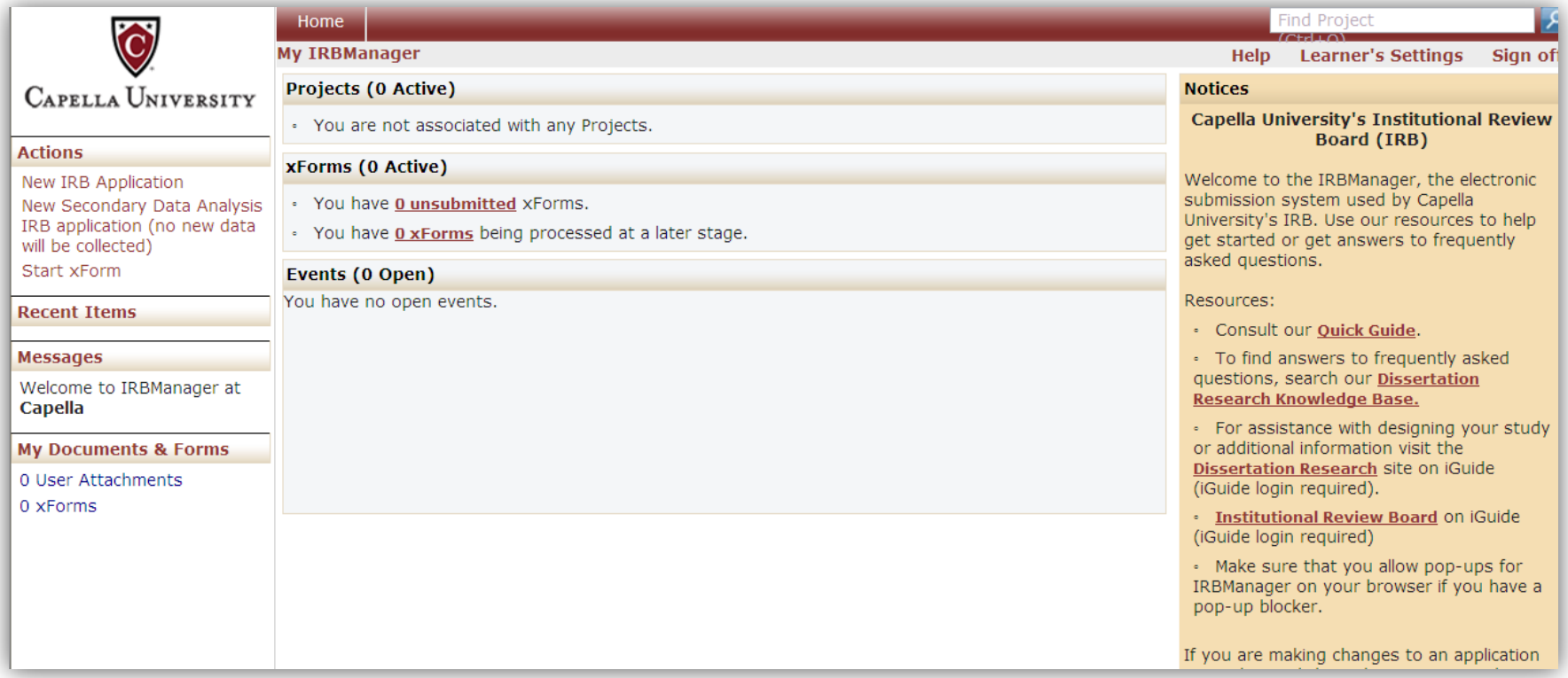
STARTING A NEW APPLICATION IN IRBMANAGER

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.

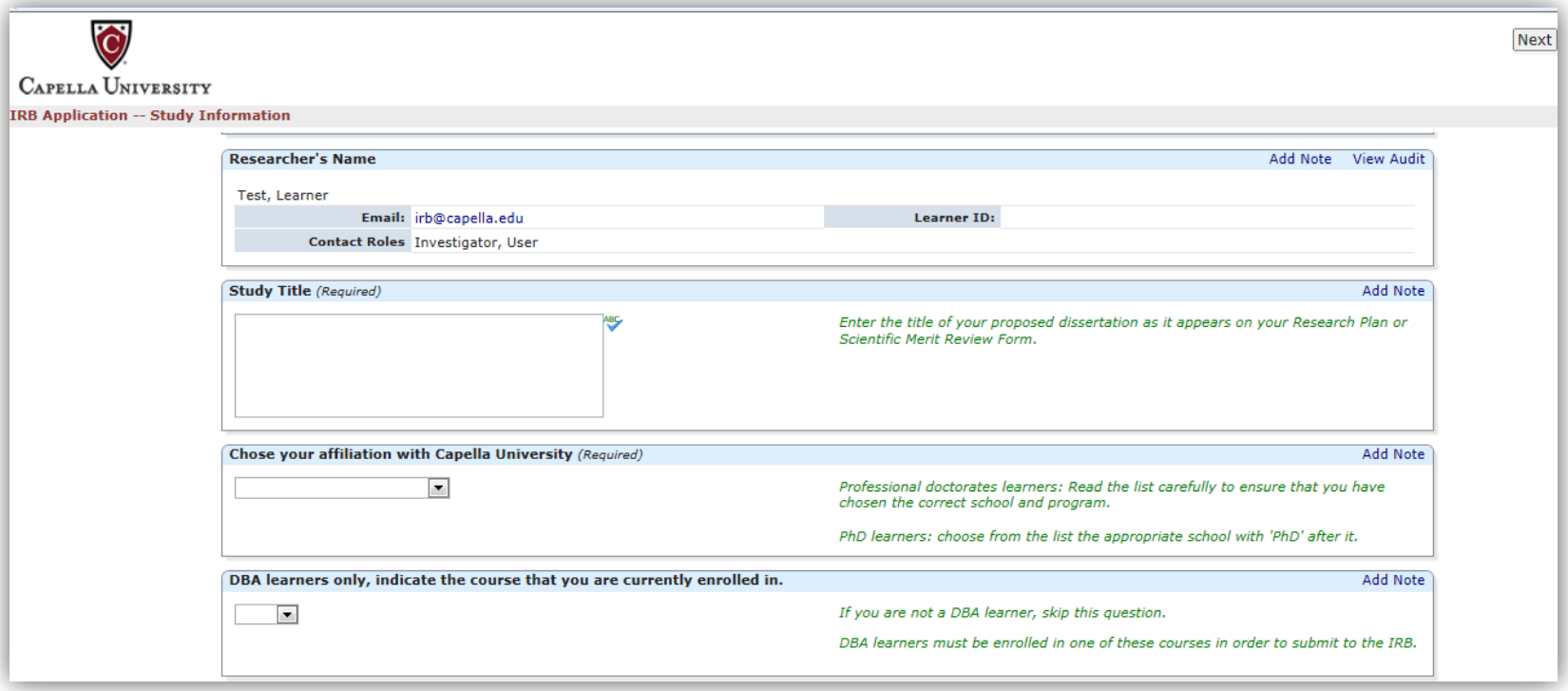
1. Ensure that you have registered with IRBManager
2. After you login to IRBManager you will see your home screen:



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)

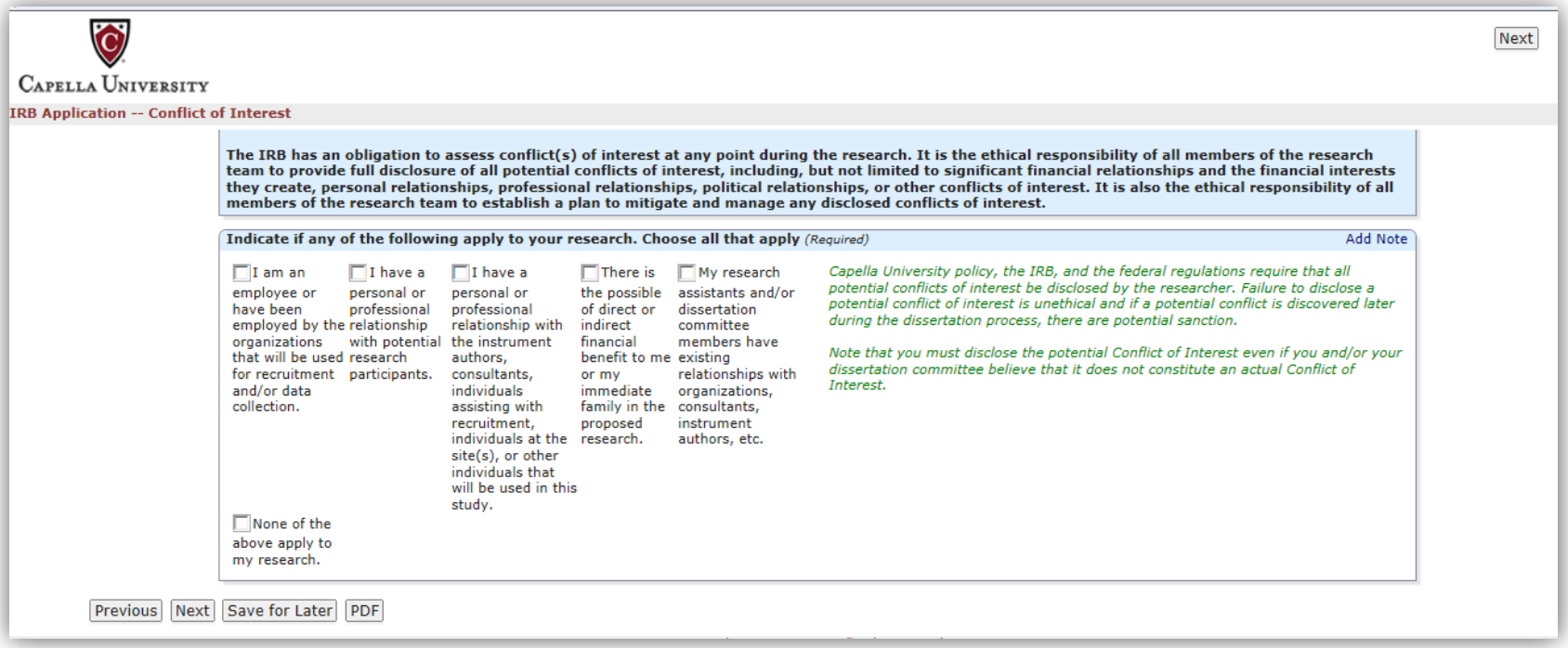
4. A new window will open containing the application. The initial screen will look like:



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)

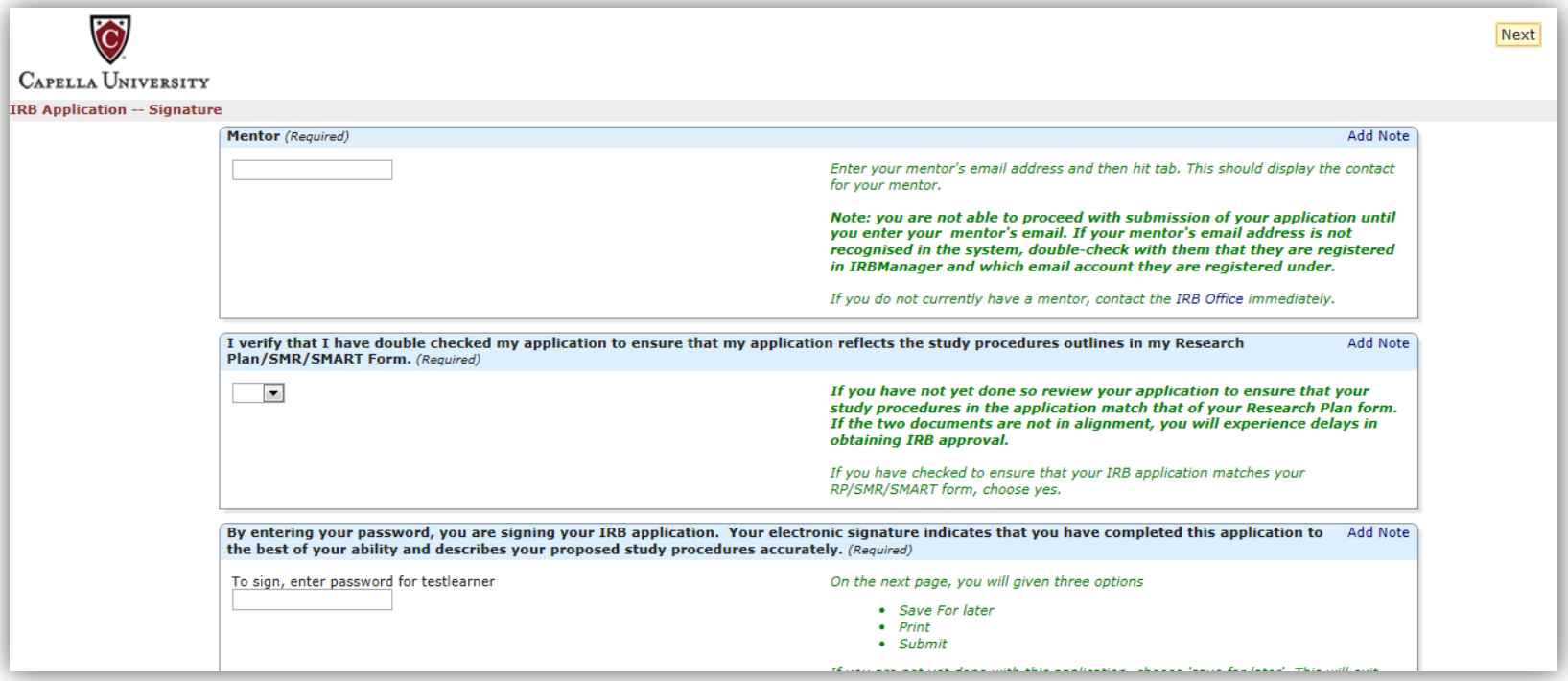


Notes on navigation:

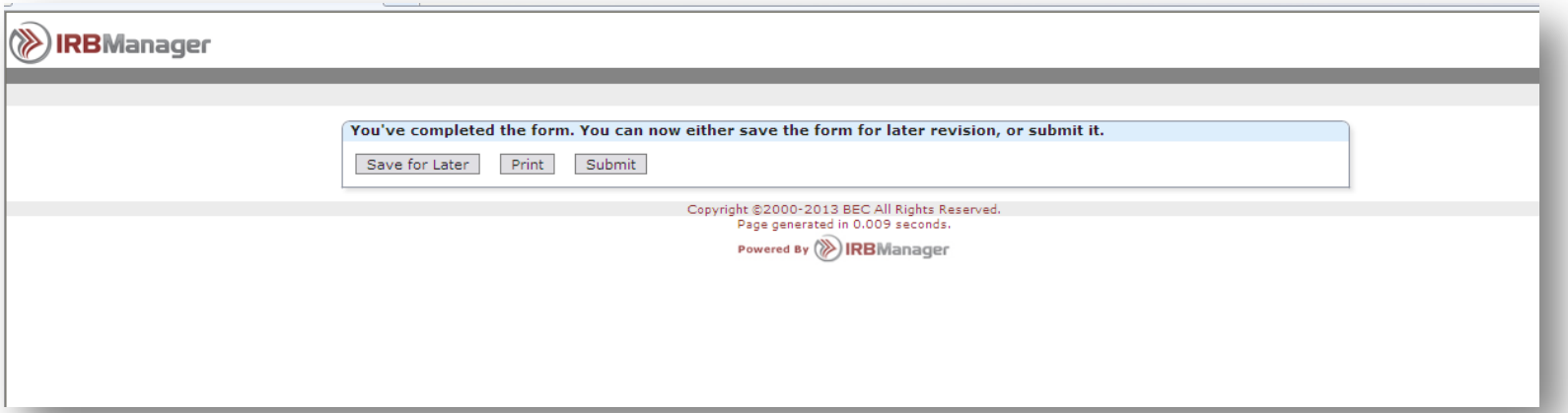
- **Previous:** will take you back one screen. To go back multiple screens hit previous until you get to the page that you wish to edit.
- **Next:** will take you forward to the next screen. You are only able to navigate to the next page if you've answered all the questions on this page.

- **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:



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

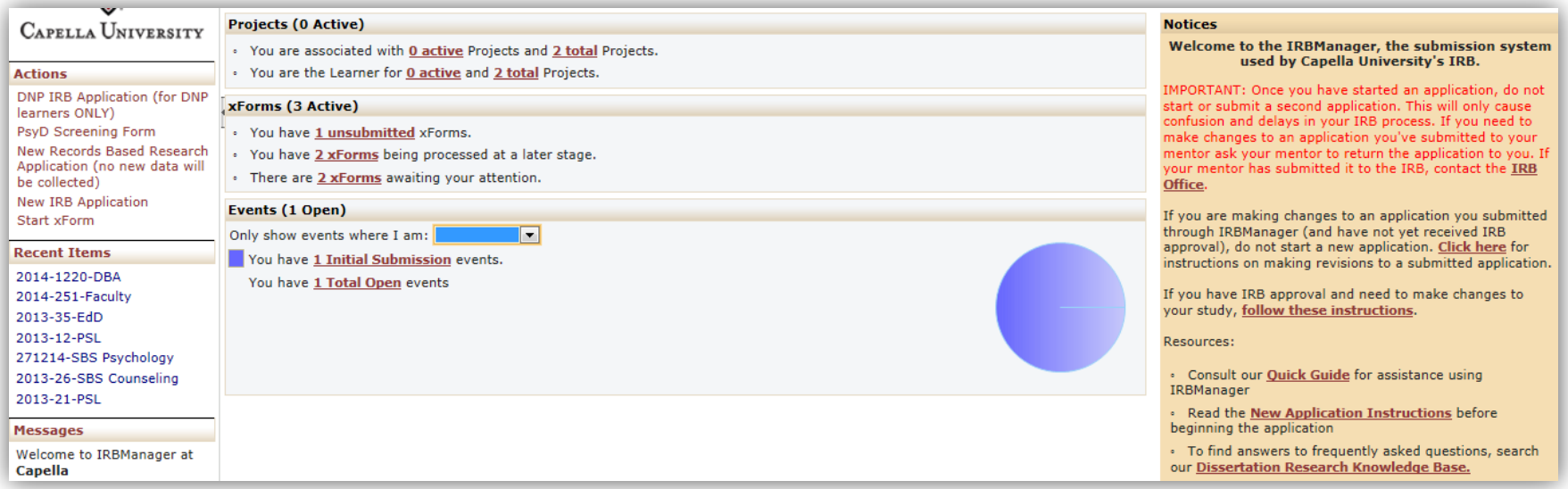


If you are ready to submit the study to your mentor, click submit.

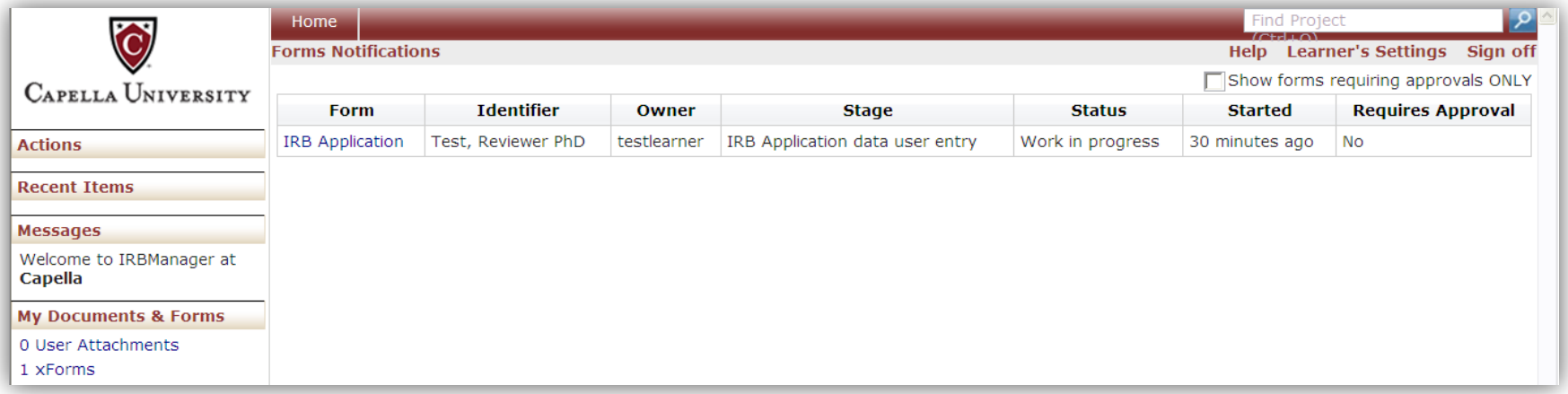
- If you need to review and make additional changes, click save for later.
- Note: When you click submit, this sends a copy to your mentor - **not** to the IRB. Your mentor must submit the study to the IRB.

RETURNING TO YOUR APPLICATION IN PROGRESS

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



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:



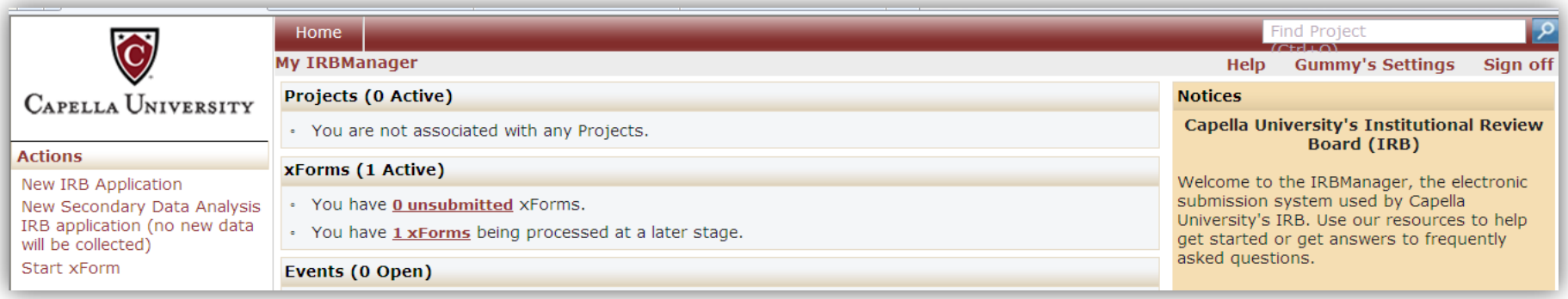
Click on the 'IRB Application' to open a copy of your application

Notes:

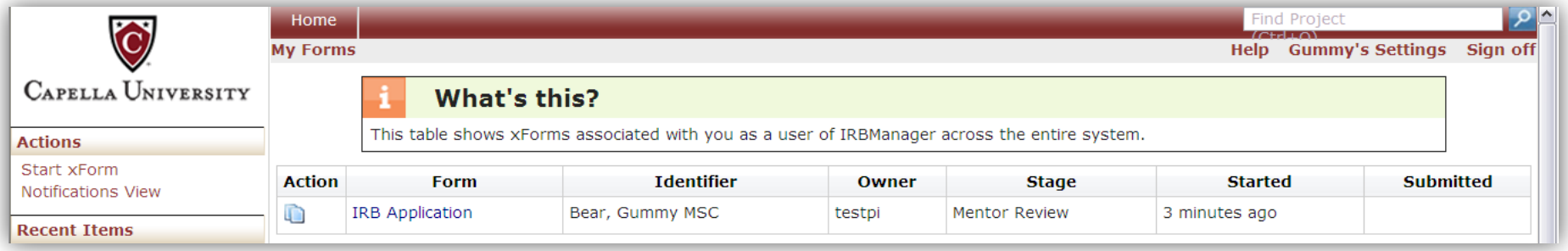
- **Stage:** "IRB Application data user entry" means that the application is currently with you for completion.
- **Status:** "Work in progress" means that the study has not yet been submitted
- **Started:** tells you when you began the application
- **Requires Approval:** ignore this column. Your application 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:



Click on '1xforms being processed at a later stage', which will take you to this screen:



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.