Whitworth University IRB Guide to Applications on OneAegis
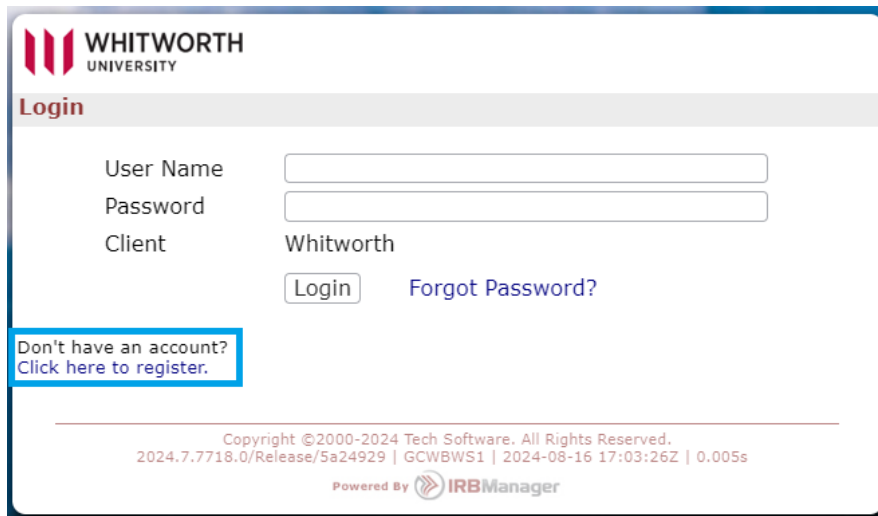
Contents

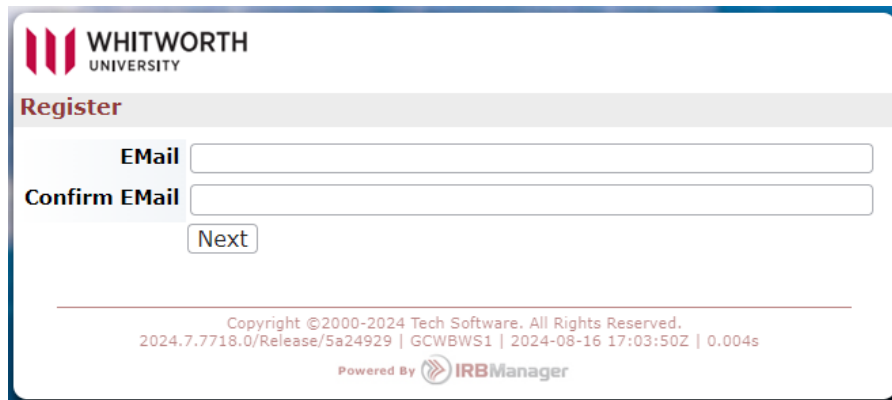## Creating Your OneAegis Account

All human subjects research at Whitworth University is required to be approved by the IRB or to be determined by the IRB to be not human subjects research or to be exempt from review. The Whitworth University IRB uses the OneAegis application tracking platform to manage applications. To get started you will need to create an account on OneAegis.

1. In your browser, navigate to the Whitworth OneAegis login page:
   https://whitworth.oneaegis.com/Login.aspx
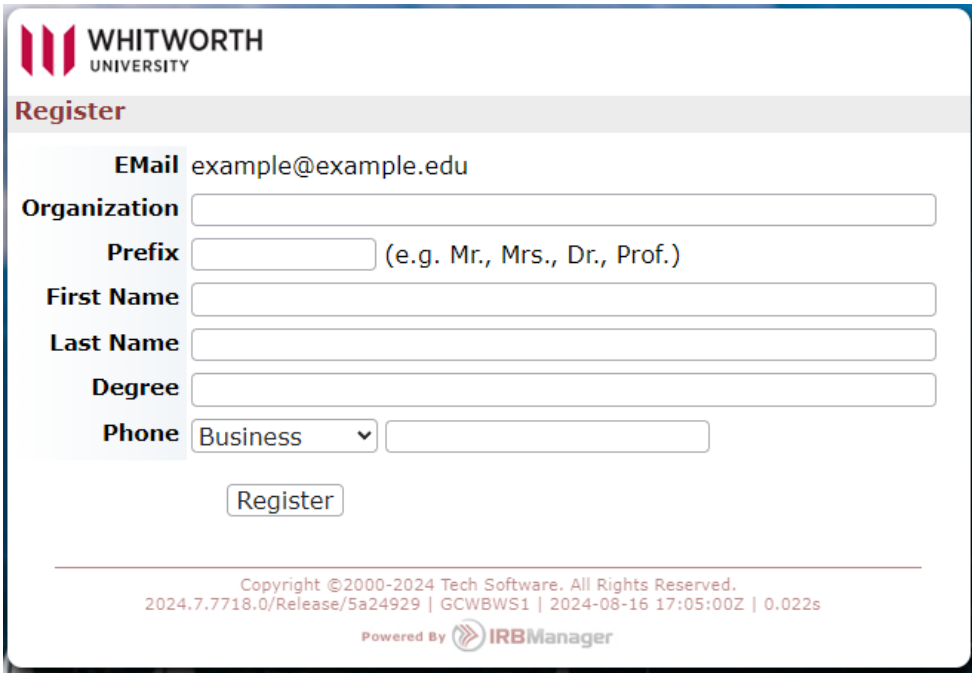2. Follow the link to create a new account:

   a. Your username will be your email. **Please use your Whitworth email.** This should also be the same email that your CITI account uses, so that OneAegis can automatically collect your CITI courses. If you originally set up your CITI account with a different email, you can add your Whitworth email to your CITI account so OneAegis can collect your courses.

   b. Your password must be at least 12 characters long and include: lowercase letters, uppercase letters, numbers, and special characters (!@#$%, etc.).
3. You may wish to associate other information with your account, such as your name, prefix, telephone, and degrees. The information you enter here will be used to identify you in official correspondence, so enter it as you would want it to appear there. You can also change or

update your personal information later.

Logging in to OneAegis

You will need to log in to OneAegis to manage your forms and projects.

1. In your browser, navigate to the Whitworth OneAegis login page:
    https://whitworth.oneaegis.com/Login.aspx

2. Use the password you set when you created your OneAegis account; this is not linked to your Whitworth account, and will not be updated if you change your Whitworth password.
3. If you have forgotten your password, click the "Forgot Password?" link, enter your email address, and a link to reset your password will be sent to you.

Managing Your Account on OneAegis

You can change your password and manage your contact information and other settings in the "Settings" menu.

1. From the dashboard, select the "Menu" (the person icon in the very top right of the screen):

   Home
   Project Type Switchboard

2. Select "IRB's Settings" (where "IRB" is your name):

   - IRB's Settings
   - Dark Mode
   - Help
   - Sign off
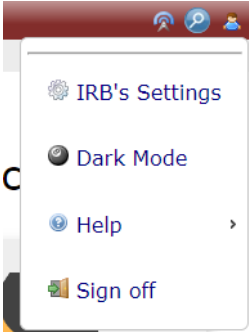
3. Here you can change your password and update your contact information:

   My Settings
   Edit Settings
   Change My Password
   Change My Profile
   My Phone Number(s)
   My Address(es)
   My Expirations
   My Attachments
   Recent Logins
   EMail Signature
   Turn on Dark Mode
   Reset Dashboard
   Switch Dashboard
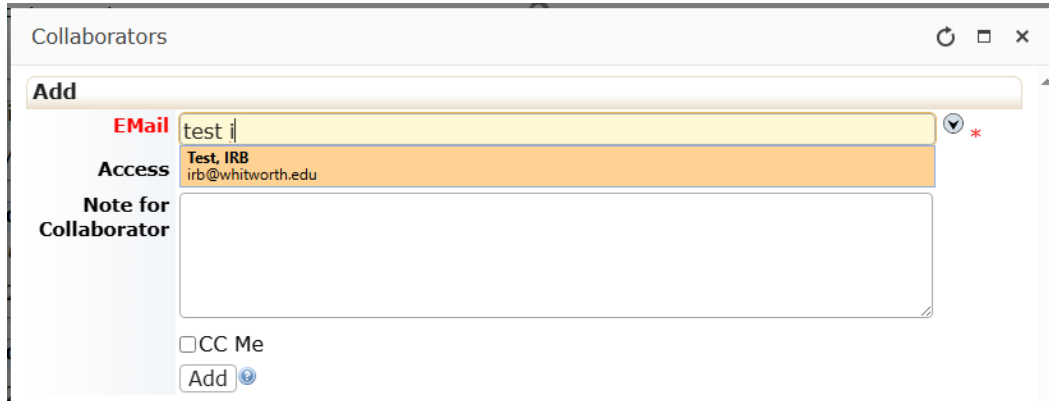
Adding Collaborators to your Form

You may add collaborators to your forms in OneAegis. These are not necessarily other researchers or project team members, but people you want to give permissions to help fill out the form.

1. At the top of the form select the "Collaborators" button at the top left of the form:

   👥 Collaborators   Section 1
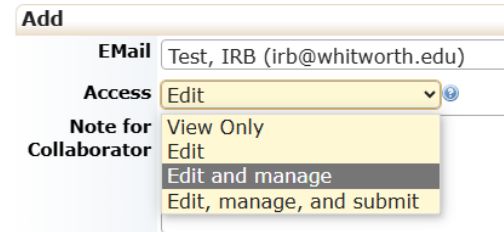
2. In the dialog-box, in the "Email" text-box, start typing the email/username of the collaborator you wish to add:

   The system will find their account and show their email/username in the drop-down menu. If your collaborator has not set up a OneAegis account yet, they will need to do that first.

3. In the "Access" drop-down, select the level of access you want to give your collaborator:

   "View Only" will let your collaborator view the form.
   "Edit" will let your collaborator view and edit the form.
   "Edit and manage" will let your collaborator view and edit the form, and add other collaborators.
   "Edit, manage, and submit" will also let your collaborator submit the form.
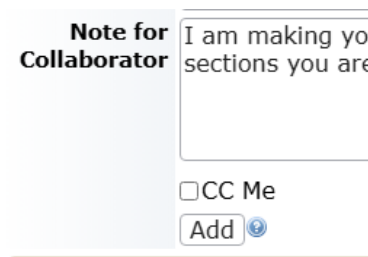
4. In "Note for Collaborator", you can add a note that will be added to the notification email that will be sent to the collaborator:

5. When you have made your selections, select "Add" to complete adding the collaborator to the form:

Note for Collaborator I am making yo sections you are

☐ CC Me

[Add] ⓘ

IRB Forms on OneAegis

OneAegis manages forms and projects for the grants office (i.e., Sponsored Programs), and the IRB (i.e., Institutional Review Board for Human Subjects Research). This guide focuses on the IRB.

Once you have logged in, select "IRB" on the Project Type Switchboard:

What do you want to focus on?

Grants   IRB   Show Everything
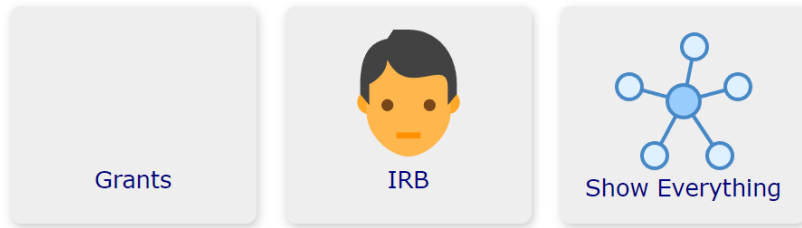
Navigating the Forms on OneAegis

When you are completing or updating a form on OneAegis, you do not need to fill it out in order, but can navigate to the part you are interested in.

There are several ways to navigate the forms:

1. The drop-down menu at the top of the page lets you jump directly to the section you are interested in:
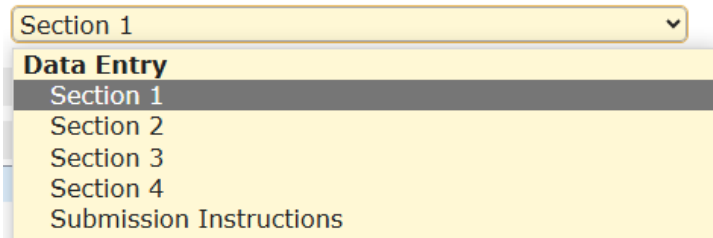
2. The "Next" button at the top right of each page will let you navigate to the next page of the form:

3. At the bottom of each page are "Previous", "Next", and other navigation buttons:
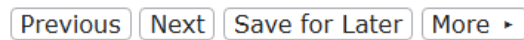
Submitting a New Application Form

When you are ready to begin your human subjects research, but before you start recruiting potential subjects, you will need to submit an application and receive approval from the IRB.

1. Navigate to the IRB Dashboard as indicated above.

IRB
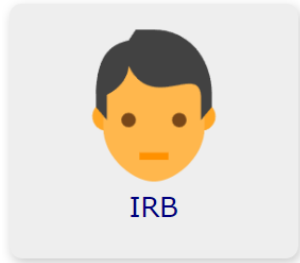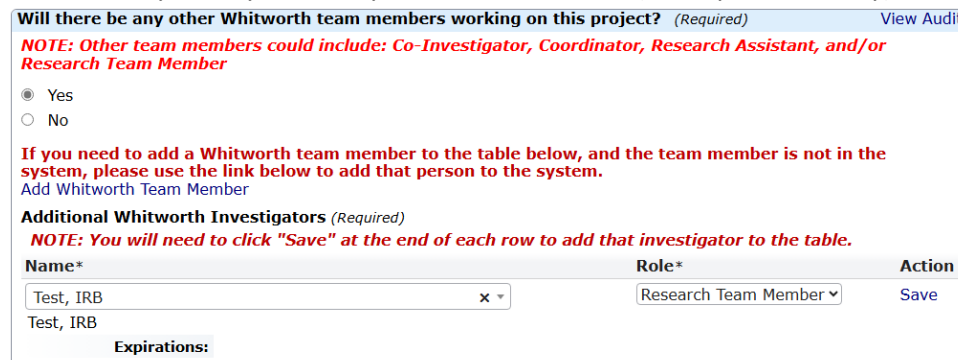
2. On the IRB Dashboard, select the link: "Start xForm":
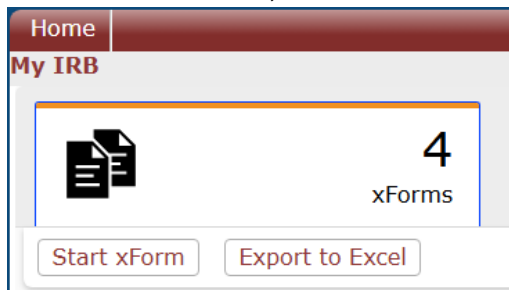
3. Then select the link, "IRB Initial Submission Application":
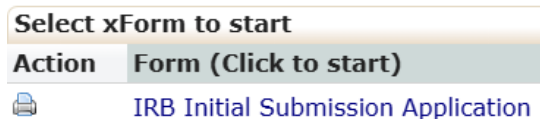
4. Follow the prompts to complete the form (4 pages). You may skip sections and come back to them later, but will not be able to submit the form until all required sections are complete.
5. Adding additional investigators
    a. For other investigators at Whitworth, have each investigator create a OneAegis account, then you can add them in the form. Start typing the investigator's name, and the form will find the account. For "Role", use "Research Team Member" if you do not need to indicate a more specific role. The investigator's CITI trainings will be added automatically shortly after they create their account (usually the next day).

b. For other investigators not at Whitworth use the question for Non-Whitworth Team Members. You will need to manually enter their name and email, and upload any CITI training completion certificates.

Will there be any Non-Whitworth team members working on this project? *(Required)*				View Audit
● Yes				
○ No				

Non-Whitworth Investigators *(Required)*
NOTE: You will need to click "Save" at the end of each row to add that investigator to the table.

First Name*	Last Name*	Email*	CITI Certificate (please attach appropriate CITI certificates).	Action
Test	Researcher	tresearcher@example.edu	Add Attachment	Save

6. When the form is complete, check the box on the last page to attest that everything in the application is complete and accurate, then select "Next".

By submitting this application, I attest that the application is complete and accurate to the best of my knowledge. *(Required)*	View Audit
NOTE: You will need to click 'Next' and 'Submit' to submit the application for review.	
☑ I Attest	

`Previous` `Next` `Save for Later` `More ▸`

7. On the submission page, select "Submit". The form will not be sent to the IRB until you select this last "Submit".

Form Completed
You've completed the form. You can now either save the form for later revision, or submit it.
`Go Back` `Save for Later` `Print` `Submit`

Submitting a Continuing Review Form

If your research project extends longer than a year (or sometimes a shorter period if the IRB judges that the level of risk requires more frequent review), you will need to submit a Continuing Review Form to maintain your approval.

The OneAegis system will send you a reminder when the deadline for Continuing Review is approaching.

1. Navigate to the IRB Dashboard as indicated above.

2. Select the project for which you wish to submit a continuing review.

> 2024-001-WW
> New From PI
> **O'Brien, Rebecca PhD**
> This is my project title

3. On the "Actions" menu on the left, under "Project Site", select "Start xForm".

> *Project-Site*
> Update
> Add Attachment
> Add Contact
> Add Event
> Add Note
> Add Related Project-
>   Site
> Add Animal
> Expirations
> Generate Doc
> Send EMail
> Start xForm
> xForms (0)

Select "IRB Continuing Review Application".

> **Select xForm to start**
>
> | Action | Form (Click to start) |
> |---|---|
> | 🖨 | IRB Closure Form |
> | 🖨 | IRB Continuing Review Application |
> | 🖨 | IRB Modification Request Form |
> | 🖨 | IRB Reportable Event Form |
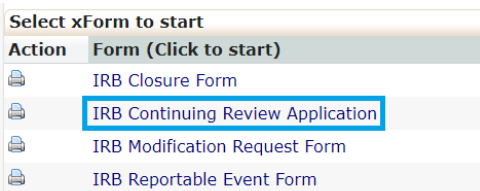
4. Complete the form (3 to 6 pages, depending on the nature of the research).

5. When the form is complete, check the box on the last page to attest that everything in the application is complete and accurate, then select "Next".

> **By submitting this application, I attest that the application is complete and accurate to the best of my knowledge.** *(Required)*   View Audit
> *NOTE: You will need to click 'Next' and 'Submit' to submit the application for review.*
> ☑ I Attest

`Previous` `Next` `Save for Later` `More ▸`

6. On the submission page, select "Submit". The form will not be sent to the IRB until you select this last "Submit".
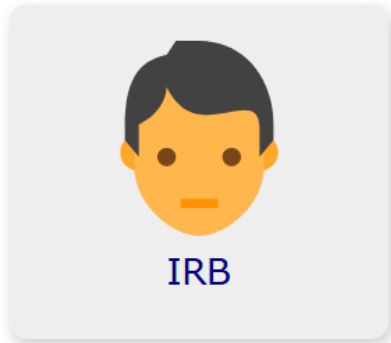
> **Form Completed**
> You've completed the form. You can now either save the form for later revision, or submit it.
> `Go Back` `Save for Later` `Print` `Submit`

Submitting a Modification Request Form

If you need to change your research protocol, for example, because of a change in the timeline, new information, an additional research site, or new investigators, you must inform the IRB and receive approval before continuing the research under the changed protocol.
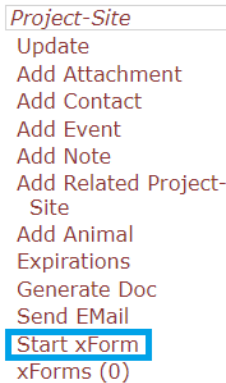
1. Navigate to the IRB Dashboard as indicated above.

2. Select the project for which you wish to submit a modification request.

   2024-001-WW
   New From PI
   O'Brien, Rebecca PhD
   This is my project title

3. On the "Actions" menu on the left, under "Project Site", select "Start xForm".

   Project-Site
   Update
   Add Attachment
   Add Contact
   Add Event
   Add Note
   Add Related Project-
     Site
   Add Animal
   Expirations
   Generate Doc
   Send EMail
   Start xForm
   xForms (0)
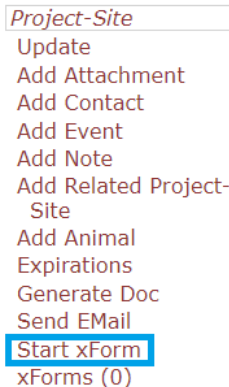
4. Select "IRB Modification Request Form".

Select xForm to start	
Action	**Form (Click to start)**
🖨	IRB Closure Form
🖨	IRB Continuing Review Application
🖨	IRB Modification Request Form
🖨	IRB Reportable Event Form

5. Complete the form (2 or 3 pages, depending on the modification)

6. When the form is complete, check the box on the last page to attest that everything in the application is complete and accurate, then select "Next".

> By submitting this application, I attest that the application is complete and accurate to the best of   View Audit
> my knowledge. *(Required)*
> NOTE: You will need to click 'Next' and 'Submit' to submit the application for review.
> ☑ I Attest

> Previous   Next   Save for Later   More ▸

7. On the submission page, select "Submit". The form will not be sent to the IRB until you select this last "Submit".
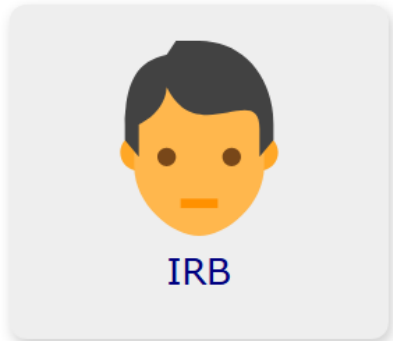
> **Form Completed**
> You've completed the form. You can now either save the form for later revision, or submit it.
> Go Back   Save for Later   Print   Submit

Submitting a Reportable Event Form

If you learn new information about your study conditions that may affect the risk to participants, if a participant suffers harm as a result of your study, if an investigator deviates from the approved study protocol, if a participant submits a complaint, or if another event occurs that should be reported to the IRB, you will need to submit the Reportable Event Form.
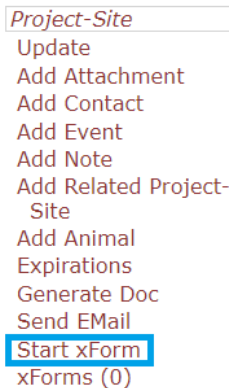
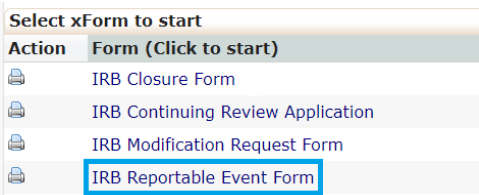1. Navigate to the IRB Dashboard as indicated above.

2. Select the project for which you wish to submit a modification request.

3. On the "Actions" menu on the left, under "Project Site", select "Start xForm".

4. Select "IRB Reportable Event Form".

5. Complete the form (2 pages).

6. When the form is complete, check the box on the last page to attest that everything in the application is complete and accurate, then select "Next".

> **By submitting this application, I attest that the application is complete and accurate to the best of**   View Audit
> **my knowledge.** *(Required)*
> *NOTE: You will need to click 'Next' and 'Submit' to submit the application for review.*
> ☑ I Attest

[Previous] [Next] [Save for Later] [More ▸]

7. On the submission page, select "Submit". The form will not be sent to the IRB until you select this last "Submit".

> **Form Completed**
> You've completed the form. You can now either save the form for later revision, or submit it.
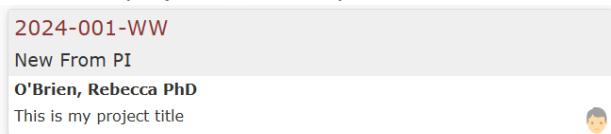> [Go Back] [Save for Later] [Print] [Submit]

Submitting a Closure Form

When you have completed your research submit the closure form. This will let the IRB know you have finished and they will not need to send reminders about continuing review.
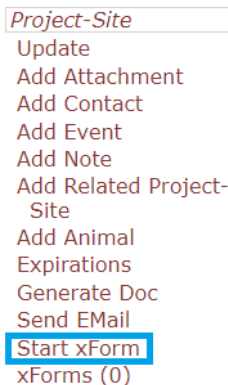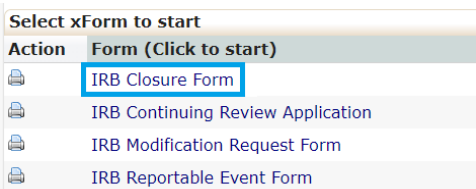
1. Navigate to the IRB Dashboard as indicated above.

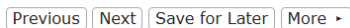2. Select the project for which you wish to submit a closure form.

2024-001-WW
New From PI
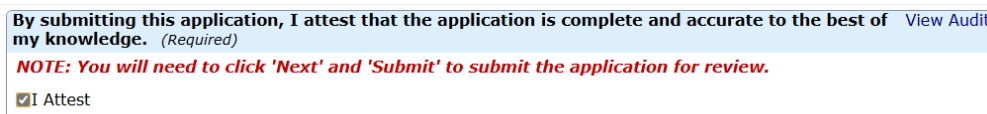**O'Brien, Rebecca PhD**
This is my project title

3. On the "Actions" menu on the left, under "Project Site", select "Start xForm".

Project-Site
Update
Add Attachment
Add Contact
Add Event
Add Note
Add Related Project-
   Site
Add Animal
Expirations
Generate Doc
Send EMail
Start xForm
xForms (0)

4. Select "IRB Closure Form".

Select xForm to start	
Action	**Form (Click to start)**
🖶	IRB Closure Form
🖶	IRB Continuing Review Application
🖶	IRB Modification Request Form
🖶	IRB Reportable Event Form

5. Complete the form (2 or 3 pages, depending on the nature of the research).
6. When the form is complete, check the box on the last page to attest that everything in the application is complete and accurate, then select "Next".

By submitting this application, I attest that the application is complete and accurate to the best of View Audit
my knowledge. *(Required)*
NOTE: You will need to click 'Next' and 'Submit' to submit the application for review.
☑I Attest

Previous | Next | Save for Later | More ▸

7. On the submission page, select "Submit". The form will not be sent to the IRB until you select this last "Submit".

Form Completed

You've completed the form. You can now either save the form for later revision, or submit it.

[Go Back] [Save for Later] [Print] [Submit]