



North Texas Regional IRB

Office of Research Compliance

IRBNet User Manual



North Texas Regional IRB

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
aadorboe@jpshealth.org
(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>

The screenshot shows the IRBNet website homepage. At the top left is the IRBNet logo with the tagline "Innovative Solutions for Compliance and Research Management". To the right is a login box with fields for "Username" and "Password" and a "Login" button. Below the login box are links for "New User Registration" and "Forgot Your Password?". A navigation menu below the header includes "Home", "The IRBNet Difference", "Demo", "Contact Us", and "FAQ". The main content area features a "Comprehensive Solutions" section with a photo of people in a meeting, followed by three sub-sections: "The Industry's Most Complete Solution", "Flexible, Intuitive and Easy to Use", and "Secure, Reliable and Cost-Effective". On the right side, there is a "Test Drive IRBNet" section with a "Demo" button, a "Satisfied Members" section with a quote from Bruce Day, Director of Research Integrity at Marshall University, and a "2014 Events - Join Us" section.

2. Look for the login box, located in the upper right portion of the website.
3. Click on **New User Registration**.

This is a close-up screenshot of the login box from the IRBNet website. It shows the "Login:" label, the "Username" and "Password" input fields, and the "Login" button. Below the input fields, the "New User Registration" link is circled in red, along with the "Forgot Your Password?" link.

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

The registration form is titled "Registration" and "New User Account Information". It contains the following fields: "First Name *", "Last Name *", "Username *", "Password *", "Confirm Password *", and "Password Hint". Below the fields are "Continue" and "Cancel" buttons. A red circle highlights the "Continue" button. A legend at the bottom left indicates that fields with an asterisk are required.

5. Review and accept the Terms of Use.

The page is titled "IRBNet: Individual User Terms of Use". It contains the following text: "To register on IRBNet, you must read and agree to these Terms of Use, including any future amendments (collectively, the 'Agreement')." Below this is a scrollable area containing three sections: "1. Acceptance of Terms.", "2. Modification of Terms.", and "3. Description of Service.". At the bottom of the scrollable area are "Accept" and "Reject" buttons. A red circle highlights the "Accept" button.

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".

Registration

Add Affiliation

Specify the organization with which you are affiliated. If you are affiliated with more than one organization, you may add additional affiliations after you complete the registration process by logging in to IRBNet and accessing your User Profile.

Search for an organization

Organization types to display Research Institutions Boards Sponsors

University of North Texas Health Science Center, Fort Worth, TX

Your Organization *

If you do not see your organization listed you may [add a new organization](#).

* required fields

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".

Registration

Your Contact Information

Specify your contact information at University of North Texas Health Science Center, Fort Worth, TX. The email address that you specify will be used for communications related to University of North Texas Health Science Center projects.

Telephone Number * - - ext.

Fax Number - - ext.

Email *

Verify Email *

* required fields

- 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).

Registration

Confirm Registration Information

Please review your information and click "Register" to complete the registration process. After you have registered, you may update your account information, and add or update affiliations at any time by logging in to IRBNet and accessing your User Profile.

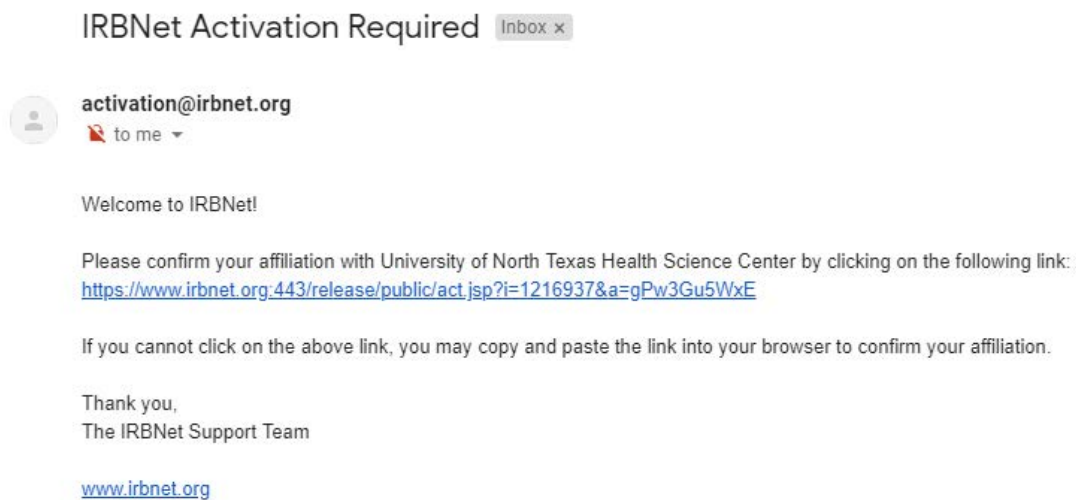
User Account Information and Password (Edit)	
Username	RResearcher123
First Name	Richard
Last Name	Researcher

Affiliations

Researcher at University of North Texas Health Science Center, Fort Worth, TX (Edit)	
Telephone Number	(222) 222-2222
Fax Number	(555) 555-5555
Email	rresearcher@research.net

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

- 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

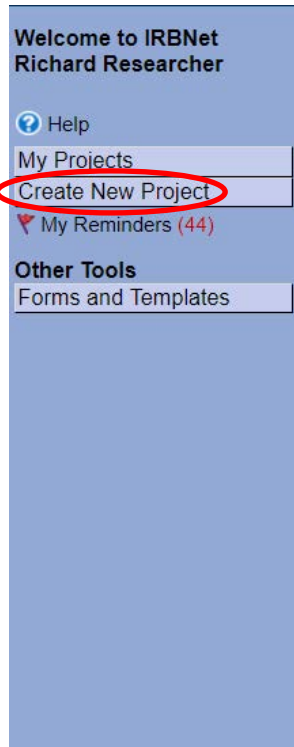
1. **Board Documents:** Documents issued by the IRB including stamped study documents, determination letters and IRB findings that are published in IRBNet under "Board Documents".
2. **Locked Package:** When a package is locked, it is being reviewed by the IRB. A package is locked by study teams upon 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 indicate 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 application 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:

Welcome to IRBNet
Richard Researcher

Project Information

Create a New Project

To create a new project, first provide the basic project information below. Once your project is created you may attach project documentation and share the project with other users.

Research Institution: University of North Texas Health Science Center, Fort Worth, T

Title: *

Local Principal Investigator:

First Name:*

Last Name:* **Degree(s):**

Keywords:

Sponsor:

You may specify an internal account number, billing identifier or reference number for this project.

Internal Reference Number:

* required fields

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.

Designer

[61403] IRBNet Usability Study

Package: 61403-1 Work in progress (Not submitted)

[Click to add a package description or notes.](#)

Step 1: [Hide Form Libraries](#)
Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library: North Texas Regional Institutional Review Board, Fort Worth, TX

Select a Document: - READ ME FIRST FOR INSTRUCTIONS

Step 2:
Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. [Learn more](#)

Documents in this Package:

There are no documents in this package.

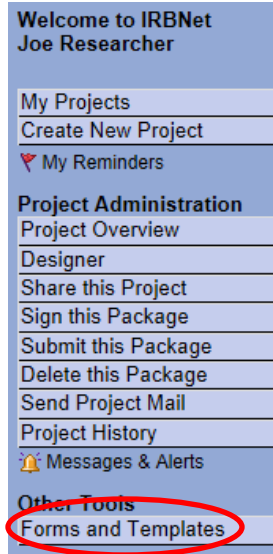
There are no Training & Credentials records linked to this package. [Link / Un-Link Training Records](#)

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):

The screenshot shows the 'Designer' interface for a new project. At the top, it says '[60865] New Project to Test out the NTRIRB Smart Form'. Below this, there's a 'Package' section with a dropdown set to '60865-1 Work in progress (Not submitted)'. A button labeled 'Click to add a package description or notes.' is visible. The main content is divided into 'Step 1' and 'Step 2'. In 'Step 1', there are dropdowns for 'Select a Library:' (set to 'North Texas Regional Institutional Review Board, Fort Worth, TX') and 'Select a Document:' (set to '- READ ME FIRST FOR INSTRUCTIONS'), with a 'Download' button. In 'Step 2', there's a section for 'Documents in this Package:' which is currently empty. At the bottom, there are two buttons: 'Start a Wizard' (circled in red) and 'Attach New Document'. A dropdown menu is open under 'Start a Wizard', showing three options: 'North Texas Regional IRB - New Protocol Application Form' (highlighted in blue), 'Orlando Health - IRB Application', and 'UMCP - IACUC Animal Study Protocol'. A red arrow points to the first option. A text box on the right contains the note: 'Please note that only the “North Texas Regional IRB – New Protocol Application Form” will be available for use.'

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

- All forms are located in the Library on IRBNet. To download all necessary forms, click on the “Forms and Templates” tab.



- You will be taken to this screen:
(NOTE: Actual content in list may differ from what is shown below.)

Forms and Templates

These libraries have been made available to you by your Boards so that you can easily download blank forms, document templates and reference materials to assist you in your work.

Select a Library:

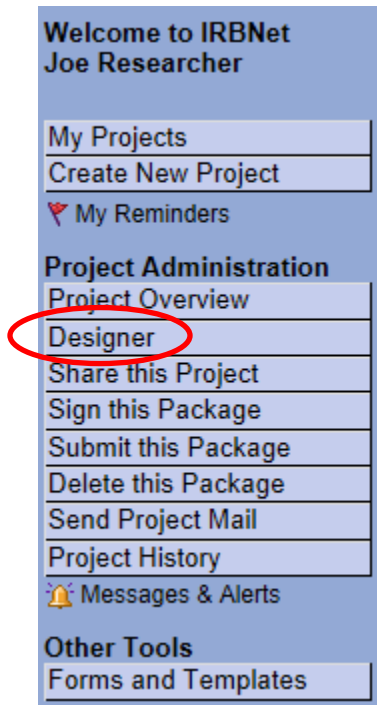
Documents in this Library:

Document Description	Last Updated	
AA.b.Read Me First	11/27/2018 11:16 AM	
Addition of Key Personnel	07/18/2018 06:06 PM	
Biospecimen Protocol Synopsis Form	11/13/2018 01:33 PM	
Case Study Review Form	11/13/2018 01:33 PM	
Chart Review Protocol Synopsis	01/29/2019 11:47 AM	
Conflict of Interest Disclosure Form	07/18/2018 06:08 PM	
Continuing Review Form	11/13/2018 01:38 PM	
Exempt Category Form	01/22/2019 11:14 AM	
Existing Dataset Review Form	11/13/2018 01:51 PM	
Expedited Category Review Form	11/13/2018 01:58 PM	
FDA Checklist	07/30/2018 04:22 PM	
FINAL Report Close-out Form (INVESTIGATOR initiated projects ONLY)	11/13/2018 01:52 PM	
FINAL Report Close-out Form (SPONSORED CLINICAL TRIALS ONLY)	11/13/2018 01:53 PM	
HIPAA Research Authorization TEMPLATE (UNTHSC version)	07/18/2018 06:10 PM	
HIPAA Research WAIVER	01/29/2019 11:47 AM	
Industry-Sponsored Clinical Trials SITE SPECIFIC Information Guidance	07/30/2018 04:23 PM	
Initial (NEW) Application Form - Convened IRB Review	11/13/2018 01:53 PM	
Protocol Synopsis Form - Template	11/13/2018 01:54 PM	
Research Involving Existing Materials or Data - Protocol Synopsis	11/13/2018 01:55 PM	
SAE (Serious Adverse Event) Form - OFF-SITE	07/18/2018 06:14 PM	
SAE (Serious Adverse Event) Form - ON-SITE	07/18/2018 06:13 PM	
SAE Guidance Document	07/18/2018 06:17 PM	
Survey Research - Protocol Synopsis Form	11/13/2018 01:56 PM	
Waiver for Documentation of Informed Consent	01/29/2019 11:47 AM	
Waiver of Informed Consent	01/29/2019 11:47 AM	

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.

Step 2:
Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. | [Learn more](#) |













Documents in this Package:

Document Type	Description	Last Modified	
▼ (please select)	Protocol-Synopsis-for-Research-Involving-Surveys_IRBNet Usability.doc	02/18/2019 05:38 PM	   

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:

Step 2:
Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. | [Learn more](#) |

Documents in this Package:

Document Type	Description	Last Modified	
▼ Questionnaire/Survey	Electronic Submission Manager Survey.docx	02/18/2019 05:41 PM	   
▼ Consent Form	Research Statement.docx	02/18/2019 05:41 PM	   
▼ Consent Waiver	Waiver of Documentation of Informed Consent.docx	02/18/2019 05:41 PM	   
▼ Protocol	Protocol-Synopsis-for-Research-Involving-Surveys_IRBNet Usability.doc	02/18/2019 05:38 PM	   
▼ Training/Certification	CITI Training_RResearcher.docx	02/18/2019 05:41 PM	   

There are no Training & Credentials records linked to this package. | [Link / Un-Link Training Records](#) |

Start a Wizard OR Attach New Document (When should I do 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:

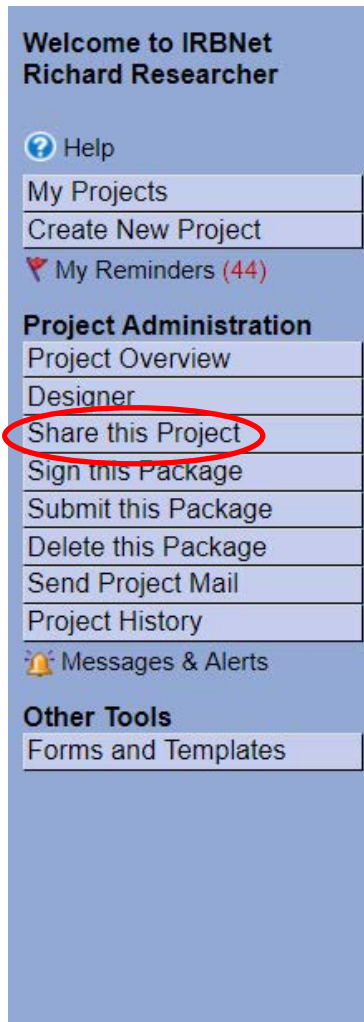
-Melissa Acosta, PhD

-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**.

Share Project

[61395-1] IRBNet Usability Study

You may share this project with other Researchers, Committee Members, Administrators and Sponsors. You may also send a complete copy of this project to a Principal Investigator at another site if this is a multi-site project. You may also transfer ownership of this project to another individual.

Share: Use this option if you wish to share your project with other Researchers, Committee Members, Administrators or Sponsors at your own institution or any other institution. For example, you may wish to share this project with other members of your research team so that you may collaborate in the design and development of the project, or with a selected Committee Member or Administrator to solicit feedback prior to submitting your project for review. You may provide any individual with **Full**, **Write** or **Read** access.

- **Multi-site:** Use this option only if your project is a multi-site project and you wish to send a complete and independent copy of this project to a Principal Investigator at another site. The local Principal Investigator will be able to obtain project documents from the lead site and may modify their copy of these documents (such as consent forms) to meet the requirements of their local Board. You will be able to monitor the progress of this project at every local site. The other local Principal Investigators will also be able to monitor the progress of this project at every local site (including your own).
- **Transfer:** Transfer your ownership of this project to another user. In doing so you will relinquish all access to this project and the designated user will be granted **Full** access.

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.

Share Project

[61395-1] IRBNet Usability Study

You may share this project with other users. Sharing a project consists of three steps:

1. Select an organization to display a list of users at that organization.
2. Specify the access that you wish to grant each user at that organization.
3. Save your changes.

Search for an Organization

Organization types to display Research Institutions Boards Sponsors

Select an Organization*

John Peter Smith Health Network (JPS), Fort Worth, TX

* required fields

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**.

User	Access Type
Tooduit, Ivan	<input type="radio"/> Full <input type="radio"/> Write <input checked="" type="radio"/> Read <input type="radio"/> No Access

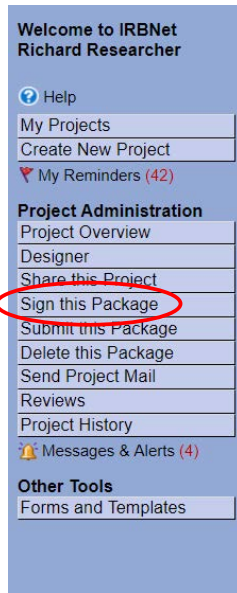
One User found.

Each user will be automatically notified that they have been granted access to this project. You may also specify additional comments to be included in this notification:

Your Comments

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.



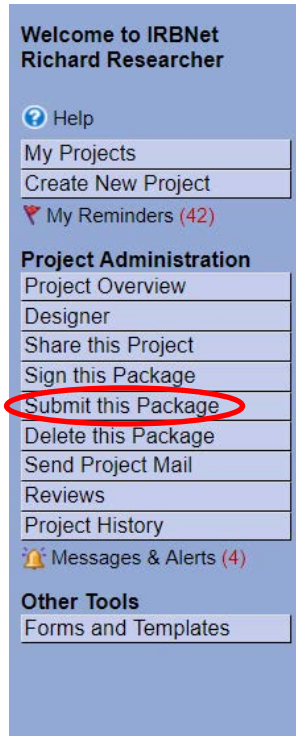
23. Select your role in the project. If you are the principal investigator, select this option from the drop down box.



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.



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:

A screenshot of a web dialog box titled 'Select a Board *'. At the top, there is a search bar with the text 'Search for an Organization' and buttons for 'Search' and 'Clear'. Below the search bar is a checked checkbox labeled 'Only show My Default Boards'. A list box contains four items: 'North Texas Regional Institutional Review Board, Fort Worth, TX', 'North Texas Regional Institutional Animal Care and Use Committee (IACUC), Fort Wort', 'North Texas Regional Institutional Biosafety Committee (IBC), Fort Worth, TX', and 'North Texas Regional Radiation Safety Committee (RSC), Fort Worth, TX'. At the bottom of the dialog are two buttons: 'Continue' (circled in red) and 'Cancel'. A red asterisk and the text '* required fields' are located at the bottom left of the dialog.

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 is unlocked. The email will contain a list of the revisions. See below for a screenshot of an example email.

From: <mailto:nc-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 "same" 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.asfmlinks.protection.outlook.com/?url=www.irbnet.org&>

-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.

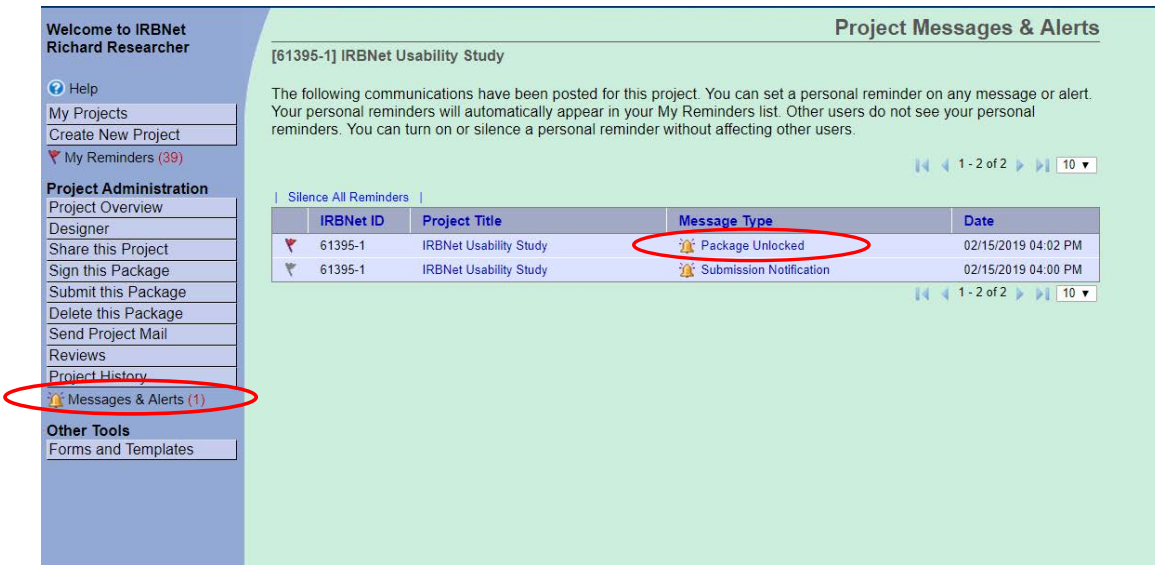
Sincerely,

Should you have any questions you may contact

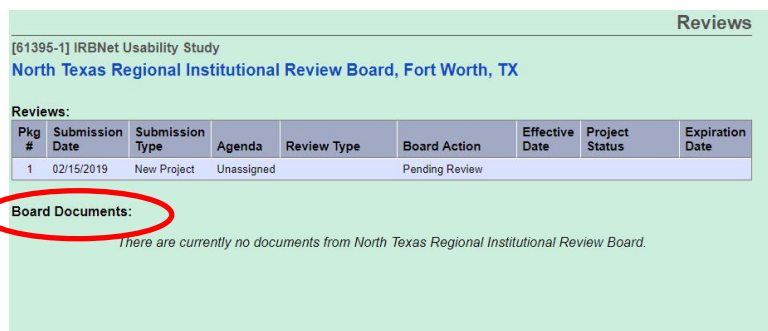
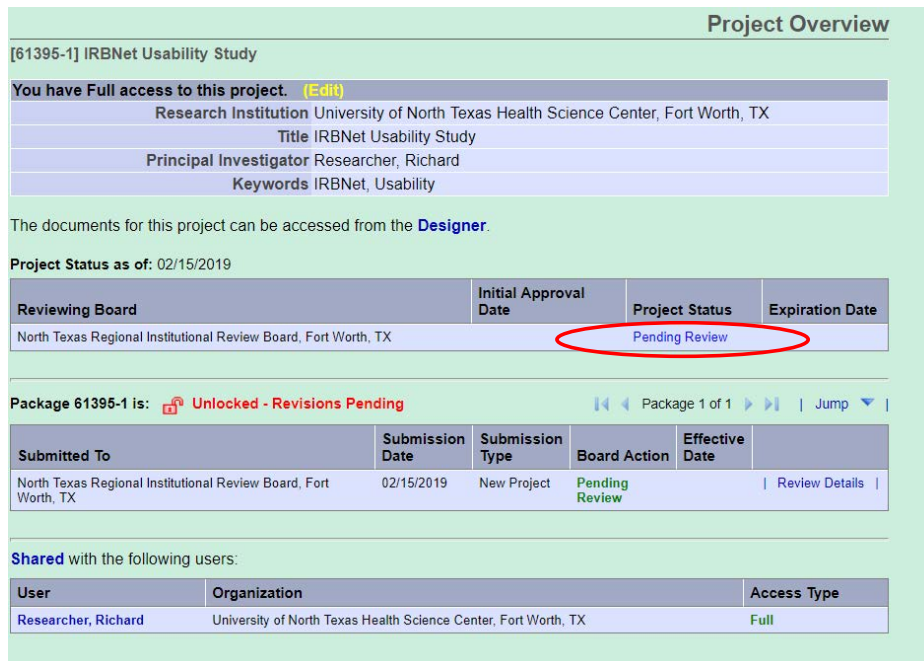
Thank you,
The IRBNet Support Team

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

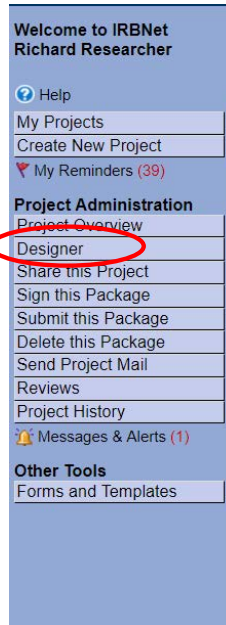
a. Under "Messages and Alerts" in the "Package Unlocked" message.



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".

Step 2:

Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. | [Learn more](#) |

Documents in this Package:

Document Type	Description	Last Modified	
Consent Form	Research Statement.docx	02/15/2019 03:57 PM	
Consent Waiver	Waiver of Documentation of Informed Consent.docx	02/15/2019 03:58 PM	
Protocol	Protocol-Synopsis-for-Research-Involving-Surveys_IRBNet Usability.doc	02/15/2019 03:56 PM	
Questionnaire/Survey	Electronic Submission Manager Survey.docx	02/15/2019 03:54 PM	
Training/Certification	CITI Training_RResearcher.docx	02/15/2019 03:53 PM	

There are no Training & Credentials records linked to this package. | [Link / Un-Link Training Records](#) |

Start a Wizard

OR

Attach New Document

When should I do this?

- 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.

The screenshot shows the 'Designer' page for a package titled '[61395] IRBNet Usability Study'. The package is currently in a state of 'Unlocked - Revisions Pending', which is highlighted in red. A button labeled 'Mark Revisions Complete' is circled in red. Below this, there is a text input field for adding a package description or notes. The page also includes instructions for Step 1 (downloading forms) and Step 2 (assembling the document package), along with a table of documents in the package.

Document Type	Description	Last Modified	
Consent Form	Research Statement.docx	02/15/2019 03:57 PM	






- 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.

This screenshot shows the 'Designer' page after the package has been locked. The status is now 'Locked - Revisions Complete'. The 'Mark Revisions Complete' button is no longer present. Instead, a link labeled 'Review details' is circled in red. The rest of the interface, including the document table, remains the same as in the previous screenshot.

Document Type	Description	Last Modified	
Consent Form	Research Statement.docx	02/15/2019 03:57 PM	

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 receiving 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	<ul style="list-style-type: none"> • No further action needed unless the PI needs to submit one of the following: <ul style="list-style-type: none"> ○ Continuing Review materials (if / when applicable) ○ A request for an amendment/modifications ○ A SAE report ○ Protocol violation / non-compliance reports ○ Or other project-related information
Exempt	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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) <ul style="list-style-type: none"> ○ 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	<ul style="list-style-type: none"> • 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) <ul style="list-style-type: none"> ○ 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	<ul style="list-style-type: none"> • 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. <i>No new packages should be submitted for projects that are Disapproved.</i>
Not Human Subjects Research	<ul style="list-style-type: none"> • 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 <i>before</i> 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	<ul style="list-style-type: none"> • 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

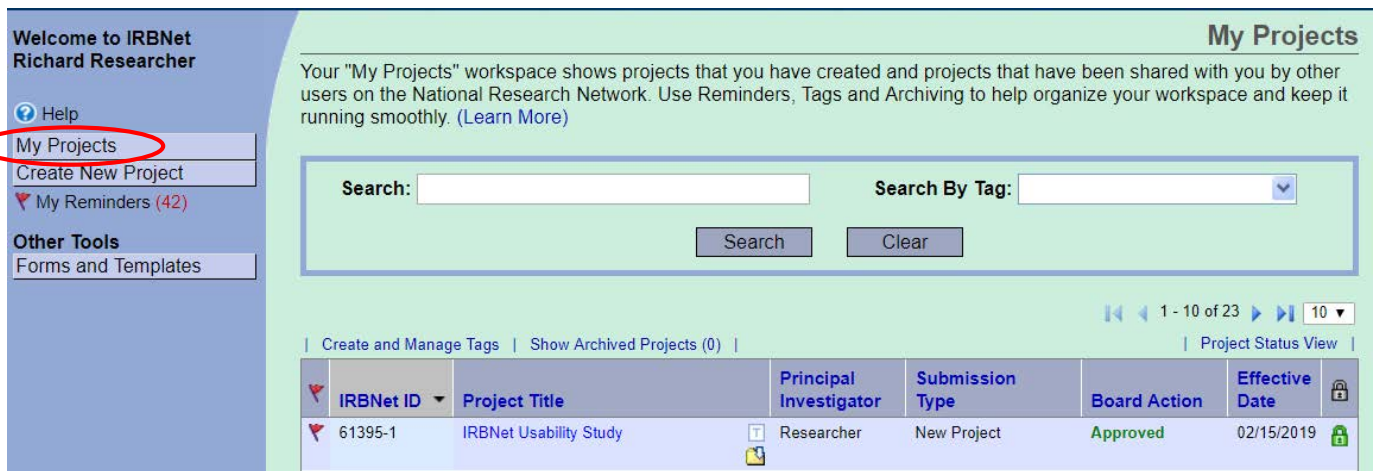
After receiving a determination, a few different scenarios will apply. As discussed in the previous section, how to proceed will vary based on the determination. This section will guide you on how to "Create a New Package".

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.

Welcome to IRBNet
Richard Researcher

Project Administration

- Project Overview
- Designer
- Share this Project
- Sign this Package
- Submit this Package
- Delete this Package
- Send Project Mail
- Reviews
- Project History
- Create a New Package**
- Messages & Alerts (4)

Project Overview

[61395-1] IRBNet Usability Study

You have Full access to this project. (Edit)

Research Institution University of North Texas Health Science Center, Fort Worth, TX

Title IRBNet Usability Study

Principal Investigator Researcher, Richard

Keywords IRBNet, Usability

The documents for this project can be accessed from the [Designer](#).

Project Status as of: 02/15/2019

Reviewing Board	Initial Approval Date	Project Status	Expiration Date
North Texas Regional Institutional Review Board, Fort Worth, TX		Active	

Package 61395-1 is: **Locked - Revisions Complete**

Package 1 of 1 | Jump

Submitted To	Submission Date	Submission Type	Board Action	Effective Date	
North Texas Regional Institutional Review Board, Fort Worth, TX	02/15/2019	New Project	Approved	02/15/2019	Review Details

Shared with the following users:

User	Organization	Access Type
Researcher, Richard	University of North Texas Health Science Center, Fort Worth, TX	Full

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.

Designer

[61395] IRBNet Usability Study

Package: 61395-2 Work in progress (Not submitted)

[Click to add a package description or notes.](#)

[Need Forms? Show Form Libraries](#)

Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. [Learn more](#)

Documents in this Package:

There are no documents in this package.

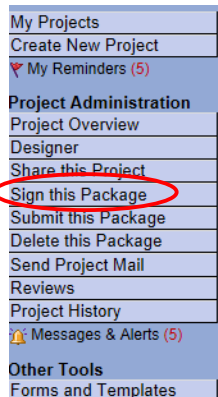
There are no Training & Credentials records linked to this package. [Link / Un-Link Training Records](#)

[Start a Wizard](#) OR [Attach New Document](#) (When should I do this?)

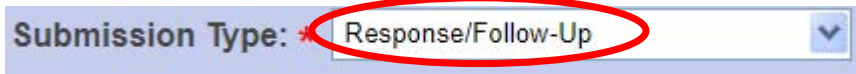
Documents from Previous Packages that you can Revise: (When should I do this?)

Pkg #	Document Type	Description	Last Modified	Submission Date	
1	Consent Form	Research Statement.docx	02/15/2019 03:57 PM	02/15/2019	
1	Consent Waiver	Waiver of Documentation of Informed Consent.docx	02/15/2019 03:58 PM	02/15/2019	
1	Protocol	Protocol-Synopsis-for-Research-Involving-Surveys_IRBNet Usability.doc	02/15/2019 03:56 PM	02/15/2019	
1	Questionnaire/Survey	Electronic Submission Manager Survey.docx	02/15/2019 03:54 PM	02/15/2019	

- 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.



- 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.



- Make sure **North Texas Regional IRB** is selected 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:

A screenshot of a web form titled 'Select a Board *'. The form includes a search bar with the text 'Search for an Organization', a search button, and a clear button. Below the search bar is a checkbox labeled 'Only show My Default Boards' which is checked. A list of boards is displayed in a scrollable area: 'North Texas Regional Institutional Review Board, Fort Worth, TX', 'North Texas Regional Institutional Animal Care and Use Committee (IACUC), Fort Worth, TX', 'North Texas Regional Institutional Biosafety Committee (IBC), Fort Worth, TX', and 'North Texas Regional Radiation Safety Committee (RSC), Fort Worth, TX'. At the bottom of the form are two buttons: 'Continue' and 'Cancel'. The 'Continue' button is circled in red. A legend at the bottom left indicates '* required fields'.

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

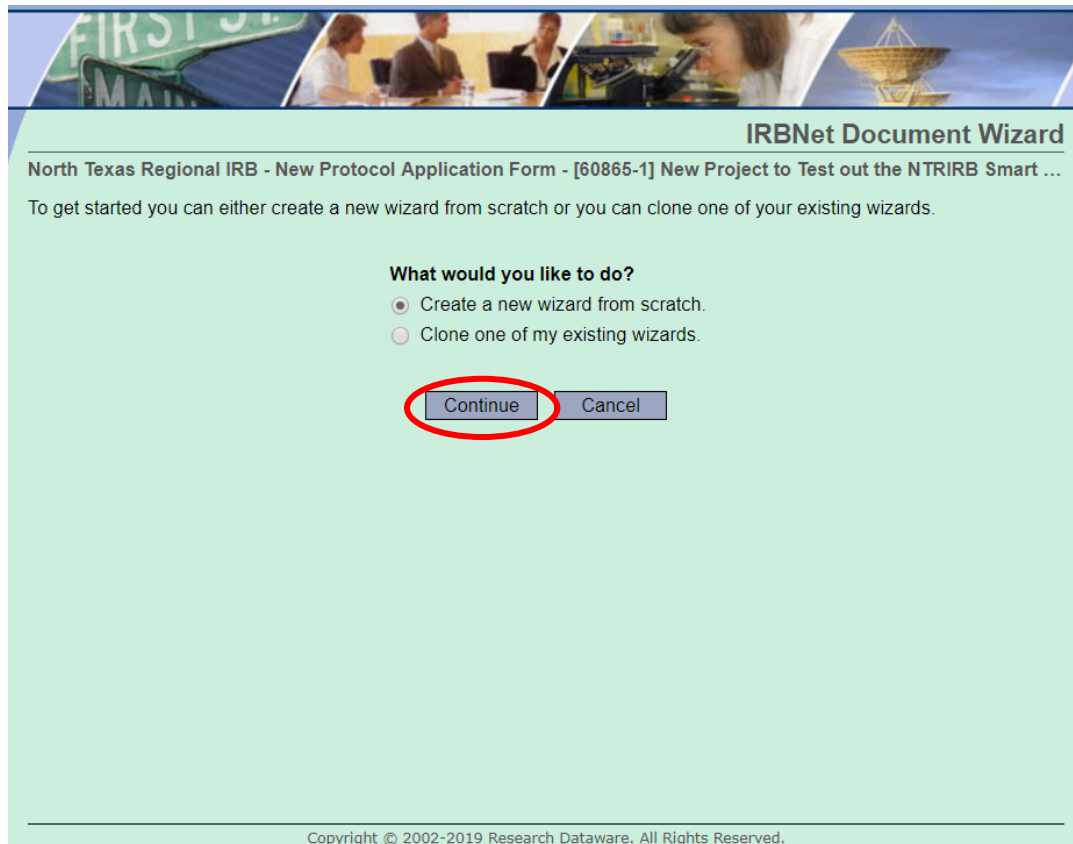
A. Wizard Form Guidance	31
B. Descriptive File Name.....	49
C. Linking CITI Training	50

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”.



The screenshot shows the IRBNet Document Wizard interface. At the top, there is a banner with a collage of images including a person at a computer, a microscope, and a satellite. Below the banner, the title "IRBNet Document Wizard" is displayed. The main content area has a light green background and contains the following text: "North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...". Below this, a message states: "To get started you can either create a new wizard from scratch or you can clone one of your existing wizards." Underneath, a question asks "What would you like to do?" with two radio button options: "Create a new wizard from scratch." (which is selected) and "Clone one of my existing wizards." At the bottom of the form, there are two buttons: "Continue" and "Cancel". The "Continue" button is circled in red. At the very bottom of the page, a copyright notice reads: "Copyright © 2002-2019 Research Dataware. All Rights Reserved."

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

IRBNet Document Wizard
North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...

Jump To: Introduction ▾ Jump

Introduction

Please read the document "READ ME FIRST" in the Forms and Templates library before beginning this application. Answer all questions and check all appropriate boxes before submission. You have the option to save your progress.

Please Note: Incomplete submissions will be returned un-reviewed.

A checklist will be presented at the end of this form to assist you with compiling a complete submission, based on your responses in this form.

Please keep the information in this form accurate and up to date. If any future changes to this project affect information in this form, please revise the appropriate sections and submit the form with your modification/amendment request.

Save and Exit Preview **Next**

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

IRBNet Document Wizard
North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...

Jump To: Principal Investigator Information ▾ Jump

Principal Investigator Information

PI Telephone *
000-000-1234

PI Fax Number

PI Email Address *
frank.researcher@unthsc.edu

PI Department *
Pharmacy

PI Institution *

JPS / Acclaim
 UNTHSC
 Other

PI Institution - Other
If you selected "Other," please specify.

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.

IRBNet Document Wizard
North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...

Jump To: Study Coordinator/Contact Person [Jump]

Study Coordinator/Contact Person *

Is the Principal Investigator the study coordinator/contact person?

Yes

No

(* required)

Save and Exit Preview Previous **Next**

Takes you to “Additional Research / Key Personnel”

Takes you to “Study Coordinator / Contact Person”

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If you selected “No” (i.e., the PI is **not** the coordinator or contact person), you will be taken here:

IRBNet Document Wizard
North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...

Jump To: Study Coordinator/Contact Person Information [Jump]

Study Coordinator/Contact Person Information

Study Coordinator/Contact Person First Name *

Jane

Study Coordinator/Contact Person Last Name *

Coordinator

Study Coordinator/Contact Person Telephone *

098-765-4321

Study Coordinator/Contact Person Fax

Study Coordinator/Contact Person Email *

jane.coordinator@unthsc.edu

Study Coordinator/Contact Person Role(s)/Responsibilities *

- Administers Informed Consent
- Recruitment
- Performs Data Analyses
- Conducts Data Collection/Research Procedures
- Other Research Related Activity

Study Coordinator/Contact Person Role(s)/Responsibilities - Other

If you selected “Other Research Related Activity,” please specify.

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If you selected “Yes” (i.e., the PI is the coordinator or contact person), you will be taken here:

IRBNet Document Wizard
North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...

Jump To: Additional Research/Key Personnel [Jump]

Additional Research/Key Personnel *

Are there additional research personnel in this study that you would like to add to this form? (*Please note that you are not required to list all of the research personnel in this form. Please list only the main research personnel in this form (e.g., co-investigator, etc.). Provide the complete list of all research personnel in the protocol synopsis.)

Yes

No

Save and Exit Preview (* required) Previous Next

Copyright © 2002-2019 Research Dataware. All Rights Reserved.

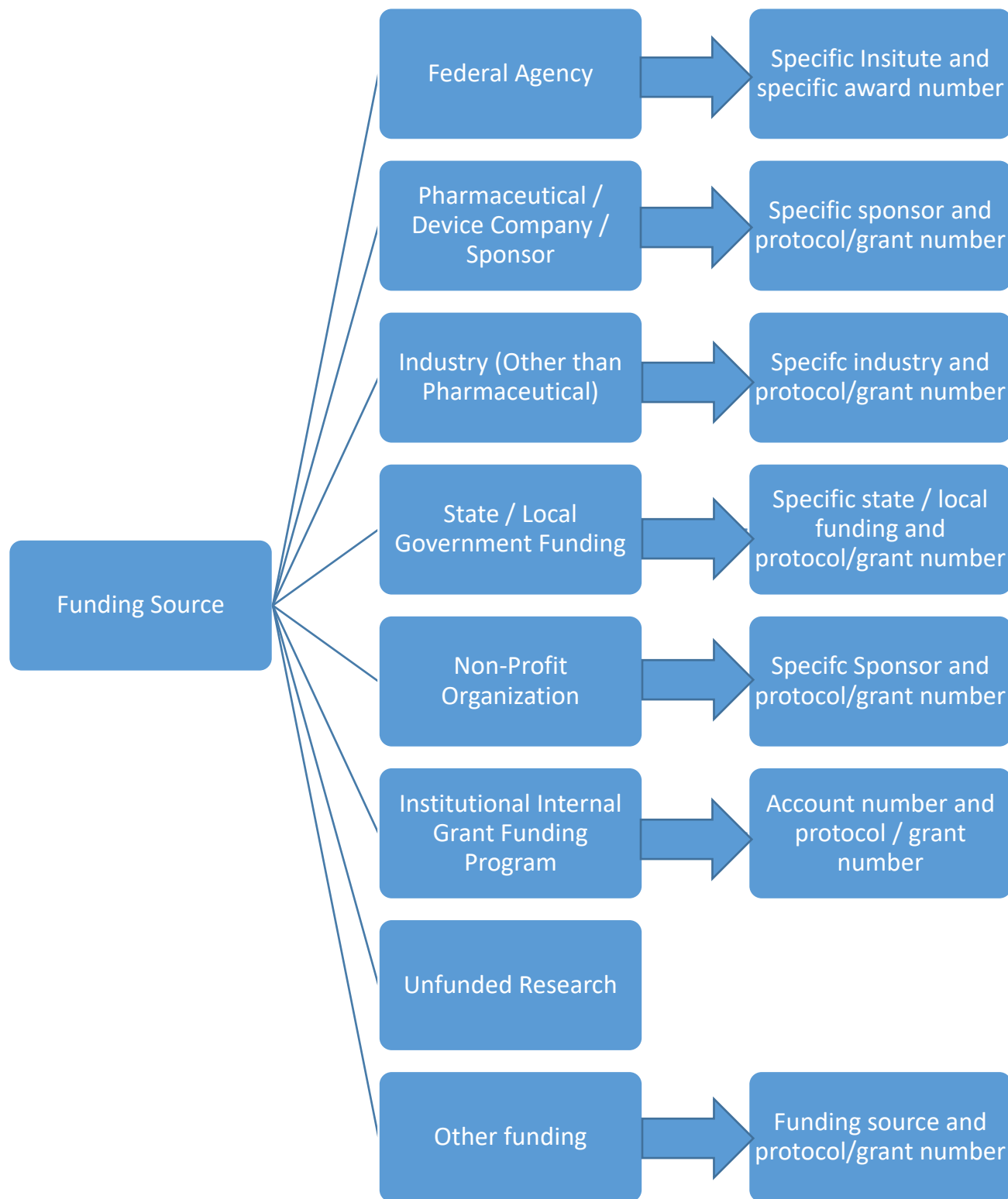
5. Please provide information about other pertinent Research/Key Personnel. The IRB recommends listing *only the main personnel* in the Wizard application form and providing a complete list of research personnel in the protocol synopsis, as this will prevent the need to update the form whenever there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

The screenshot shows the 'IRBNet Document Wizard' interface. At the top, it says 'North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...'. Below this is a 'Jump To:' dropdown menu set to 'Additional Research/Key Personnel Information' and a 'Jump' button. The main section is titled 'Additional Research/Key Personnel Information' and contains two bullet points: 'A COI disclosure form is required for each additional research personnel to be added (for Expedited and Full Board protocols)' and 'REMINDER: Upload/link each applicable current CITI training record with this submission.' Below this is a section for 'Additional Personnel 1' with a red 'X' icon. It includes several required fields: 'Additional Personnel First Name *' (filled with 'John'), 'Additional Personnel Last Name *' (filled with 'Statistician'), 'Additional Personnel Telephone *' (filled with '678-091-5432'), 'Additional Personnel Fax' (empty), 'Additional Personnel Email *' (filled with 'john.statistician@unthsc.edu'), and 'Additional Personnel Role(s)/Responsibilities *' (with a checkbox for 'Administers Informed Consent' which is unchecked).

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.

The screenshot shows the 'IRBNet Document Wizard' interface. At the top right, the title 'IRBNet Document Wizard' is displayed. Below it, the breadcrumb path reads 'North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...'. A 'Jump To:' dropdown menu is set to 'Funding Source', with a 'Jump' button to its right. The main heading is 'Funding Source *'. Below this, a note states: 'Indicate the category of the sponsor (REMINDER: Upload a copy of your grant application and Notice of Award)'. A list of eight categories follows, each with an unchecked checkbox: 'Federal Agency', 'Pharmaceutical/ Device Company/ Sponsor', 'Industry (Other Than Pharmaceutical)', 'State/ Local Government', 'Non-Profit Organization', 'Institutional Internal Grant Program', 'Unfunded Research (No Specific Resources are Available or Allocated to This Activity)', and 'Other'. At the bottom, there are four buttons: 'Save and Exit', 'Preview', '(* required)', and 'Previous' followed by 'Next'.

- 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”.



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”

The screenshot shows the 'IRBNet Document Wizard' interface. At the top, it says 'North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...'. Below this, there is a 'Jump To:' dropdown menu with 'Contract Research Organizaton (CRO)' selected and a 'Jump' button. The main heading is 'Contract Research Organizaton (CRO) *'. Below the heading, it says 'List specific CRO. If there is no CRO, enter "Not Applicable."' followed by a text input field containing 'A CRO'. At the bottom, there are buttons for 'Save and Exit', 'Preview', 'Previous', and 'Next', along with a note '(* required)'.

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.

The screenshot shows the 'IRBNet Document Wizard' interface. At the top, it says 'North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...'. Below this, there is a 'Jump To:' dropdown menu with 'Purpose of Study' selected and a 'Jump' button. The main heading is 'Purpose of Study *'. Below the heading, it says 'Briefly describe in layman's terms.' followed by a rich text editor. The rich text editor has a toolbar with various icons for bold, italic, underline, strikethrough, bulleted list, numbered list, indent, outdent, link, unlink, undo, redo, source code, and ABC. The text area contains the placeholder text 'This is the purpose of the study...'. At the bottom, there are buttons for 'Save and Exit', 'Preview', 'Previous', and 'Next', along with a note '(* required)'.

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.

The screenshot shows the 'Project Information' page of the IRBNet Document Wizard. At the top, it says 'IRBNet Document Wizard' and 'North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...'. Below this is a 'Jump To:' dropdown menu set to 'Project Information' with a 'Jump' button. The main heading is 'Project Information'. Underneath is a section titled 'Certificate of Confidentiality *' with a question: 'For those non-NIH funded studies that involve information that needs to be protected from subpoena, will a Certificate of Confidentiality be requested from NIH or another federal agency? (Note that a protocol does not have to be NIH funded in order to obtain such a Certificate.)'. There are three radio button options: 'Yes', 'No', and 'Not Applicable', with 'Not Applicable' selected. Below that is a section titled 'Study Subjects *' with the question: 'Will this research study recruit any subjects from the following categories? Check all that apply:'. There are six checkboxes: 'Pregnant Women', 'Minors (<18)', 'Cognitively Impaired', 'Prisoners', 'Employees of research site or sponsor', and 'UNTHSC students', all of which are currently unchecked.

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.

The screenshot shows the 'Type of Review' page of the IRBNet Document Wizard. At the top, it says 'IRBNet Document Wizard' and 'North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...'. Below this is a 'Jump To:' dropdown menu set to 'Type of Review' with a 'Jump' button. The main heading is 'Type of Review *' with the instruction: 'Indicate the review type.'. There are three radio button options: 'Full Committee Review', 'Exempt Review', and 'Expedited Review', with 'Full Committee Review' selected. At the bottom, there are four buttons: 'Save and Exit', 'Preview', '(* required)', and 'Next'. The '(* required)' button is highlighted in blue.

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.

The screenshot shows the 'IRBNet Document Wizard' interface. At the top, it says 'North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...'. Below this is a 'Jump To:' dropdown menu set to 'Type of Research Project' with a 'Jump' button. The main section is titled 'Type of Research Project *'. A reminder states: 'REMINDER: Please upload/submit all applicable study-related documents, in addition to the protocol (i.e., consent form/HIPAA authorization form, recruitment materials, waiver requests, consent scripts, etc.)'. There are three radio button options: 'Investigator-Initiated Study', 'Student/Medical Resident Research Project', and 'Clinical Trial (Drug/Device/Biologic)'. The 'Clinical Trial' option is selected. At the bottom, there are buttons for 'Save and Exit', 'Preview', '(* required)', 'Previous', and 'Next'.

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.

The screenshot shows the 'IRBNet Document Wizard' interface. At the top, it says 'North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...'. Below this is a 'Jump To:' dropdown menu set to 'FDA Products' with a 'Jump' button. The main section is titled 'FDA Products *'. The question is 'Will this study be subject to FDA regulations? (involving drug, device, biologic, HDE)'. There are two radio button options: 'Yes' and 'No'. At the bottom, there are buttons for 'Save and Exit', 'Preview', '(* required)', 'Previous', and 'Next'.

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.

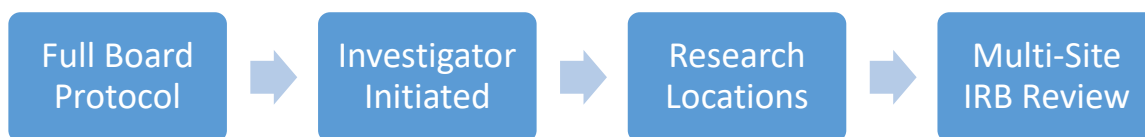
The screenshot shows the 'IRBNet Document Wizard' interface. At the top, it says 'North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...'. Below this is a 'Jump To:' dropdown menu set to 'Research Locations' with a 'Jump' button. The main section is titled 'Research Locations *'. The question is 'Where will this research be conducted?'. There are three radio button options: 'UNTHSC Facilities', 'JPS Facilities', and 'Other Sites'. Both 'UNTHSC Facilities' and 'JPS Facilities' are selected. At the bottom, there are buttons for 'Save and Exit', 'Preview', '(* required)', 'Previous', and 'Next'.

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.

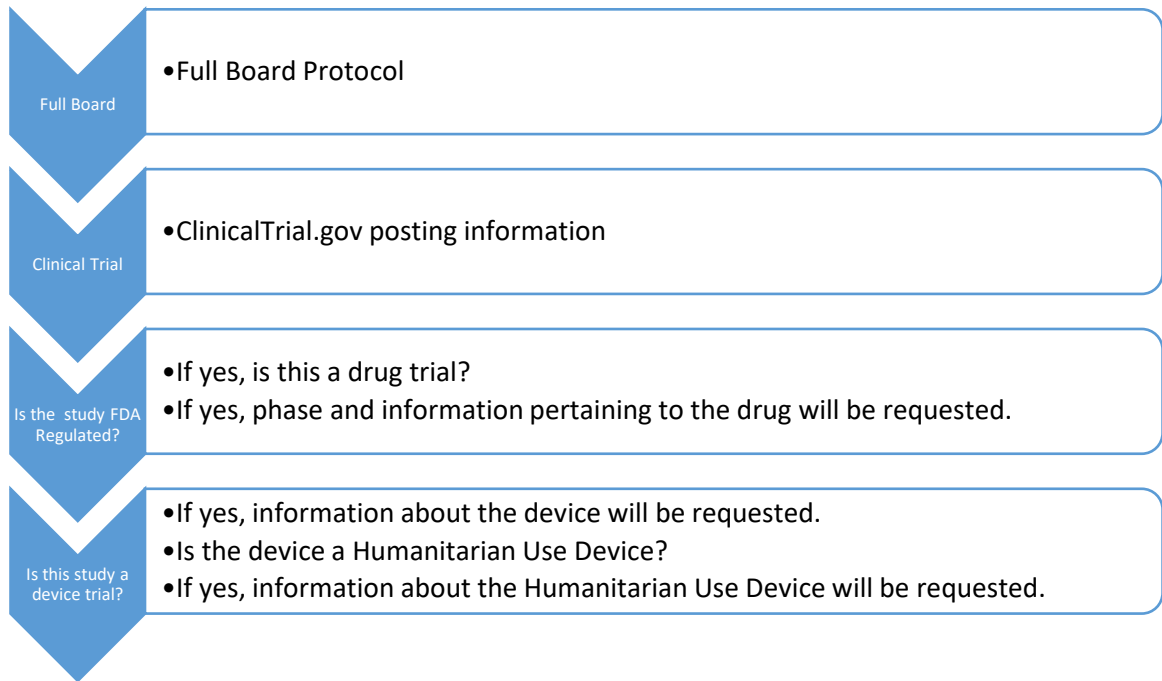
The screenshot shows a web form titled "North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...". At the top right, there is a "Jump To:" dropdown menu with "Multi-Site IRB Review" selected and a "Jump" button. The main heading is "Multi-Site IRB Review *". Below this, the question is "Are other IRBs involved in the approval of this project?". A note in red text states: "(Note: This does NOT apply to FDA-regulated sponsored clinical trials)". There are three radio button options: "Yes", "No", and "Not Applicable". At the bottom, there are buttons for "Save and Exit", "Preview", "Previous", and "Next". A red asterisk and the text "(* required)" are positioned between the "Preview" and "Previous" buttons.

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:



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.

North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...

Jump To: Clinical Trial Information [Jump]

Clinical Trial Information

ClinicalTrial.gov Posting *

Will this trial be posted on ClinicalTrials.gov?

(REMINDER: If "Yes", the following language should be included in your consent form: "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.")

Yes
 No
 Pending

ClinicalTrial.gov Identifier

NT000

[Save and Exit] [Preview] (* required) [Previous] [Next]

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North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...

Jump To: Drug/Biologic Trial [Jump]

Drug/Biologic Trial *

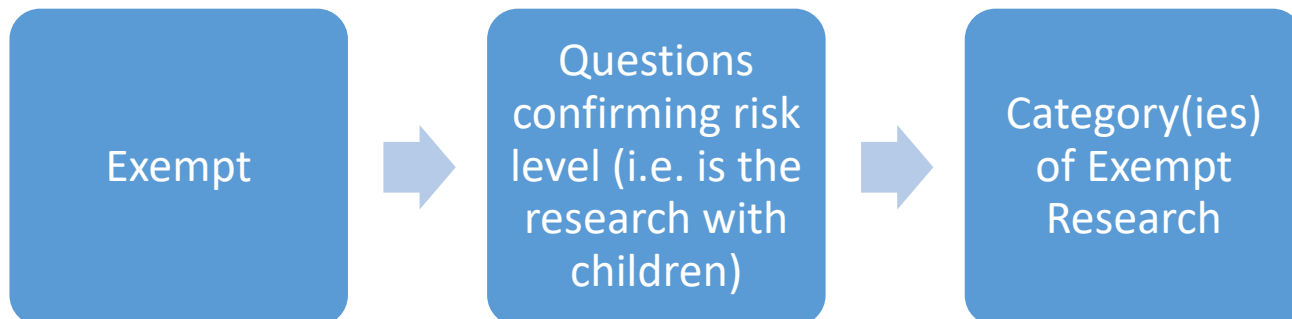
Is this study a drug trial?

Yes
 No

[Save and Exit] [Preview] (* required) [Previous] [Next]

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- 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:

North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...

Jump To: **Exempt Review Information**

Exempt Review Information

Excessive Risk *

Does the project present physical, psychological, social or legal risks to the participants reasonably expected to exceed those risks normally experienced in daily life or in routine diagnostic physical or psychological examination or testing?

Also, consider the consequences if participant data inadvertently becomes public.

Yes
 No

Incarcerated Participants *

Are any of your participants incarcerated?

Yes
 No

Information Identifiers *

Are you obtaining or recording any information about the subjects including health-related information that contains any identifiers (see list below)?

- Names
- Telephones Numbers
- Fax Numbers
- Dates Related to Individuals (e.g. Birth Date, Admission Date, Discharge Date, etc.)
- Electronic mail Addresses
- Social Security Numbers
- Medical Record Numbers
- Health Plan Beneficiary Numbers
- Account Numbers
- Certificate/ License Numbers
- Vehicle Identifiers and Serial Numbers Including License Plate Number
- Device Identifiers and Serial Numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) Address Numbers
- Biometric Identifiers, Including Finger and Voice Prints
- Any Other Unique Identifying Number, Characteristic, or Code; Except a Code Used Alone or in Combination With Other Information to Identify an Individual Who is The Subject of The Information
- Address, Street Address, City, Precinct ZIP Code, and Their Equivalent Geocodes. Exception for ZIP Codes: the initial three digits of the ZIP Code may be used, if according to current publicly available data from the Bureau of the Census.
- Full face photographic images and any comparable images

Exempt Review Category example screenshot (Cont.):

If you select "Yes", this may NOT qualify for Exempt Category Review. Please complete and submit this submission form and package. The IRB will notify you should the review type change and if additional documentation is required.

Yes
 No

Category of Research *

Please select all categories that relate to your research:

- Educational Practices and Strategies
- Observation of Public Behavior
- Survey or Interview
- Benign Behavioral Intervention(s) (Please contact the IRB Office for further instructions/guidance)
- Retrospective Record or Chart review
- Existing Human Biological Specimens
- Secondary Dataset Study
- Public Benefit or Services Programs
- Taste and Food Evaluation

(* required)

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- 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:

North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...

Jump To: Expedited Categories [Jump]

Expedited Categories *

Expedited Categories:

- **Category 1:** Clinical studies of drugs and medical devices ONLY when condition (a) or (b) is met:
 - a. Research on drugs for which an investigational new drug application is not required.
 - b. Research on medical devices for which:
 - i. an investigational device exemption application is NOT required OR
 - ii. medical device is cleared/approved for marketing and it is being used in accordance with its cleared/approved labeling.

Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is NOT eligible for expedited review.

- **Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from:
 - a. Healthy, non-pregnant adults who weigh at least 110 pounds.
 - Contact IRB Staff for criteria
 - b. Other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected.
 - Contact IRB Staff for criteria
- **Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means.
 - Placenta removed at delivery.
 - Deciduous teeth taken during exfoliation or routine patient care.
 - Permanent teeth if routine patient care indicates a need for extraction.
 - Excreta and external secretions (including sweat).
 - Uncannulated saliva
 - Amniotic fluid obtained at the time of membrane rupture prior to or during labor
 - Supra- and subgingival dental plaque and calculus. [Collection is not more invasive than routine prophylactic teeth scaling and it is done according to accepted techniques.]
 - Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings.
 - Hair and nail clippings in a non-disfiguring manner.
 - Sputum collected after saline mist nebulization.

Expedited Review Category example screenshot (cont.):

- **Category 4:** Collection of data through noninvasive procedures routinely done in clinical practice. Where medical devices are employed, they must be cleared/approved for marketing.
 - Physical sensors applied to the body surface or at a distance AND do not involve input of significant amounts of energy into the subject or an invasion of subject's privacy.
 - Weighing or testing sensory acuity.
 - Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiograph.
 - Magnetic resonance imaging (MRI)
 - Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing (appropriate to age, weight, and health of the individual).

NOTE: Studies intended to evaluate the safety and effectiveness of a medical device are NOT eligible for expedited review, including studies of cleared medical devices for new indications. To qualify for this subcategory, the study CANNOT involve general anesthesia, sedation or procedures with X-rays or microwaves (such as CT/CAT Scan, etc).

- **Category 5:** Research involving materials (data, documents, records, or specimens) that:
 - a. Have already been collected for some other purpose.
 - b. Will be collected for nonresearch purposes (such as medical treatment or diagnosis)
- **Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes.
- **Category 7:** Research where condition (a) or (b) is applicable:
 - a. Individual or group characteristics or behavior (research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior).
 - b. Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Select the categories that apply:

- Category 1
- Category 2
- Category 3
- Category 4
- Category 5
- Category 6
- Category 7

[Save and Exit] [Preview] (* required) [Previous] [Next]

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).

IRBNet Document Wizard
North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...

Jump To:

Biological Information

Human Specimens Storage *

Does the study involve storage or banking of human specimens or identifiable private information for use in the future studies (e.g., submission to a repository)?

Yes
 No

Human Specimens Storage - Explanation

If "Yes," please describe and note page where discussed in informed consent document:

B I U S [List icons] **Formats** **Font Family** **Font Sizes**

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.

IRBNet Document Wizard
North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...

Jump To:

Signature and Investigator Responsibilities (PI Statement of Assurance)

- The principal investigator agrees to accept responsibility for the scientific conduct of the project, that the scientific portion of the protocol is original and contains no false, fictitious, or fraudulent statements or data. Signature certifies that all listed investigators have reviewed the proposal and that the research will be conducted in full compliance with North Texas Regional IRB and relevant institutional policies and federal regulations.
- The principal investigator certifies that the Conflict of interest Disclosure Statements enclosed are up-to-date for all key personnel on this project.
- The principal investigator certifies that sufficient staff and resources are available to conduct the research.
- The principal investigator certifies that all project personnel have the proper education, experience and expertise to conduct the study.
- **If applicable**, continuing review is required in order to maintain the approval status and the Principal Investigator is aware that progress reports must be submitted to the IRB in a timely manner.
- The principal investigator certifies that ALL personnel involved in carrying out the research are familiar with the ethical guidelines for research involving human participants and have taken such training and other related training required by the North Texas Regional IRB.
- All changes in the study must be approved by the North Texas Regional IRB prior to implementation.
- Serious adverse events (SAEs) must be reported to the North Texas Regional IRB (Via a SAE form).

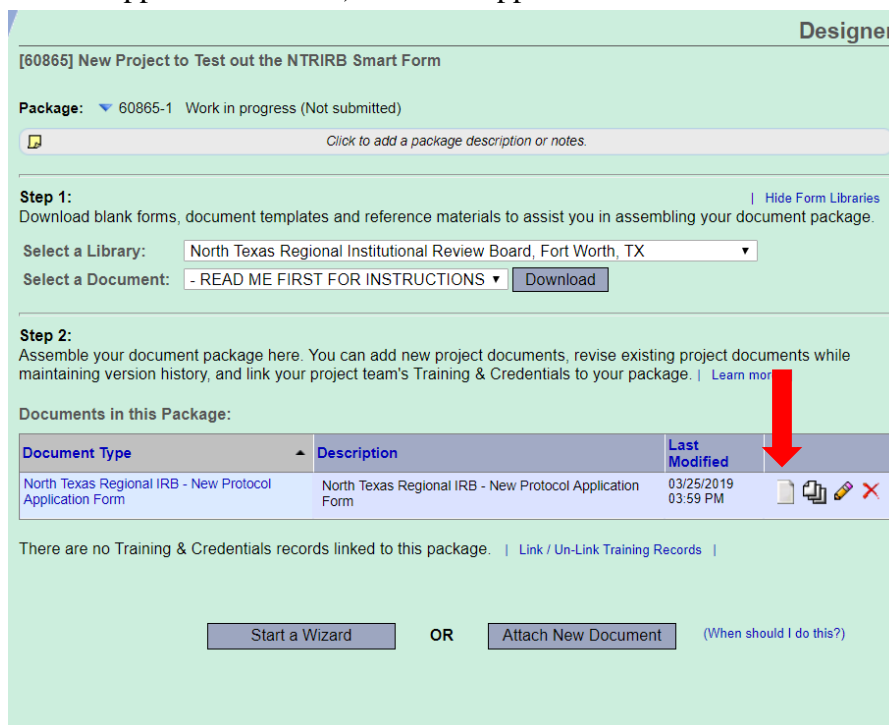
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REMINDER: Please note that there will not be a specific place in this section/page to provide an electronic, or physical signature. **Therefore, the Principal Investigator (PI) must electronically sign the submission package in IRBNet before the project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

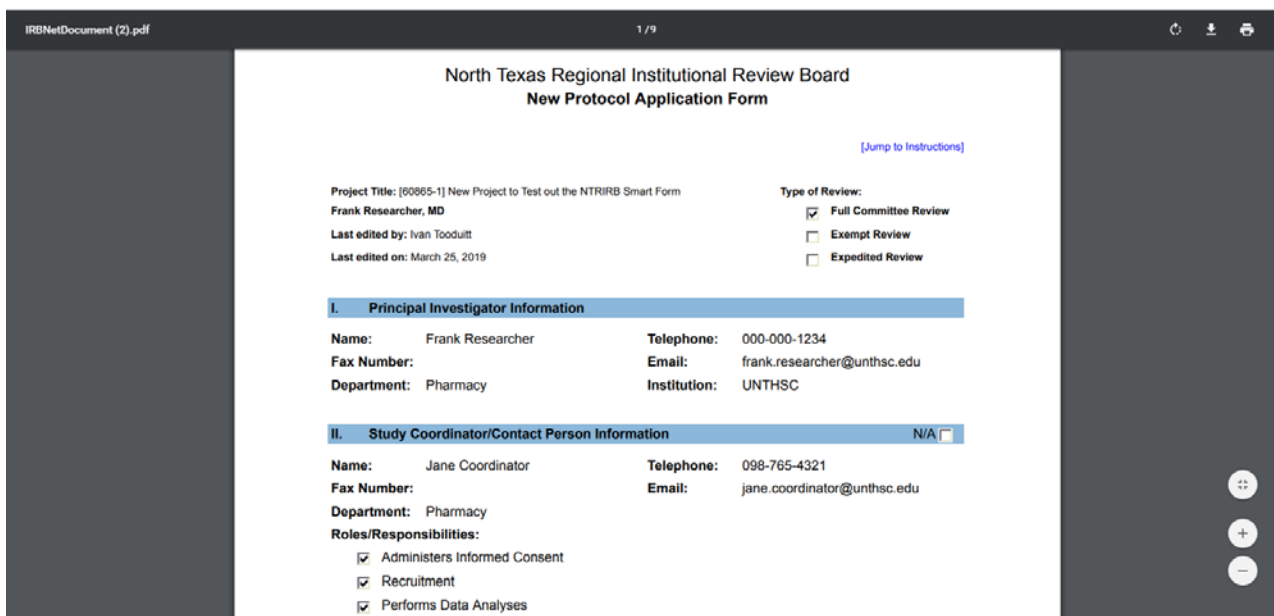
18. The last page includes instructions and a list of all applicable documents/forms that need to be submitted in IRBNet in addition to the study application. The items on this page generate based on the investigator’s responses within the Wizard application form (NOTE: If the investigator goes back 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.

The screenshot shows the 'IRBNet Document Wizard' interface. At the top, the title is 'North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...'. Below the title, there is a 'Jump To:' dropdown menu with 'Form Complete' selected. A red circle highlights the 'Jump' button next to the dropdown. The main content area is titled 'Form Complete' and contains text regarding 'Principal Investigator attestation' and a list of 'Additional required documentation' items such as Curriculum Vitae, Medical licenses, COI Disclosure Form, Consent Form, FDA IND Determination Letter, HIPAA Authorization Form, Human Subjects Research Training Credentials, Investigator Brochure(s)/Package Insert(s), Request for Waiver of HIPAA Authorization, Request for Waiver of Informed Consent, Site-Specific Protocol Information for Sponsored Clinical Trials, Sponsor/Clinical Protocol, Standardized Test(s)/Assessment(s), and Survey(s)/Questionnaire(s).

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

This screenshot shows the 'IRBNet Document Wizard' interface with the 'Jump To:' dropdown menu open. The dropdown list includes options like 'Study Coordinator/Contact Person', 'Additional Research/Key Personnel Information', 'Funding Source', 'Contract Research Organization (CRO)', 'Purpose of Study', 'Project Information', 'Type of Review', 'Type of Research Project', 'FDA Products', 'Research Locations', 'Research Locations Information', 'Multi-Site IRB Review', 'Multi-Site IRB Review - Other IRB Approvals', 'Expedited Categories', 'Type of Study', 'Biological Information', and 'Signature and Investigator Responsibilities (PI Statement of Assurance)'. The 'Form Complete' option is highlighted in blue. A red circle highlights the 'Jump' button. The main content area is partially visible, showing the 'Form Complete' section header and some text. At the bottom, there are buttons for 'Save and Exit', 'Preview', and 'Previous'.

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:

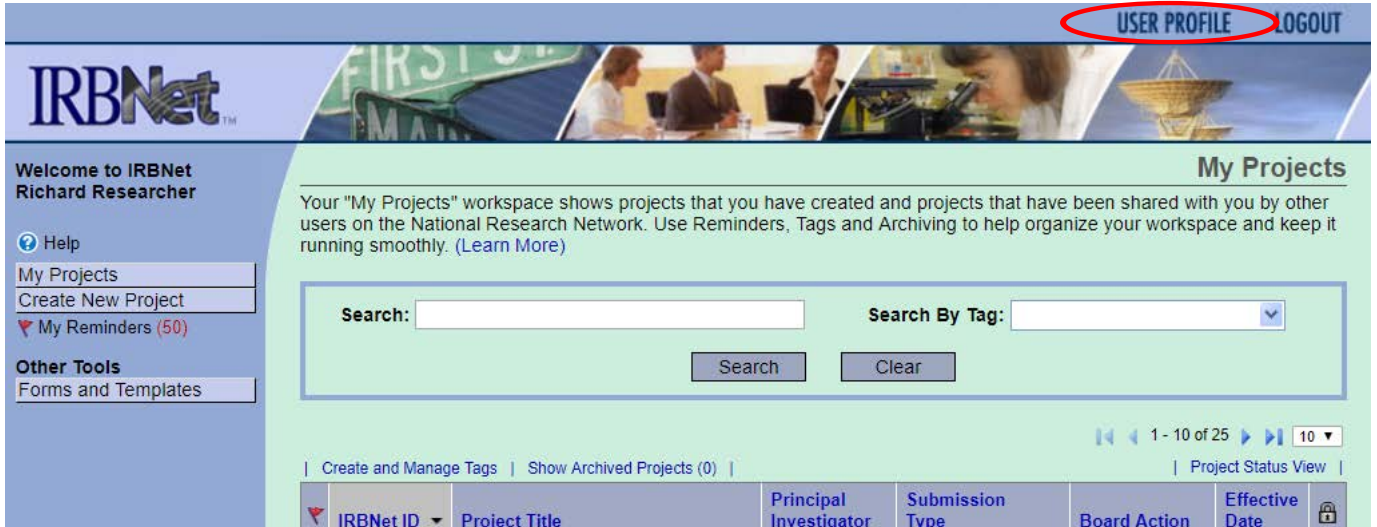
- Title of training
- First initial and last name of key personnel to which the training belongs.

Type of Document	Example of Document	Description Example
Protocol Synopsis	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Consent Form • Consent Script • Cover Letter 	Consent Form – clean Consent Script – track change – English Consent Script – clean – Spanish – V.3
Consent Waiver	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • HIPAA Research Authorization 	HIPAA Authorization – clean HIPAA Authorization – track change
Advertisement	<ul style="list-style-type: none"> • Recruitment ad • Recruitment flyer 	Recruitment flyer – clean Recruitment flyer – clean Recruitment flyer – track change – English Recruitment flyer – clean – Spanish
Questionnaire / Survey	<ul style="list-style-type: none"> • Pre-screening questionnaire • Survey • Questionnaire 	Pre-screen – clean MMSE – clean – English Dietary questionnaire – tracked change
Data Collection Sheet	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Protection of Human Subjects training • Good Clinical Practices training • Conflict of Interest Declarations 	CITI training – RResearcher COI Disclosure - RResearcher

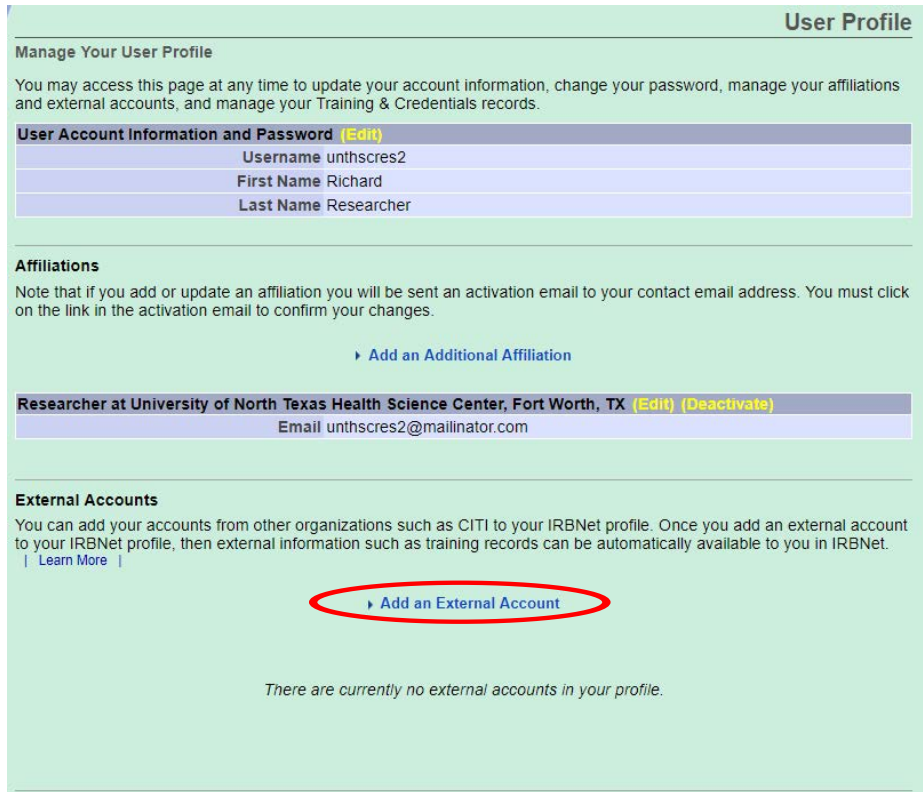
C. Linking CITI Training to User Profile

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.

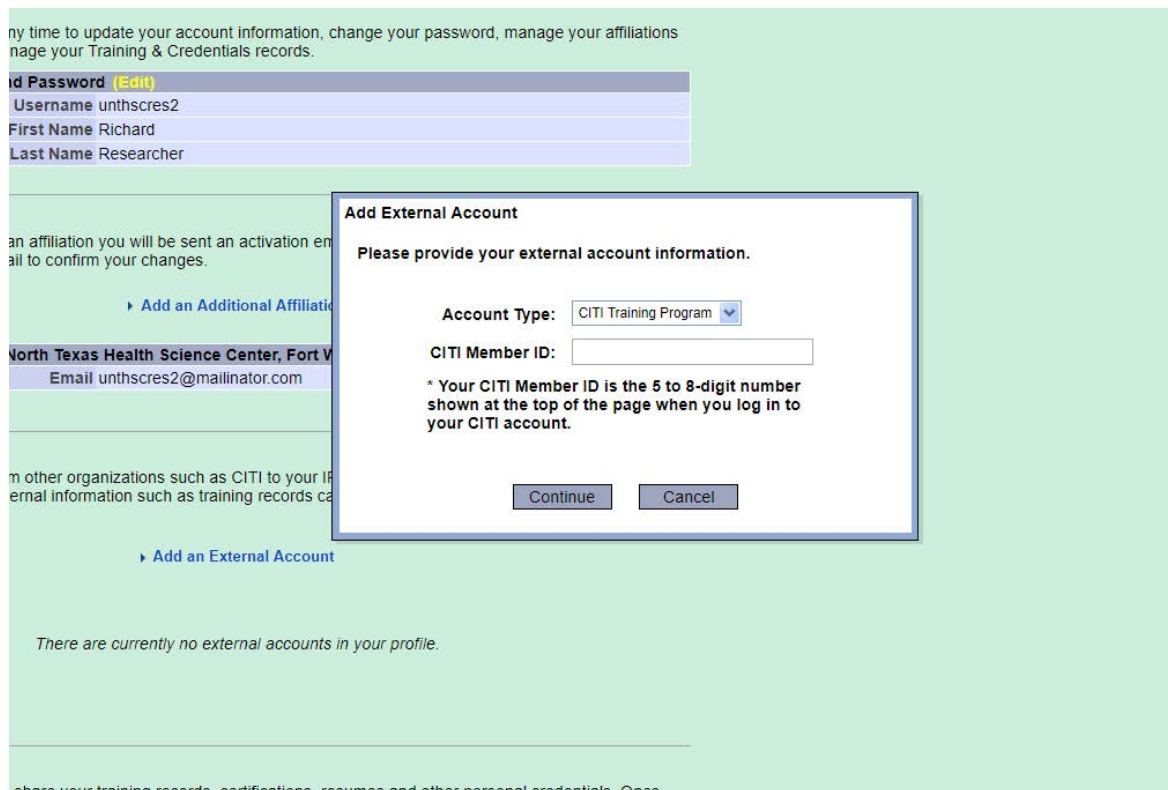
1. After logging in, select "User Profile" at the top of the page.



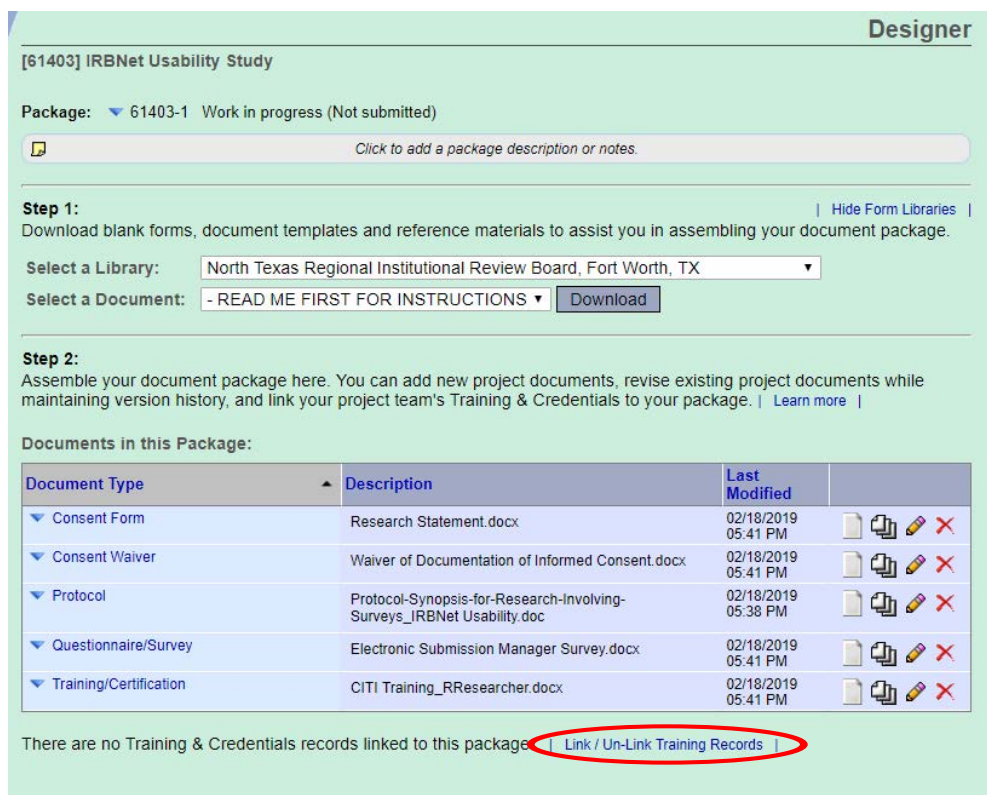
2. In your "User Profile", find the "External Accounts" section. Click "Add an External Account".



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".



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.