



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 North Texas Regional IRB Administrative Office at:

NorthTexRegIRB@unthsc.edu

Main Phone Line: (817) 735-0409

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

Carissa Jensen, MPH, CPMP
CJensen03@jpshealth.org
(817) 702-2817

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I. Registering with IRBNet

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

IRBNet Innovative Solutions for Compliance and Research Management

Home | The IRBNet Difference | Demo | Contact Us | FAQ

Comprehensive Solutions

The Industry's Most Complete Solution
IRBNet's unmatched suite of electronic solutions drives compliance and productivity for your Administrators, Committee Members, Researchers and Sponsors. These powerful research design, management and oversight tools support your IRB, IACUC, IBC, COI and other Boards with a unified solution.

Flexible, Intuitive and Easy to Use
Your own forms. Your own processes. Your own standards. Powerful reporting and performance metrics. The data you need. From electronic submissions to form wizards, to agendas, minutes, and more. Our easy to use, web-based tools are rapidly launched and backed by our best practices expertise and the industry's leading support team.

Secure, Reliable and Cost-Effective
IRBNet's secure web-based solution is accessible to your research community anytime, anywhere. Our enterprise-class technology is cost-effective and designed to accommodate institutions of any size.

Test Drive IRBNet
See for yourself... [Demo](#)

Satisfied Members

"Our first electronic meeting went so smoothly! It was over so fast the members didn't know what to do. They just sat there for a few minutes in disbelief."
- Bruce Day
Director, Office of Research Integrity
Marshall University

[Next](#)

[2014 Events - Join Us](#)

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

Login: Username Password Login

[New User Registration](#) [Forgot Your Password?](#)

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

* 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.

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 primary 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

8. Provide a recovery email address and phone number. This can be a personal email address and cell phone number. Next, when you click “Verify Now,” you will begin the process of validating your IRBNet user account.

Account Recovery Information

Recovery Email Address and Phone Number

Please provide an email address and phone number where you can receive account recovery and security messages. Your Recovery Email (required) should be an email address that is accessible to you even if you are **not** logged in to your institutional network. Your Recovery Phone (optional) should be a phone number capable of receiving text messages.

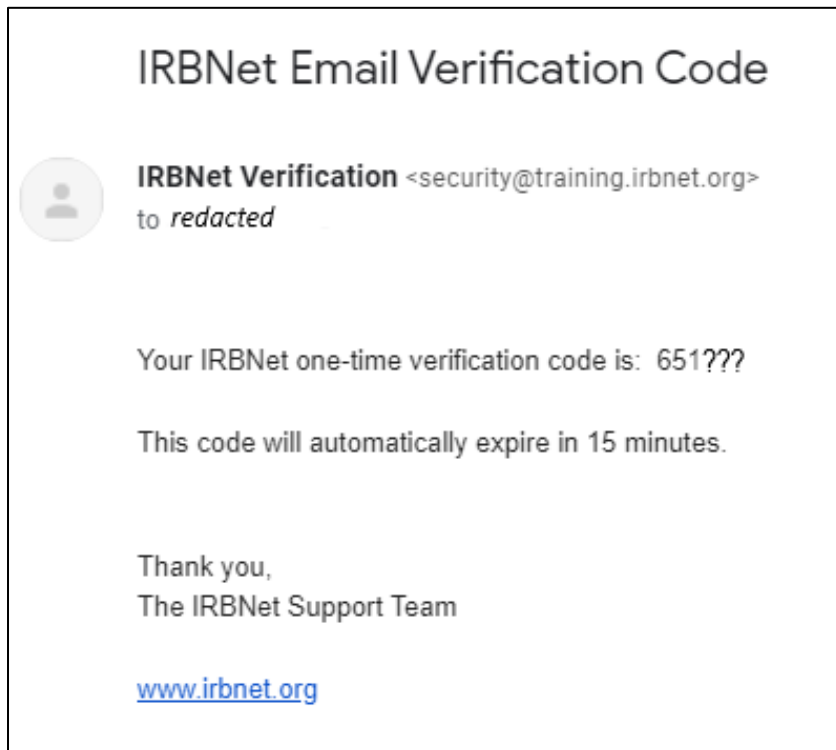
Please provide and verify your Recovery Email address to continue. You may change your Recovery Email address and Recovery Phone number at any time from your User Profile.

Recovery Email *

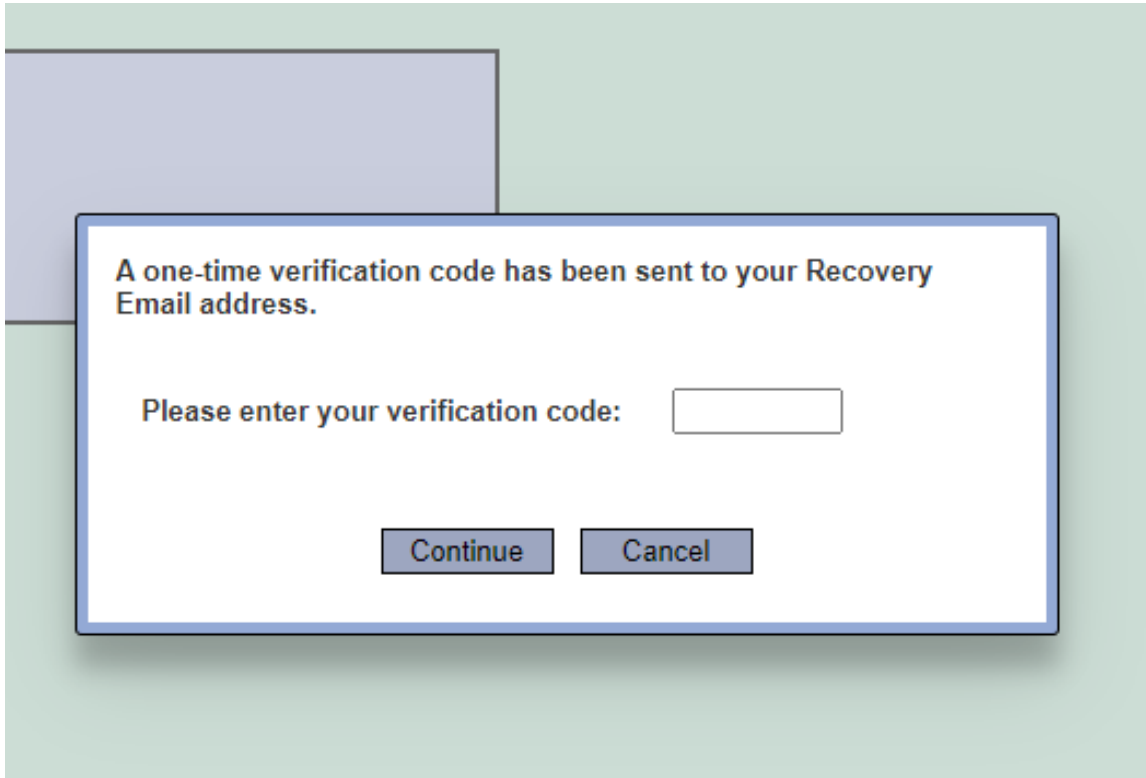
Recovery Phone

* required fields

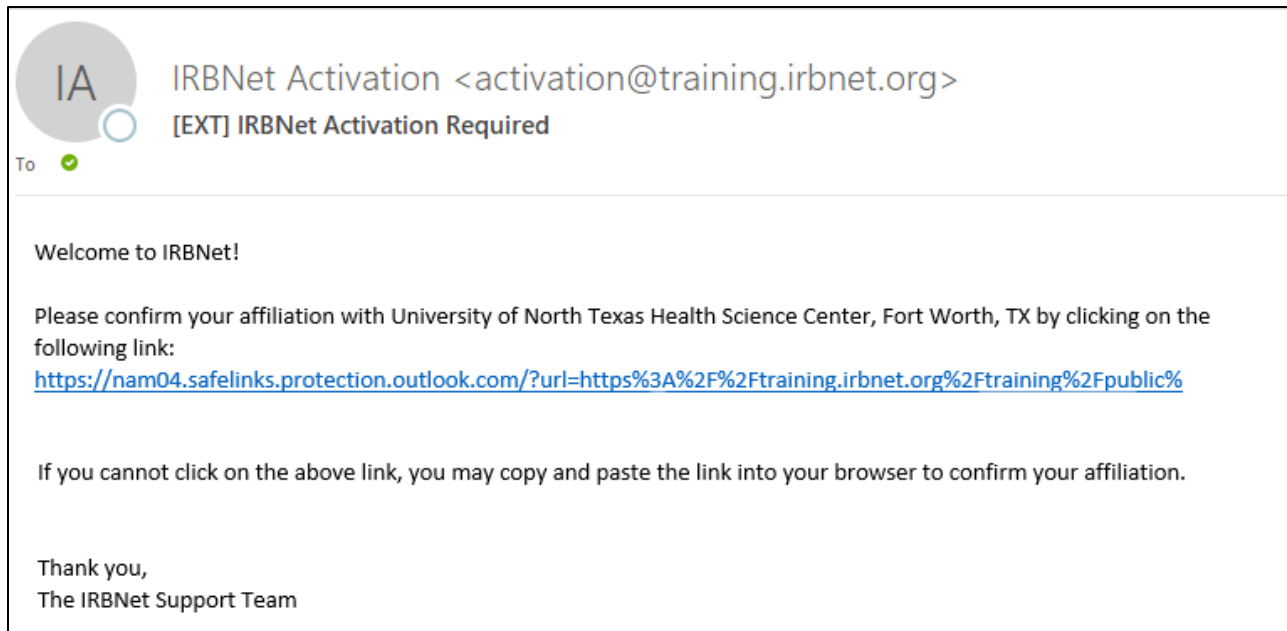
9. Check the e-mail address that you just listed as your recovery e-mail address to find a six-digit verification code from IRBNet (see example e-mail below).



10. Enter the six-digit verification code from the IRBNet verification email into the pop-up box that appeared on the IRBNet website when you clicked “Verify Now.” Click “Continue.”



11. After providing the verification code, you will then need to log into your primary e-mail address and open another e-mail from IRBNet (see example below). Click on the provided link in the e-mail to confirm your affiliation with your institution.



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 and cannot be edited by the study team. A package is locked by study teams upon initial submission and again 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, submit adverse event reports or protocol deviations, 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 next package containing the continuing review 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 as a whole; includes the initial study submission, as well as any continuing reviews, amendments, adverse events, etc.
7. **Unlocked Package:** A package is unlocked when the IRB has requested additional documentation or information. The study team is able to make revisions and updates to an unlocked package.
8. **Wizard Application Form:** IRB application form for a new study. Guidance for completing this document is available in Appendix A.

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:

Internal Reference Number:

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

* 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 Designer page is where you will later upload your completed study documents.

Designer

[71893] IRBNet Usability Study

Package: 71893-1 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: IRB Forms and Template Guidance Note - Please Read

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](#)

OR [\(When should I do this?\)](#)

- 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** of this document.

The screenshot shows the 'Designer' page for a package titled '[71893] IRBNet Usability Study'. The package status is '71893-1 Work in progress (Not submitted)'. There is a text box for adding a package description or notes. The interface is divided into two steps:

- Step 1:** Download blank forms, document templates and reference materials to assist you in assembling your document package. It includes a 'Select a Library' dropdown set to 'North Texas Regional Institutional Review Board, Fort Worth, TX' and a 'Select a Document' dropdown set to 'IRB Forms and Template Guidance Note - Please Read' with a 'Download' button.
- 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. A note states 'There are no documents in this package.' and 'There are no Training & Credentials records linked to this package.'

At the bottom, there are two main options: 'Start a Wizard' (highlighted with a red circle and a red arrow pointing to the dropdown menu) and 'Attach New Document'. The dropdown menu lists: 'North Texas Regional IRB - New Protocol Application Form', 'Orlando Health - IRB Application', and 'UMCP - IACUC Animal Study Protocol'. A note specifies: 'Please note that only the "North Texas Regional IRB – New Protocol Application Form" will be available for use.'




- Visit the [NTR IRB Forms page](#) to download the required forms and templates for your project. **NOTE:** Forms and templates are no longer available for download in IRBNet.

The screenshot shows the website for the North Texas Regional Institutional Review Board. The main heading is 'Institutional Review Board Forms'. The page includes a navigation menu on the left with categories like 'Guidance on Human Subject Research', 'Instructional Guidance and Sources for Human Subject Investigators', 'Investigator Guidebook', 'Request a Consultation', 'Categories of Review' (with sub-items: Exempt Review, Full Board Review, Expedited Review, Continuing Review of a Research Project, Protocol Amendments and Modifications), and 'Other Information and Guidelines' (with sub-item: Informed Consent).




The main content area contains instructions for submitting forms, including an 'Important Note' that states: 'THE PRINCIPAL INVESTIGATOR MUST HAVE FULL ACCESS TO THE IRBNET PROTOCOL PACKAGE IN ORDER FOR IT TO BE REVIEWED BY THE IRB.' It also provides a general reminder: '*As a general reminder, Full Board submissions MUST be received by CLOSE OF BUSINESS (5:00 PM CT) on the day of the submission deadline in order to be considered for the upcoming IRB Meeting.*'

8. Scroll down on the NTR IRB Forms page to find the full library of available forms and templates offered by the NTR IRB. Download any needed files by clicking the MS Word icon or the Adobe PDF icon to the right of each listed document.




Protocol Synopsis:

Protocol Synopsis Template (General)	02/2022		
Protocol Synopsis Template (Chart Reviews) – Not to be used for Data Registry projects	11/2019		

Serious Adverse Event (SAE):

SAE Form – OFF-SITE	11/2019	
SAE Form – ON-SITE	12/2019	
SAE Guidance Document	11/2019	

Waiver Forms:

Waiver of Informed Consent	01/2019	
Waiver of Documentation of Informed Consent	01/2019	
Waiver of HIPAA Authorization	01/2019	

Save to your computer, complete all necessary fields within each required document, and save again to ensure that your files are ready to be uploaded. (NOTE: Actual list of forms may differ from what is shown above.)

9. Make sure you have completed all sections of the NTR 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.).
10. Once all necessary forms have been completed, click **My Projects** (left hand menu) and select your current project.

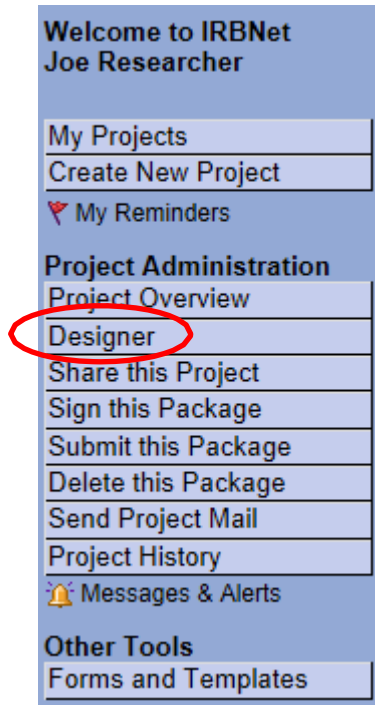
Search: Search By Tag:

1 - 10 of 72

[Create and Manage Tags](#) | [Show Archived Projects \(4\)](#) | [Project Status View](#)

IRBNet ID	Project Title	Principal Investigator	Submission Type	Board Action	Effective Date
71893-1	IRBNet Usability Study	Researcher	Work in progress (Not submitted)		

11. Navigate back to the **Designer** page to upload your application and all supporting documents.



12. Once you click **Attach a New Document**, you will be prompted to upload a document from your computer.

13. 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	
<div style="border: 1px solid #ccc; padding: 2px;"> ▼ (please select) </div>	Protocol-Synopsis-for-Research-Involving-Surveys_IRBNet Usability.doc	02/18/2019 05:38 PM	   

- Attach all supporting documents such as the protocol synopsis, interview questions, CITI Training Completion Reports, letters 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](#) |

OR

(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 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**.

- Once all files have been uploaded, you may need to share your study with others. **Please note that PI's 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.

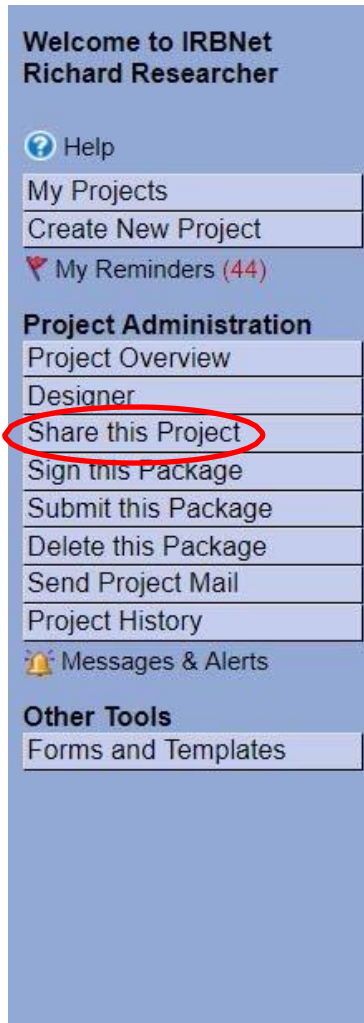
**For JPS projects, please ensure the following OCR staff have full access to the project:*

- Melissa Acosta, PhD, Director
- Andrew Adorboe, MSN, BSN, Research Integrity Manager
- Carissa Jensen, MPH, CPMP, Research Integrity Specialist

**For UNT Dallas projects, please ensure the following individual has full access to the project:*

- Dr. Alicia Brossette, Executive Director, Office of Sponsored Projects

16. 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.

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

Share Project

[71893-1] 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.

18. 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.

19. 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. 17). The North Texas Regional IRB requires that PIs have full access to the project package in order to start the review process.
20. 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
Tooduitt, 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

Save Cancel

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

21. PI's 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.



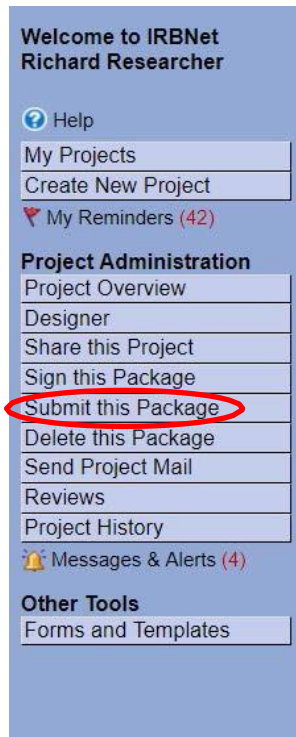
22. Select your role in the project. If you are the principal investigator, select this option from the drop-down box.



23. 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. 18-20).

24. 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.

25. 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 Wort
- North Texas Regional Institutional Biosafety Committee (IBC), Fort Worth, TX
- North Texas Regional Radiation Safety Committee (RSC), Fort Worth, TX

Continue Cancel

* required fields

26. 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**

27. 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: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=https://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.

Welcome to IRBNet
Richard Researcher

Project Messages & Alerts
[61395-1] IRBNet Usability Study

The following communications have been posted for this project. You can set a personal reminder on any message or alert. Your personal reminders will automatically appear in your My Reminders list. Other users do not see your personal reminders. You can turn on or silence a personal reminder without affecting other users.

IRBNet ID	Project Title	Message Type	Date
61395-1	IRBNet Usability Study	Package Unlocked	02/15/2019 04:02 PM
61395-1	IRBNet Usability Study	Submission Notification	02/15/2019 04:00 PM

- b. Under "Board Documents" which can be accessed by clicking, "Pending Review".

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		Pending Review	

Package 61395-1 is: **Unlocked - Revisions Pending**

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

Shared with the following users:

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

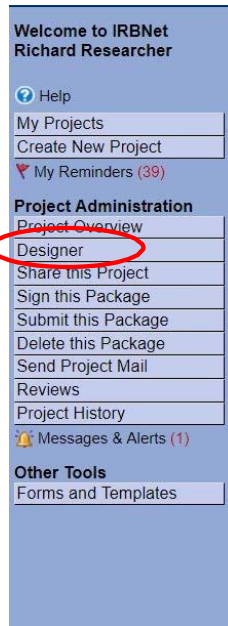
Reviews
[61395-1] IRBNet Usability Study
North Texas Regional Institutional Review Board, Fort Worth, TX

Reviews:

Pkg #	Submission Date	Submission Type	Agenda	Review Type	Board Action	Effective Date	Project Status	Expiration Date
1	02/15/2019	New Project	Unassigned		Pending Review			

Board Documents:
There are currently no documents from North Texas Regional Institutional Review Board.

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 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 to your computer, revise it in an 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 change 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.



- 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.



- 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 be edited. 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 until one of the following: <ul style="list-style-type: none"> ○ Submission of Continuing Review (if / when applicable), Amendment/Modifications and SAEs by using “Create New Package” (see Section VI of this manual)
Exempt	<ul style="list-style-type: none"> • No further action is needed unless modifying the study • All modifications (including changes the Key Personnel) should be submitted to the IRB by using “Create New Package” (see Section VI of this manual)
Approved with Modifications	<ul style="list-style-type: none"> • Review the IRB’s findings provided in the Determination (found in “Board Documents”) • Address the comments by “Creating New Package” (see Section VI of this manual) <ul style="list-style-type: none"> ○ Classify as “Response/Follow Up” when asked for “Submission Type” (toward the end of the submission process) • Upload new/modified documents (track change / clean versions) • A memo signed by the PI OR message back in IRBNet if the PI signs the package • 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 comments by “Creating New Package” (see Section VI of this manual) <ul style="list-style-type: none"> ○ Classify 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, addressing all the requested changes/modifications • Submit to notify the IRB the new package is ready for review
Disapproved	<ul style="list-style-type: none"> • The IRB’s findings and justification will be included in the Determination letter (found in Board Documents) • If you would like to resubmit for IRB review, you will need to submit as a New Project (follow steps in Section III: Project Creation). <i>No new packages should be submitted for projects that are Disapproved.</i> • Please note the new submission will need to address the IRB’s findings
Not Human Subjects Research	<ul style="list-style-type: none"> • No further action is needed unless modifying the study • All modifications (including changes the 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

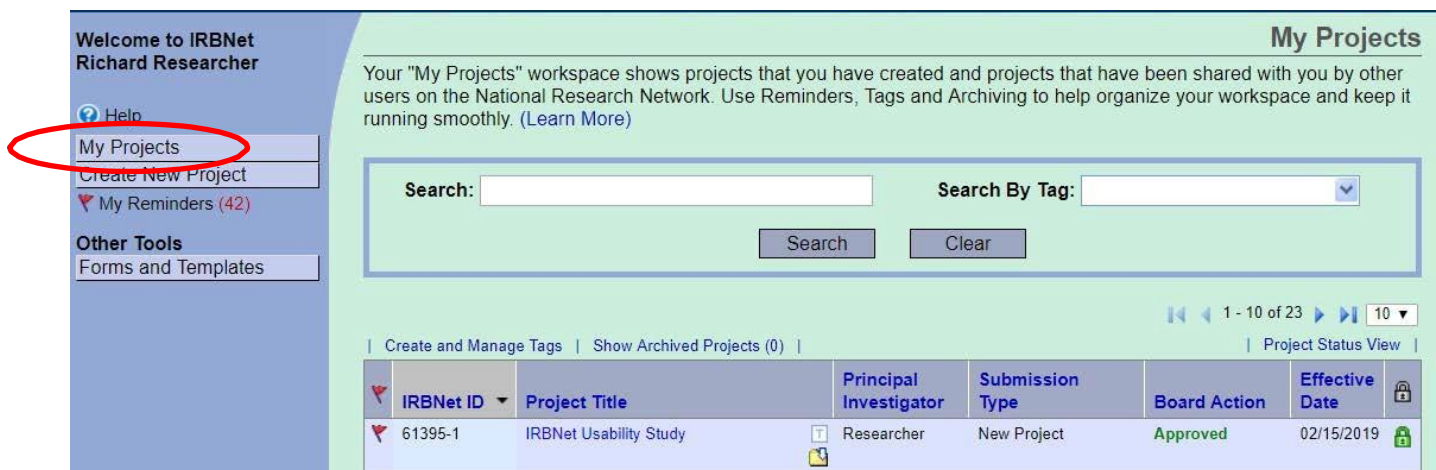
After receiving a determination, a few different scenarios will apply. As discussed in the previous section, how to proceed will vary based on the determination. This section will guide you on how to "Create a New Package".

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

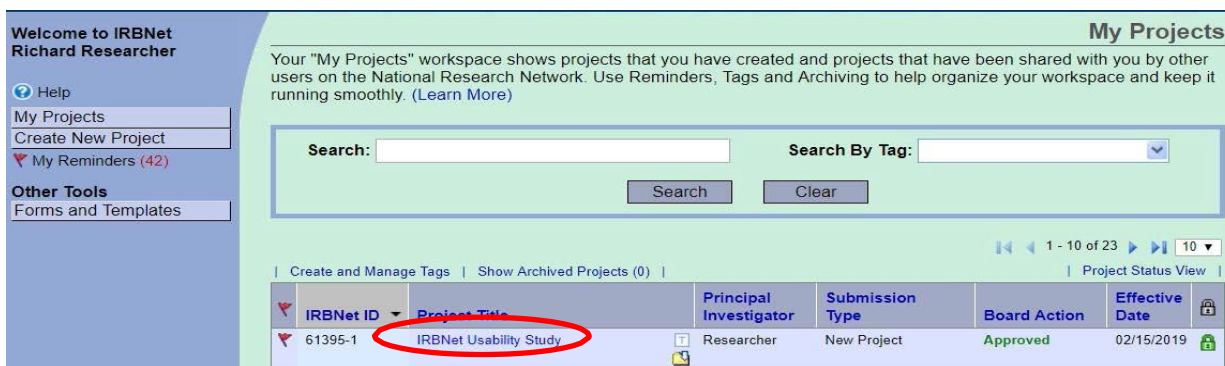
- Amending/Modifying a Project (i.e. adding key personnel, updating study documents)
- Responding to modifications when a project has been Deferred or Approved with Modifications
- Submitting a Continuing Review

Steps to Create a New Package:

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 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

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.

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.

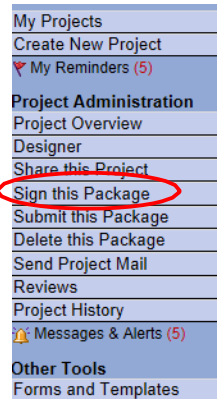
There are no Training & Credentials records linked to this package. Link / Un-Link Training Records

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

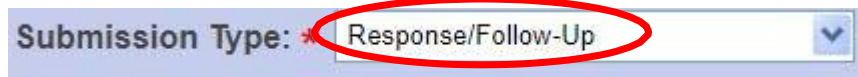
Documents from Previous Packages that you can Revise: (When should I do this?)

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 *'. At the top, there is a search bar with the text 'Search for an Organization', a search button, and a clear button. Below the search bar is a checked checkbox labeled 'Only show My Default Boards'. A dropdown list shows four options: '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', and 'North Texas Regional Radiation Safety Committee (RSC), Fort Worth, TX'. At the bottom of the form, there are two buttons: 'Continue' and 'Cancel'. The 'Continue' button is circled in red. A red asterisk and the text '* required fields' are located at the bottom left of the form.

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

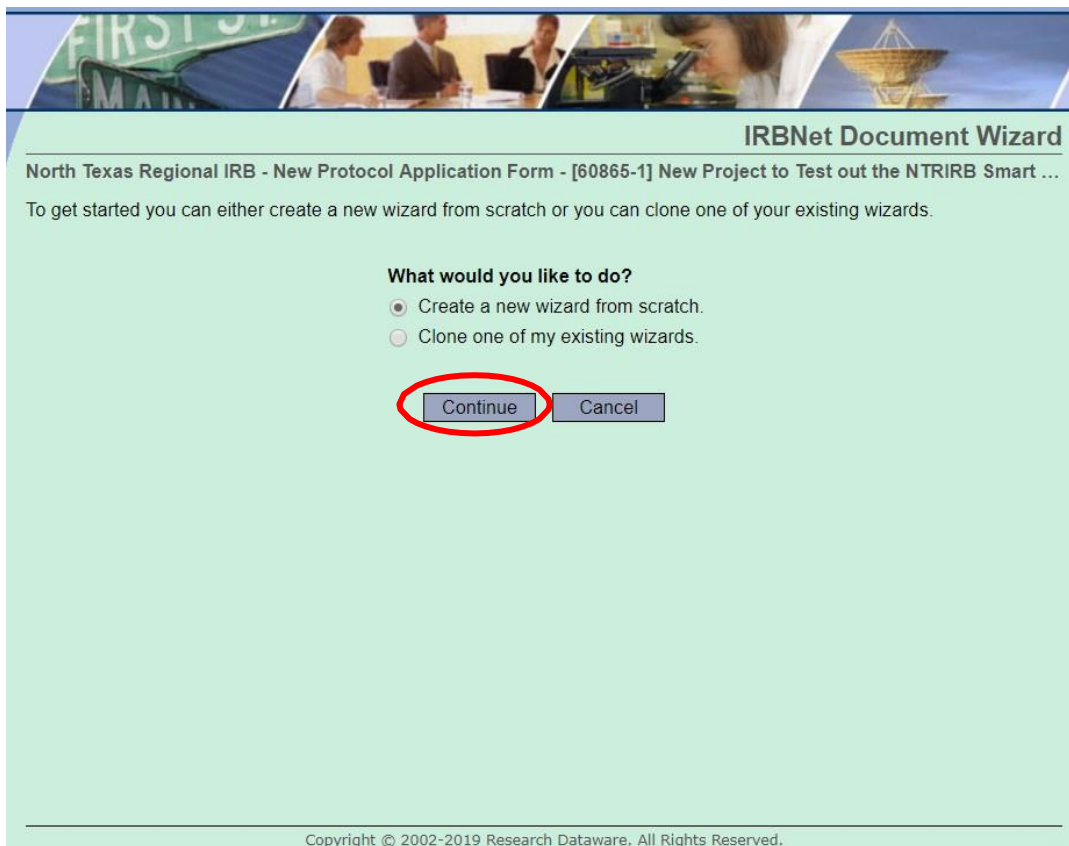
- A. Wizard Form Guidance 31
- B. Developing Descriptive File Names..... 48
- C. Linking CITI Training 49

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 the text "IRBNet Document Wizard" and a subtitle "North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...". Below the banner, the text reads: "To get started you can either create a new wizard from scratch or you can clone one of your existing wizards." Underneath, there is a section titled "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 this section, there are two buttons: "Continue" and "Cancel". The "Continue" button is circled in red. At the very bottom of the page, there is a copyright notice: "Copyright © 2002-2019 Research Dataware. All Rights Reserved."

- 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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- 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
[Empty field]

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.
[Empty field]

- 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.

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

(* required)

Save and Exit Preview Previous Next

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

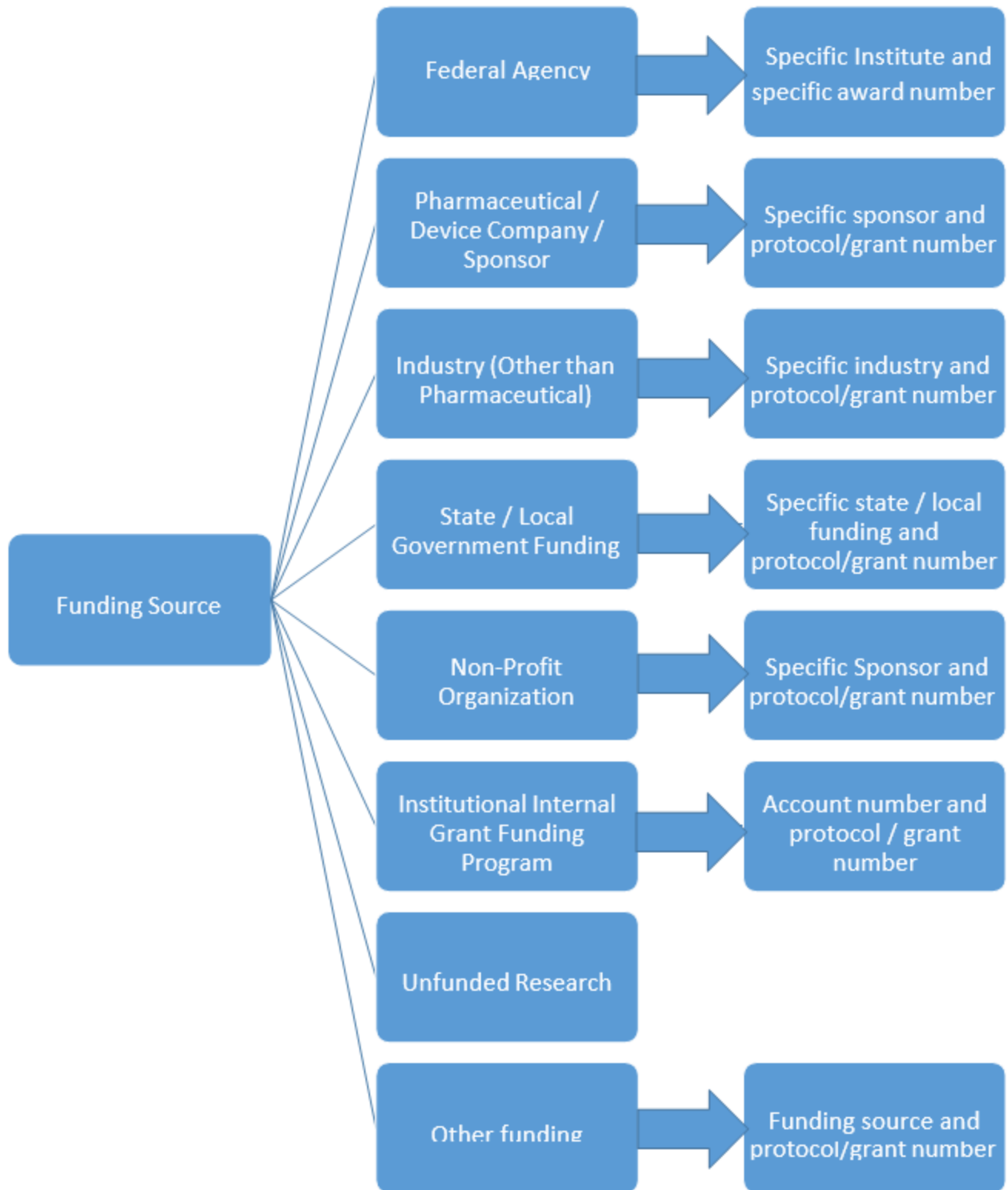
- Please provide information about other pertinent Research/Key Personnel. The IRB recommends listing *only the main personnel* in the Wizard application form and providing a complete list of research personnel in the protocol synopsis, as this will prevent the need to update the form whenever there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

The screenshot shows a web form titled "IRBNet Document Wizard" for a "New Protocol Application Form". The form is for "Additional Research/Key Personnel Information". It includes a "Jump To:" dropdown menu set to "Additional Research/Key Personnel Information" and a "Jump" button. Below this, there are instructions: "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." The form then lists "Additional Personnel 1" with fields for: "Additional Personnel First Name" (John), "Additional Personnel Last Name" (Statistician), "Additional Personnel Telephone" (678-091-5432), "Additional Personnel Fax" (empty), "Additional Personnel Email" (john.statistician@unthsc.edu), and "Additional Personnel Role(s)/Responsibilities" (Administers Informed Consent).

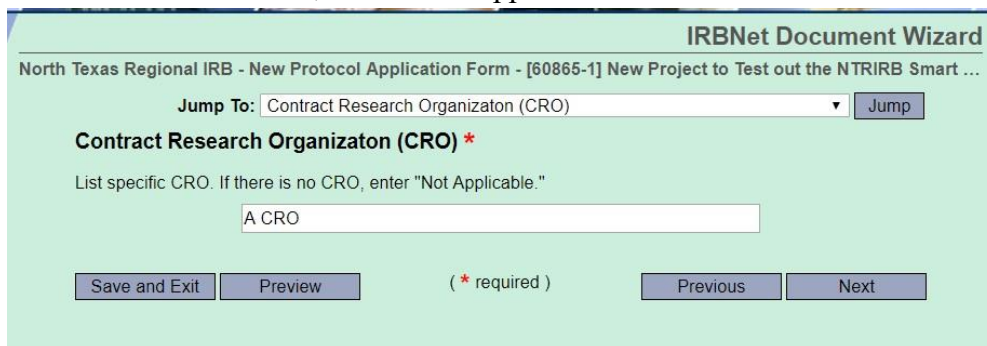
6. The Wizard application form will guide you through questions about the study. Based on answers to certain questions, the Wizard application form will generate the appropriate additional pages that need to be completed. Not all of the additional pages will be generated for every project.
 - a. First, 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 section is titled 'Funding Source *'. Below this title, a note states: 'Indicate the category of the sponsor (REMINDER: Upload a copy of your grant application and Notice of Award)'. There are eight radio button options listed: '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 of the form, there are four buttons: 'Save and Exit', 'Preview', 'Previous', and 'Next'. A note '(* required)' is positioned between the 'Preview' and 'Previous' buttons.

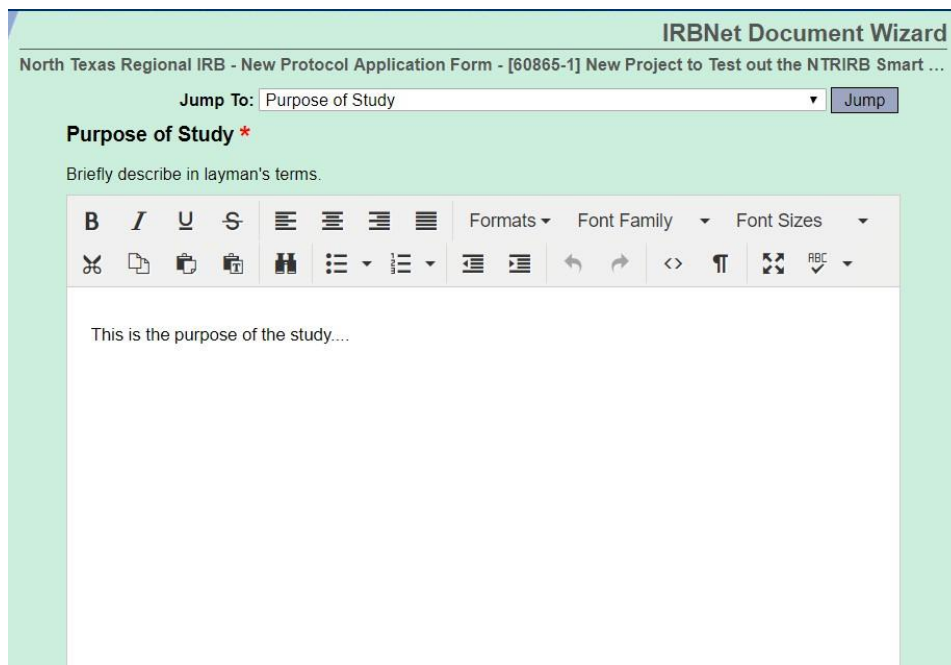
- b. Listed below are all of the possible “funding source” options, which are followed by the type of information that will be requested on the subsequent page after you click “Next”.



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



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

- 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.

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', 'Previous', and 'Next', along with a note '(* required)'.

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', 'Previous', and 'Next', along with a note '(* required)'.

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', 'Previous', and 'Next', along with a note '(* required)'.

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.

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

Jump To: Multi-Site IRB Review [Jump]

Multi-Site IRB Review *

Are other IRBs involved in the approval of this project?

(Note: This does NOT apply to FDA-regulated sponsored clinical trials)

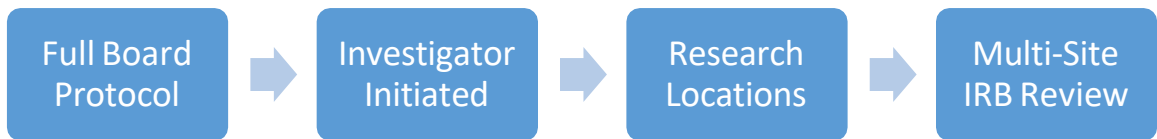
Yes

No

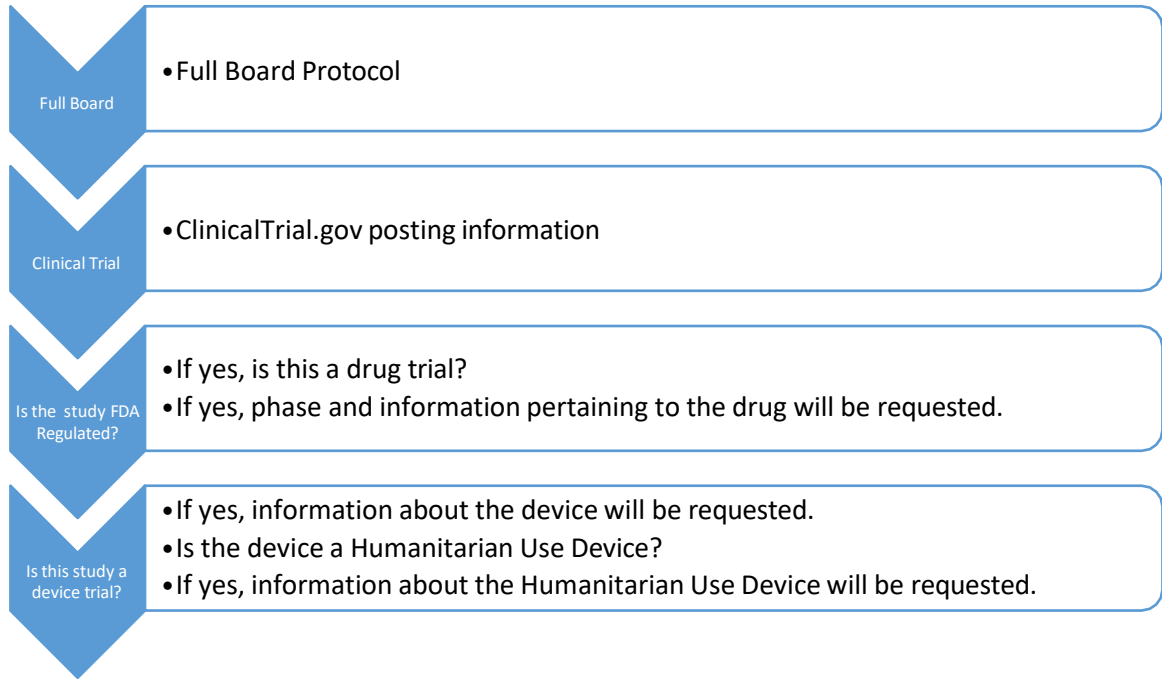
Not Applicable

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

15. Based on your responses to items 10 & 11 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:

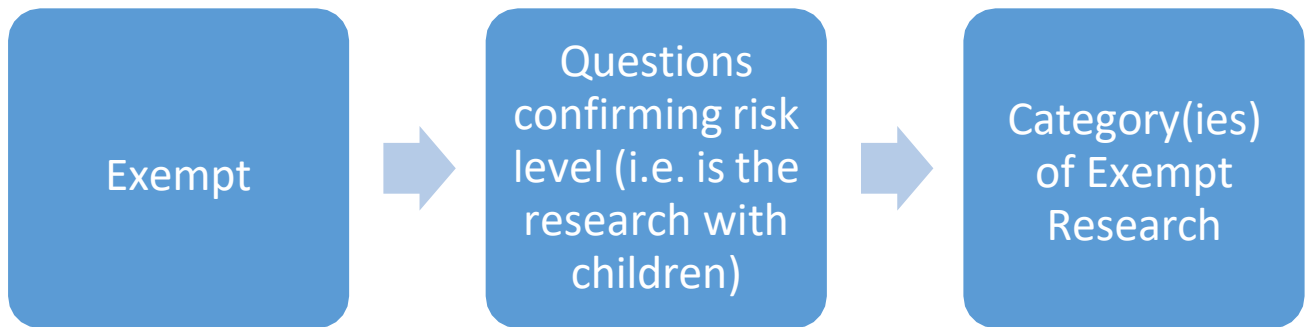


b. If “Full Board Protocol” followed by “Clinical Trial” is selected, the following pages will be generated:



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.

- 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 [Jump]

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
- Telephone 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
- Certificates/ 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

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

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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 *

Expedited Categories:

- **Category 1:** Clinical studies of drugs and medical devices ONLY when condition (a) or (b) is met:
 - Research on drugs for which an investigational new drug application is not required.
 - Research on medical devices for which:
 - an investigational device exemption application is NOT required OR
 - 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:
 - Healthy, non-pregnant adults who weigh at least 110 pounds.

Contact IRB Staff for criteria
 - 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:
 - Have already been collected for some other purpose.
 - 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:
 - Individual or group characteristics or behavior (research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior).
 - 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

(* required)

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):

IRBNet Document Wizard

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

Jump To:

Form Complete

Principal Investigator attestation:
 By signing this package in IRBNet, I attest that I have read and understand the Investigator Responsibilities (PI Statement of Assurance), and I agree to adhere to them for the duration of the project.
 If you have any questions or concerns about this application or any other IRB issue, please feel free to contact the IRB Office.
 Based on your responses, the following additional documentation must be included with this package before submission. Upload additional documentation in the Designer.

For a complete list of documents required for initial submission, please refer to the "READ ME FIRST" document located in the Forms and Templates Library.

Additional required documentation (NOTE: Only one Protocol Synopsis document needs to be submitted. If multiple protocol synopsis documents are appearing in the list below, please contact the North Texas Regional IRB if you are unsure of which document to complete and submit):

- Curriculum Vitae (CV) - *Required for PI only*
- Medical licenses for all applicable key personnel
- COI Disclosure Form(s)
- Consent Form
- FDA IND Determination Letter
- HIPAA Authorization Form, if involving health information
- 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)
- Survey(s)/Questionnaire(s)

The list of required documentation will differ based on your responses to the Wizard application form.

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

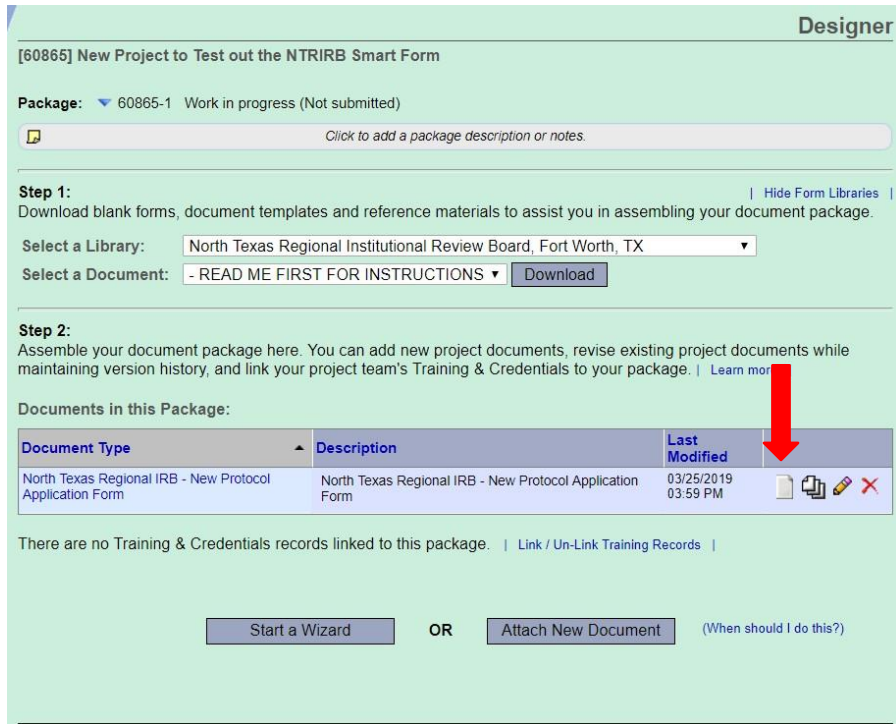
- Human Subjects Research Training Credentials
- Investigator Brochure(s)/Package Insert(s)
- Request for Waiver of HIPAA Authorization
- Request for Waiver of Informed Consent
- Site-Specific Protocol Information for Sponsored Clinical Trials
- Sponsor/Clinical Protocol
- Standardized Test(s)/Assessment(s)
- Survey(s)/Questionnaire(s)

NOTE: Upon the IRB's review of the submission, it is possible that additional documents may be required. The IRB will inform the PI/Study team if any additional documentation (or information) is required for the review of the study.

Please click Preview to review the information you have provided in this form. Refer to the end of the document for this checklist as you continue to prepare this submission. Please use this checklist to ensure that you have attached all the necessary documentation for complete IRB review.

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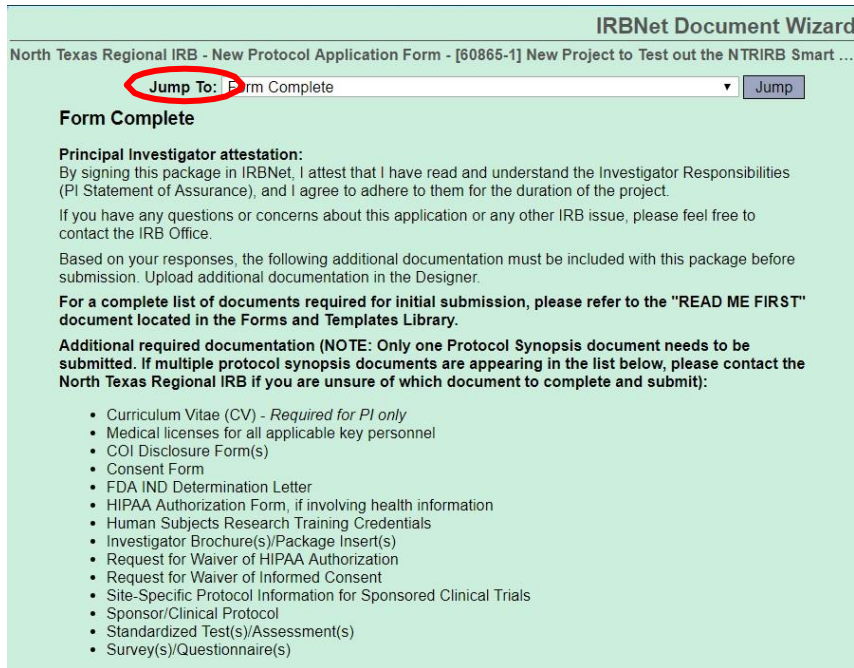
20. On the Designer page, the Wizard application form (titled “North Texas Regional IRB – New Protocol Application Form”) will now appear as a new document in the package:



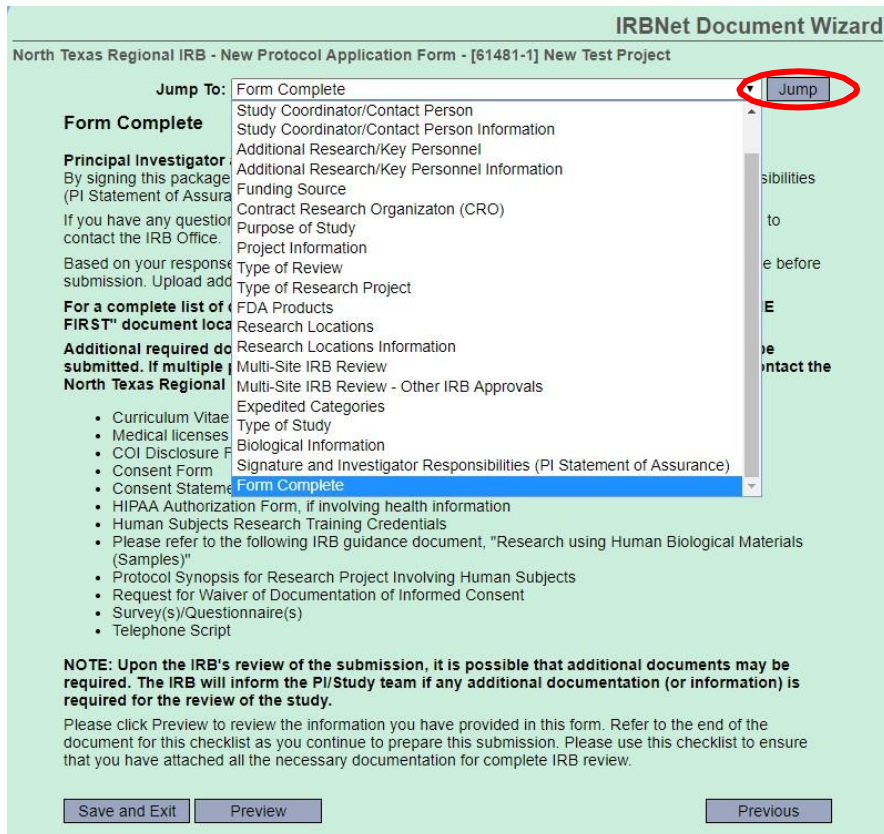
21. By clicking the “View this Document” button (document icon, as shown in screenshot above), the investigator can download a PDF version of their completed Wizard application Form.



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:

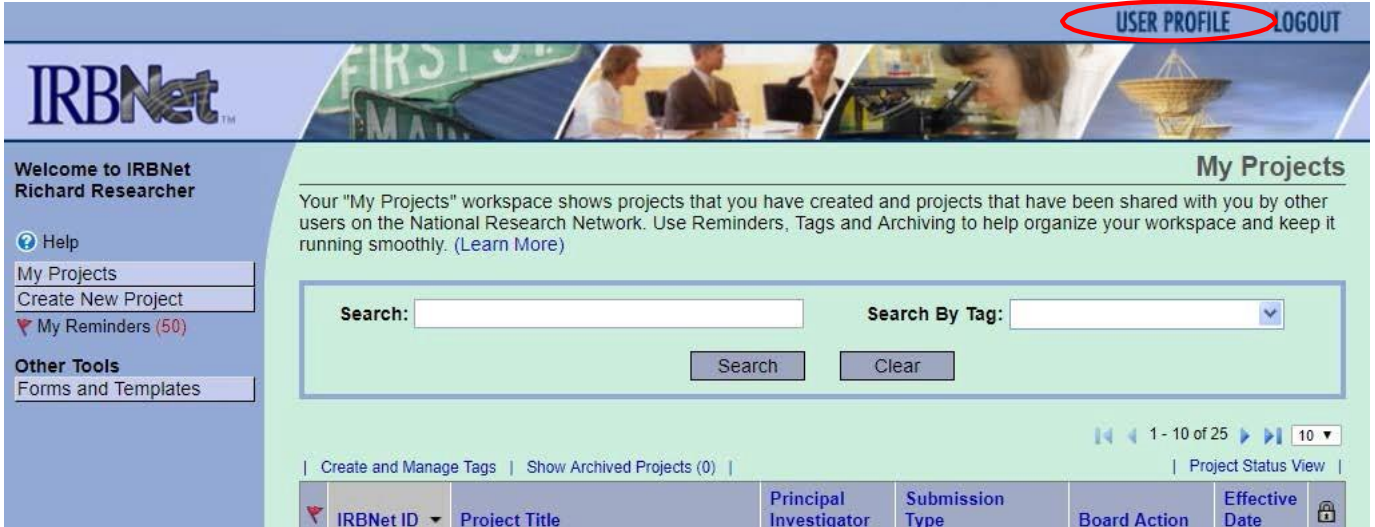
- Title of training
- First initial and last name of key personnel to which the training belongs.

Type of Document	Example of Document	Description Example
Protocol Synopsis	<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

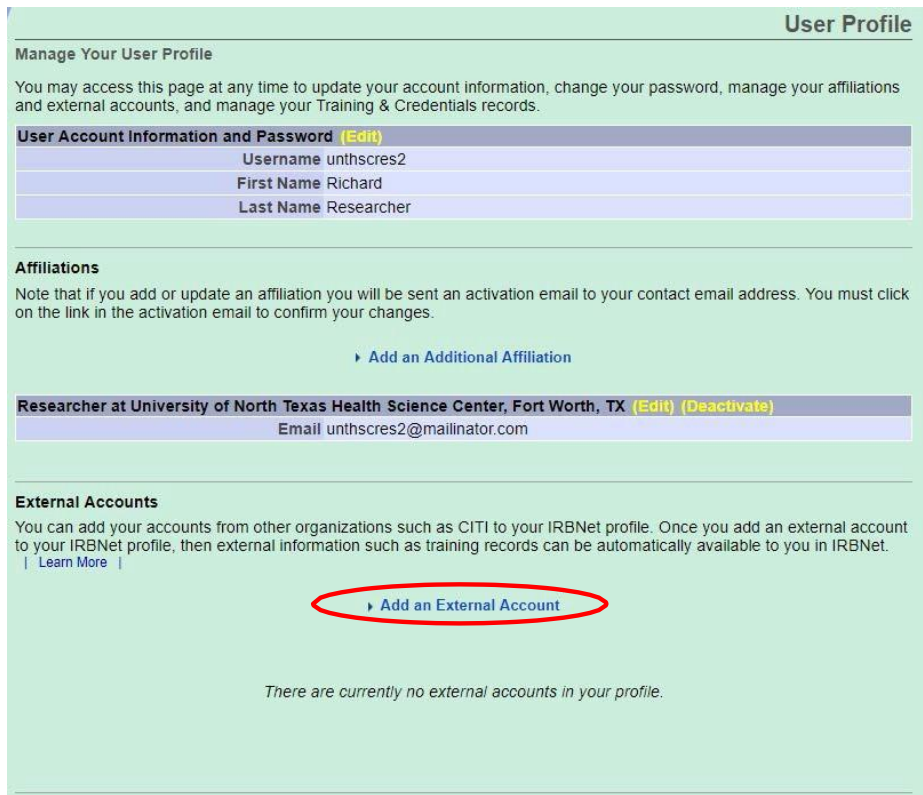
C. Linking CITI Training to User Profile

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.

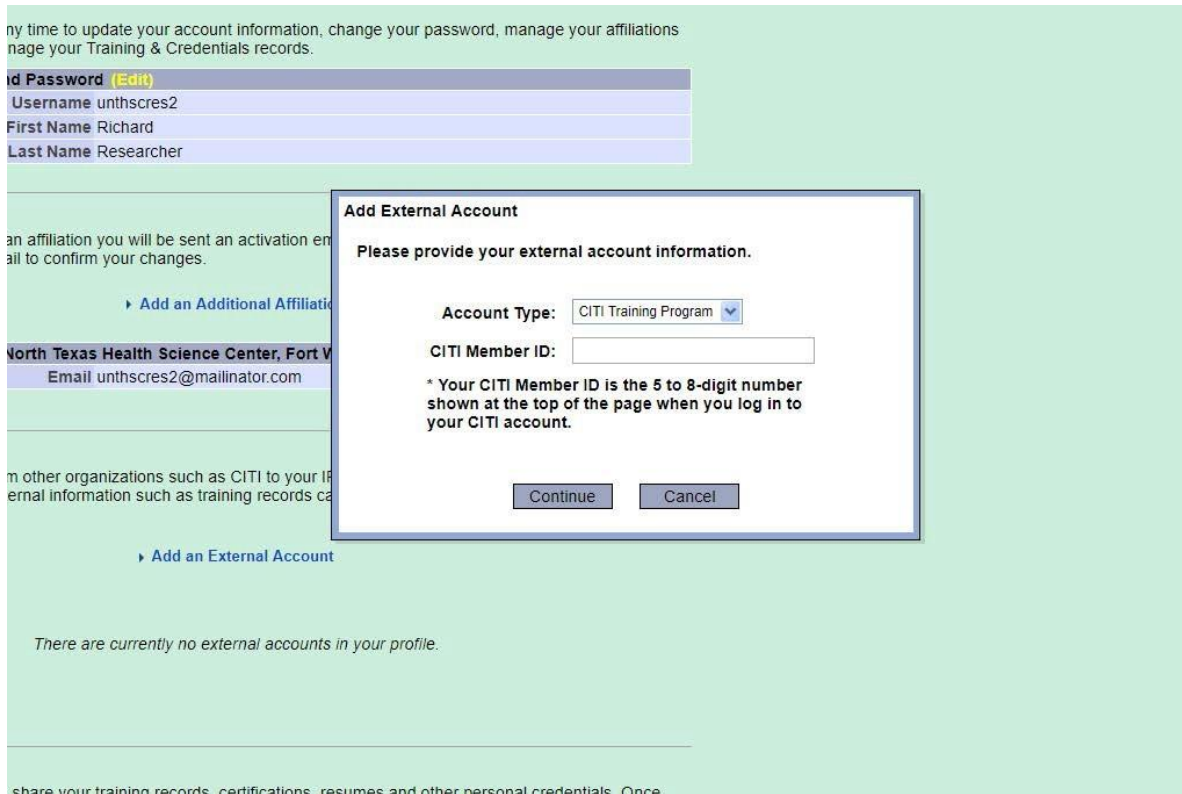
1. After logging in, select "User Profile" at the top of the page.



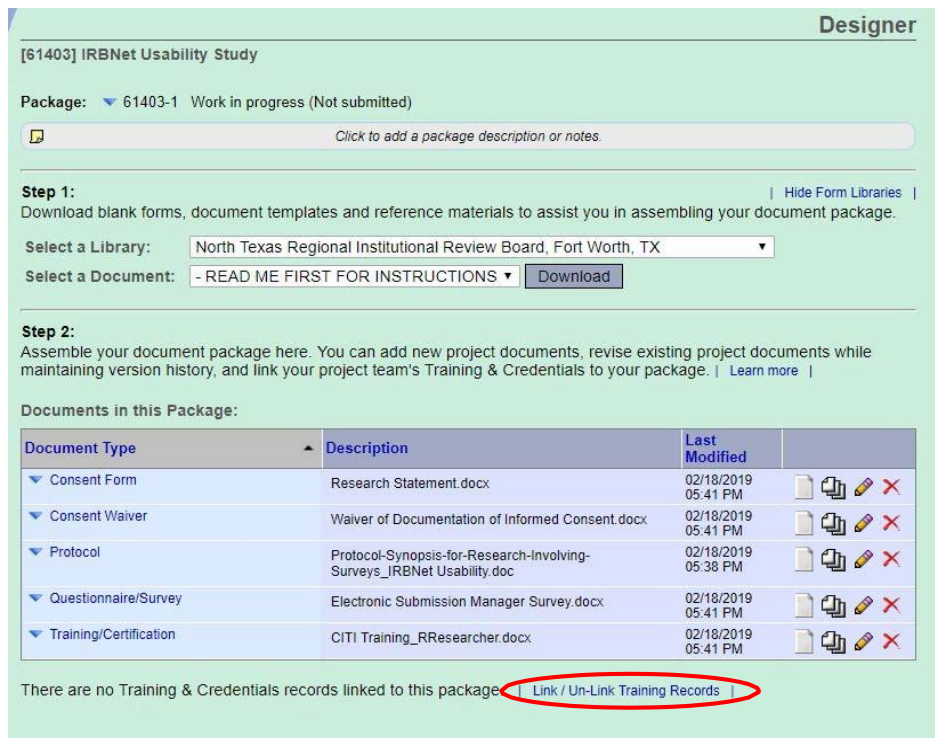
2. In your "User Profile", find the "External Accounts" section. Click "Add an External Account".



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.