NORTH TEXAS REGIONAL IRB

North Texas Regional IRB

Office of Research Compliance

IRBNet User Manual

IRBNet User Manual

The IRB Office for the North Texas Regional IRB is pleased to announce the adoption of the industry leading IRBNet suite of tools, bringing electronic protocol management, on-line submissions and many other important research oversight features to our research community.

This user manual is designed to assist investigators and study teams in the use of IRBNet. You will find step by step instructions for registration, initial project submission and amendments. Thank you to the University of Southern Indiana for allowing us to use their manual to format and structure this document.

For additional questions, or if you encounter any problems, please contact the following persons:

Tania Ghani, MS, CIP
Assistant Director,
North Texas Regional IRB
Tania.Ghani@unthsc.edu
817-735-2038

Itzel Peña Pérez, MS, CIP
Assistant Director,
North Texas Regional IRB
Itzel.Pena@unthsc.edu
817-735-0673

For John Peter Smith Health Network (JPS) researchers: Prior to uploading the protocol into IRBNet, please ensure that the JPS feasibility assessment form has been submitted and evaluated by the JPS Office of Clinical Research (ORC). Contact persons for JPS:

Melissa Acosta, PhD
MAcosta02@jpshealth.org
(817) 702-5913

Andrew Adorboe
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(817) 702-5156

Somer Blair, PhD
(JPS feasibility form)
sblair@jpshealth.org
(817) 702-8253

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I. Registering with IRBNet

1. Navigate to http://www.irbnet.org

2. Look for the login box, located in the upper right portion of the website.

3. Click on **New User Registration.**

4. Fill in the information necessary to create your account, then click continue.

Registration

New User Account Information

All users must be REGISTERED to access IRBNet. Registration is free.

The first step is to enter your basic account information and create your IRBNet Username and Password.

First Name *	
Last Name *	
Username *	
Password *	
Confirm Password *	
Password Hint	

Continue   Cancel

* required fields

5. Review and accept the Terms of Use.

IRBNet: Individual User Terms of Use

To register on IRBNet, you must read and agree to these Terms of Use, including any future amendments (collectively, the "Agreement").

1. **Acceptance of Terms.**

This Agreement governs your participation as an individual user of IRBNet. IRBNet is a service provided by Research Dataware, LLC and both the company and service name are used interchangeably in this Agreement. In addition, when using particular IRBNet owned or operated services, you shall be subject to any posted guidelines or rules applicable to such services which may be posted from time to time. All such guidelines or rules are hereby incorporated by reference into this Agreement. IRBNet may also offer other services that are governed by different Terms of Use.

If this Agreement or any future changes are unacceptable to you, your sole remedy is to terminate your use of the Service. If you do not accept and abide by this Agreement, you may not use the services offered by IRBNet. By accessing or using the Service, you confirm your acceptance of, and agree to be bound by, this Agreement and any future changes to this Agreement. You agree to use the Service only in accordance with this Agreement. Nothing in this Agreement shall be deemed to confer any third party rights or benefits.

2. **Modification of Terms.**

Although we may attempt to notify you via your submitted e-mail address when major changes to the Agreement are made, you should visit this page periodically to review these terms. IRBNet may, in its sole discretion, modify or revise these terms and conditions and policies at any time without notice to you, and you agree to be bound by such modifications or revisions.

3. **Description of Service.**

Accept   Reject

6. Select the appropriate institution, depending on your affiliation (JPS, UNTHSC, UNT Dallas). To do this, type the full name of your affiliation in the **search for an organization** space, then click continue. The example provided here is for a UNTHSC investigator. Click "Continue".

7. Enter your contact information. The e-mail address entered will be the one used to contact you regarding IRB decisions related to your future protocol(s) so make sure it is one you can check OFTEN. Click "Continue".

8. Confirm that all information that you have entered is correct, and confirm that you are listed as a **Researcher** at the appropriate institution (JPS, UNTHSC, UNT Dallas).

Finalize your registration by clicking **Register** when everything is complete.

9. After completing your registration, you will receive an e-mail from IRBNet (see example below). Use the provided link within this e-mail to finalize your registration. After confirming your affiliation, you're all set and ready to submit projects!
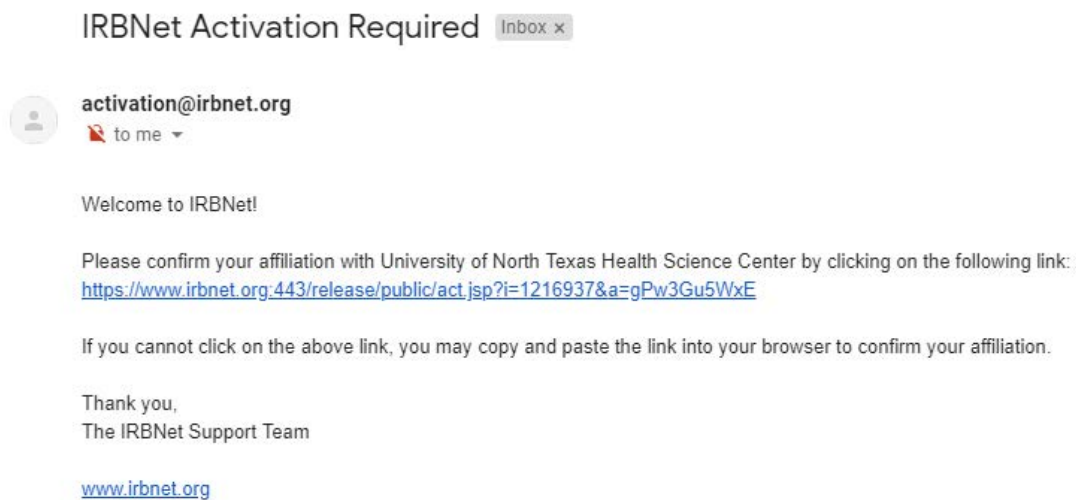
II. Helpful Definitions

1. **Board Documents:** Documents issued by the IRB including stamped study documents, determination letters and IRB findings that are published in IRBNet under "Board Documents".

2. **Locked Package:** When a package is locked, it is being reviewed by the IRB. A package is locked by study teams upon initial submission and when revisions are complete.

3. **Submission:** Any type of project or package sent to the IRB for review.

4. **Package:** Refers to each individual submission for a project. A new package is created when researchers wish to amend / modify their project or submit documents for Continuing Review. When researchers submit a new package, the number after the dash of the IRBNet ID will change. For example, if a researcher is submitting a Modification to add key personnel (see instructions below) for IRBNet ID 123456-1, the IRBNet ID will read 123456-2 for the new package containing the documents.

5. **Pending Review:** Project status indicating that the project is still under review. Until the project has received a determination, the status will inidicate it is pending review.

6. **Project:** Refers to the Project in it's entirety from initial submission, Continuing Review, Amendments, etc.

7. **Unlocked Package:** A package is unlocked when the IRB has requested additional documentation or information or that revisions to the submission / package are required.

8. **Wizard Application Form:** IRB apprication form for a new study. Guidance for completing this document is available in Appendix A (pg. 32).

III. Project Creation

1. Navigate to www.irbnet.org and login using the username and password you created from the previous section. If you have not created an account, please follow the necessary steps in the **Registration** section of this manual.
    Please note that IRBNet sessions will time out. Ensure you are saving changes/refreshing the page frequently in order to avoid losing work.

2. On the left side of the page, select **Create New Project,** under "My Projects."

3. The following screen will appear:

4. Enter the title of the project and your name. If the study is sponsored, please enter the sponsor / funding agency's name in the sponsor box. The keywords box may be useful for you if you have several studies and need to find this study at a later time based upon a specific keyword. Once you have entered this information, click Continue.

5. You will be taken to the Designer page and this screen. The "Read Me First" document will provide IRBNet guidance specific to the North Texas Regional IRB.

6. After reviewing the "Read Me First" document, proceed to "Step 2" of the Designer page to access the Wizard application form. To begin the application form, click "Start a Wizard" (you will need to select "North Texas Regional IRB – New Protocol Application Form" from the drop-down that appears):

For additional information about completing the Wizard application form, please refer to **Appendix A o**f this document.

7. All forms are located in the Library on IRBNet. To download all necessary forms, click on the "Forms and Templates" tab.
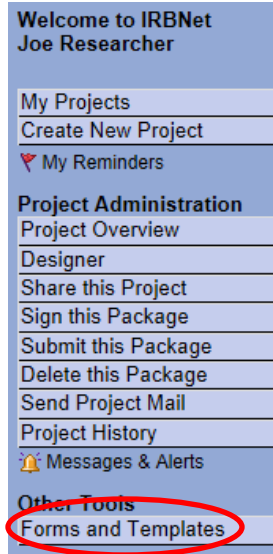
8. You will be taken to this screen:

(NOTE: Actual content in list may differ from what is shown below.)

9. Download any files by clicking the paper icon next to the title, complete all necessary fields, and save to your computer to upload.

10. Make sure you have completed all sections of the IRB Application Form and created all additional, relevant documents that pertain to your research study (e.g. protocol synopsis, consent form, recruitment materials, surveys, etc).

11. Once all necessary forms have been completed, click **My Projects** (left hand menu) and select your current project.

12. Navigate to the **Designer** page to upload application and all supporting documents.
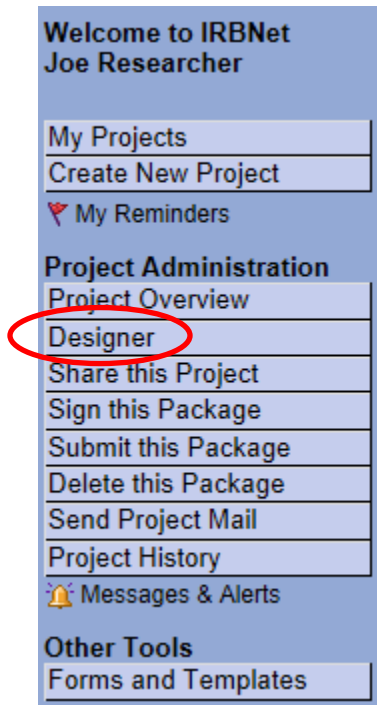
13. Once you click, **Attach a New Document**, you will be prompted to upload a document from your computer.

14. In the Document Type drop-down box, select the appropriate document type.

    Please keep in mind the following when uploading "clean" versions of documents:

    a. Due to the size and placement of the approval stamp, please allow 1.5 inches at the bottom of each page. The stamp will be located at the bottom left-hand side of the page. Please note that this is a pre-determined location and cannot be reformatted or rearranged.

    b. If your document contains images, the IRB recommends submitting PDF "clean" versions in order to minimize the chance that the stamp will alter the formatting of the document.

15. Attach all supporting documents such as protocol synopsis, surveys, interview questions, CITI Training Completion Reports, letter of support, etc. as separate documents and label them as such. Your designer page might look something like this:

Helpful Hint: Provide a descriptive file name for each document in order to facilitate better document management for the study team as well as IRB review. Instructions on how to develop IRB recommended file names are available in **Appendix B.**

Reminder: Please remember to include the appropriate CITI trainings, conflict of interest forms (COIs), CVs, and medical licenses. Researchers can upload CITI training certificates *or* "link" them to the package. Instructions on how to link CITI trainings are located in **Appendix C**.

16. Once all files have been uploaded, you may need to share your study with others. **Please note that PIs must have full access to the IRBNet protocol package in order for it to be reviewed by the IRB.** A PI or study coordinator might also share with other key personnel such as a Co-Investigator, Data Analyst, etc. To share your project with another person, they must be registered with IRBNet.
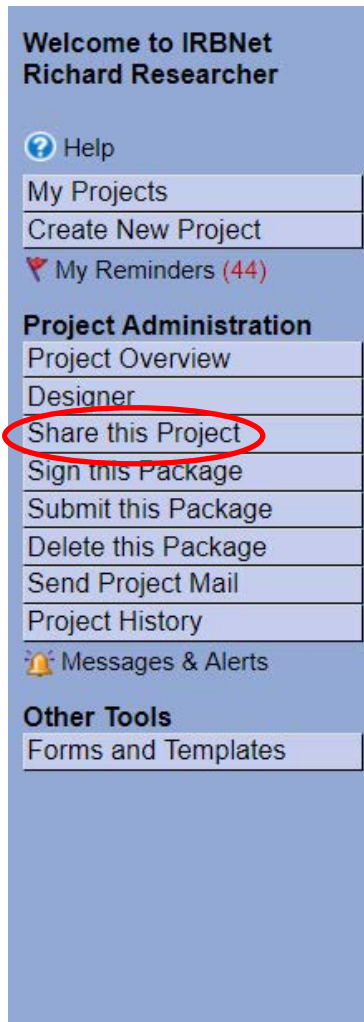*For JPS projects, please ensure the following OCR staff have **full** access to the project:
-Melissa Acosta, PhD
-Andrew Adorboe, MSN, BSN

*For projects involving the Office of Clinical Trials (OCT), please ensure the following have **full** access to the project:
-Vicki Cannon

17. Select the **Share this Project** tab located on the left side of the page.

When considering what type of access to give (full, write, read), please keep in mind the following definitions:

-**Full:** users can perform all functions without restriction (i.e. editing project documents, sharing the project with other users, submitting document packages for review and deleting document package).
-**Write:** users can view and edit project documents, collaborate with other users. They may not grant access to other users, submit packages for review or perform any other administrative functions.
-**Read:** users can view project documentation, communicate with the project team, and add their signature.

18. The following screen will appear. Select the first option to **Share.**

19. The following screen will appear, and you can search for the organization with which the person you would like to share the project with is affiliated. For this example, the person being added is a JPS researcher.

20. Once the organization is selected, you will need to search for the specific user. Users must have their own IRBNet account in order for the system to grant them access. Please note the different sharing levels (described on pg. 15). The North Texas Regional IRB requires that PIs have full access to the project package in order to start the review process.

21. Once the user is found, you may grant appropriate level of access. Within the comments box, you can enter any additional comments that will be included in the e-mail to the specified IRBNet user which notifies them of their new access to your project. Then click **Save.**

As a reminder, PIs must have full access to the project before the IRB will start the review process.

22. PIs must click the **Sign this Package** tab on the left side of the page.
NOTE: Other individuals may sign the package, however, the IRB will not begin the review process if the PI has not signed the package.
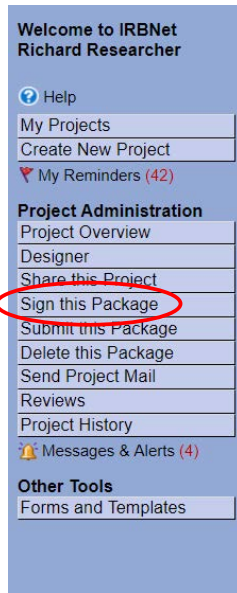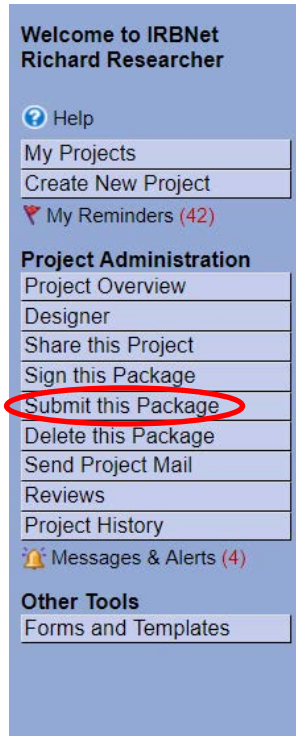
23. Select your role in the project. If you are the principal investigator, select this option from the drop down box.

24. Once you click **Sign,** you will receive a notification from IRBNet that you have signed the package. Anyone else that you selected to share the project with will receive an e-mail notifying them of your signature as well.

Please note that signing the package does not submit it to the IRB. You must also complete the steps to submit the package (described on pgs. 19-20).

25. When you are ready to submit your package to the IRB for review, navigate to the left hand tool bar and select **Submit this Package. Please note the IRB will not have access or be able to review the project if this step is not complete.**

Welcome to IRBNet
Richard Researcher

❓ Help
My Projects
Create New Project
🚩 My Reminders (42)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
🔔 Messages & Alerts (4)

Other Tools
Forms and Templates

The IRB will not proceed with the review of projects that are incomplete, unclear or inconsistent. If any revisions are needed, you will be notified with an email from IRBNet.

Thus, please ensure you have provided all required documents and information prior to submitting to avoid delays in the review process.

26. The page below will appear. Make sure to select **North Texas Regional IRB** and click **Continue.**

IRBNet supports multiple models of review. Using the "Submit" feature, you may electronically submit this document package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and given access to view your electronic documents. Each Board will also be permitted to electronically record their review decision, which will be stored as a permanent part of your project record. You will be automatically notified when the review decision is electronically recorded.

Please select a Board:

Search for an Organization [   ]   [Search]   [Clear]

☑ Only show My Default Boards

Select a Board *

North Texas Regional Institutional Review Board, Fort Worth, TX
North Texas Regional Institutional Animal Care and Use Committee (IACUC), Fort Worth
North Texas Regional Institutional Biosafety Committee (IBC), Fort Worth, TX
North Texas Regional Radiation Safety Committee (RSC), Fort Worth, TX

[Continue]   [Cancel]

* required fields

27. Select **New Project,** from the dropdown box. Feel free to add any comments, which will be included in the email notifying the North Texas Regional IRB that the project has been submitted. When you are ready, click **Submit.**

The following users at **North Texas Regional Institutional Review Board** will be automatically notified of your submission:

Administrator, Louise
Administrator, Gerald

Submission Type: New Project

You may also specify additional comments to be included in this notification.

Your Comments:

Submit   Cancel

28. This will lock your project and the North Texas Regional IRB will be notified of your submission so the review process can begin.

Submit Package

Submission Confirmation - [61395-1] IRBNet Usability Study

This package has been successfully submitted for review.

Submitted by Richard Researcher to Louise Administrator; Gerald Administrator; at North Texas Regional Institutional Review Board, Fort Worth, TX on 02/15/2019.

These users will automatically receive notification of this submission.

Return to the **Project Overview**.

IV. Making Requested Revisions to a project prior to IRB determination

Modifications may be necessary after the IRB has reviewed your initial protocol submission. This section of the user manual will guide you in the necessary steps to submit modifications and any additional information to your project. If modifications are required, you will receive notification in the following ways:

-An email from IRBNet indicating that the package in unlocked. The email will contain a list of the revisions. See below for a screenshot of an example email.

From   mailto:no-reply@irbnet.org]
Sent:
To:
Subject: IRBNet Package Unlocked

Please note that North Texas Regional Institutional Review Board has unlocked the following submission on IRBNet:

Project Title:

Lock Status: Unlocked - Revisions Pending
Date:

Message from

Hi Dr

Thank you so much for submitting the requested revisions.   We have just a few minor changes/clarifications required for approval:

1.   Please indicate under "What security measures will be taken to protect PHI?" (pg. 3 of the protocol) how the master list will be kept secure (i.e. password protected computer which only study personnel will have access to).

2.   The IRB Chair wanted to confirm that "name" would be an adequate identifier to use on the master list since occasionally, participants can have the same name. It is common for researchers to use MRN on the master list (sometimes in addition to name). If you choose to use MRN, please update the protocol to reflect this change. However, if you will only use name, no changes to the protocol are necessary (since this is currently listed in the protocol).

3.   In the ?Potential Risks? section of the protocol (pg. 4), it looks like you describe the risk of medication discrepancies, however the IRB needs you to describe the informational the study poses to the participant. Here?s some example language (feel free to tailor to your project):

"A potential risk includes breach of confidentiality. The master list (containing identifiable data) will be kept on a password protected computer that will only be accessible to study personnel."

4.   Please provide evidence of Human Subject Research Protection training for Dr

Please feel free to call or email with any questions/clarifications.

Sincerely,

Should you have any questions you may contact

Thank you,
The IRBNet Support Team

https://na01.safelinks.protection.outlook.com/?url=www.irbnet.org&amp

-An email from IRBNet indicating that the package is unlocked with instructions on how to access the Board Document in IRBNet (how to access the Board Document is described in the proceeding pages) that will contain the list of IRB findings. See below for screenshot of example email. You will also receive an additional notification indicating that a Board Document has been published.

From
Sent:
To:
Subject: IRBNet Package Unlocked

Please note that North Texas Regional Institutional Review Board has unlocked the following submission on IRBNet:

Project Title:
Principal Investigator:

Lock Status: Unlocked - Revisions Pending
Date:

Message from   :

Hi   ,

Thank you for providing the requested revisions. After reviewing the study with the IRB Chair, the following edits/revisions are required for approval.

In the published Board Document section, please find the list of requested clarifications/revisions (dated   ).

A reminder to make ALL edits in "tracked changes" (or highlight/distinguish the changes in some other manner if tracked changes is not available) and upload this version as well as a clean copy into IRBNet with descriptive titles distinguishing the versions from each other. Please also provide a response to each comment in either a memo (uploaded in this package) or in an IRBNet message.

Note: For any documents that will be revised, please use the edit feature in IRBNet to upload the modified study document (in place of the previously submitted document). All old versions of documents should be removed before the submission is sent back to the IRB.

Please let us know should you have any additional questions.

Sincerely,

Should you have any questions you may contact   .

Thank you,
The IRBNet Support Team

1. In IRBNet, you can access the IRB's requested revisions (and other communication) in the following places:

   a. Under "Messages and Alerts" in the "Package Unlocked" message.
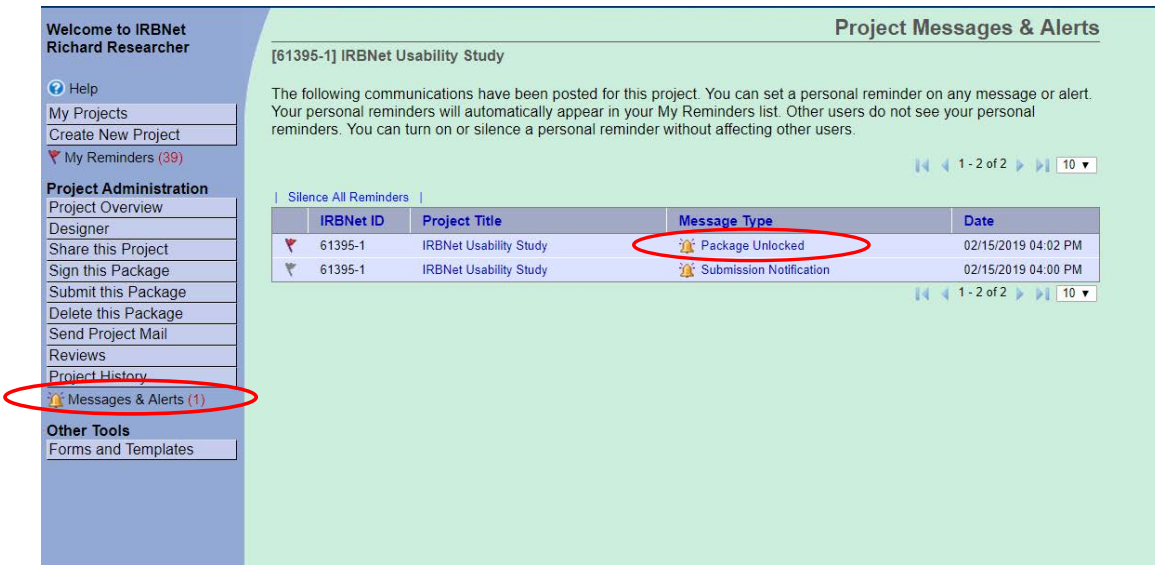
   b. Under "Board Documents" which can be accessed by clicking, "Pending Review".
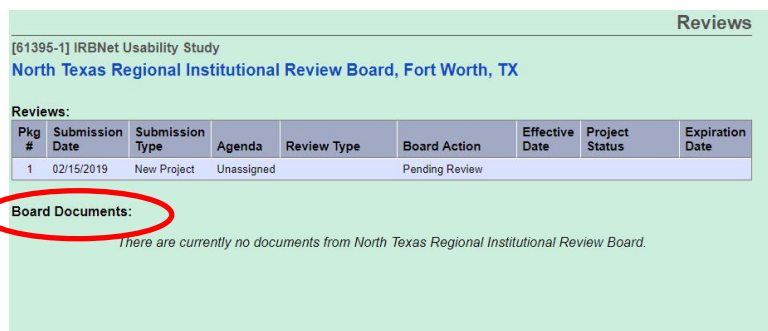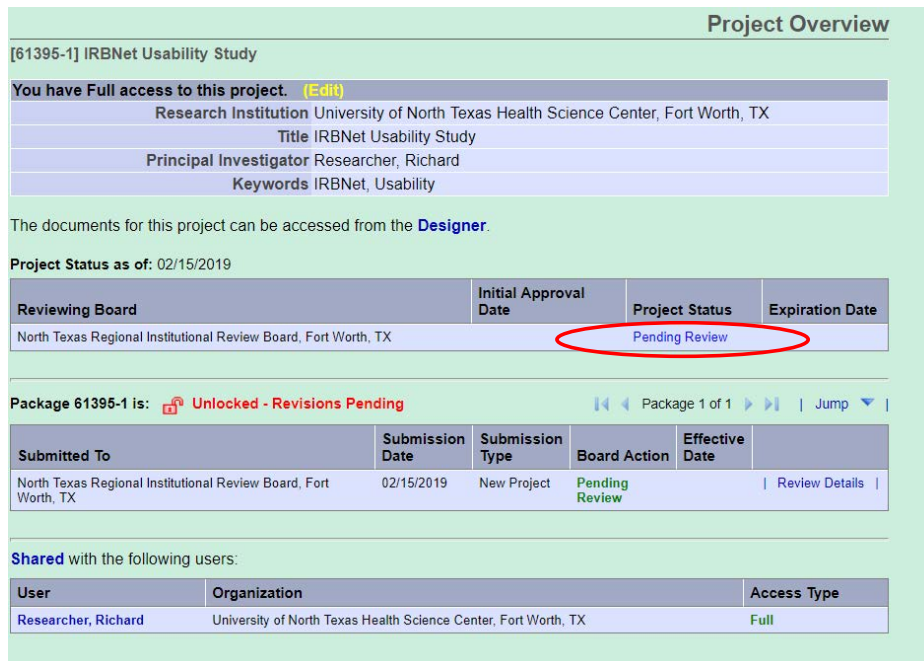
2. To make requested revisions, return to the Designer to edit, upload or delete documents.
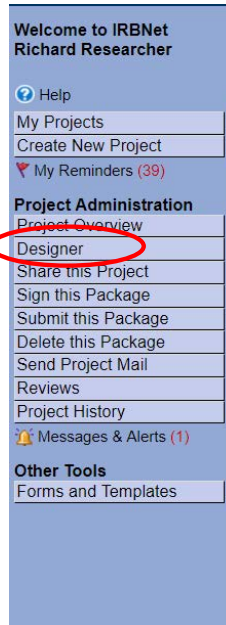
If you are revising a previously submitted document, you can use the edit feature (pencil icon) in IRBNet to upload a modified study document (in place of the previously submitted document). Please note that you will need to download the document on your computer, revise in appropriate program (i.e. Microsoft Word, Adobe, etc.) and re-upload as IRBNet cannot save edits to documents already uploaded. If you are uploading a new document (i.e. something requested by the IRB or a tracked changes version), use "Attach New Document".

3. Once all appropriate/requested changes are made, click **Mark Revisions Complete** to resubmit the revised submission. Keep in mind that your project will be locked and you will be unable to make any further changes after **Mark Revisions Complete** is clicked. If additional revisions are needed, follow steps 1-3.

4. Upon completion of review you will receive a notification from IRBNet to the email provided at registration and can view the determination letter by clicking **Review Details** on the Designer page.

5. When your study receives an IRB Determination, you can download the determination letter and stamped documents (if applicable) from the Board Documents section of the project, which can be accessed from the Designer page or "Review Details" (as described above). Once the project has received a determination, it will be locked and unable to edit. Please see the next chapter for how to proceed after recieving a determination.

Board Documents:

Document Type	Description	Last Modified	View
Approval Letter	Approval Letter	02/15/2019 04:50 PM	
Stamped Document	Consent Waiver - Waiver of Documentation of Informed Consent.docx (stamped)	02/15/2019 04:51 PM	
Stamped Document	Consent Form - Research Statement.docx (stamped)	02/15/2019 04:51 PM	
Stamped Document	Questionnaire/Survey - Electronic Submission Manager Survey.docx (stamped)	02/15/2019 04:51 PM	
Stamped Document	Protocol - Protocol-Synopsis-for-Research-Involving-Surveys_IRBNet Usability.doc (stamped)	02/15/2019 04:51 PM	

V. How to Proceed After Receiving an IRB Determination

As mentioned above, there are several Determinations that can be issued by the IRB. Please review the table below for guidance on how to proceed with each Determination.

Determination	Next Steps

Approved	• No further action needed unless the PI needs to submit one of the following:
	   o Continuing Review materials (if / when applicable)
	   o A request for an amendment/modifications
	   o A SAE report
	   o Protocol violation / non-compliance reports
	   o Or other project-related information

Exempt	• No further action is needed unless the PI wants to modify the study • All requests for modifications (including changes the Key Personnel) should be submitted to the IRB by using the "Create New Package" activity (see Section VI of this manual)
Approved with Modifications	• Review the IRB's findings provided in the Determination letter(found in "Board Documents") • Address the comments by "Creating New Package" (see Section VI of this manual) o Classify the package as "Response/Follow Up" when asked for "Submission Type" (toward the end of the submission process) • Upload new/modified documents (track change / clean versions) • Upload a memo signed by the PI **OR** the PI can submit a project mail message (in IRBNet that describes how the PI has addressed all of the IRB's findings • Submit to notify the IRB the package is ready for review • If all comments are addressed, the IRB will issue a Board Action/Approval Letter and stamp all relevant documents
Deferred	• Review IRB findings provided in the Determination (found in "Board Documents") • Address the IRB's comments and findings by "Creating New Package" (see Section VI of this manual) o Classify the package as "Response/Follow Up" when asked for "Submission Type" (toward the end of the submission process) • Upload ALL study documents to prepare for next IRB meeting • Please include a memo signed by the PI that describes how the PI has addressed all of the Board's findings • Submit to notify the IRB the new package is ready for review
Disapproved	• The IRB's reasons for disapproval will be included in the Determination letter (found in Board Documents) • If you would like to submit a new, different project, please do so by creating a new project in IRBNet. *No new packages should be submitted for projects that are Disapproved.*
Not Human Subjects Research	• No further action is needed unless the project develops into a systematic research investigation or intervention (e.g., data originally collected for non-research purposes used for research analysis), please contact the North Texas Regional Institutional Review Board for appropriate guidance and review *before* initiating any research activity. • All requests for modifications (including changes to Key Personnel) should be submitted to the IRB by using "Create New Package" (see Section VI of this manual)
Withdraw	• To withdraw a project, the PI must notify the IRB through a message in IRBNet

VI. Next Steps: Modifying a Project that has Received a Determination

After receiving a determination, a few different scenarios will apply. As discussed in the previous section, how to proceed will vary based on the determination. This section will guide you on how to "Create a New Package".

There are several situations in which researchers would want to "Create a New Package". They include:

- Amending/Modifying a Project (i.e. adding key personnel, updating study documents)
- Responding to modifications when a project has been Deferred or Approved with Modifications
- Submitting a Continuing Review
  1. Login to www.irbnet.org using your username and password.
  2. Select **My Projects** on the left side of the screen.

3. Select the project you wish to modify.

4. Once you click into the study, click on the **Create a New Package** tab.

5. Proceed with attaching new documents or editing previously approved
documents. Note that IRBNet tracks new packages by updating the number
after the dash. In this case, "-2" indicates this is the second package.

6. When all necessary documents have been uploaded, click **Sign this Package** on the left hand side of the screen. This process will be the same as when you initially submitted a new project.
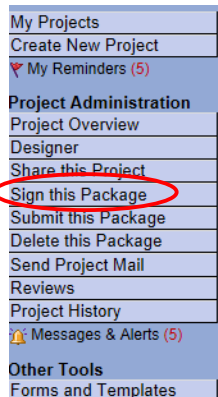
7. Once signed, click Submit this Package on the left hand side of the screen. This process will be the same as submitting a new project with the exception of selecting the appropriate "Submission Type". "Response/Follow-Up" should be used in situations where study teams are responding to feedback from the IRB when a project is Deferred or Approved with Modifications. "Amendment/ Modification" should be used in situations where study teams are modifying the study documents, changing key personnel, etc. after the project has received initial approval.

8. Make sure **North Texas Regional IRB** is selected and click **Continue**.

9. This will lock the package and the North Texas Regional IRB will be notified of your submission so the review process can begin.

Submit Package

Submission Confirmation - [61395-1] IRBNet Usability Study

This package has been successfully submitted for review.

Submitted by Richard Researcher to Louise Administrator; Gerald Administrator; at North Texas Regional Institutional Review Board, Fort Worth, TX on 02/15/2019.

These users will automatically receive notification of this submission.

Return to the **Project Overview**.

Appendices
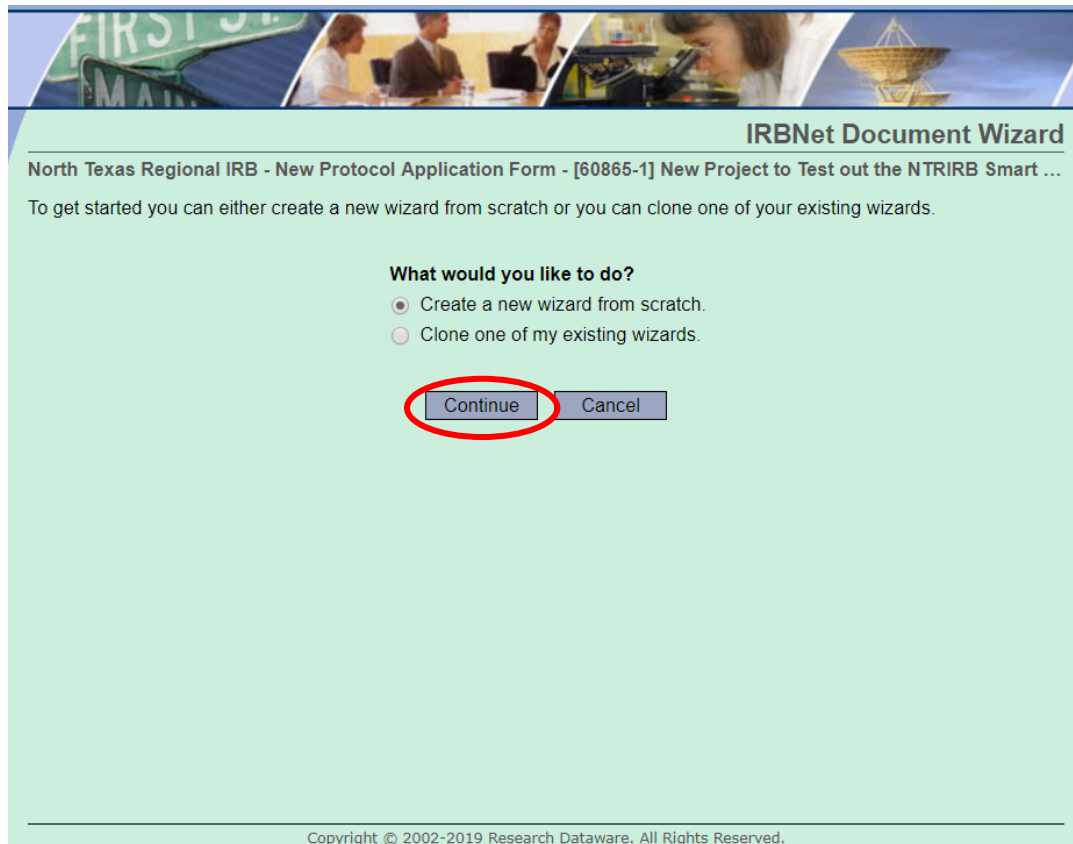
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A. How to Complete the Wizard Application Form in IRBNet:

1. If this is the first project you are submitting in IRBNet, select "Create a new wizard from scratch".

   If you have submitted a previous project using the Wizard application form, you can "Clone one of my existing wizards" to copy information from a previous submission. The IRB recommends cloning forms only when creating similar types of studies.

   For this example, we will "Create a new wizard from scratch", then select "Continue".

2. You will be taken to the Introduction page. Please follow the instructions provided, then click "Next":

3. Please fill in the applicable information about the principal investigator (PI):

4. If the Principal Investigator is the study coordinator/contact person for the study, please select "Yes". After hitting "Next", you will be taken to the "Additional Research / Key Personnel Information" page.

However, if the PI is *not* the study coordinator/contact person, please select "No". After hitting, "Next", you will be taken to the "Study Coordinator / Contact Person" page.

5. Please provide information about other pertinent Research/Key Personnel. The IRB recommends listing *only the main personnel* in the Wizard application form and providing a complete list of research personnel in the protocol synopsis, as this will prevent the need to update the form whenever there is a key personnel change in your study:

6. The Wizard application form will guide you through questions about the study. Based on answers to certain questions, the Wizard application form will generate the appropriate additional pages that need to be completed. Not all of the additional pages will be generated for every project.

a. First, you will be asked to provide information about the project's Funding Source(s). Please note that you may select multiple funding sources, as applicable.

b. Listed below are all of the possible "funding source" options, which are followed by the type of information that will be requested on the subsequent page after you click "Next".

Funding Source

- Federal Agency → Specific Insitute and specific award number
- Pharmaceutical / Device Company / Sponsor → Specific sponsor and protocol/grant number
- Industry (Other than Pharmaceutical) → Specifc industry and protocol/grant number
- State / Local Government Funding → Specific state / local funding and protocol/grant number
- Non-Profit Organization → Specifc Sponsor and protocol/grant number
- Institutional Internal Grant Funding Program → Account number and protocol / grant number
- Unfunded Research
- Other funding → Funding source and protocol/grant number

7. In the next section, you will be asked to enter information about the Contract Research Organization (CRO).

    i.   If there is no CRO, enter "Not Applicable"

8. You will then be asked to describe the purpose of the study. The IRB recommends keeping the purpose brief, as you will still need to submit a detailed protocol synopsis, or site-specific protocol information. However, please note there is no character limit on this page.

9. The Project Information page will ask you to provide information about Certificate of Confidentiality, the subject population to be included in the study, recruitment of subjects, and any waivers being requested.

10. On the next page, you will select the Type of Review, which will be followed by a page that asks you about the Type of Research Project. Your selections on these pages will generate the information that is requested on subsequent pages. The screenshots and charts (below) outline the type of information that will be requested, based on your responses.

11. The Type of Research Project section will ask you to indicate if this is an Investigator-Initiated Study, Student / Resident Research Project, or a Clinical Trial.

12. Then, you will be asked if the study is subject to FDA Regulations. Please note this page will appear regardless of the type of review or type of research project selected.

13. The Wizard application form will then request the location where the research will be taking place. Please note this page will appear regardless of the type of review or type of research project selected.

14. Following the Research Locations, the form will ask if other IRBs are involved in the approval of the project. Please note this page will appear regardless of the type of review or type of research project selected.

15. Based on your responses to items 16 & 17 above (Type of Review & Type of Research Project pages), a series of questions will appear for you to complete.

a. For example, if "Full Board Protocol" is selected (on the Type of Review page) followed by "Investigator Initiated" (on the Type of Research Project page), the following pages will be generated:
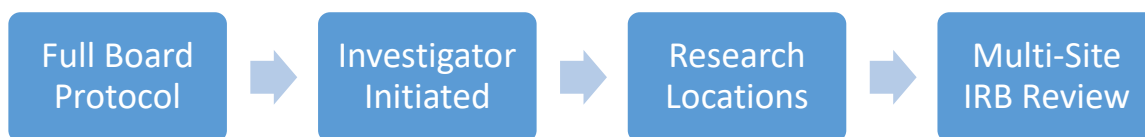
b. If "Full Board Protocol" followed by "Clinical Trial" is selected, the following pages will be generated:

Full Board
•Full Board Protocol

Clinical Trial
•ClinicalTrial.gov posting information

Is the study FDA Regulated?
•If yes, is this a drug trial?
•If yes, phase and information pertaining to the drug will be requested.

Is this study a device trial?
•If yes, information about the device will be requested.
•Is the device a Humanitarian Use Device?
•If yes, information about the Humanitarian Use Device will be requested.

Some screenshots relevant to FDA studies are provided below. Note: These will only generate if you have previously selected "Yes," when asked if the study is regulated by the FDA.

c. If the "Type of Review" selected is "Exempt", subsequent pages will ask for information related to risk and category. See the graphic below for an example scenario:
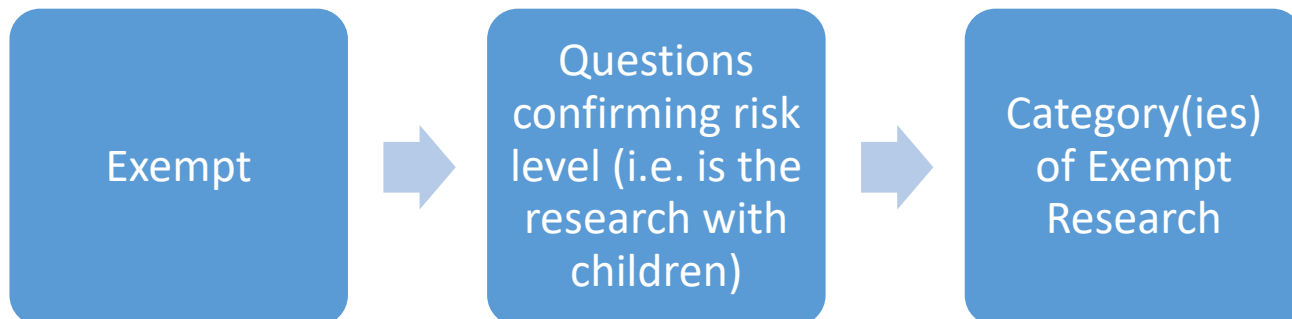
Based on the category(ies) that you select, the subsequent page (or pages, depending on your selection) will generate. You will need to complete the information on these subsequent pages as applicable.

Exempt Review Category example screenshot:

Exempt Review Category example screenshot (Cont.):

d. If the "Type of Review" selected is "Expedited", subsequent pages will ask for information related to category and type of study. See the graphic below for an example scenario:

Based on the category(ies) that you select, the subsequent page (or pages, depending on your selection) will generate. You will need to complete the information on these subsequent pages as appropriate.

Expedited Review Category example screenshot:

Expedited Review Category example screenshot (cont.):

16. The Biological Information page will ask if the study involves Human Specimens Storage. If so, provide a description in the required field (Note: there is no character limit in this field).

17. Signature and Investigator Responsibilities: This page will appear for all studies. The PI/investigator should read this page, and ensure they understand each item as written (or contact IRB staff with any questions). Clicking "Next" will take you to the last page of the application form.

REMINDER: Please note that there will not be a specific place in this section/page to provide an electronic, or physical signature. **Therefore, the Principal Investigator (PI) must electronically sign the submission package in IRBNet before the project is formally submitted to the North Texas Regional IRB.** This will require the PI to log into IRBNet and sign the package.

18. The last page includes instructions and a list of all applicable documents/forms that need to be submitted in IRBNet in addition to the study application. The items on this page generate based on the investigator's responses within the Wizard application form (NOTE: If the investigator goes back to previous sections of the form and makes any revisions that affect the items included in this list, the listed items will change based on the revised responses):

19. Once the investigator hits the "Save/Exit" button, they will be taken back to the Designer page.

20. On the Designer page, the Wizard application form (titled "North Texas Regional IRB – New Protocol Application Form") will now appear as a new document in the package:
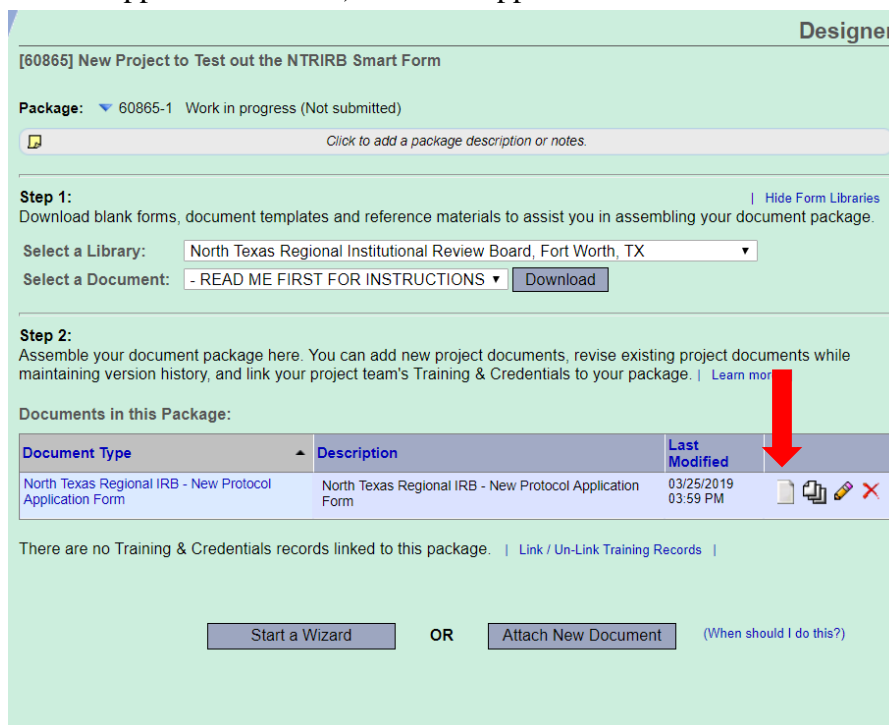
21. By clicking the "View this Document" button (document icon, as shown in screenshot above), the investigator can download a PDF version of their completed Wizard application Form.
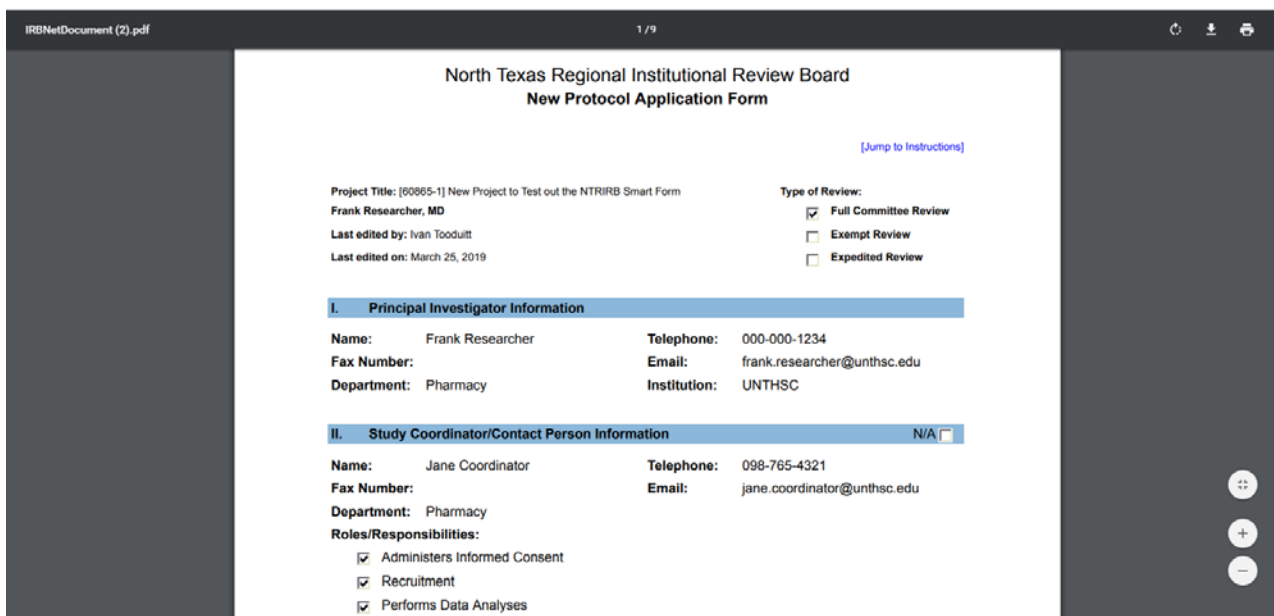
22. Note that throughout the application form, you have the option to "Jump" to another section.

a. Click the drop down, select the section you wish to visit, and select "Jump".

B. Developing Descriptive File Names

Packages will more than likely contain multiple documents and additional documents will be added throughout the review process. In order to facilitate IRB review, it is important to select the appropriate "Document Type" and enter clear, descriptive titles in the "Description" field. description. The IRB recommends the following elements be included as part of the title:

-Title or Type of document
-Language (if applicable)
-Track change or clean (if applicable)
-Date of revision or version (if applicable)

For trainings and COIs, the IRB recommends:

-Title of training
-First initial and last name of key personnel to which the training belongs.

| Type of Document	Example of Document	Description Example
Protocol Synopsis	• Protocol Synopsis for Research Involving Human Subjects • Protocol Synopsis for Research Involving Chart Review • Protocol Synopsis for Research Involving Surveys	Protocol – clean Protocol – track change – V. 4
Consent Form	• Consent Form • Consent Script • Cover Letter	Consent Form – clean Consent Script – track change – English Consent Script – clean – Spanish – V.3
Consent Waiver	• Waiver of Informed Consent • Waiver of Documentation of Informed Consent	Waiver of Informed Consent – clean Waiver of Documentation of Informed Consent – track change
HIPAA Consent / Authorization	• HIPAA Research Authorization	HIPAA Authorization – clean HIPAA Authorization – track change
Advertisement	• Recruitment ad • Recruitment flyer	Recruitment flyer – clean Recruitment flyer – clean Recruitment flyer – track change – English Recruitment flyer – clean – Spanish
Questionnaire / Survey	• Pre-screening questionnaire • Survey • Questionnaire	Pre-screen – clean MMSE – clean – English Dietary questionnaire – tracked change
Data Collection Sheet	• Any document that describes what data will be collected as part of the project	Oncology Study Data Collection Sheet Pulmonology Chart Review Data Collection Sheet
Training / Credentials	• Protection of Human Subjects training • Good Clinical Practices training • Conflict of Interest Declarations	CITI training – RResearcher COI Disclosure - RResearcher

C. Linking CITI Training to User Profile

IRBNet can link your CITI training to your User Profile, which, in turn, can be linked to individual projects. To do this, follow the screenshots below.
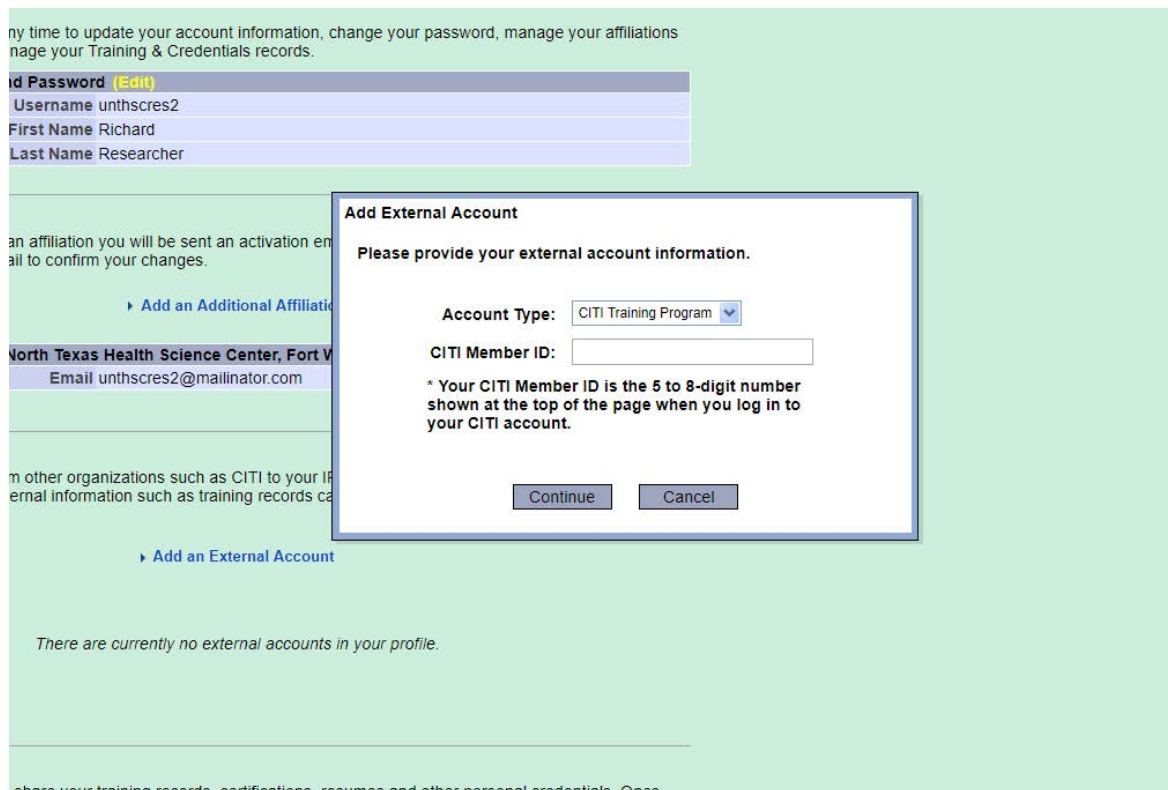
1. After logging in, select "User Profile" at the top of the page.
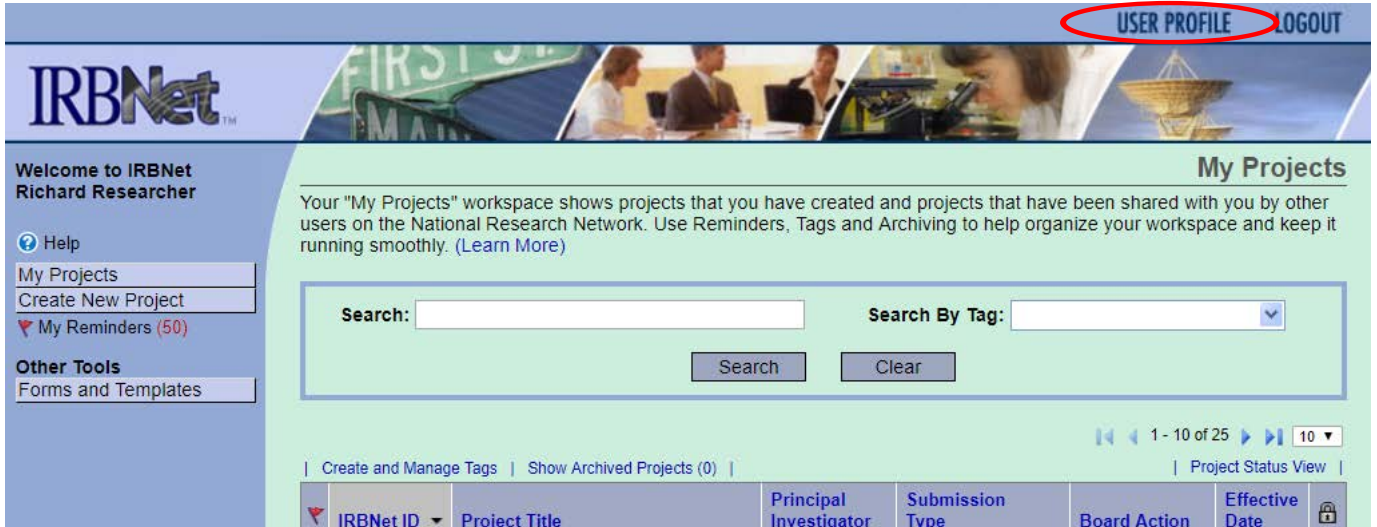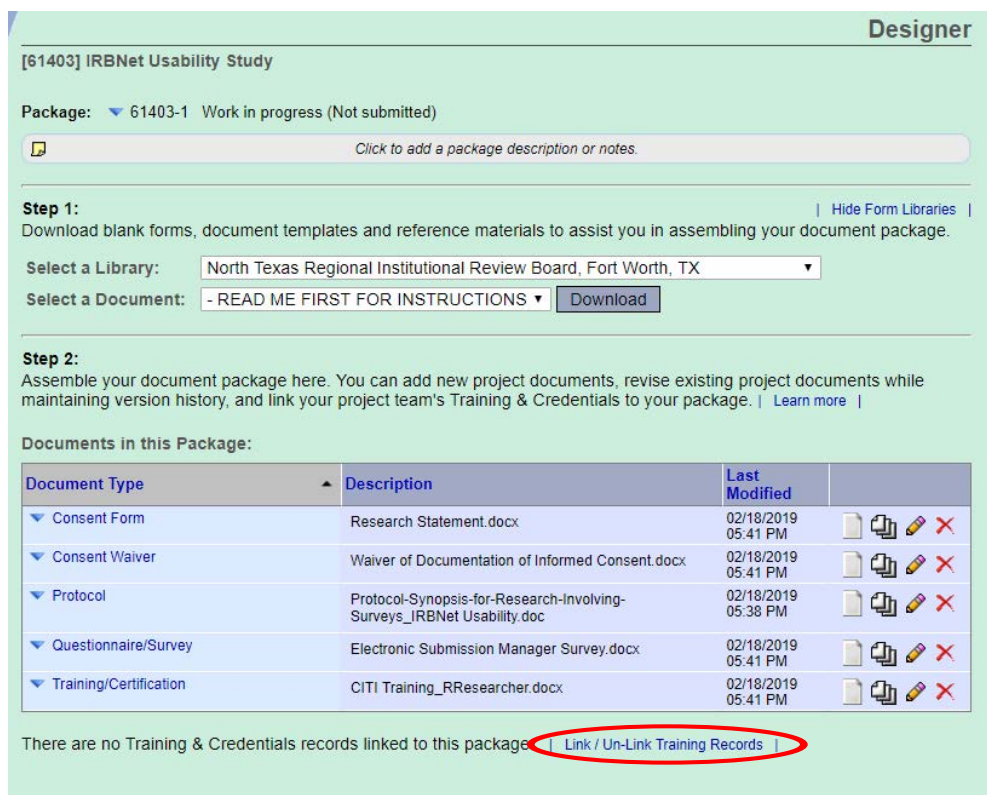

2. In your "User Profile", find the "External Accounts" section. Click "Add an External Account".
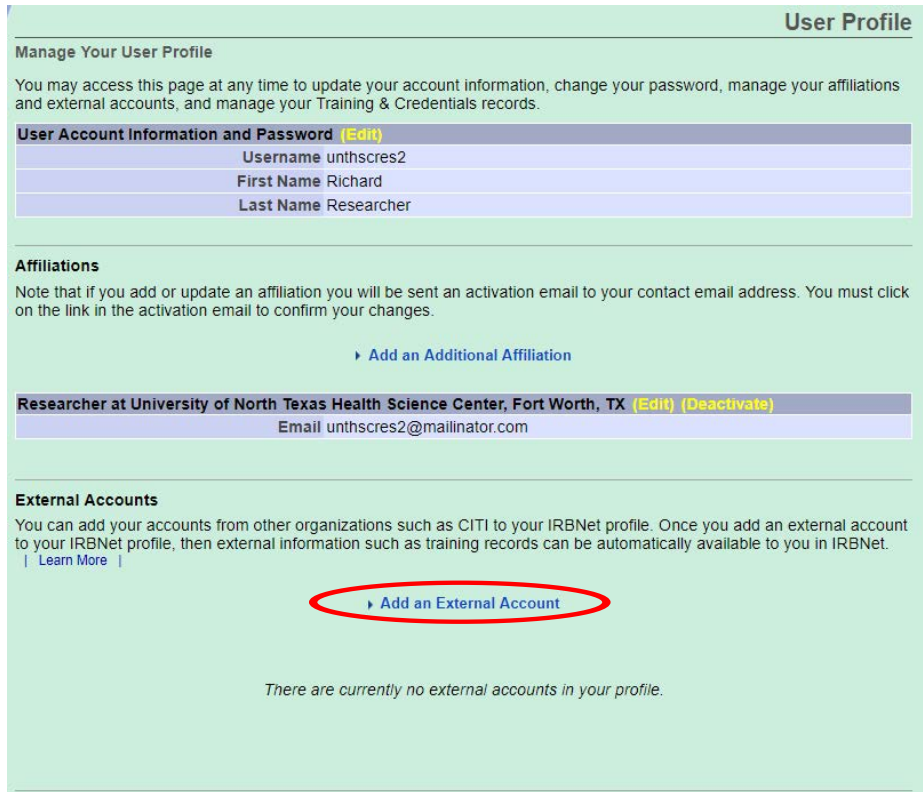
3. The system will prompt you to insert your CITI Member ID.

4. After linking your CITI account, you can link your credentials to individual projects by navigating to the Designer page and selecting **"Link / Un-Link Training Records"**.

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North Texas Regional IRB

IRBNet User Manual

We hope you find this manual useful in submitting your projects to the IRB.

Thank you to the University of Southern Indiana for allowing us to use their manual to format and structure this document.