BRADLEY University

# Committee on the Use of Human Subjects

## Directions to Apply for IRB Approval And Utilize the OneAegis Account

Bradley University IRB Application Instruction

**SETTING UP AN ACCOUNT IN ONEAEGIS:** ..... **3**
**STARTING AN INITIAL APPLICATION:** ..... **4**
**HOW TO ADD COLLABORATORS TO YOUR APPLICATION:** ..... **6**
**THE REVIEW PROCESS BEFORE IT IS FORWARDED TO THE IRB:** ..... **7**
**THE FLOW OF THE APPROVAL PROCESS:** ..... **9**
**NOTES ABOUT THE INITIAL APPLICATION:** ..... **11**
**IF THE APPLICATION IS RETURNED TO YOU FOR MODIFICATIONS:** ..... **13**
**HOW TO SUBMIT A REVISION OF A PROTOCOL ALREADY APPROVED:** ..... **15**
**HOW TO SUBMIT A FINAL STATUS AND PROTOCOL CLOSURE FORM:** ..... **17**
**HOW TO SUBMIT A CONTINUING REVIEW FORM:** ..... **19**
**HOW TO SUBMIT A NOTICE OF AN ADVERSE EVENT FORM:** ..... **21**
**HOW TO SEE WHERE YOUR PROTOCOL IS IN THE REVIEW PROCESS.** ..... **23**

## Setting up an Account in OneAegis:

OneAegis is the name of the software used at Bradley to manage IRB/CUHSR activities. Please search for bradley.oneageis.com or navigate to https://bradley.oneaegis.com/.

You will receive a login page that looks like this:

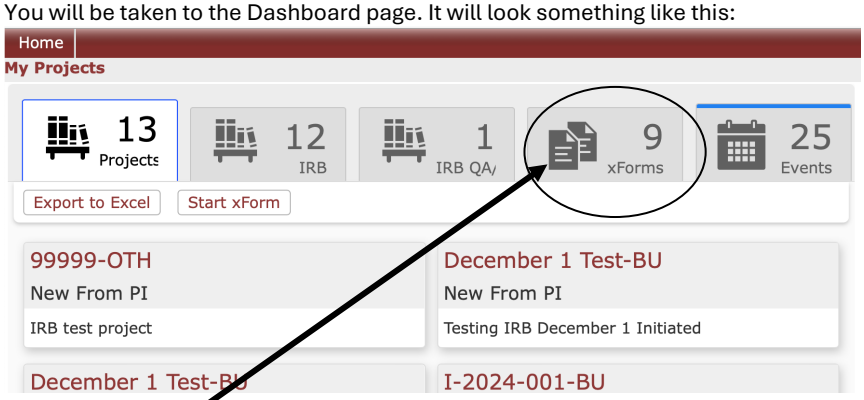

OneAegis is compatible with Bradley's Single Sign On (SSO) service. You may login in with your BUnetID.

Note: OneAegis is linked with CITI Program training courses and will pull course completion dates for your CITI account into the OneAegis system. If you originally set up your CITI account with an email address that does not match your standard Bradley email format (e.g., [BUnetID]@fsmail.bradley.edu or [BUnetID]@mail.bradley.edu), please log into your CITI Program account.

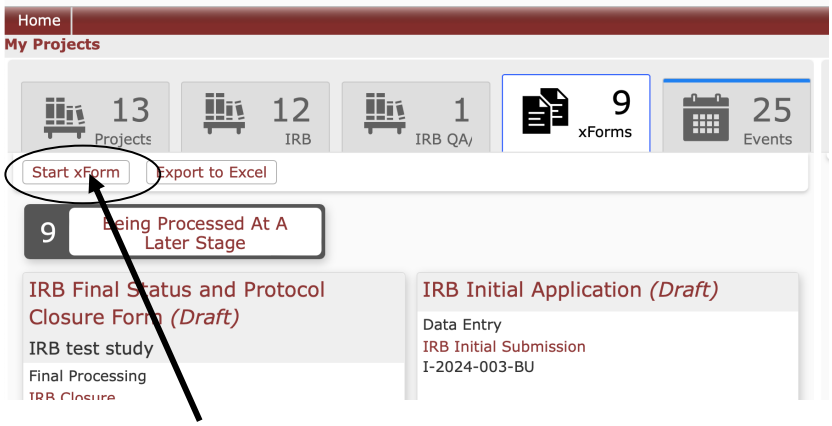
Once logged into CITI, click on your name in the upper right-hand section of the window and select Profile. In the resulting window, select Edit Profile, and then add your email in the standard Bradley Email format in the secondary email address entry box and select Update.

## Starting an Initial Application:

1. Navigate to https://bradley.oneaegis.com/.
2. Login with your BUnetID
3. You will be taken to the Dashboard page. It will look something like this:



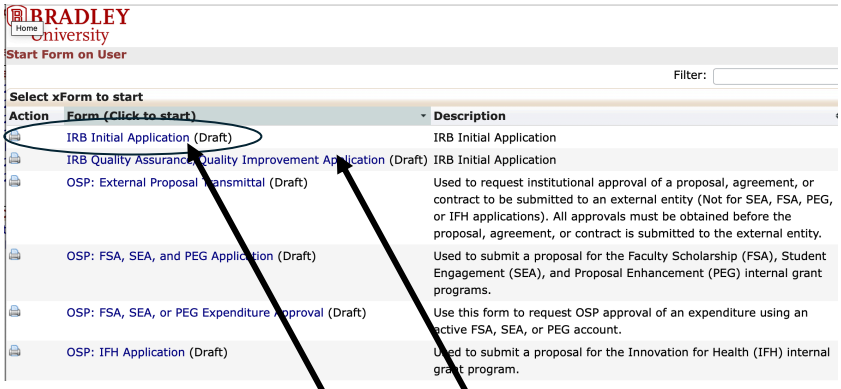

4. Click on xForms. The Dashboard will look like this:




5. Click on Start xForm

6. You will be taken to the page where you may access all the applications that are available to you. For IRB, this should only be the initial application. For applications related to existing projects, go first to that project on the dashboard and click Start X Form. For example, revision request, closure, and adverse event will only be visible when first selecting the existing project.

**Commented [RD1]:** Only the applications that are available via the dashboard will be visible here. To start applications that are related to existing projects, they will first need to go into that project and then click Start xForm. For example: revision request, closure, AE, continuing review won't be visible on the dashboard - only within an existing project.

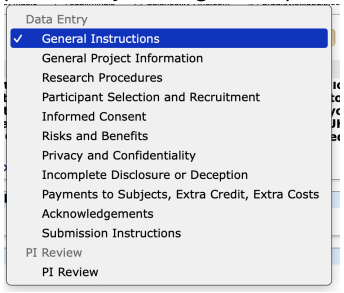



7. Click on the link for the IRB Initial Application or IRB Quality Assurance, or Quality Improvement if you are doing a QA/QI project.

8. Progress through the application by providing all the required information. Please note that OneAegis is affiliated with CITI. The status of your CITI modules will be pulled into your application as long as the CITI account contains the OneAegis email address.

9. Be sure to click next at the bottom of each section to progress through the application.

10. Once the general project information is complete you can navigate through the application by clicking the drop-down menu at the top of the application.




11. Once the application is complete, you must click “Next” and “Submit “to move the application forward in the review process.

Commented [RD2]: “Next” and then “Submit”

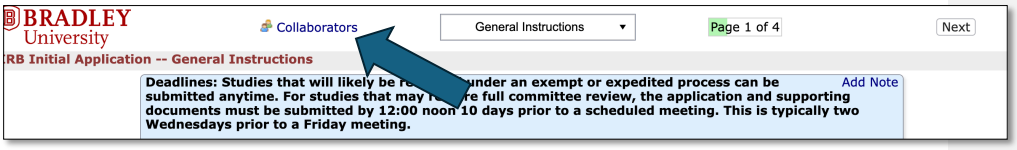
12. If you desire the see the application and all its questions, you can click on the print icon in front of the form that you would like to preview.

13. If at any time you need to navigate back to the dashboard while in the application, you can click on the Bradley University logo at the top left of the form.

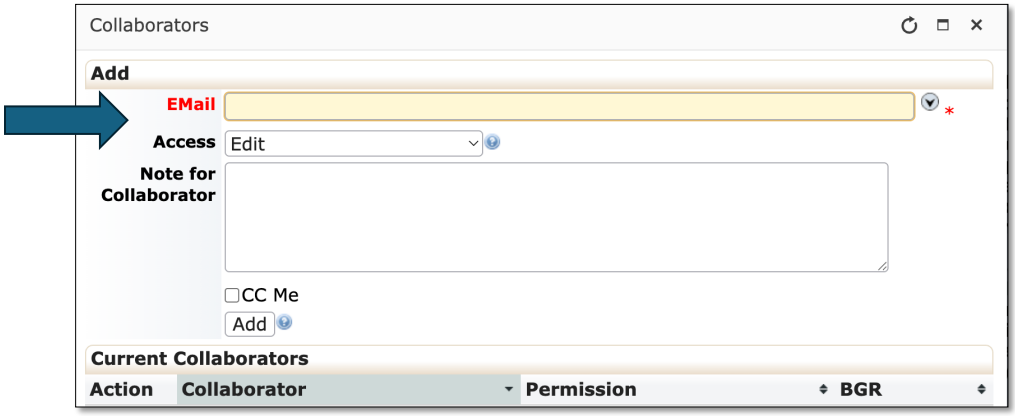
# How to Add Collaborators to your Application:

When you fill out the application you will be able to state who is all involved in the project. However, you as the form submitter have the rights to see and edit the application. To add others who will be involved with your project and want to be involved in contributing to the application (PI, Co-PI, or other team members), you can include them as Collaborators. To be added as a Collaborator, the individuals must have logged into OneAegis at least once. If you cannot add someone, please have them login. Once they have logged in, you will be able to add them to the submission form.

From within the Protocol Submission form, you will see Collaborators at the top left of the screen:



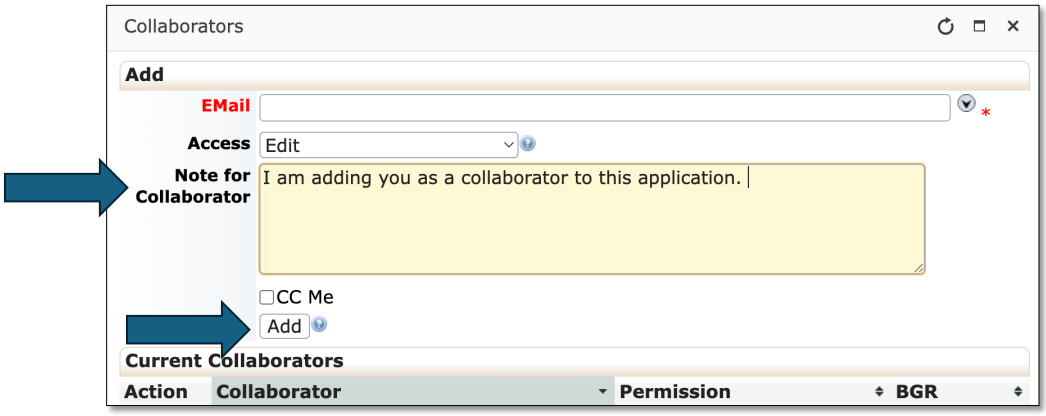

Here you will add their email and access level:




**Access Levels**:

- **View Only**: the individual will be able to view the form but will not be able to make any changes.
- **Edit**: the individual will be able to edit, but not submit the form
- **Edit and Manage**: the individual will be able to view, edit, add and remove collaborators.
- **Edit, Manage, and Submit**: the individual will be able to view, edit, add and remove collaborators, and submit the form

**Note for Collaborator:**
In "Note for Collaborator," you can add a note that will be added to the notification email that will be sent to the collaborator. Adding a "Note for Collaborator" is optional.




Select "Add" to complete adding the collaborator to the application.

## The review process BEFORE it is forwarded to the IRB:

1. The Roles of different individuals:
    a. The individual who starts the application from their OneAegis is always considered the **Form Submitter (FS)**.
    b. The **Principal Investigator (PI)** for research or the **Project Leader (PL)** for QA/QI is the individual who is ultimately responsible for the research or QA/QI project.
    c. The Form Submitter can simultaneously be the PI or PL which is very common.
    d. Students can be the PI or PL. If they are PI or PL there must be a **Faculty Advisor (FA).** Students should only be allowed to be PI or PL if the project is a capstone project, senior project or a graduate student project in which the student is solely responsible for generating and conducting the project. Otherwise, it is recommended that the Lead Faculty be the FS/PI/PL and the students be added as team members but not as the PI/PL. Students who are not the PI or PL can be added as collaborators and participate in filling out the form. Students who are the PI of PL can add faculty as collaborators. In every case if the student is the PI or PL, the protocol will always be sent to

the Faculty advisor for approval before it is sent to the Department Chair and moved on in the review process.

e. The **Department Chair (DC)** will always do a review before it is moved forward to the IRB.

2. As the application moves to different individuals, an email is sent. In the email, it will state what review should occur from whom. The email will have a link to the application in OneAegis that needs review.

3. The following are examples of how the process may occur with different individuals:
   **FS and PI/PL are the same with no students:**
   a. The Form Submitter is the individual from whose account was used to generate the application. This is important as correspondence will be going primarily to the form submitter with CC to the PI/PL and Faculty advisor.
   b. If the PI/PL and FS are the same, the next person to get the application is the DC. The DC may send it back with comments or submit it to the IRB. If the FS, PI/PL and DC are all the same person, the DC will still get the application to be submitted to the IRB.

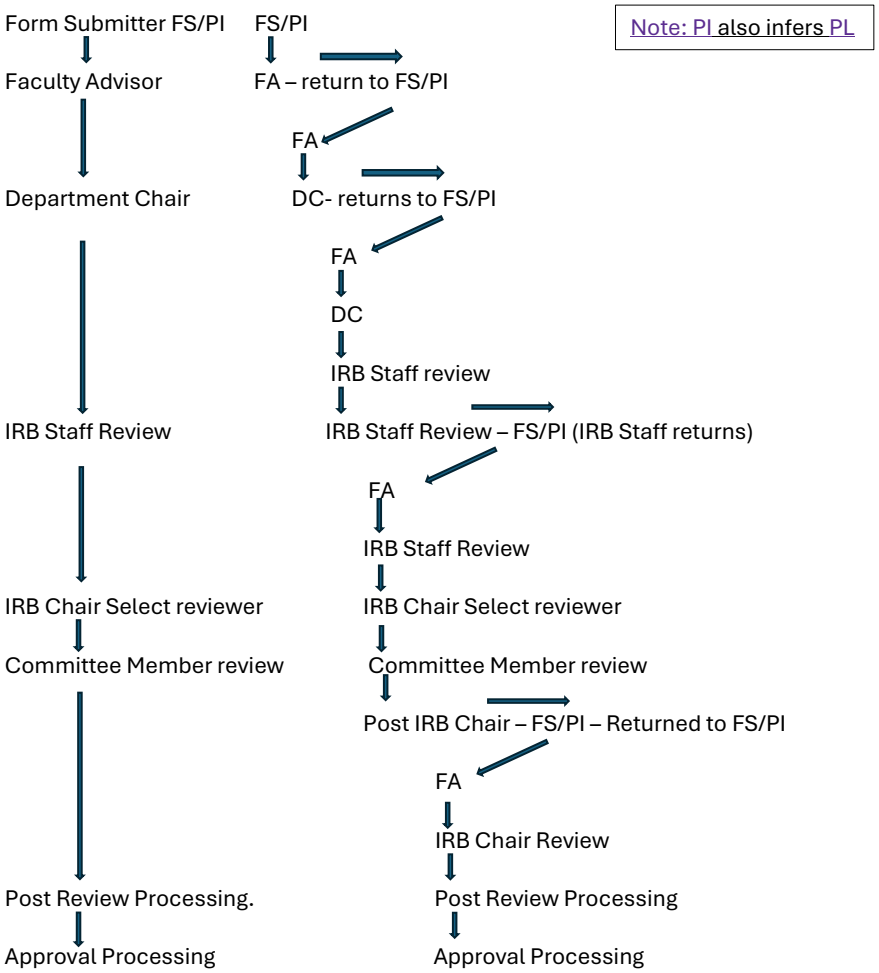
4. **FS and PI/PL are different with no students:**
   a. Once the FS submits the application it will go to the PI/PL for review. It can go back to the FS for Modifications.
   b. Once the PI/PL submits it, it will go to the DC for review and submission.

5. **If the FS and PI/PL are the same person, but they are a student:**
   a. Once the FS submits the application, it will go to the FA for review. It can go back to the FS for Modifications.
   b. Once the FA submits it, it will go to the DC for review and submission.
   c. This may be the arrangement for Graduate Students or Seniors doing capstone research projects or scholarly projects. Otherwise, it is recommended that the Lead Faculty be the FS/PI/PL and the students be added as team members, but not as the PI/PL.

6. Team members who are added will not be involved in the chain of emails. To add team members (via search box), they will need to have signed into OneAegis to establish their presence in the system. If you are unable to find someone to add, including the Department Chair, check to make sure they have signed into the OneAegis system.

## The Flow of the Approval Process:

The left-hand column refers to the process of submissions moving the application through to approval WITHOUT any returns for modification.
The right-hand column shows the flow and loop back should the protocol be sent back for revisions.



Here is an example email that a student researcher (as the form submitter and PI/PL) submitted and needs to have the faculty advisor review. Note the link to the application.

# IRB Initial Application from PI Researcher, Test Ready for Faculty Advisor Review

**OneAegis on behalf of Administrative Email, IRB <no-reply@bradley.oneaegis.com>** 9:16 PM (0 minutes ago)
to me

PI: Researcher, Test
Title: Biomedical Research Test of OneAegis #14
Click here to open the form and complete your review IRB Initial Application

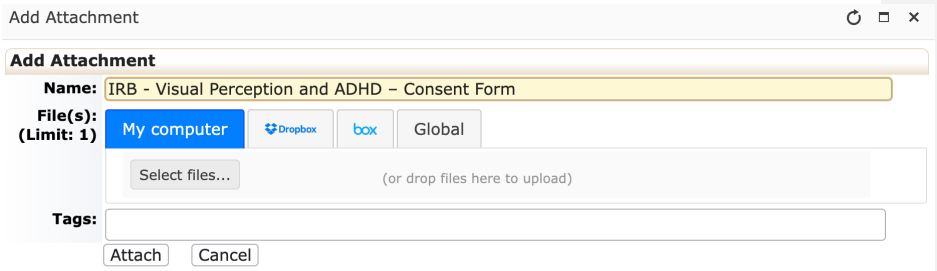
At the end of the Faculty Advisor review (or PI review or Department Chair review) there will be a place for comments should you return it to the Form Submitter for revisions.

## Notes About the Initial Application:

1. You can start an application, leave the system, and come back to it. You will need to look for the unsubmitted xForms on the dashboard under the xForms bubble.

2. Attachments: You will be asked to attach several documents throughout the application process. The following items are attachments that are uploaded to the system. You may want to have them loaded on your computer and ready to upload.
    a. **CV** of the PI/PL – required. If a student is a PI/PL, then the Faculty Advisor will need to upload their CV.
    b. Documents related to the **reliance agreement**, if applicable
    c. Letter from an institutional official that **permits the use of an off-campus site** for data collection, if applicable. An example would be a letter from a school official if collecting data from students in a high school.
    d. Sample **recruitment materials**, such as flyers or emails.
    e. Any **data collection forms, surveys, questionnaires, and screening tools** for inclusion/exclusion.
    f. Any **photos or links to materials** that will help the reviewers understand your procedures. Pictures of equipment as applied to your subjects should be included. Video formats are accepted.
    g. **Consent forms and assent forms**, if applicable

3. Most all document types are supported in the OneAegis upload system. When you click the "Add Attachment" button, **a space to name the document** is provided. Please name it clearly with an abbreviated title and the document form. Examples: "IRB - Visual Perception and ADHD – Consent Form," or "Perceptions of Teacher Confidence – Recruitment email".




4. If you are submitting a **revised document**, please indicate that in the file name. Example: "Visual Perception and ADHD – Consent form revised - **v2"**

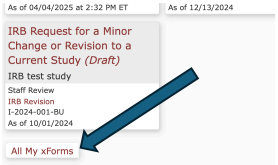
5. Reliance agreements: If you are seeking a reliance agreement in which another institution is the IRB of record, you will stop at this point and submit your

application. You will need to be in contact with the CUHSR chair to manage this agreement.

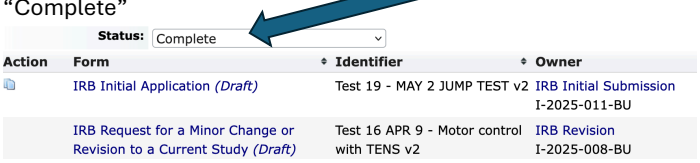
6. Cut and Paste: You should be able to cut and paste larger chunks of text into textboxes.

7. Copying a full protocol: You can copy a completed protocol. This may be desirable if a researcher is developing a protocol that is similar to one that was previously submitted. This will allow the researcher to make changes to the existing information rather than filling out a new form from scratch. This is ONLY recommended for projects that are VERY similar. Otherwise, you should fill out a new application. The following are the steps to making a copy:

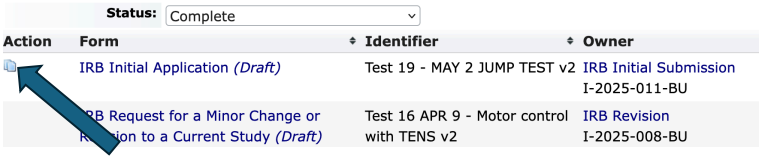
   a. Navigate to the dashboard.
   b. At the bottom of the bubble dashboard click on the box “All My xForms”




   c. At the top of the next page click on the dropdown menu at the top to “Complete”




   d. Find the protocol that you wish to copy and click the 2 pieces of paper icon under the action column.



## If the Application is Returned to You for Modifications:

1. It is common that the IRB reviewer (or the full committee review) will request revision to your application or ask for more information.
2. If the protocol is returned to you, you will receive an email that will have some instructions on it and a link to your application. Below is an example of the email.

### Requires Revisions to Initial Application for I-2025-002

OneAegis on behalf of Administrative Email, IRB <no-reply@bradley.oneaegis.com> Wed, Feb 5, 10:37 PM (21 hours ago)
to me, IRB, Andrew

Study Number: I-2025-002
PI: Researcher, Test
Title: Biomedical Research Test of OneAegis #14

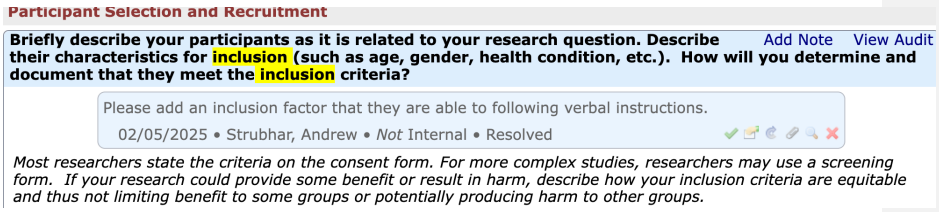
IRB Comments:

Please see the blue boxes within the application for instructions for revisions to the application or its attachments. Overall, the consent language is too technical and uses a great deal of professional jargon. The consent needs to be at the reading level of the participants.

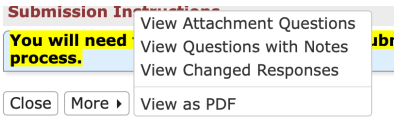
Click here to open the form and complete your revisions IRB Initial Application

**Commented [RD3]:** Change this from "review" to "revisions." Might need to check the send email action you copied this from in the system to make sure it also says "revisions" instead of "review."

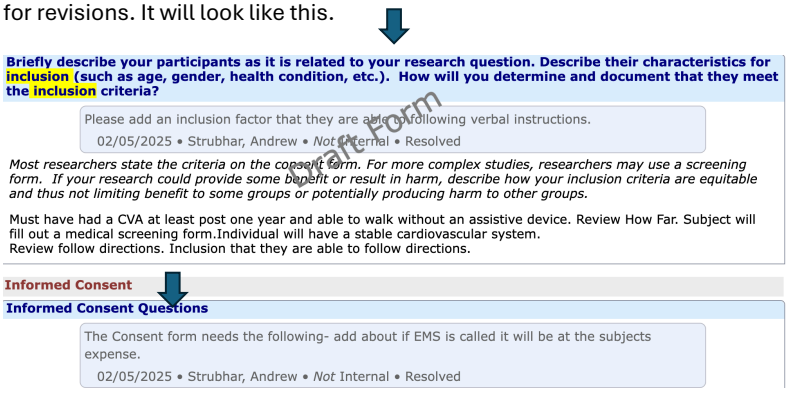
3. Notice that this letter refers you to blue boxes within the application where comments from the reviewers will be found and directions for change. The email may contain more global comments as well. Here is an example of a blue box instruction.




4. At the very bottom of the returned form, you will see a button called "More." When that is clicked, it will open up three choices. Choose Question with Notes




5. When this occurs, you will have a page that lists all the pages that have instructions for revisions. It will look like this.

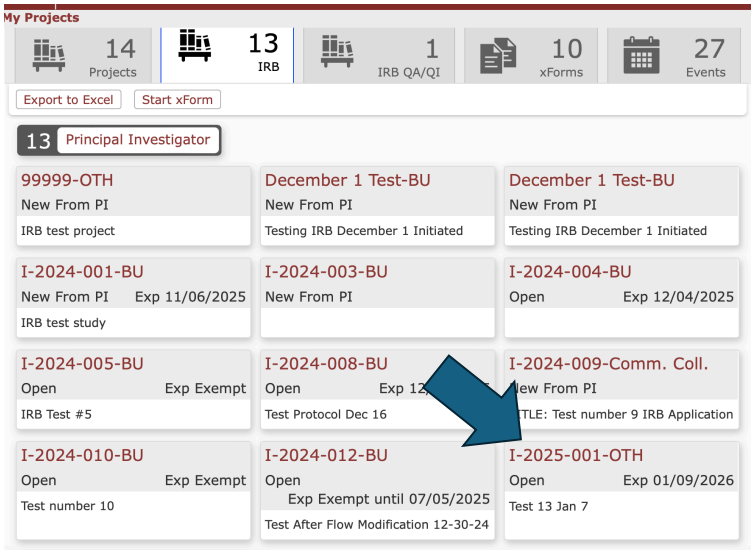



6. If you click on the question or heading (arrows above), you will be taken back to the application to revise the application.

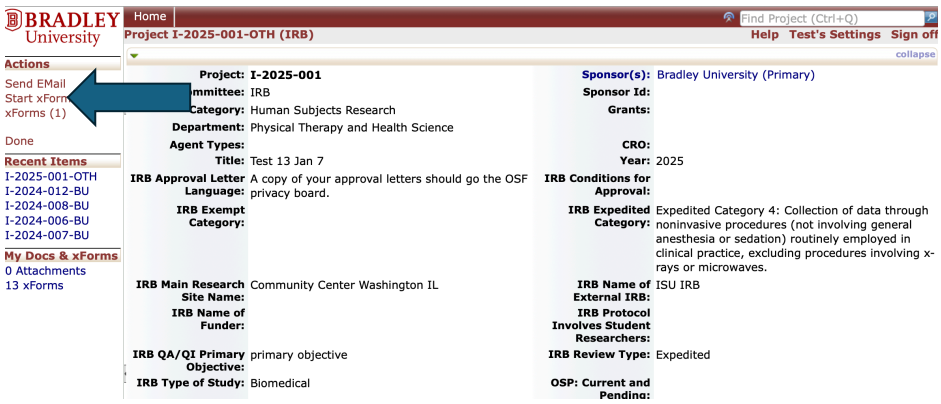
7. Changes that are submitted will automatically be highlighted in yellow. This will help keep track of the changes that are made in the review process.

# How to Submit a Revision of a Protocol Already Approved:

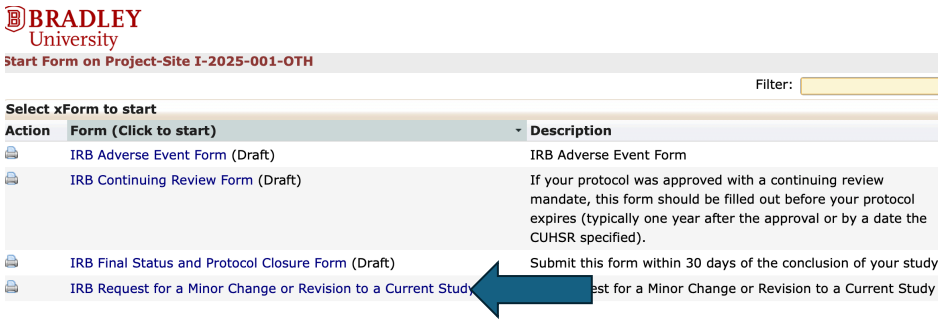
1. This submission is used if you need to make a minor revision to a protocol. The form will ask you specific questions regarding the change. Any change that deviates from the originally approved protocol should have the change approved.
2. Login into OneAegis
3. On the dashboard, find the protocol (project) that you want to revise and click on that.



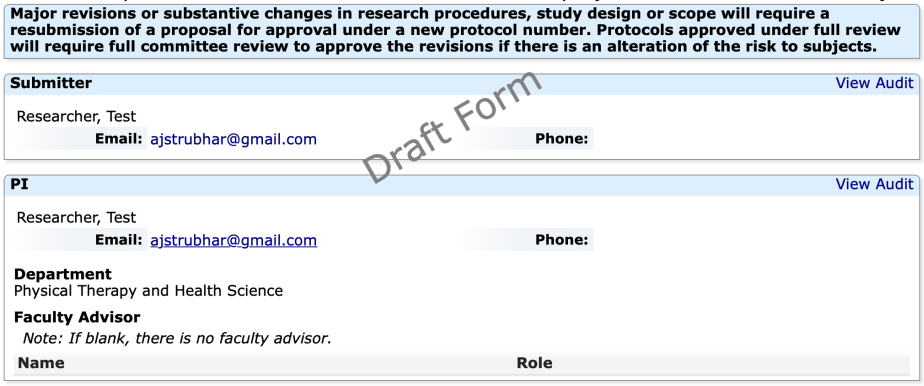

4. On the next form in the Left Menu Box Click on Start xForm.



5. This page should open the forms available to you for this protocol. Select IRB Request for Minor Change or Revision to a Current Protocol *or* IRB QA/QI Request for a Minor Change or Revision to a Current Project for QA/QI projects. If your project was QA/QI, there will be a separate request form.



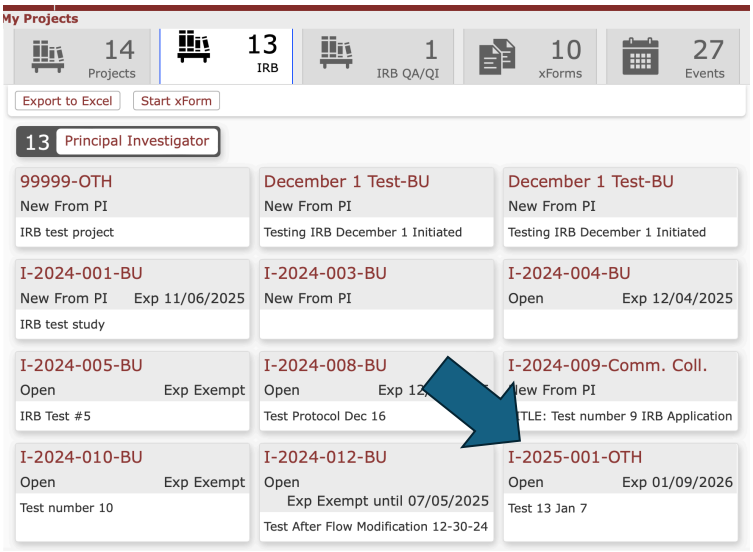

6. Complete the form. It should have all the basic project information on it already.



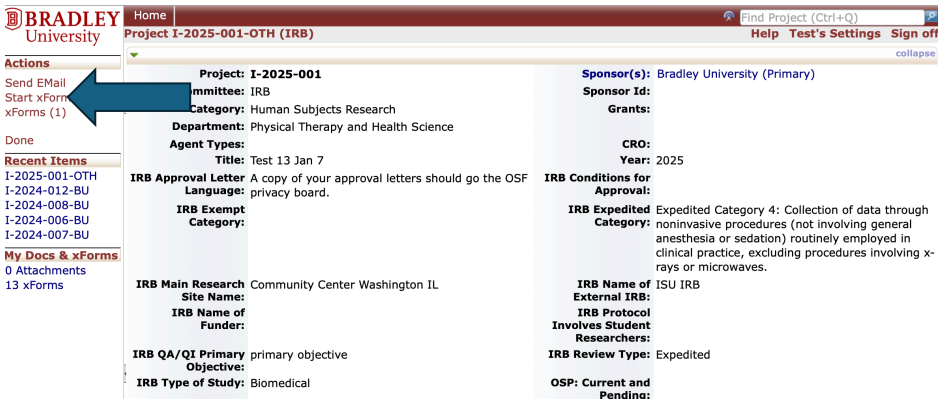

7. Submit the form. It will go through an approval process, and you should receive an email when it is approved. If the reviewer has questions or comments, they will send the form back to you asking for more information. You will make the changes and submit the form.

# How to Submit a Final Status and Protocol Closure Form:

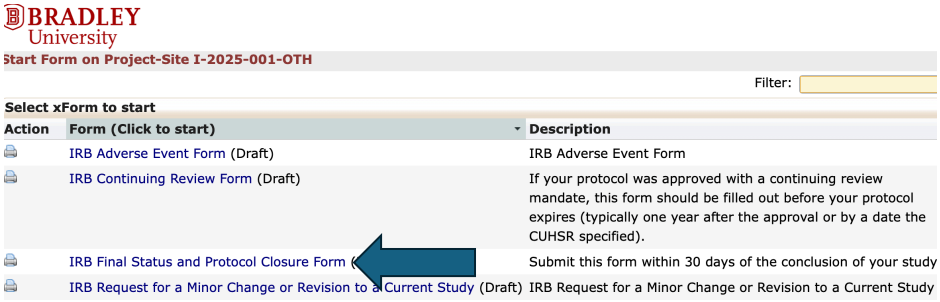
1. This is used when it is time to close a protocol. This should be done once you have completed your data collection and will no longer have any interaction with the subjects. The form will ask you specific questions regarding the protocol events. If you forget to close out your protocol, you will get an email approximately one month before the time specified that the protocol was approved for.
2. Login into OneAegis
3. On the dashboard, find the protocol (project) that you want to close and click on that.




4. On the next form in the Left Menu Box Click on Start xForm.



5. This page should open the forms available to you for this protocol. Select IRB Final Status and Protocol Closure Form *or* IRB QA/QI Final Status and Protocol Closure Form for QI/QA projects.

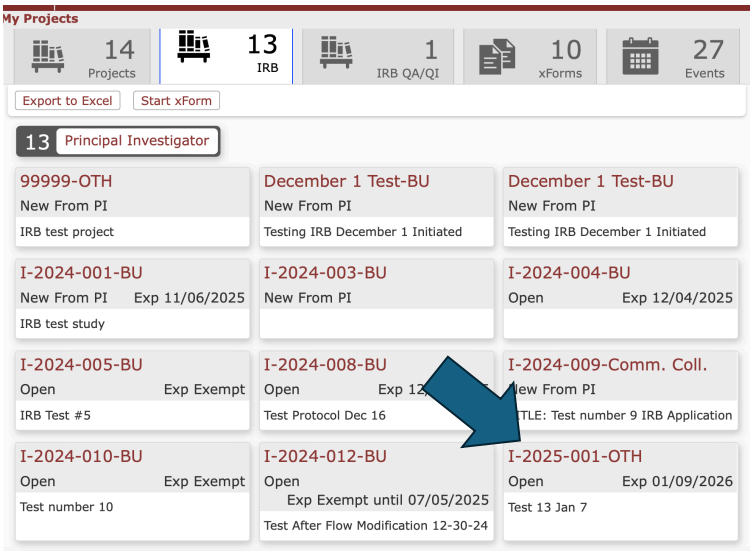



6. Complete the form. It should have all the basic project information on it already.

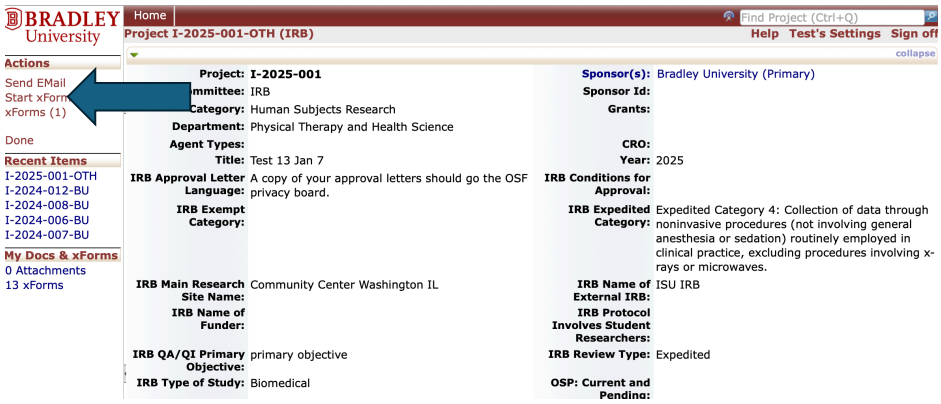
7. Submit the form. It will go through an approval process, and you should receive an email when it is approved. If the reviewer has questions or comments, they will send the form back to you asking for more information. You will make the changes and submit the form.

## How to Submit a Continuing Review Form:

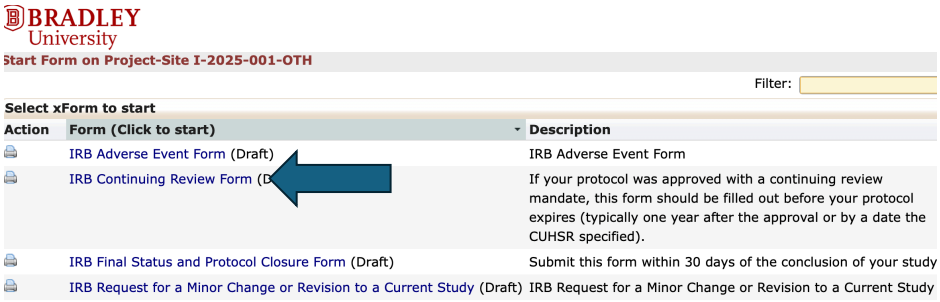
1. If your protocol was approved with a continuing review mandate, this form should be filled out before your protocol expires (typically one year after the approval or by a date the CUHSR specified). If you extend your protocol beyond a year, you must fill out this form so that your protocol can be approved for another time frame.
2. Login into OneAegis
3. On the dashboard, find the protocol (project) that needs a continuing review and click on that.




4. On the next form in the Left Menu Box Click on Start xForm.



5. This page should open the forms available to you for this protocol. Select IRB Continuing review form.




6. Complete the form. It should have all the basic project information on it already.

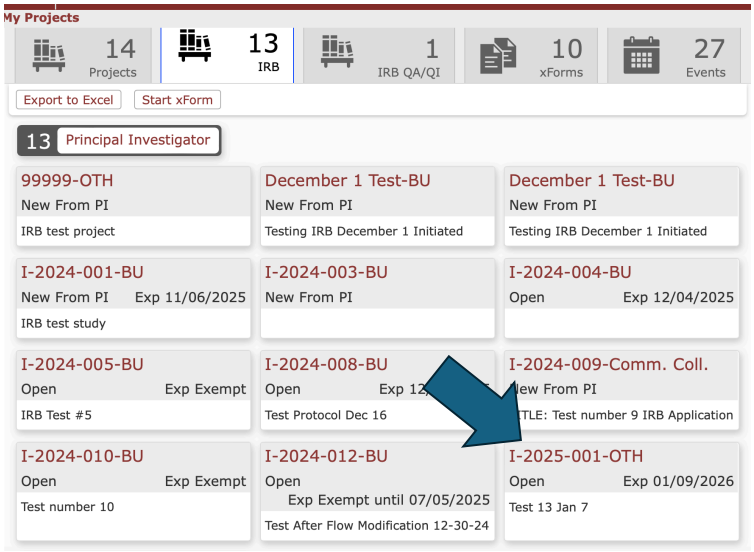
7. Submit the form. It will go through an approval process, and you should receive an email when it is approved. If the reviewer has questions or comments, they will send the form back to you asking for more information. You will make the changes and submit the form.

## How to Submit a Notice of an Adverse Event Form:

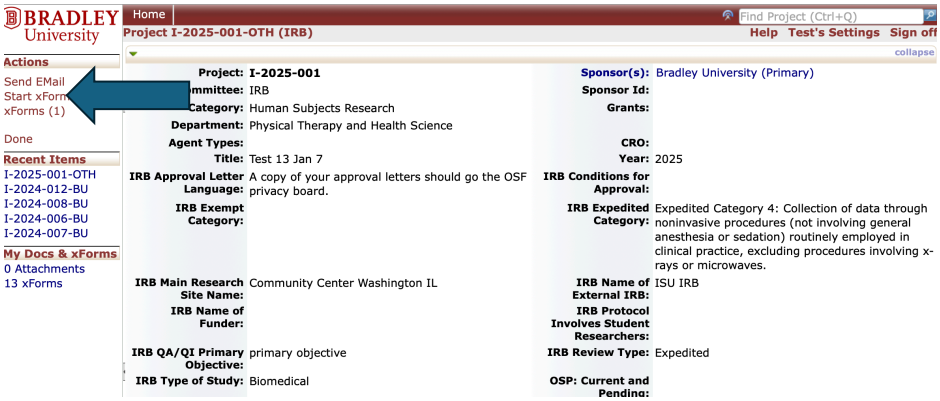
1. **Federal regulation requires that any Adverse Events associated with participation in a research study be reported to the IRB. Submit this form no later than 5 business days after an event or immediately if a serious, life-threatening event occurs.**
2. ***The Office for Human Research Protections (OHRP) defines an Adverse Event as:*** *Any untoward or unfavorable medical occurrence in a human subject, including any abnormal signs (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.*
3. ***In addition, Bradley University defines Adverse Events that qualify as:*** *Any serious, unexpected, physical, psychological or social research-related event, which is* ***definitely, probably or possibly*** *related to the study; where the risk is not included, or exceeds the nature, severity, or frequency described in the protocol, study consent form, Investigator's Brochure or other study information previously reviewed and approved by the IRB.*

4. Login into OneAegis

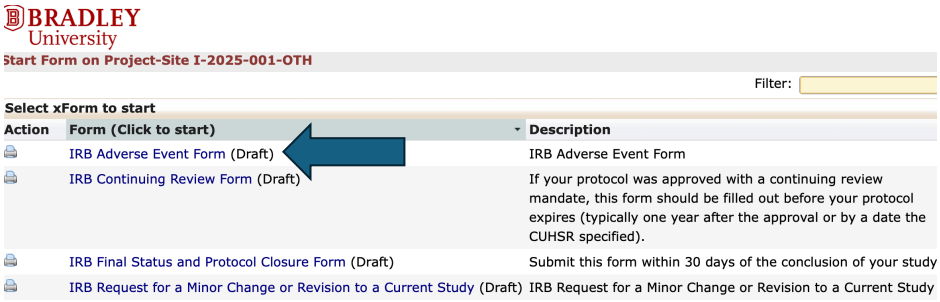
5. On the dashboard, find the protocol (project) that will report an adverse event and click on that.



6. On the next form in the Left Menu Box, Click on Start xForm.



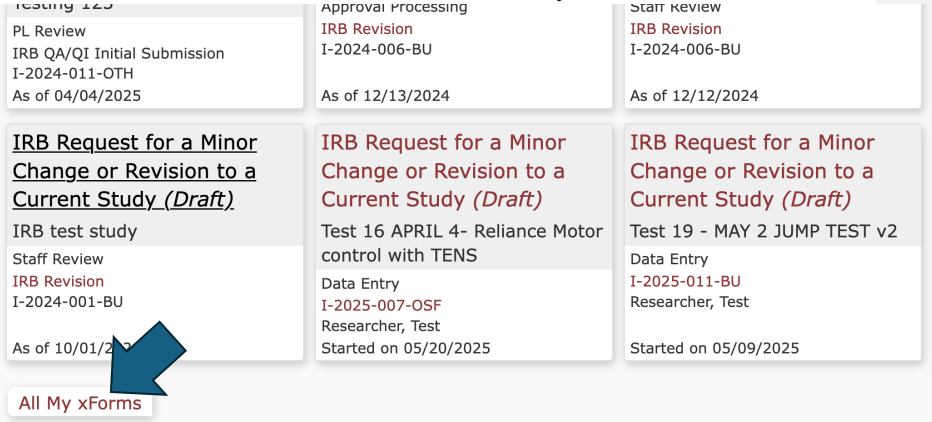

7. This page should open the forms available to you for this protocol. Select IRB Adverse Event Form.



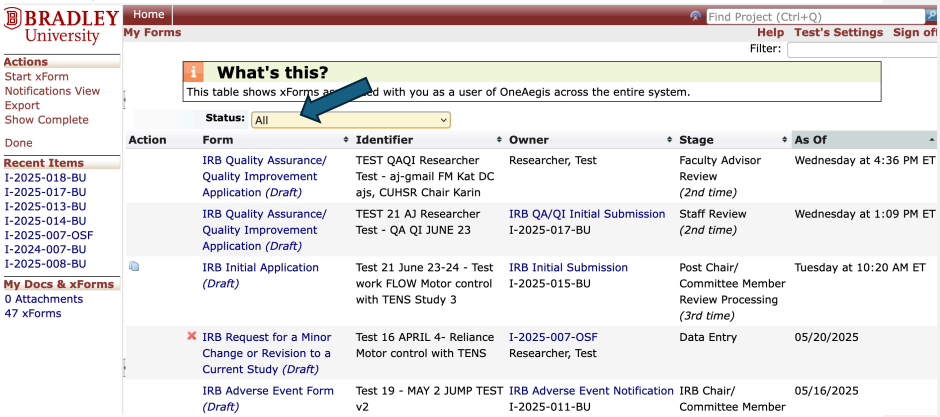

8. Complete the form. It should have all the basic project information on it already.
9. Submit the form. It will go through an approval process, and you should receive an email when it is approved. If a serious event has occurred, the IRB can require you to halt your data collection. If the reviewer has questions or comments, they will send the form back to you asking for more information. You will make the changes and submit the form.

# How to see where your protocol is in the review process.

1. Go the bottom of the bubble dashboard and click All My xForms.




2. At the top in the status box make sure all is selected.




3. Across the top of the table, you will see stages as a heading. This is the stage that it is in. If the stage is data entry that indicated that the form submitter as the application.