IRBManager Guidebook

Researcher Role

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ABOUT IRBMANAGER

IRBManager is a web-based IRB application submission, tracking, and management system. This system allows researchers to securely submit their IRB applications for processing by the IRB Office.

LOGGING INTO YOUR IRBMANAGER ACCOUNT

You can log into IRBManager at https://osu-chs.my.irbmanager.com. Your username is your email address. You create your own password. If you are new to IRBManager, you can click here to register.

HOME PAGE

After you log into IRBManager, you will be directed to IRBManager's Home Page. Depending upon your role(s) (i.e., researcher, IRB committee member, IRB administrator) within IRBManager, you will see slightly different menus.

You can return to the Home page at any point by clicking the Home button **Home**.

Left Side
On the left side of the screen you will see a menu which includes the following:"

Actions	Depending on the page you are viewing, the sections in this category will change. On some pages you will be able to add an attachment or an xForm, or send an email. [Done] will typically take to you to previous page.
Recent Items	Will list any recently viewed items.
Messages	Will display important messages from the IRB Office.
My documents and forms	**User Attachments** – will display any attachments not associated with a specific event or study within IRBManager. **xForms** – allows you to start a new IRB application and will also display any application that you are associated with.

Center

Information and status updates pertaining to your applications will be displayed in the center of the screen.

Studies	Summary information about your studies.
xForms	List of forms that have not been submitted and forms that have been submitted.
Events	Open events on your studies. The events section on the dashboard shows the submissions open by name of event (e.g., New Application, Continuing Review, Amendment, etc.).
My Studies	Your active studies.

Right Side

The right side menu includes the following:

Find Study	Will enable you to search for a specific study.
Take a tour…	Will provide you with a high-level tour of IRBManager.
Help	For assistance email chsirb@okstate.edu
Settings	Enables you to change your account information.
Sign Off	Sign off will sign you out of IRBManager.
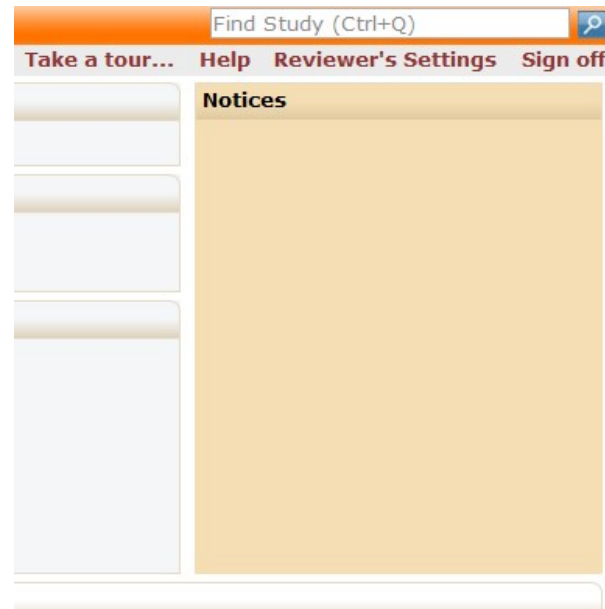
STUDY/PROTOCOL PAGE

From the Home page you can view all studies you are involved with by clicking on the study number (in blue) under the section "My Studies".

Protocol Code	Site	Investigator	Study Title
01-111-Psy	Psychology	Test Investigator	Test Study Survey
0110.1-Nurs	Nursing	Test Investigator	Test Study - Expedited 1
0110.2-Psy	Psychology	Test Investigator	Expedited Study Test #2

VIEWING ALL AVAILABLE QUESTION OPTIONS

If you wish to view all available question options in the IRB Application form please follow the steps below.

1. Once signed into IRBManager, under the heading "Actions", click on "Start xForm".
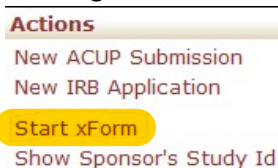
2. Click on the printer icon located next to the form name "Application for Review of Human Participant Research".

Select xForm to start	
Action	**Form (Click to start)** ▾
🖨	Application for Review of Human Subjects Research
🖨	Humanitarian Use Device

3. This will open the form and display all available options for each question.

STARTING A NEW IRB APPLICATION
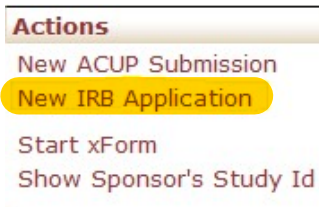
You can start a new IRB application by following the instructions below.

1. From the home page, click on *New IRB Application* under the section "Actions" located on the left-hand side of the screen.

Actions
New ACUP Submission
New IRB Application
Start xForm
Show Sponsor's Study Id

2. Next, you will begin creating your new IRB application.

Guidance for most questions can be found next to the question.

Will you be working with any other collaborating institutions as part of this project? *(Required)*	Add Note View Audit
⦿ Yes ○ No	➡ Generally, when one or more institutions work together equally on a research endeavor, it is a collaboration.

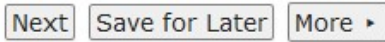While you are completing the IRB application, IRBManager will provide you with any "issues" that it detects with the form as you progress. The "issues" will be listed at the top of the screen for your review and correction.

The following issues exist. Click on an issue to jump there.
- Title of Project - Required.
- Main PI - Required.
- College - Required.
- Campus - Required.
- Collaborating Institutions - Required.

The buttons located at the bottom of each section will help you navigate through the application. Your work in IRBManager is saved each time you click the buttons [Next], [Previous], or [Save for Later] located at the bottom of the webpage.

| Previous	Takes you to the previous screen/question.
Next	Will move to the next question. If there are any required questions which have not been answered you will not be able to proceed to the next section until the questions have been answered.
Save for Later	Saves your progress and allow you to return at a later time to complete the application.
View Attachment Questions	View attachments.
View Questions with Notes	View questions which contain notes.
PDF	Creates a PDF of your form.

Starting a new application for submission

Things to consider
- All PIs, Co-PIs and Faculty Advisers must have an IRBManager account before being listed anywhere in the application.
- Application questions are asked in different formats, such as short answer, check boxes, drop down menus, etc.
- The [Add Note] link allows you to leave notes for the reviewer or the IRB office on a specific question(s).

Submitting a new application
1. Once logged into IRBManager you can begin a new IRB Application by clicking on the link [New IRB Application] under the Action heading.
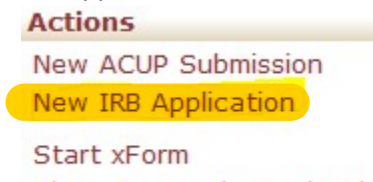
2. Begin completing the sections of the form. Below are brief descriptions of each section of the IRB application form.

Part 1 – Administrative Information
Part 1 of the IRB application requests some basic information pertaining to your research. Such information encompasses items such as title of project, your college and department, and if the research is funded externally.

Part 2 – Determination of Research

Part 2 of the IRB application helps determine whether the proposed project is research related and requires the submission of the application.

Part 3 – Determination of Human Participants

Part 3 of the IRB application helps determine whether the proposed project is human subject research related and requires the submission of the application. If either part 2 or 3 is no, then a determination of non-human subjects form is completed.

Part 4 – Purpose & Benefits

Part 4 of the IRB application requests you provide the purpose, results, and benefits of the research intended.

Part 5 – Participants

Part 5 of the IRB application requests information pertaining to the human participants. Questions pertain to the following:

- International population
- Native American population
- Studies with prisoners

Part 6 – Recruitment

Part 6 of the IRB application request information pertaining to recruitment methods

Part 7 – Compensation/Remuneration

Part 7 of the IRB application request information pertaining to compensation to be given to subjects.

Part 8 – Study Overview & Location

Part 8 of the IRB application request information pertaining to basic study design and location of study. Such questions pertain to the following:

- Social, behavioral, educational, or methodology questions
- Existing data social, or behavioral
- Biomedical methodology questions
- Use of existing biological materials methodology questions

Part 9 – Risks

Part 9 of the IRB application request information pertaining to the risk of the study. Description of risks and safeguards in place to mitigate those risks, Handling of adverse events and unanticipated problems, Certificates of confidentiality and National Institute of Health privacy certificates

Part 10 – Privacy & Confidentiality

Part 10 of the IRB application request information pertaining to the consent process. Such questions pertain to the following:

- Description of privacy and confidentiality measures
- Use of audio/video recordings and photograph description of measures in place

- Studying employee/supervisor relationship confidentiality measures
- Use of deception

Part 11 – Consent Process

Part 11 of the IRB application describes the procedures you will use to consent participants and/or obtain parent/guardian permission and assent for your study.

Part 12 – Other Regulatory Applicability

Part 12 of the IRB application request information pertaining to compliance and review by the following:
- Health Insurance Portability and Accountability Act (HIPAA)
- The Family Educational Rights and Privacy Act (FERPA)
- Protection of Pupil Rights Amendment (PPRA)
- Institutional Biosafety Committee
- Institutional Animal Care and Use Committee
- Laser Safety
- Radiation Safety

Training Verification

The training verification page will verify your CITI training compliance. All training must be completed prior to the submission of your application.

All investigators who plan to conduct studies involving human subjects must complete the required human subjects training modules via the CITI website.   Add Note   View Audit
Training instructions can be found on our webpage: IRB Training
Note: All CITI training is updated in the system each morning. If you are missing a requirement, it will take until the next morning for it to update the requirement as complete in IRBManager.

Note: All CITI training is updated in the system each morning. If you are missing a requirement, it will take until the next morning for it to update the requirement as complete in IRBManager.

The following specialized modules have been identified as being required based upon responses in this application.   Add Note
These courses can be found on the CITI website. They will be listed under the IRB SBE or Biomedical Specialized Modules Course as optional. It is necessary to list them as optional so you do not need to complete all modules. Please complete the ones listed below. If there are not any listed below, then no additional training modules are necessary.

Consent Tools Used by Researchers (ID: 16944)   Add Note   View Audit

PI:

Contact	Expires (as of 12/06/2017)
	02/02/2018

Protocol Attachments

At the end of the application you will be required to attach any additional documents required by the IRB for review. <u>Microsoft Word (.docx) and Adobe PDF (.pdf) files will only be accepted</u>.

PI Review and Signature

The submission page requires attesting that you have read the Investigator Obligations. You must enter your password to electronically sign the application.

Finally, you **must** click [Submit] in order to submit your application.

Submitting an application on behalf of a PI

If someone other than the PI submits the application xForm, the PI will receive an email informing them that they need to review and approve the submission in order for the application to be submitted to the IRB office for review.

> Dear
>
> The following new protocol has been submitted to the Oklahoma State University IRB and has listed you as the principle investigator.
>
> Study Title:
> Submitted By:
>
> Please click Application for Review of Human Subjects Research to go directly to the form for review and signature.

After the PI reviews the xForm and attachments, they can save the form for later, print a copy, accept the application and submit to the IRB by entering in the password in the "Submit" box.

Approval of the submitted application by the PI

1. Once the PI has reviewed the application and made any notes where applicable, they will click on the [Next] button located at the bottom of the screen.

   Next | Save for Later | More ▸

2. The PI will need to answer a few questions prior to completing their review.
3. The PI Review screen will be displayed, allowing the PI to either sign off on the application or send the application back to the submitter for corrections.

After reviewing the submission on the previous page, is it ready for submission to the IRB?	Add Note	View Audit
(Required)		

   ○ Needs changes and clarifications before submission
   ○ Ready for Submission

4. On the PI Review screen you would select "Ready for Submission" in order to approve of the application and allow the application to progress to the next stage.
5. You must read and agree to each of the statements listed. At the bottom of the screen you will be required to enter your password in order to sign off on the application.
6. Click [Next].
7. Click [Submit] in order to complete your sign off, approval, and review of the application.

   You've completed the form. You can now either save the form for later revision, or submit it.
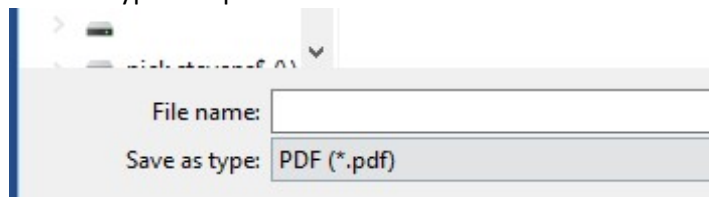
   Save for Later | Print | Submit

Converting Microsoft Word documents to Adobe PDF

You can easily convert Microsoft Word documents to Adobe PDF

1. Open your Microsoft Word document.
2. Click on the [File] tab and select "Save As".
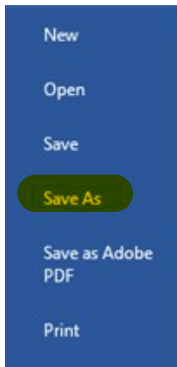
3. Next, select the location to save the converted document and select "PDF (*.pdf)" from the "Save as type" dropdown menu.
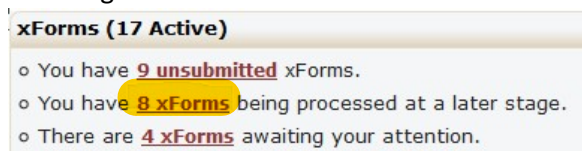

4. Click [Save].

CHECKING ON THE STATUS OF YOUR APPLICATION, CONTINUING REVIEW

IRB Application – Status of your application
If you wish to check on the status of your IRB application please follow the instruction below.

1. Once logged into IRBManager, from the Home page click on your xForms "being processed at a later stage".

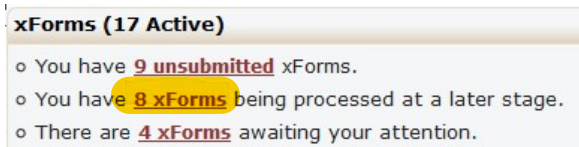2. You can check the status of your IRB application by looking at the "Stage" column next to your application.

IRB Application Stage	Stage Description
Application Data Entry	Application has been started by the submitter. It has not yet been submitted to the IRB. -or- Application has been returned by faculty advisor or IRB Office for revision.
PI Signature for Project Coordinator Submission	Awaiting principal investigator sign off on IRB application, if someone other than the principal investigator is submitting the protocol (such as a coordinator or graduate student on behalf of a PI).
Faculty Adviser Review and Signature	Awaiting faculty adviser review and sign off on IRB application.
IRB Office Pre-Review	Application is submitted to the IRB Office. A prereview is conducted to determine if the application is complete and ready to be reviewed. Turnaround time is estimated at 1-2 days.
IRB Office Determination of Review Level	The application is evaluated for review level. The application is assigned a tracking number. Turnaround time is estimated at 1-2 days.
Non-Human Participant Review	Waiting in the queue for NHS Review. Turnaround time is estimated at 1 week.
Exempt Review	Waiting in the queue for exempt review. Turnaround time is estimated at 1 week.
Send for Expedited Review	Protocol has been sent to the expedited reviewer. IRB office is waiting for the IRB member to complete the expedited review. Turnaround time is 2 weeks.
IRB Office Review of Non-Full Board Studies	Expedited Review has been received by the IRB from the faculty member and is awaiting for IRB office review and forwarding to PI. Turnaround 1-2 days.
Post Approval for Non-Full Board Studies	NHS, Exempt, or Expedited protocol has been approved and is waiting for IRB Office to generate approval letters and stamped letters and stamped documents. Turnaround time is estimated at 1 day.
Full Board Pre-Review	Protocol has been sent to the Full Board reviewer. IRB office is waiting for the IRB member to complete the Full Board pre-review. Turnaround time is 1-2 weeks.
Under Full Board Review	Protocol has completed Full Board pre-review process and is on the agenda for the next scheduled Board meeting.

Office Processing of Full Board Determination	The processing of the full board application by the IRB office after the IRB Board meeting has occurred. Turnaround time is estimated at 2-3 days.
Post Approval Full Board Studies	Full Board protocol has been approved and is waiting for the IRB office to generate approval letters and stamped documents. Turnaround time is estimated at 1 day.

IRB Continuing Review – Status of your review

If you wish to check the status of your IRB continuation review please follow the instructions below.

1. Once logged into IRBManager, from the Home page click on your xForms "being processed at a later stage".

   xForms (17 Active)
   - You have **9 unsubmitted** xForms.
   - You have **8 xForms** being processed at a later stage.
   - There are **4 xForms** awaiting your attention.

2. You can check the status of your IRB application by looking at the "Stage" column next to your application.

IRB Application Stage	Stage Description
Application Data Entry	Application has been started by the submitter. It has not yet been submitted to the IRB. -or- Application has been returned by faculty advisor or IRB Office for revision.
PI Signature for Project Coordinator Submission	Awaiting principal investigator sign off on IRB application, if someone other than the principal investigator is submitting the protocol (such as a coordinator or graduate student on behalf of a PI).
Faculty Adviser Review and Signature	Awaiting faculty adviser review and sign off on IRB application.
IRB Office Pre-Review	Application is submitted to the IRB Office. A prereview is conducted to determine if the application is complete and ready to be reviewed. Turnaround time is estimated at 1-2 days.
IRB Office Determination of Review Level	The application is evaluated for review level. The application is assigned a tracking number. Turnaround time is estimated at 1-2 days.

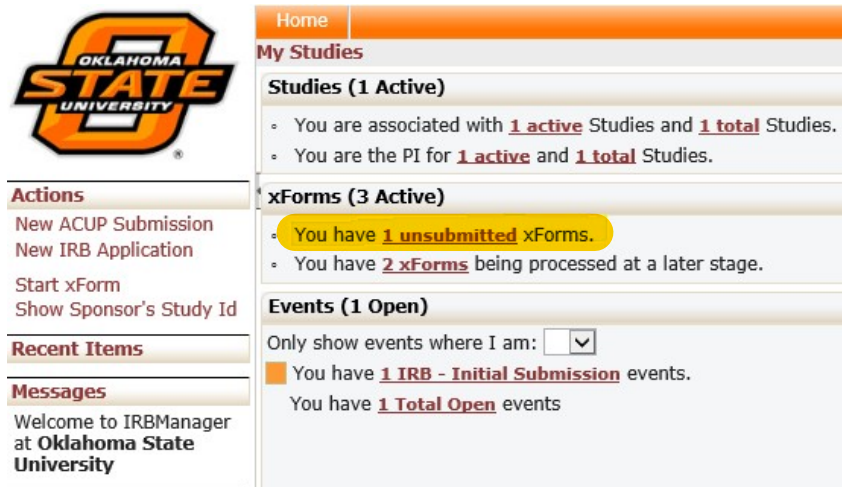|	
Send for Expedited Review	Protocol has been sent to the expedited reviewer. IRB office is waiting for the IRB member to complete the expedited review. Turnaround time is 2 weeks.
IRB Office Review of Non-Full Board Studies	Expedited Review has been received by the IRB from the faculty member and is awaiting for IRB office review and forwarding to PI. Turnaround 1-2 days.
Post Approval for Non-Full Board Studies	NHS, Exempt, or Expedited protocol has been approved and is waiting for IRB Office to generate approval letters and stamped letters and stamped documents. Turnaround time is estimated at 1 day.
Under Full Board Review	Protocol has completed Full Board pre-review process and is on the agenda for the next scheduled Board meeting.
Office Processing of Full Board Determination	The processing of the full board application by the IRB office after the IRB Board meeting has occurred. Turnaround time is estimated at 2-3 days.
Post Approval Full Board Studies	Full Board protocol has been approved and is waiting for the IRB office to generate approval letters and stamped documents. Turnaround time is estimated at 1 day.

IRB Application – Expiration Date(s)

If you wish to check the expiration date of your IRB application(s) you can do so from the Home page. Expiration dates are listed at the bottom of the Home page next to the Title of your IRB application.

Study	Site	PI	Title	Expires
2017-006-K-12 School	K-12 School	Temp, User 1	Humans survey fish on what they enjoy eating for supper	
2017-007-ECESchool	Early Childhood Education School	Temp, User 1	stuff	
2017-008-ECESchool	Early Childhood Education School	Temp, User 1	[TEST] animals training humans to use radioactive material in labs	

RETURNING TO YOUR APPLICATION IN PROGRESS

When you log back into IRBManager after beginning your application, your screen will look like the following:
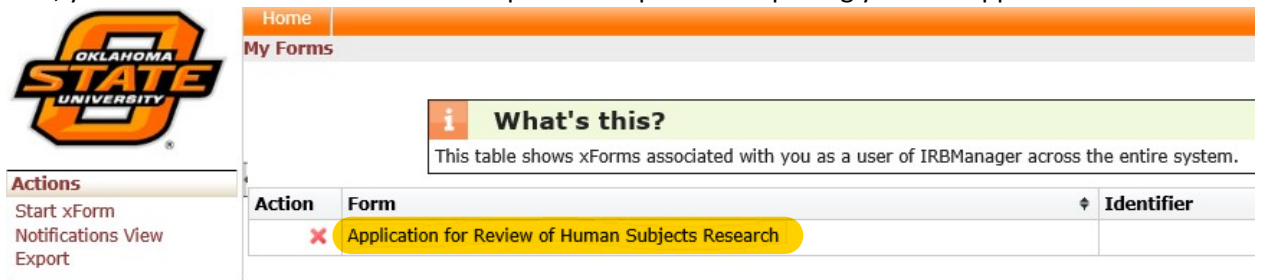

1. You will click on the xForm, "unsubmitted xForms", awaiting your attention.
2. Next, you will click on the form in order to pick back up with completing your IRB application.
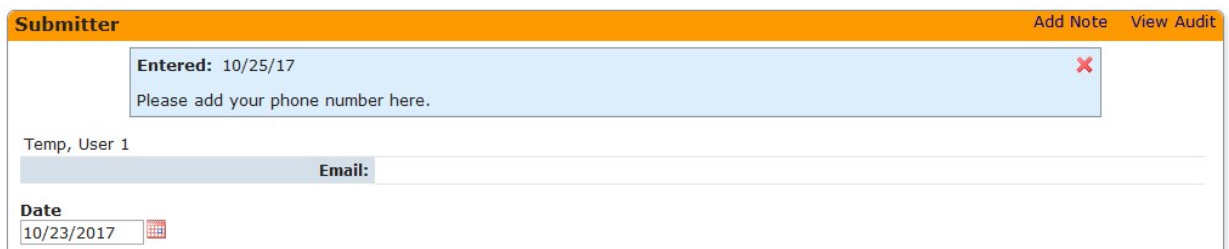

Revising a submitted application

1. After you have submitted your application you may be notified by reviewers that your application needs correcting.
2. You will receive notification via email when corrections are needed to your IRB application. You can click the link in the email, which will take you to the form directly.

Revisions Requested for IRB Exempt Protocol

Today, 8:23 AM

Dear

The reviewer has identified revisions and/or clarifications that need to be addressed before approval for your Exempt Application can be given.

Protocol Number:
Title:

The revisions are as follows:

Click Application for Review of Human Subjects Research to go directly to your protocol.

Sincerely,
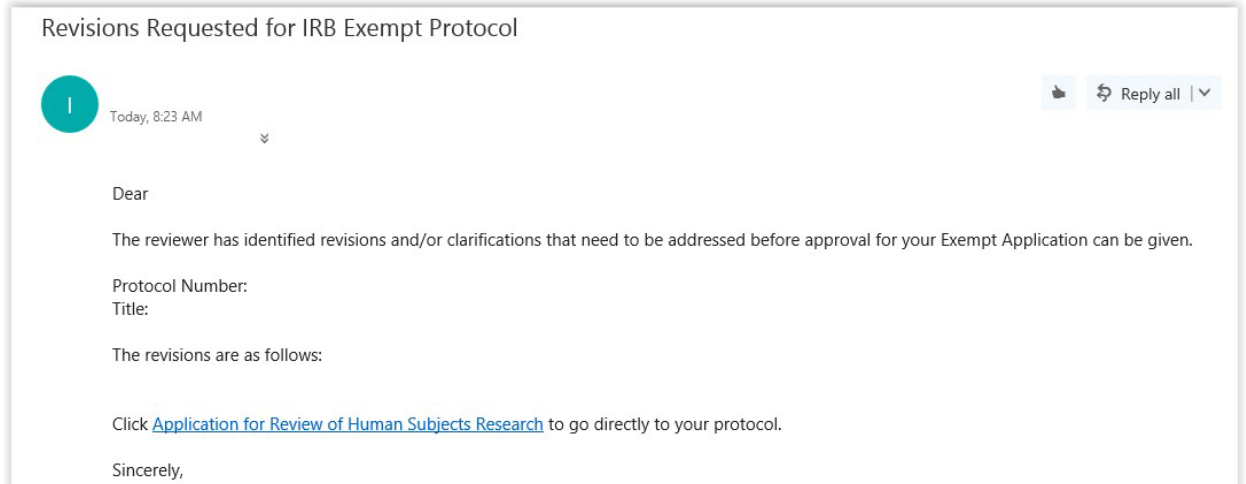
3. Once logged into IRBManager you can find your IRB application which needs attention under the xForms heading and click on the xForms next to "awaiting your attention".

xForms (16 Active)

o You have **9 unsubmitted** xForms.
o You have **7 xForms** being processed at a later stage.
o There are **4 xForms** awaiting your attention.
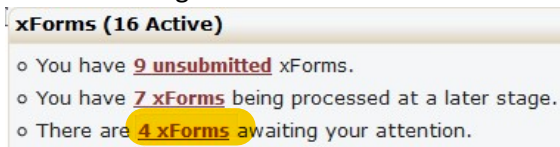
4. Next, you will select the application which needs attention from the list.
5. You can easily locate any question which need attention by looking for any blue boxes as shown below.

Submitter   Add Note   View Audit

Entered: 10/25/17   ✗

Please add your phone number here.

Temp, User 1

Email:

Date
10/23/2017

You see a list of questions which need to be addressed by clicking on the button [View Questions with Notes] located at the bottom of the page.

View Attachment Questions
View Questions with Notes
View Changed Responses

Next   Save for Later   More ▸   View as PDF

6. Once you have addressed each of the questions you may resubmit the application.

SUBMITTING A CONTINUING REVIEW PROGRESS REPORT

You will complete a Continuing Review Progress Report form in order to extend your IRB approval date. This form must be submitted at least two weeks in advance for Expedited Review or by the Full Board deadline prior to your expiration date for Full Board studies. Please follow the instruction below in order to complete this process.

1. From the Dashboard under the section titled "My Studies", click on the study you wish to complete a continuation form.

My Studies (1 Active)			
Study ▼	Site ⬍	PI ⬍	
2017-006-K-12 School	K-12 School		

2. Next, you will see details pertaining to the study you selected displayed.

Actions

Send EMail
Start xForm
xForms (0)

Done

3. On the left-hand-side of the screen, under the heading "Actions", click on "Start xForm".
4. Next, click on "Continuing Review Progress Report", in order to start your Form for the IRB application you are within.

Select xForm to start	
Action	Form (Click to start) ▼
🖨	Continuing Review Progress Report or Study Closure
🖨	Modification
🖨	Reportable New Information

5. Work through each section of the IRB Continuation form.
6. After you have addressed each section of the IRB Continuation form you must click on the button [Submit] in order to submit your form to the IRB Office.

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

Save for Later   Print   Submit

7. You will be notified via email of any corrections and once the continuation has been approved.

SUBMITTING A MODIFICATION

You will complete a Modification form if you need to make any changes to your approved IRB. Please follow the instruction below in order to complete this process.

1. From the Dashboard under the section titled "My Studies", click on the study you wish to complete a continuation form.

My Studies (1 Active)			
Study ▼	**Site** ◆	**PI** ◆	
2017-006-K-12 School	K-12 School		

2. Next, you will see details pertaining to the study you selected displayed.
3. On the left-hand-side of the screen, under the heading "Actions", click on "Start xForm".

   Actions

   Send EMail
   Start xForm
   xForms (0)

   Done

4. Next, click on "Modification, in order to start your form for the IRB application you are within.

Select xForm to start	
Action	**Form (Click to start)** ▼
🖨	Continuing Review Progress Report or Study Closure
🖨	Modification
🖨	Reportable New Information

5. Work through each section of the IRB Modification form.
6. After you have addressed each section of the IRB Modification form you must click on the button [Submit] in order to submit your form to the IRB Office.

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

   Save for Later   Print   Submit

7. You will be notified via email of any corrections and once the modification has been approved.

SUBMITTING A REPORTABLE EVENT

If you need to submit a reportable event pertaining to an unanticipated problem or adverse event that has occurred as part of your research project.

1. From the Dashboard under the section titled "My Studies", click on the study you wish to complete a continuation form.

My Studies (1 Active)			
Study ▼	Site ◆	PI ◆	
2017-006-K-12 School	K-12 School		

2. Next, you will see details pertaining to the study you selected displayed.
3. On the left-hand-side of the screen, under the heading "Actions", click on "Start xForm".

Actions

Send EMail
Start xForm
xForms (0)

Done

4. Next, click on "Reportable New Information", in order to start your form for the IRB application you are within.

Select xForm to start	
Action	Form (Click to start) ▼
🖨	Continuing Review Progress Report or Study Closure
🖨	Modification
🖨	Reportable New Information

5. Complete the IRB form.
6. After you have addressed each section of the form you must click on the button [Submit] in order to submit your form to the IRB Office.

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

Save for Later   Print   Submit

7. You will be notified via email of any corrections and once the reportable item has been acknowledged.

CLOSING OUT AN IRB APPLICATION

You will complete a Study Closure form when all study procedures have come to an end. Please follow the instructions below in order to complete the Study Closure form.

1. From the Dashboard under the section titled "My Studies", click on the study you wish to complete a continuation form.

Study		Site		PI	
2017-006-K-12 School	▼	K-12 School	◆		◆

My Studies (1 Active)

2. Next, you will see details pertaining to the study you selected displayed.
3. On the left-hand-side of the screen, under the heading "Actions", click on "Start xForm".
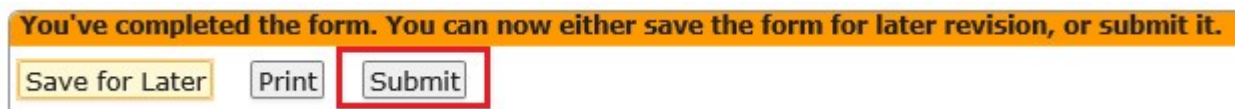
Actions

Send EMail
Start xForm
xForms (0)

Done
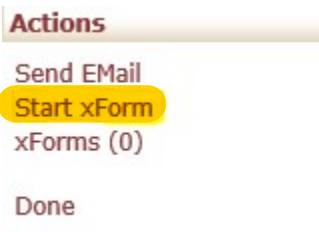
4. Next, click on "Continuing Review Progress Report or Study Closure," in order to start your form for the IRB application you are within.

Select xForm to start

Action	Form (Click to start) ▼
🖶	Continuing Review Progress Report or Study Closure
🖶	Modification
🖶	Reportable New Information

5. Complete the Study Closure form and ensure that your study meets the criteria for closure.
6. After you have addressed each section of the Study Closure form you must click on the button [Submit] in order to submit your form to the IRB Office.

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

Save for Later   Print   Submit

7. You will be notified via email of any corrections and once the closure has been approved.

WITHDRAWING AN IRB APPLICATION

If you need to withdraw your already submitted IRB application you will need to contact the IRB Office via email chsirb@okstate.edu.

ACCESSING YOUR APPROVED STAMPED DOCUMENTS

You can access attached documents and any IRB Office generated documents such as approval letters and stamped consent forms by following the instructions below.

1. From the Home screen, click on the active studies link shown below.

2. Click on the study you wish to access approved and stamped documents.

3. Next, under the heading "Events", located at the bottom of the screen, you will see details pertaining to the study you selected displayed. Click on the # next to the heading you wish to view the attachments. For example: the initial submission shown in the image below has 4 attachments. You can click on "4" to view these attachments.

4. From the attachments screen you can download each attachment listed for your review.

5. Attached documents will be listed under "Attachments" and any IRB Office generated documents will be listed under "Generated Docs".