New Records Based Research application'.
  - b. If you are collecting any new data as part of your research, you must use the standard IRB application. Failure to chose the correct application will result in delays to your IRB approval.
  - c. DNP learners **ONLY** should click on DNP IRB Application
  - d. Learners enrolled in the Doctor of Psychology program (PsyD) learners may wish to use the PsyD screening from to determine if they need to submit an IRB application (NOTE: This screening form is only available for PsyD use)
4. A new window will open containing the application. The initial screen will look like:

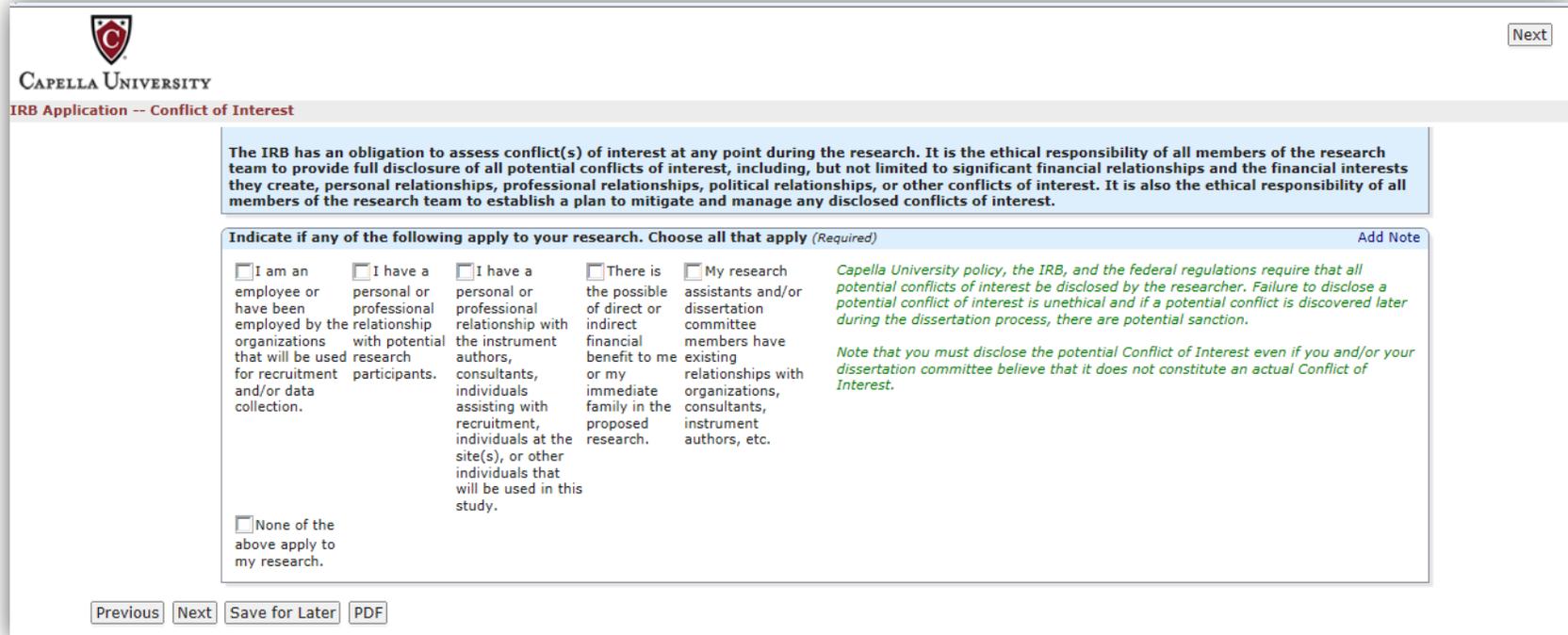


The screenshot shows the 'IRB Application -- Study Information' form. At the top left is the Capella University logo. A 'Next' button is in the top right corner. The form is divided into several sections:

- Researcher's Name:** Includes a text field for 'Test, Learner', an 'Email' field with 'irb@capella.edu', a 'Learner ID' field, and 'Contact Roles' set to 'Investigator, User'. There are 'Add Note' and 'View Audit' links.
- Study Title (Required):** Features a large text area with a microphone icon and a blue checkmark. A note reads: 'Enter the title of your proposed dissertation as it appears on your Research Plan or Scientific Merit Review Form.' There is an 'Add Note' link.
- Chose your affiliation with Capella University (Required):** Contains a dropdown menu. A note states: 'Professional doctorates learners: Read the list carefully to ensure that you have chosen the correct school and program. PhD learners: choose from the list the appropriate school with 'PhD' after it.' There is an 'Add Note' link.
- DBA learners only, indicate the course that you are currently enrolled in:** Includes a dropdown menu. A note says: 'If you are not a DBA learner, skip this question. DBA learners must be enrolled in one of these courses in order to submit to the IRB.' There is an 'Add Note' link.

Notes:

- You must answer all the questions on a page before you can proceed to the next page.
  - Your name, email address, and “contact roles” will automatically populate based on your registration information.
5. When you have completed all the questions on the initial page, click next
  6. This will take you to questions around conflict of interest (all learners must answer this question)



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IRB Application -- Conflict of Interest

The IRB has an obligation to assess conflict(s) of interest at any point during the research. It is the ethical responsibility of all members of the research team to provide full disclosure of all potential conflicts of interest, including, but not limited to significant financial relationships and the financial interests they create, personal relationships, professional relationships, political relationships, or other conflicts of interest. It is also the ethical responsibility of all members of the research team to establish a plan to mitigate and manage any disclosed conflicts of interest.

Indicate if any of the following apply to your research. Choose all that apply (Required) [Add Note](#)

I am an employee or have been employed by the organizations that will be used for recruitment and/or data collection.

I have a personal or professional relationship with potential research participants.

I have a personal or professional relationship with the instrument authors, consultants, individuals assisting with recruitment, individuals at the site(s), or other individuals that will be used in this study.

There is the possible of direct or indirect financial benefit to me or my immediate family in the proposed research.

My research assistants and/or dissertation committee members have existing relationships with organizations, consultants, instrument authors, etc.

*Capella University policy, the IRB, and the federal regulations require that all potential conflicts of interest be disclosed by the researcher. Failure to disclose a potential conflict of interest is unethical and if a potential conflict is discovered later during the dissertation process, there are potential sanction.*

*Note that you must disclose the potential Conflict of Interest even if you and/or your dissertation committee believe that it does not constitute an actual Conflict of Interest.*

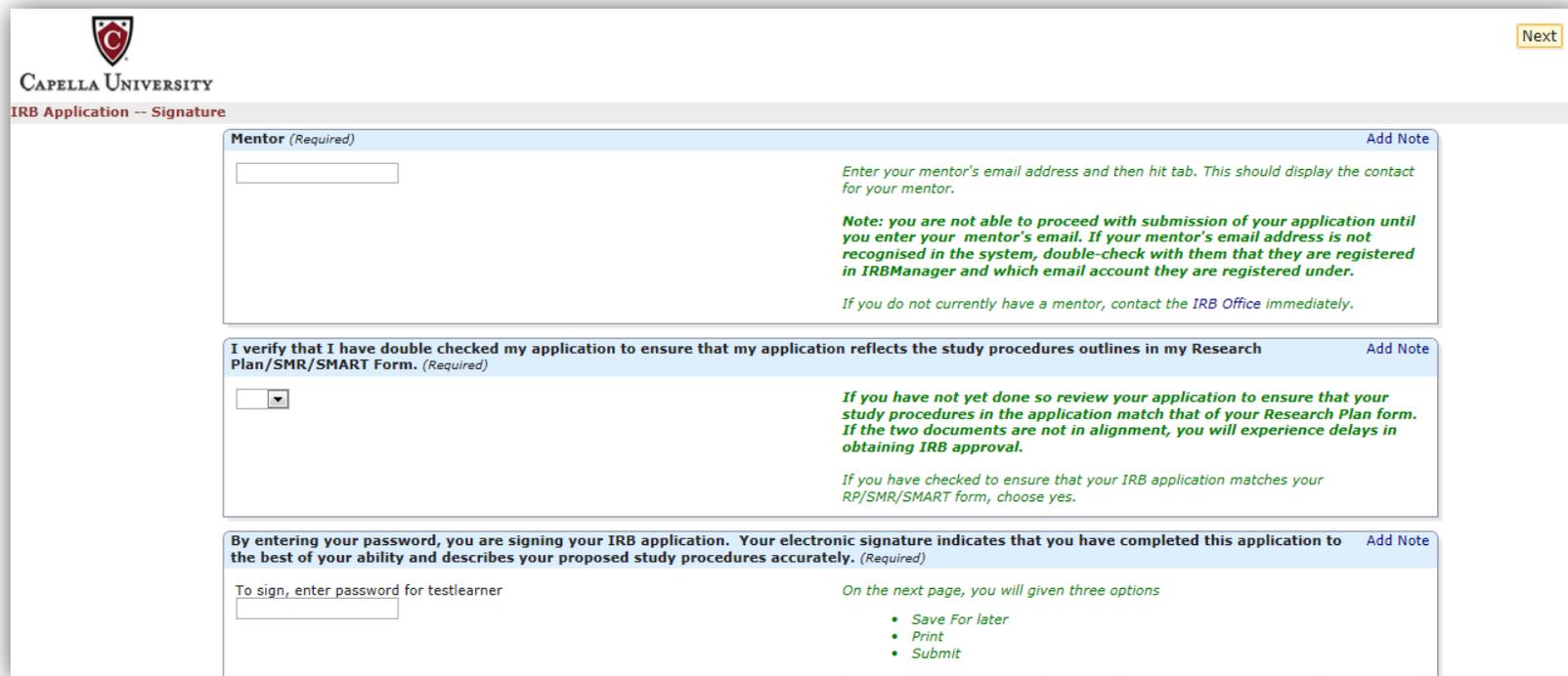
None of the above apply to my research.

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

Notes on navigation:

- **Previous:** will take you back one screen. To go back multiple screens hit previous until you get to the page that you wish to edit.
- **Next:** will take you forward to the next screen. You are only able to navigate to the next page if you've answered all the questions on this page.

- **Save for Later:** will save your answers and exit you from the form. You will then be able to come back to the form later to finish completing.
  - **PDF:** This will create a pdf version of the form with the answers you've given so far. You may find this useful if you wish to have a friend/family member read the application to see if it's readable or to send a copy to your mentor prior to submitting the application. Also, this is a way to see the rest of the basic questions that will be asked in the application.
7. As you continue through the form, you'll be asked questions about your population, study procedures, etc. These questions will vary depending on your study design, due to the IRB application responding to the information you input.
  8. After you have answered all the question on the application, you will need to enter your mentor's email address (the one that he/she used to register in IRB Manager), verify alignment between your approved RP/SMART from and the IRB application, and enter your IRB Manager\_password to sign the application:



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IRB Application -- Signature

Next

**Mentor (Required)** Add Note

*Enter your mentor's email address and then hit tab. This should display the contact for your mentor.*

**Note: you are not able to proceed with submission of your application until you enter your mentor's email. If your mentor's email address is not recognised in the system, double-check with them that they are registered in IRBManager and which email account they are registered under.**

*If you do not currently have a mentor, contact the IRB Office immediately.*

**I verify that I have double checked my application to ensure that my application reflects the study procedures outlines in my Research Plan/SMR/SMART Form. (Required)** Add Note

*If you have not yet done so review your application to ensure that your study procedures in the application match that of your Research Plan form. If the two documents are not in alignment, you will experience delays in obtaining IRB approval.*

*If you have checked to ensure that your IRB application matches your RP/SMR/SMART form, choose yes.*

**By entering your password, you are signing your IRB application. Your electronic signature indicates that you have completed this application to the best of your ability and describes your proposed study procedures accurately. (Required)** Add Note

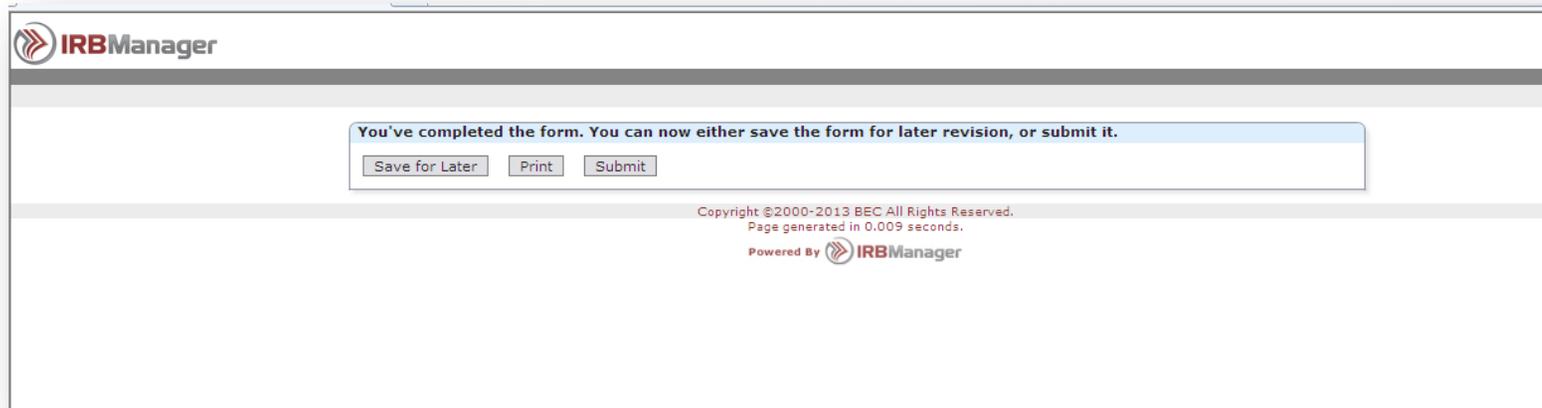
To sign, enter password for testlearner

*On the next page, you will given three options*

- Save For later
- Print
- Submit

*If you are not yet done with this application, please leave for later. This will exit*

9. After you click next, you'll receive the following screen:



If you are ready to submit the study to your mentor, click submit.

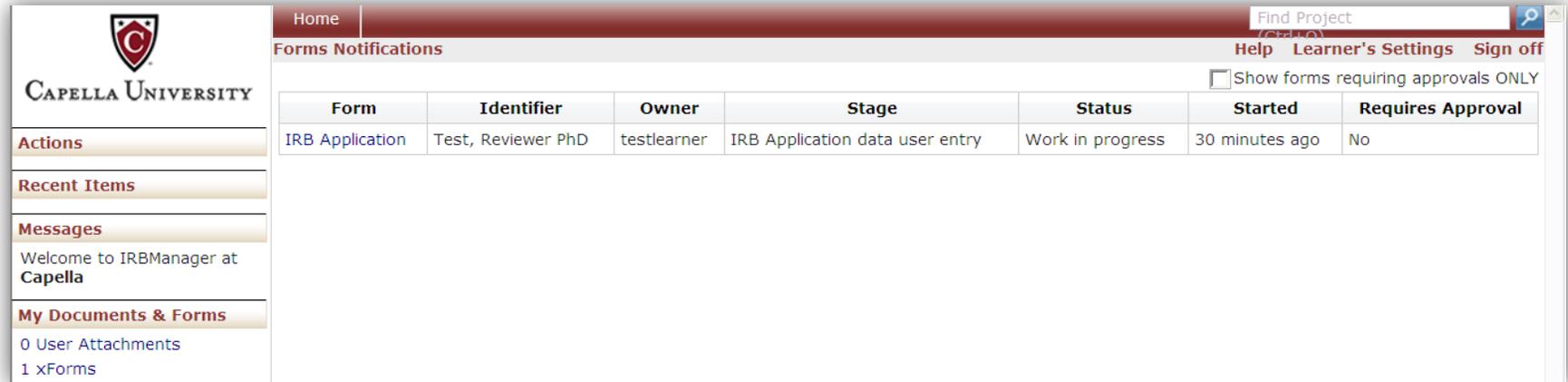
- If you need to review and make additional changes, click save for later.
- Note: When you click submit, this sends a copy to your mentor - **not** to the IRB. Your mentor must submit the study to the IRB.

## RETURNING TO YOUR APPLICATION IN PROGRESS

When you log into IRBManager after beginning your application, your screen will look like this:

<p><b>CAPELLA UNIVERSITY</b></p> <hr/> <p><b>Actions</b></p> <p>DNP IRB Application (for DNP learners ONLY)</p> <p>PsyD Screening Form</p> <p>New Records Based Research Application (no new data will be collected)</p> <p>New IRB Application</p> <p>Start xForm</p> <hr/> <p><b>Recent Items</b></p> <p>2014-1220-DBA</p> <p>2014-251-Faculty</p> <p>2013-35-EdD</p> <p>2013-12-PSL</p> <p>271214-SBS Psychology</p> <p>2013-26-SBS Counseling</p> <p>2013-21-PSL</p> <hr/> <p><b>Messages</b></p> <p>Welcome to IRBManager at Capella</p>	<p><b>Projects (0 Active)</b></p> <ul style="list-style-type: none"> <li>You are associated with <b>0 active</b> Projects and <b>2 total</b> Projects.</li> <li>You are the Learner for <b>0 active</b> and <b>2 total</b> Projects.</li> </ul> <hr/> <p><b>xForms (3 Active)</b></p> <ul style="list-style-type: none"> <li>You have <b>1 unsubmitted</b> xForms.</li> <li>You have <b>2 xForms</b> being processed at a later stage.</li> <li>There are <b>2 xForms</b> awaiting your attention.</li> </ul> <hr/> <p><b>Events (1 Open)</b></p> <p>Only show events where I am: <input type="text" value=""/></p> <ul style="list-style-type: none"> <li>You have <b>1 Initial Submission</b> events.</li> <li>You have <b>1 Total Open</b> events</li> </ul> 	<p><b>Notices</b></p> <p><b>Welcome to the IRBManager, the submission system used by Capella University's IRB.</b></p> <p><b>IMPORTANT:</b> Once you have started an application, do not start or submit a second application. This will only cause confusion and delays in your IRB process. If you need to make changes to an application you've submitted to your mentor ask your mentor to return the application to you. If your mentor has submitted it to the IRB, contact the <b>IRB Office</b>.</p> <p>If you are making changes to an application you submitted through IRBManager (and have not yet received IRB approval), do not start a new application. <a href="#">Click here</a> for instructions on making revisions to a submitted application.</p> <p>If you have IRB approval and need to make changes to your study, <a href="#">follow these instructions</a>.</p> <p>Resources:</p> <ul style="list-style-type: none"> <li>Consult our <a href="#">Quick Guide</a> for assistance using IRBManager</li> <li>Read the <a href="#">New Application Instructions</a> before beginning the application</li> <li>To find answers to frequently asked questions, search our <a href="#">Dissertation Research Knowledge Base</a>.</li> </ul>
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Click on the xform awaiting your attention (you will know that this is unsubmitted as it's also listed as an unsubmitted xform). Note you should only have one xform awaiting your attention—if you have more than one you should delete the extra forms or contact the IRB Office) and you'll see this screen:



Form	Identifier	Owner	Stage	Status	Started	Requires Approval
<a href="#">IRB Application</a>	Test, Reviewer PhD	testlearner	IRB Application data user entry	Work in progress	30 minutes ago	No

Click on the 'IRB Application' to open a copy of your application

Notes:

- **Stage:** "IRB Application data user entry" means that the application is currently with you for completion.
- **Status:** "Work in progress" means that the study has not yet been submitted
- **Started:** tells you when you began the application
- **Requires Approval:** ignore this column. Your application will have to be reviewed by your mentor and will need IRB approval (this column refers to studies using research teams and is not applicable to Capella researchers).

### Checking on the status of your application after submitting

After you have submitted your IRB application to your mentor, when you login to IRBManager you'll see this screen:



Home Find Project (Ctrl+Q)

**My IRBManager** Help Gummy's Settings Sign off

**Projects (0 Active)**

- You are not associated with any Projects.

**xForms (1 Active)**

- You have **0 unsubmitted** xForms.
- You have **1 xForms** being processed at a later stage.

**Events (0 Open)**

**Notices**

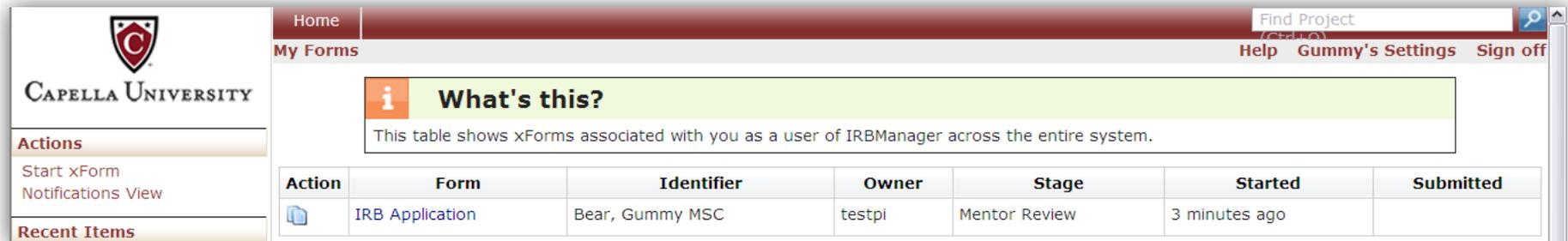
**Capella University's Institutional Review Board (IRB)**

Welcome to the IRBManager, the electronic submission system used by Capella University's IRB. Use our resources to help get started or get answers to frequently asked questions.

**Actions**

- New IRB Application
- New Secondary Data Analysis IRB application (no new data will be collected)
- Start xForm

Click on 'xforms being processed at a later stage', which will take you to this screen:



Home Find Project (Ctrl+Q)

**My Forms** Help Gummy's Settings Sign off

**What's this?**

This table shows xForms associated with you as a user of IRBManager across the entire system.

Action	Form	Identifier	Owner	Stage	Started	Submitted
	IRB Application	Bear, Gummy MSC	testpi	Mentor Review	3 minutes ago	

**Actions**

- Start xForm
- Notifications View

**Recent Items**

In the stage column, you'll be able to see where in the process your application is. Note that you won't be able to edit the IRB application when it is at any stage other than "IRB Application data user entry."

- **Mentor Review:** Your application is with your mentor for review. Your mentor will either submit it to the IRB, or return it to you for changes. You will receive an autoemail from IRB Manager if your mentor returns the application to you.
- **Internal IRB Review:** This means that your study has been submitted to the IRB. However, it is not yet under review. It is currently in screening to ensure that all required documents have been submitted. You will not receive an autoemail from IRB Manager when your mentor submits it for IRB review, but you can check the status in IRB Manager any time.

- **Under Review:** Your application has been received by the IRB, screened, and is currently with a reviewer. You will receive an autoemail from IRB Manager when your study is sent to the IRB reviewer.
- **Deferred:** Your study was reviewed and changes are necessary. You will receive an email with a copy of the decision letter and instructions on how to make changes to your application and submit again to the IRB.
- **Approved with Conditions:** Your study was reviewed by the IRB and only minor changes or site permission letters are needed by the IRB. You will receive an email with a copy of the decision letter and instructions on add information to your application and/or make minor revisions and submit your application again to the IRB.
- **Approved:** Your study was reviewed and approved by the IRB. You will receive a copy of your approval letter by email.

**Note: You are not able to begin recruitment or data collection until your study has been approved by the IRB and you have received a copy of your approval letter. Conducting research activities prior to IRB approval is a violation of federal regulations and Capella University policies.**