North Texas Regional IRB

Office of Research Compliance

IRBNet User Manual

IRBNet User Manual

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

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

For additional questions, or if you encounter any problems, please contact the 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
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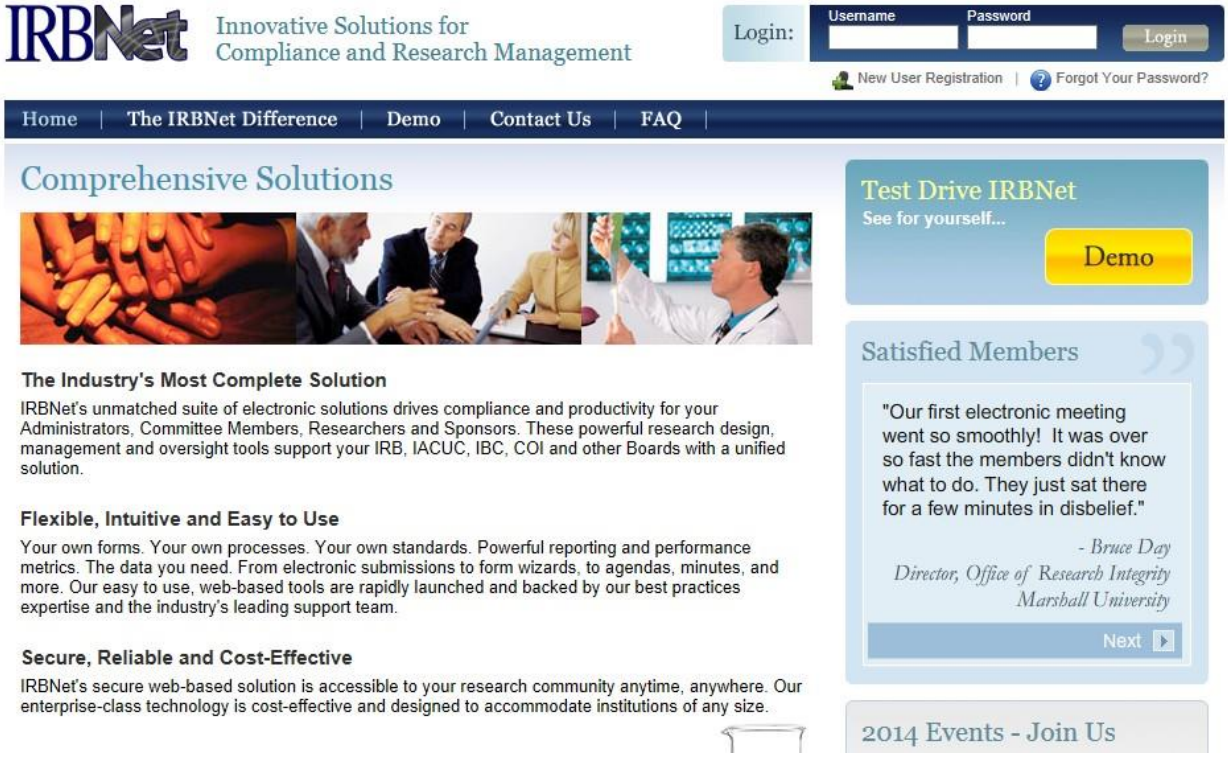
I. Registering with IRBNet

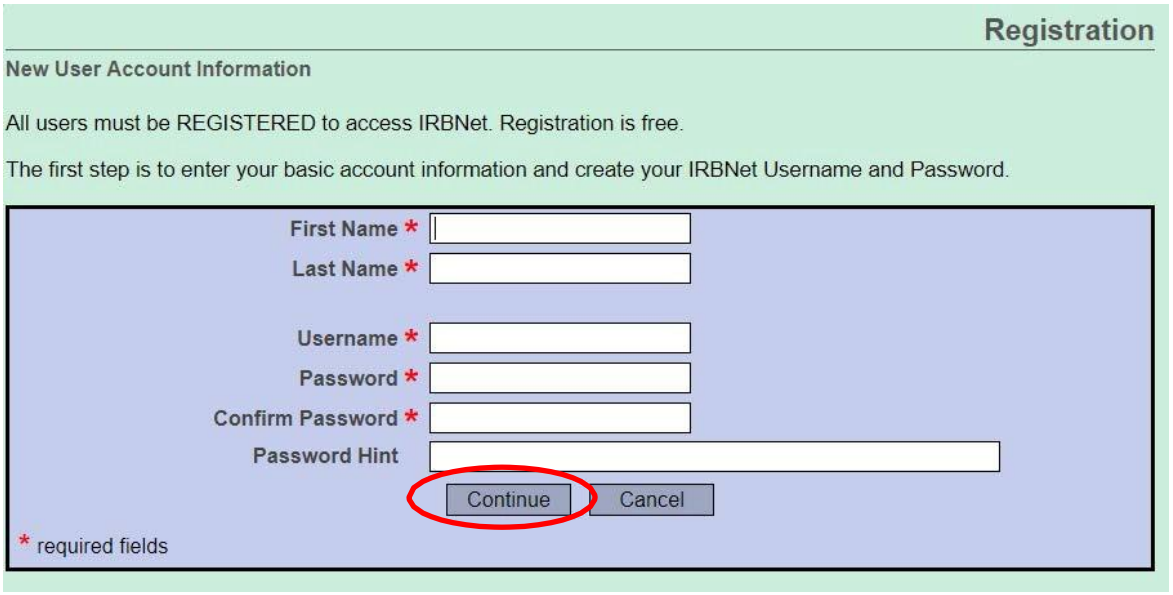
1. Navigate to http://www.irbnet.org



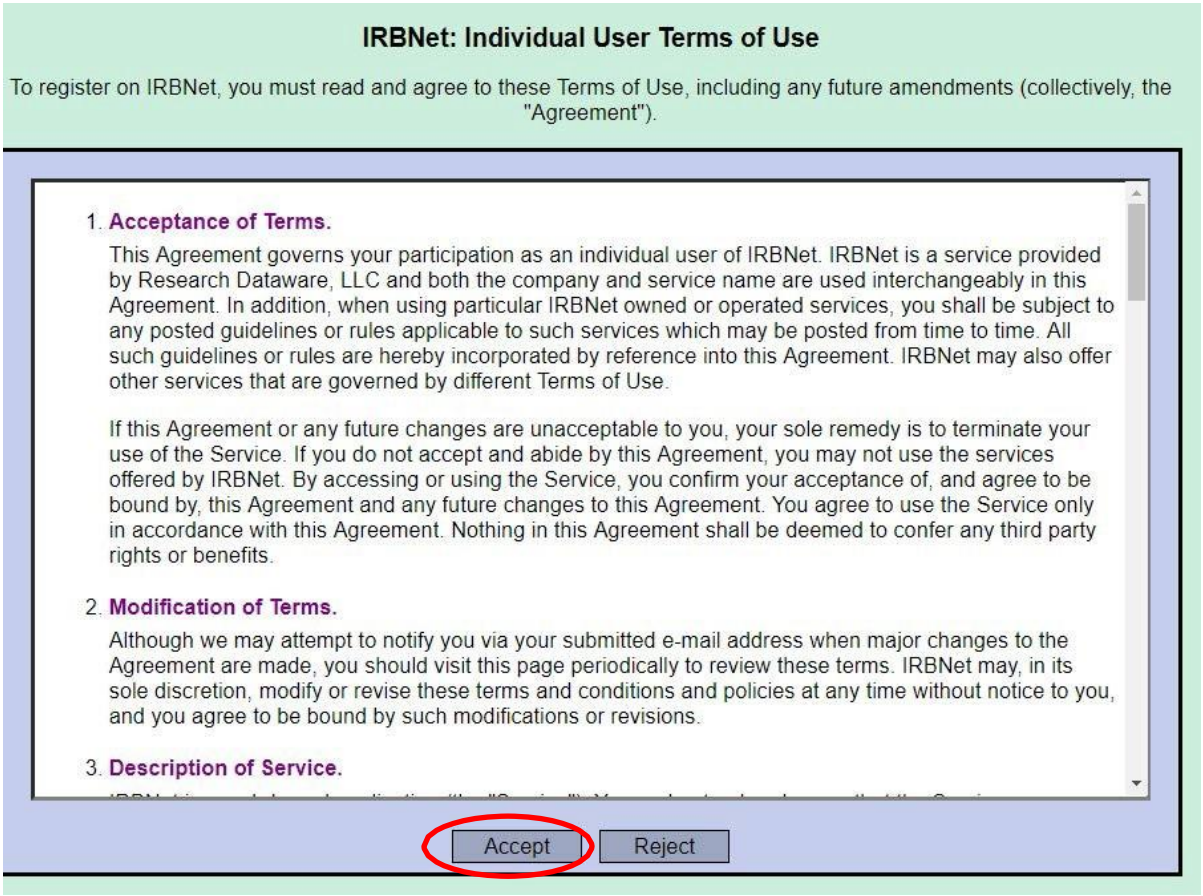
2. Look for the login box, located in the upper right portion of the website.

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

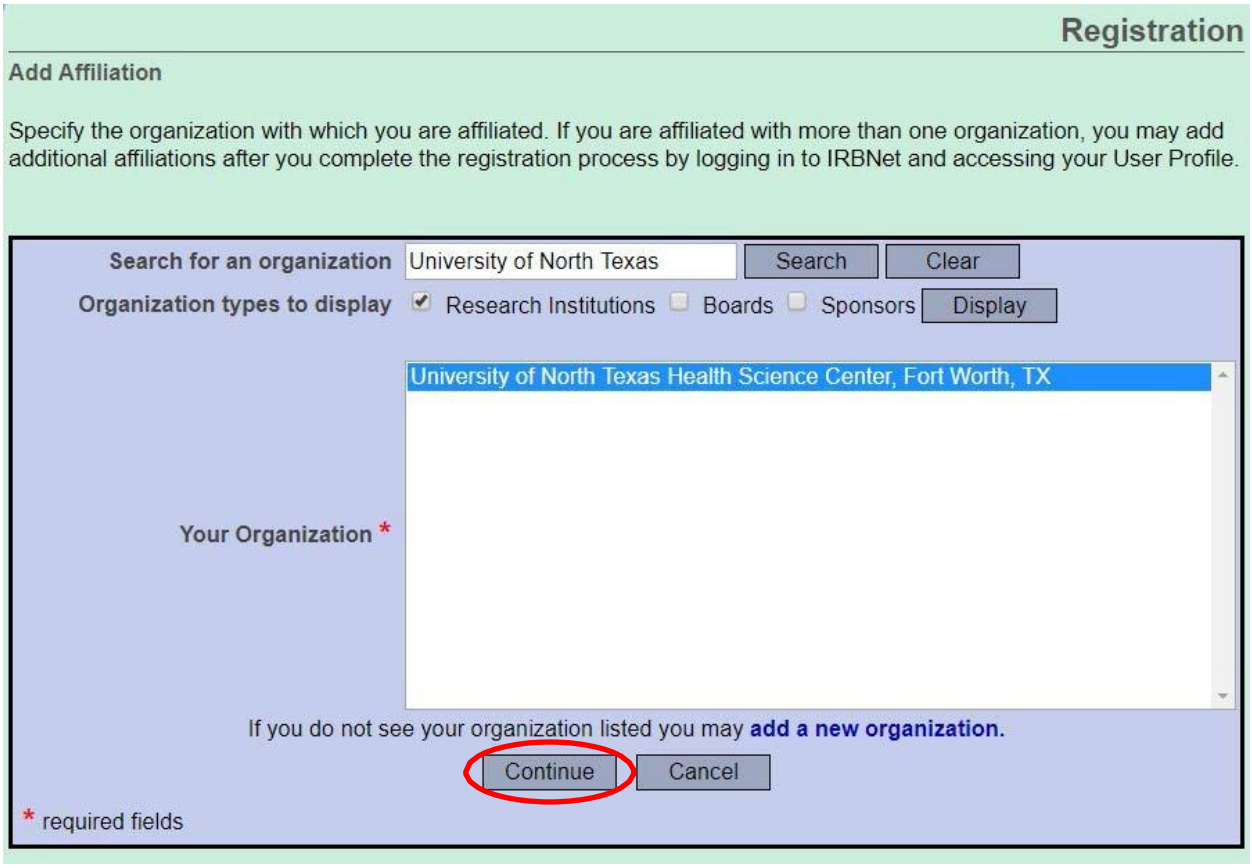
4. Fill in the information necessary to create your account, then click continue.



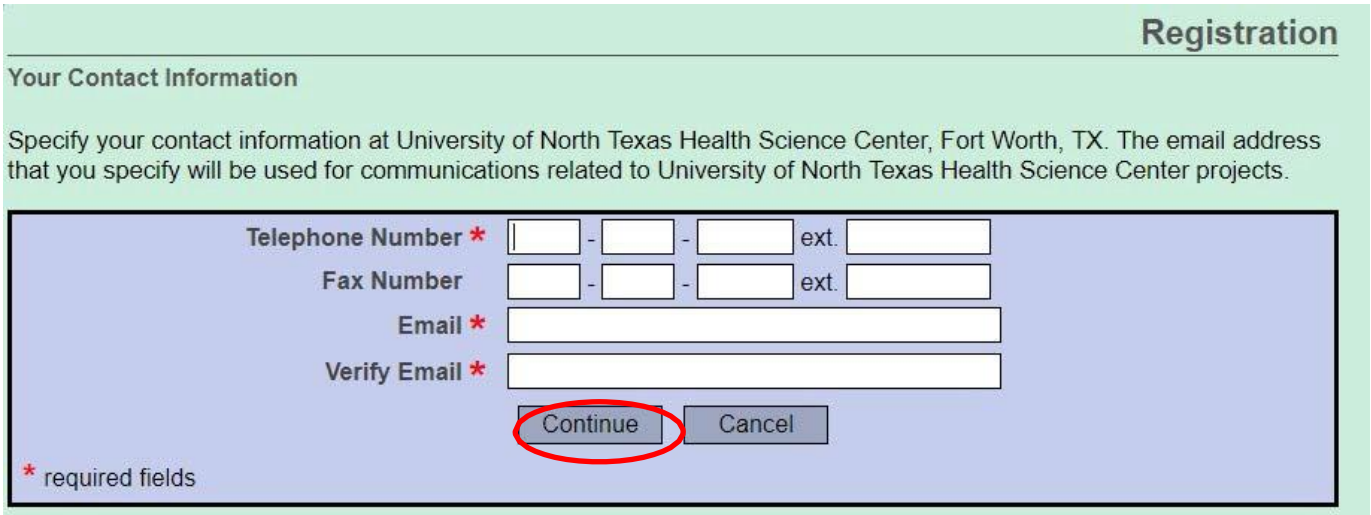
5. Review and accept the Terms of Use.



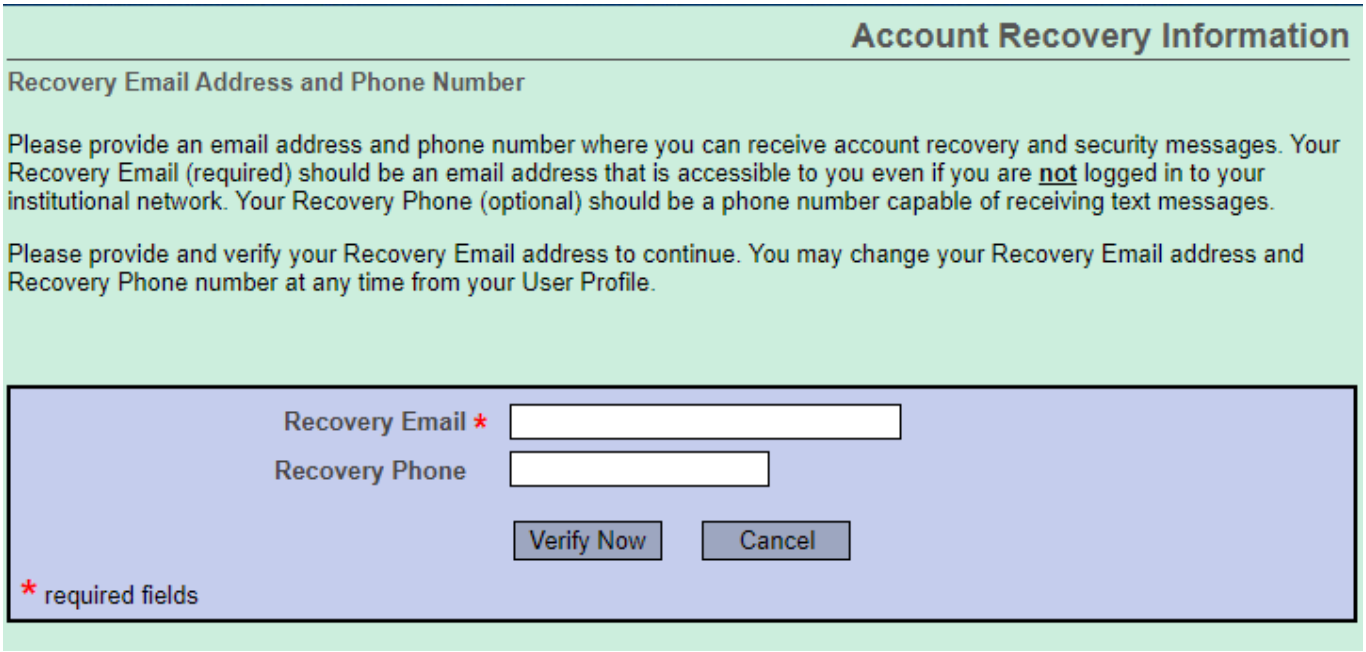
6. Select the appropriate institution, depending on your affiliation (JPS, UNTHSC, UNT Dallas). To do this, type the full name of your affiliation in the **search for an organization** space, then click continue. The example provided here is for a UNTHSC investigator. Click "Continue."



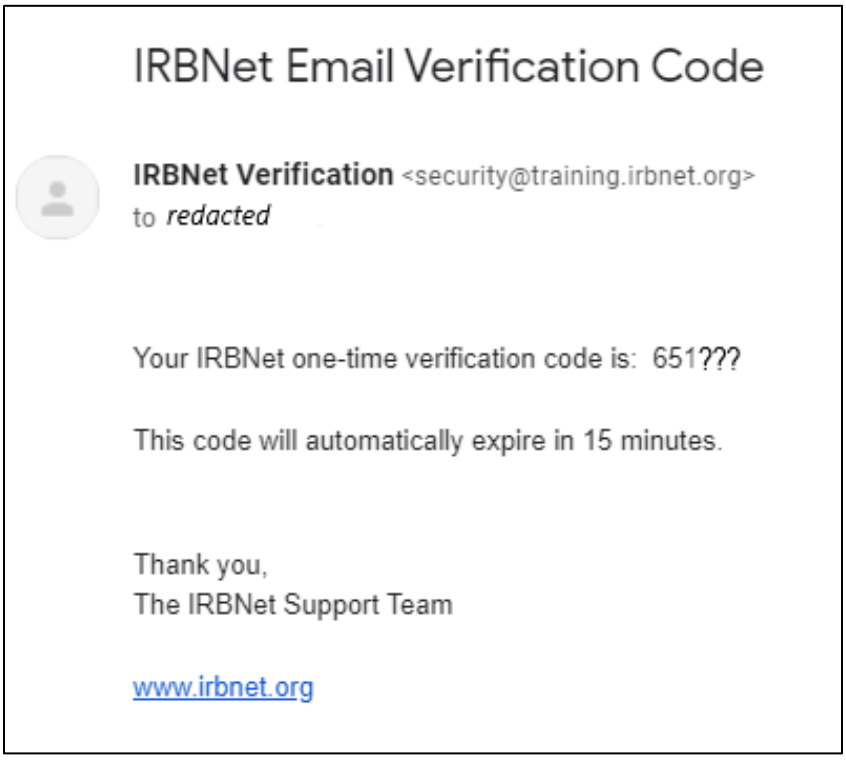
7. Enter your contact information. The primary e-mail address entered will be the one used to contact you regarding IRB decisions related to your future protocol(s), so make sure it is one you can check **OFTEN**. Click "Continue."



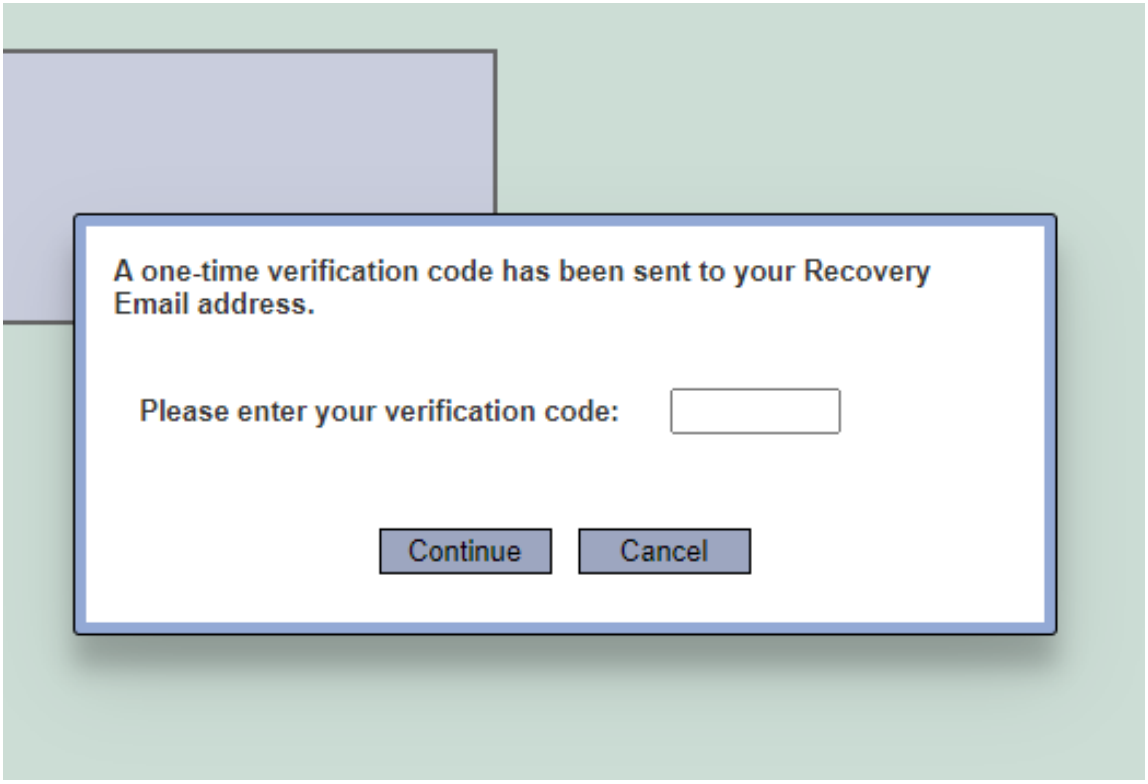
8. Provide a recovery email address and phone number. This can be a personal email address and cell phone number. Next, when you click "Verify Now," you will begin the process of validating your IRBNet user account.



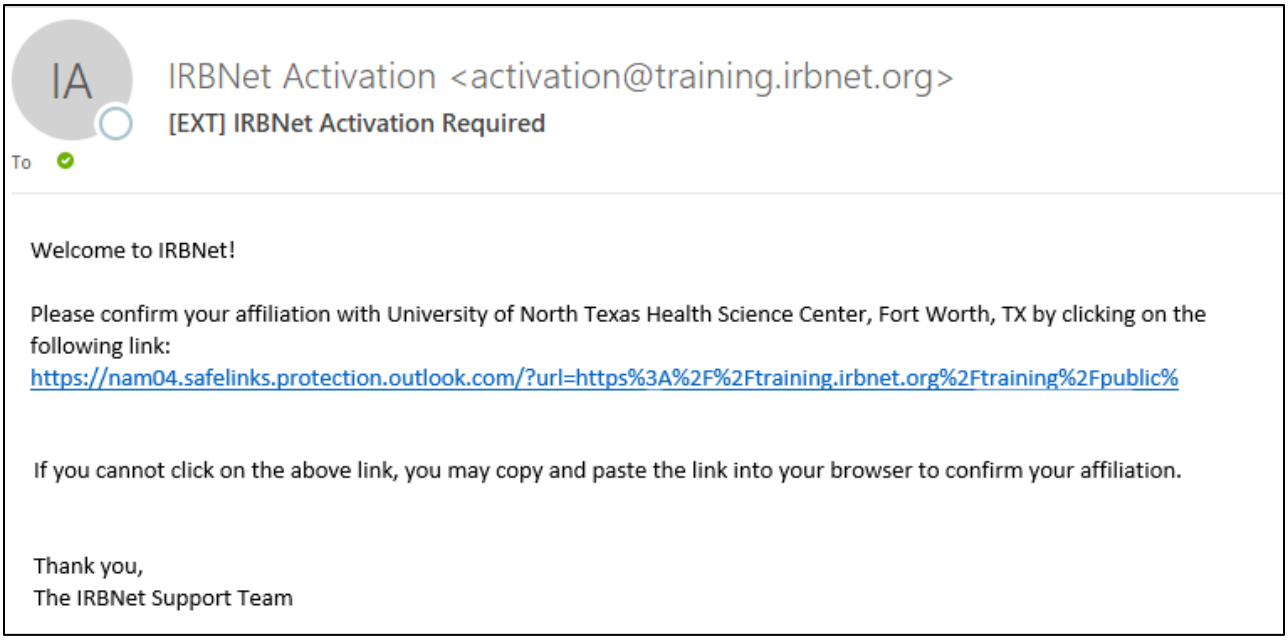
9. Check the e-mail address that you just listed as your recovery e-mail address to find a six-digit verification code from IRBNet (see example e-mail below).



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.

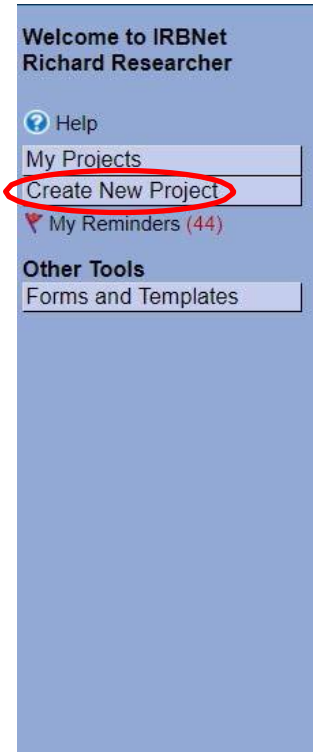
8. **Wizard Application Form**: IRB application form for a new study. Guidance for completing this document is available in Appendix A.

III. Project Creation

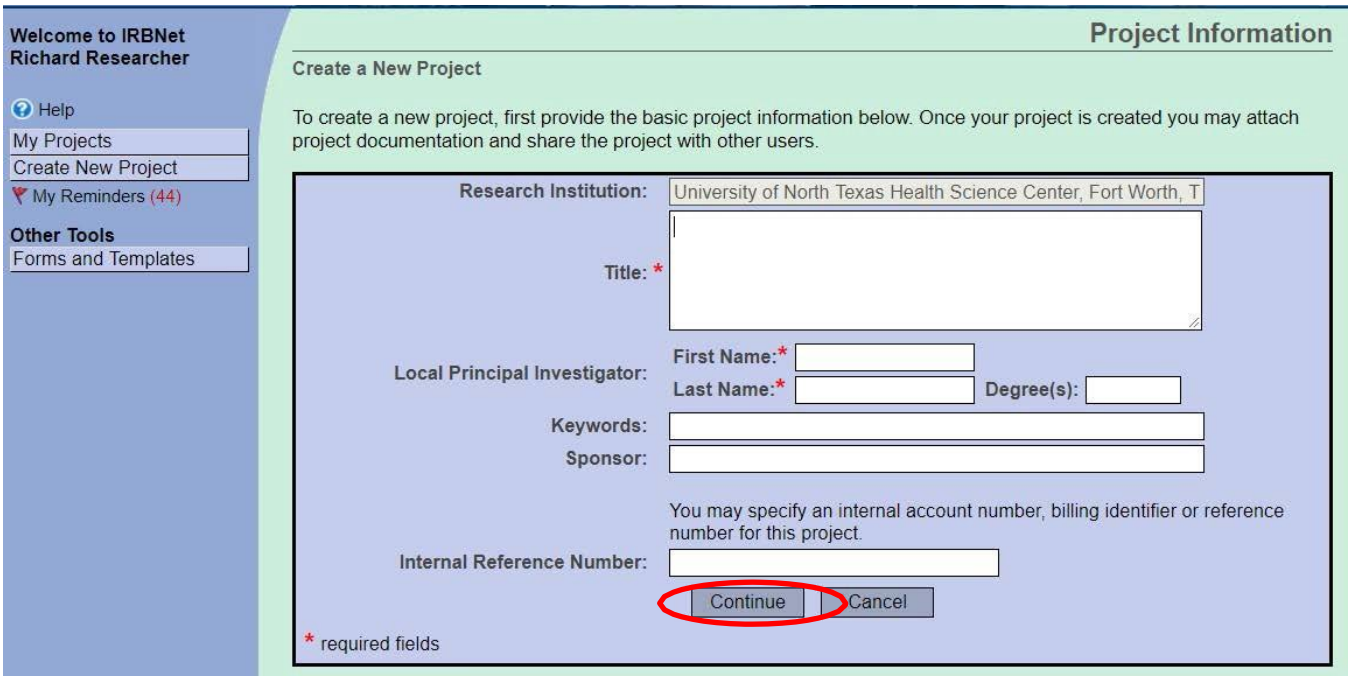
1. Navigate to www.irbnet.org and login using the username and password you created from the previous section. If you have not created an account, please follow the necessary steps in the **Registration** section of this manual.

   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."

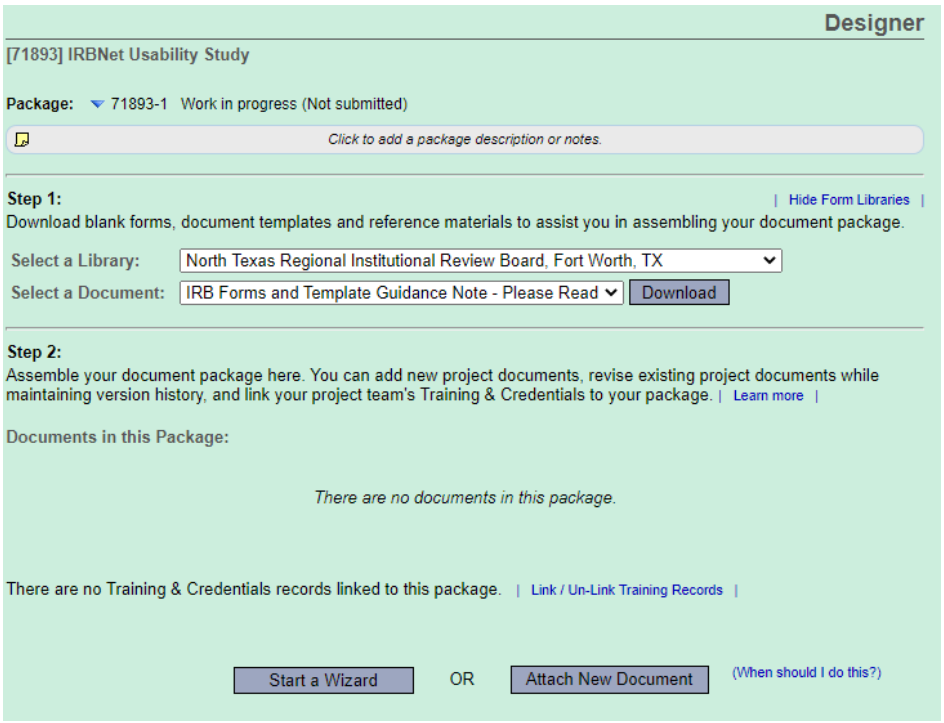


3. The following screen will appear:

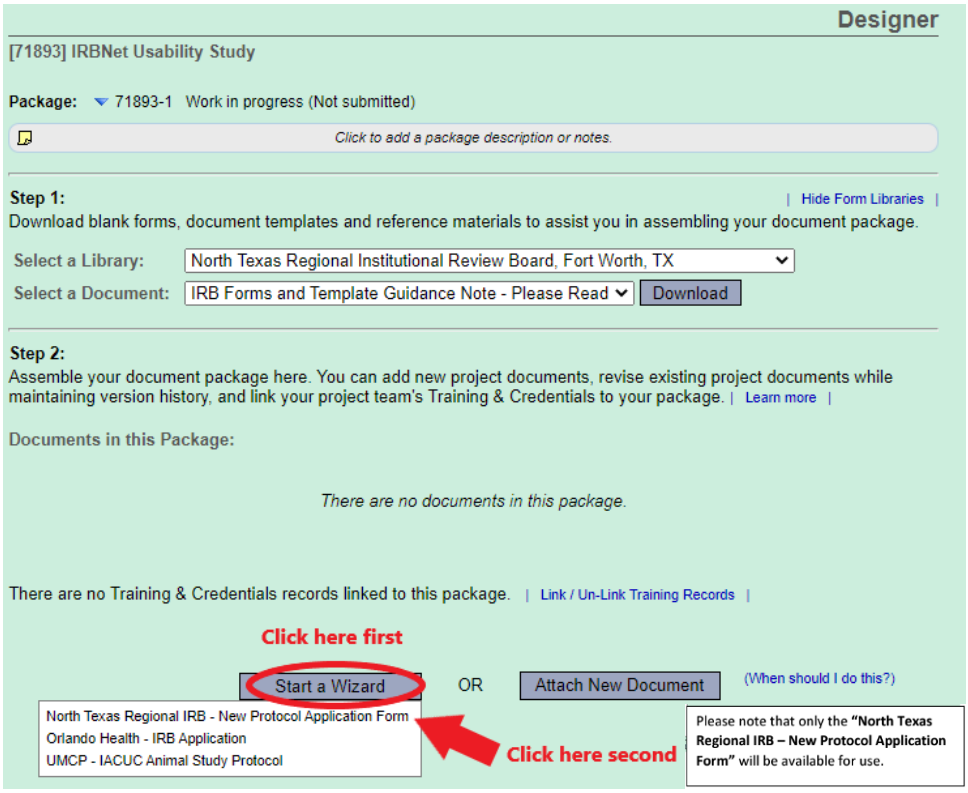


4. Enter the title of the project and your name. If the study is sponsored, please enter the sponsor / funding agency's name in the sponsor box. The keywords box may be useful for you if you have several studies and need to find this study at a later time based upon a specific keyword. Once you have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

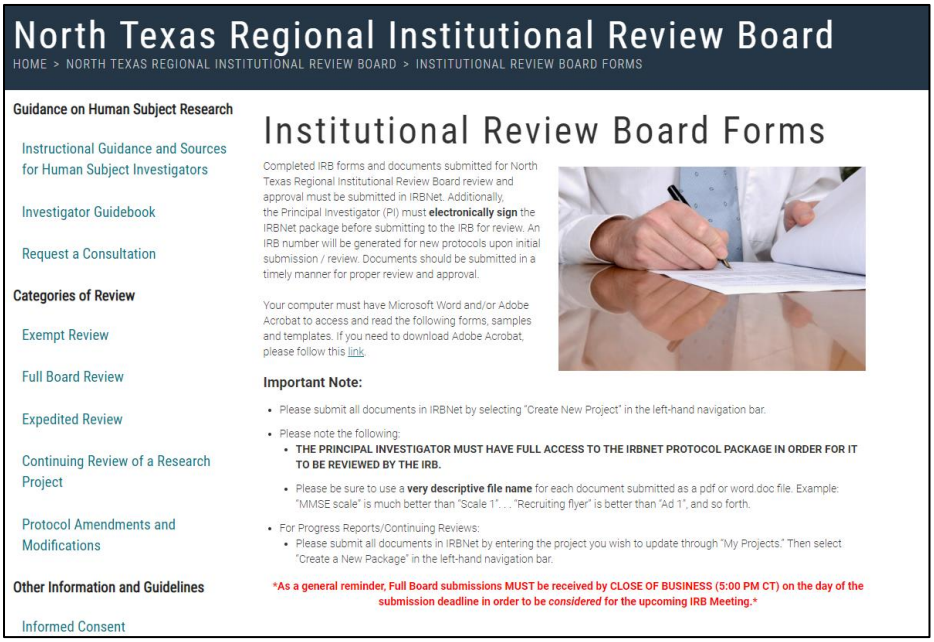
5. You will be taken to the Designer page and this screen. The Designer page is where you will later upload your completed study documents.



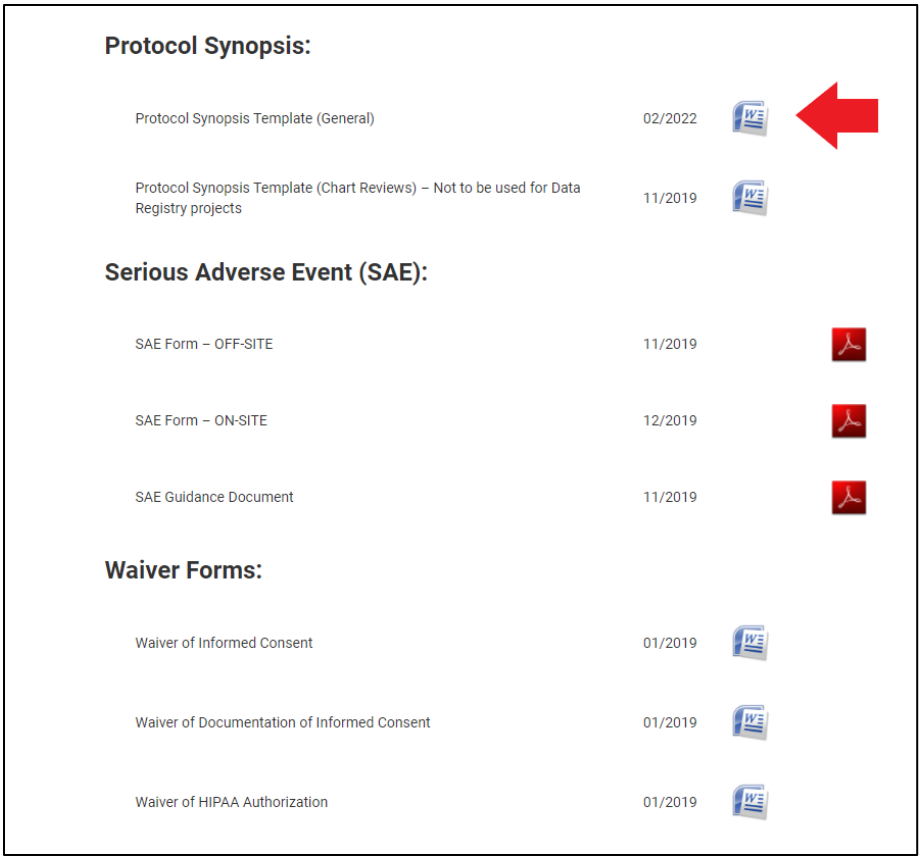
6. Proceed to "Step 2" of the Designer page to access the Wizard application form. To begin the application form, click "Start a Wizard" (you will need to select "North Texas Regional IRB – New Protocol Application Form" from the drop-down that appears). For additional information about completing the Wizard application form please, refer to **Appendix A** of this document.



7. 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.



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.

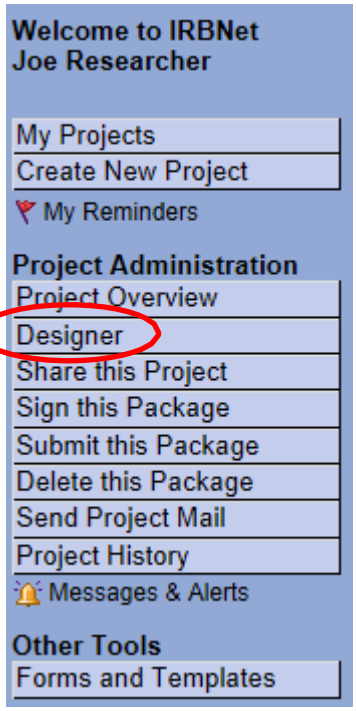


Save to your computer, complete all necessary fields within each required document, and save again to ensure that your files are ready to be uploaded. (**NOTE**: Actual list of forms may differ from what is shown above.)

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.).

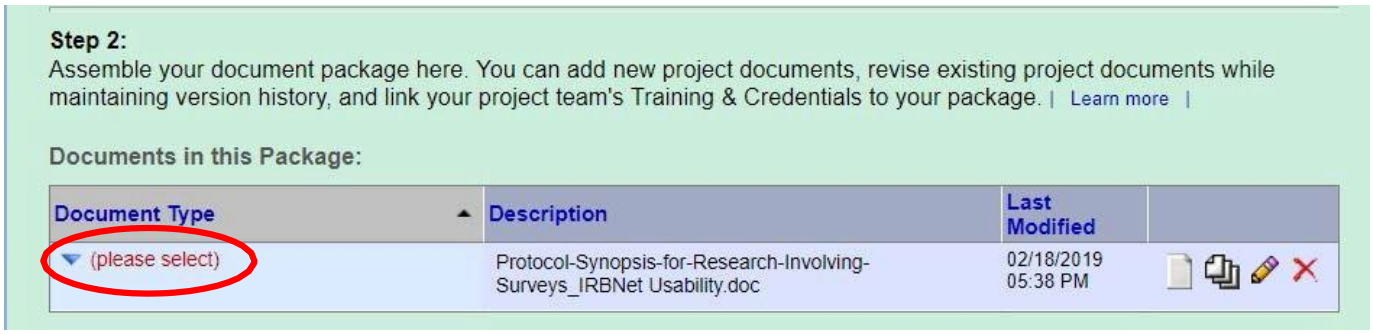
10. Once all necessary forms have been completed, click **My Projects** (left hand menu) and select your current project.

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.



14. 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:

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**.

15. 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.

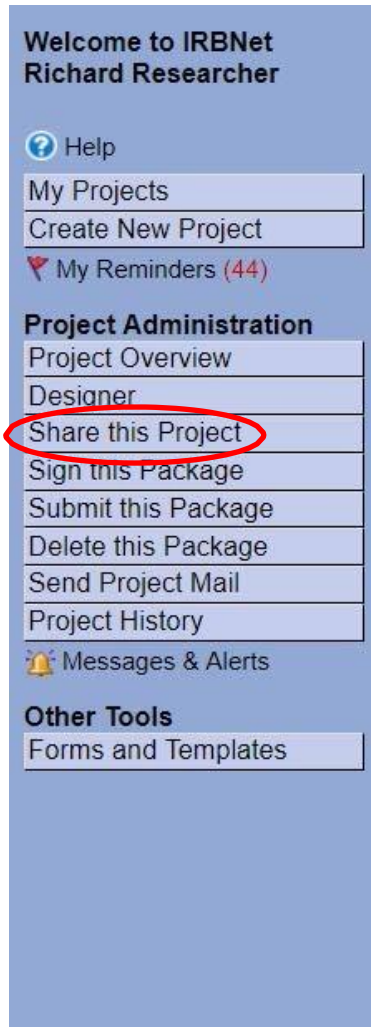
**For JPS projects, please ensure the following OCR staff have full access to the project:*

-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

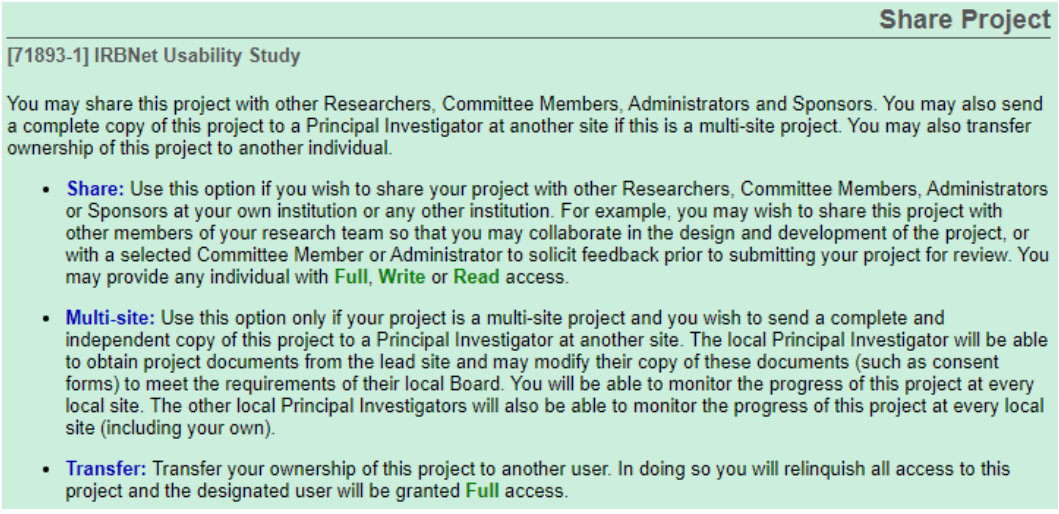
16. Select the **Share this Project** tab located on the left side of the page.



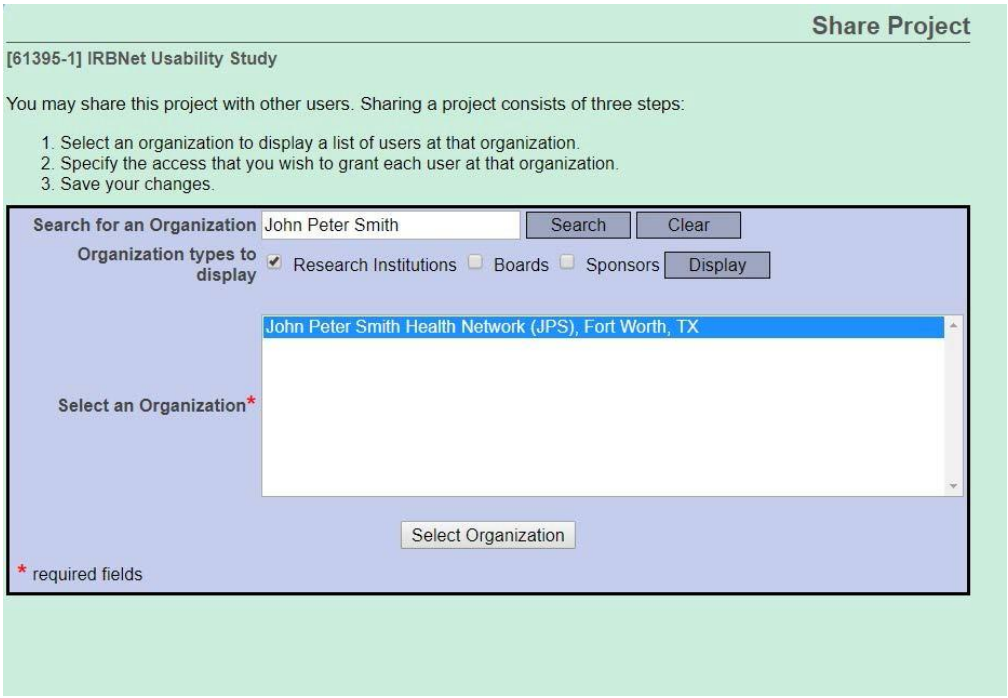
When considering what type of access to give (full, write, read), please keep in mind the following definitions:

-**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.**

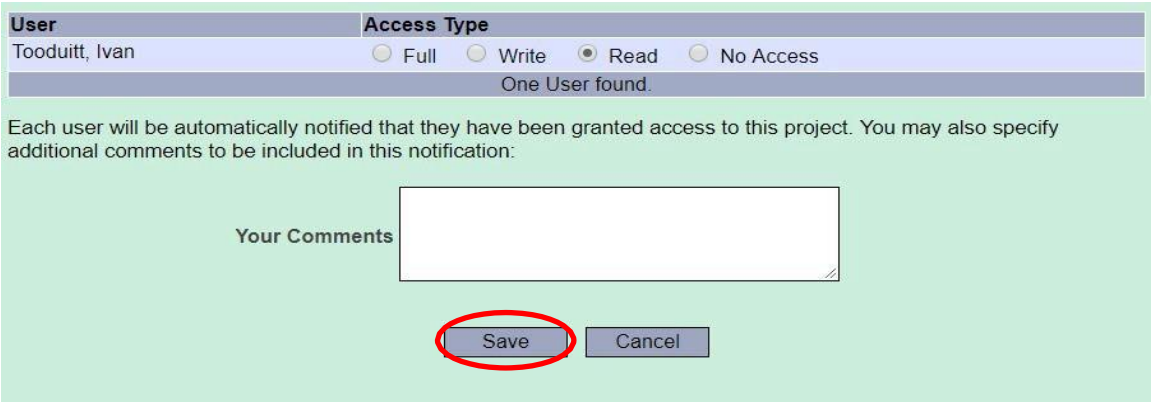


18. The following screen will appear, and you can search for the organization with which the person you would like to share the project with is affiliated. For this example, the person being added is a JPS researcher.



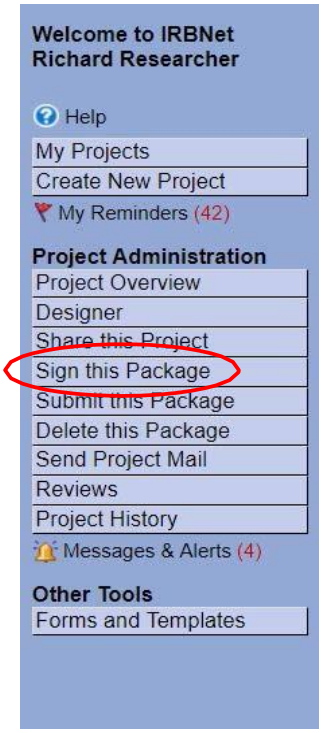
19. Once the organization is selected, you will need to search for the specific user. Users must have their own IRBNet account in order for the system to grant them access. Please note the different sharing levels (described on pg. 17). The North Texas Regional IRB requires that PIs have full access 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.**



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.

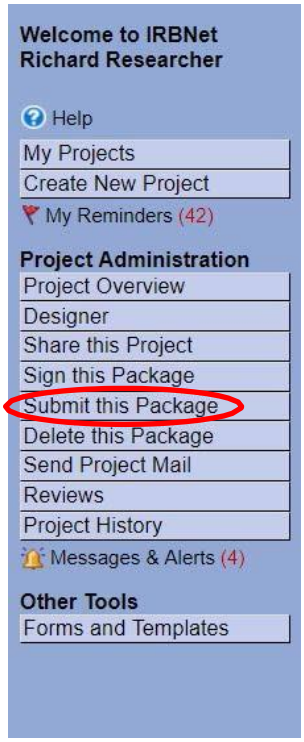


22. Select your role in the project. If you are the principal investigator, select this option from the drop-down box.

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).

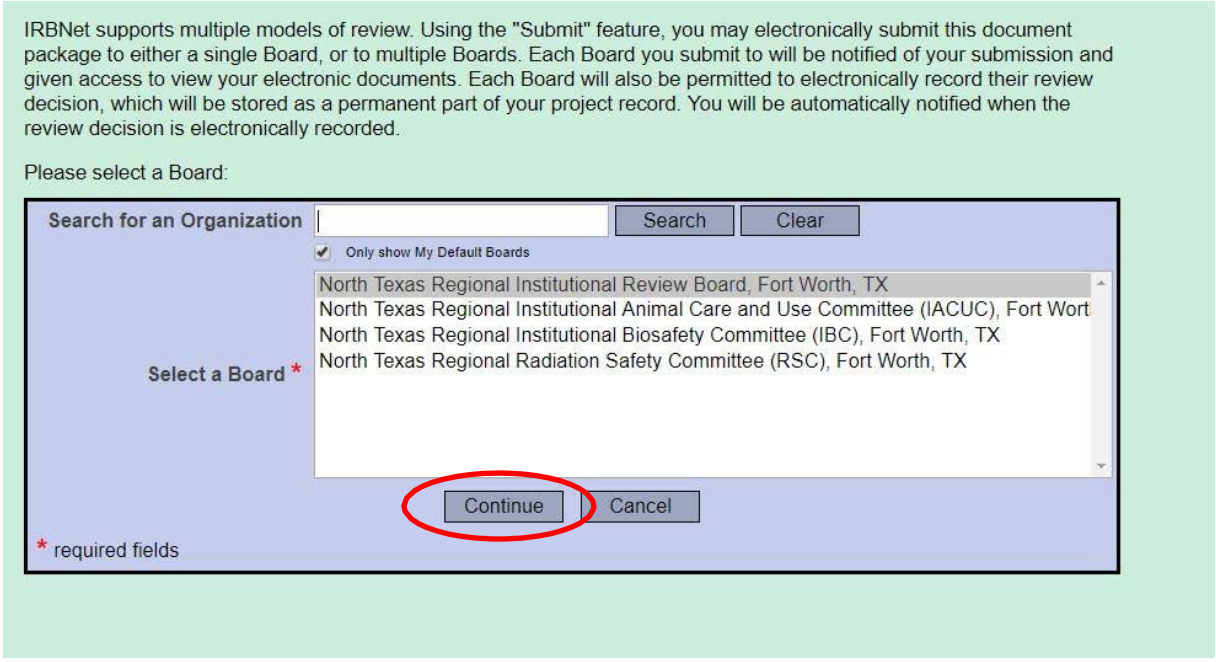
24. When you are ready to submit your package to the IRB for review, navigate to the left-hand tool bar and select **Submit this Package. Please note the IRB will not have access or be able to review the project if this step is not complete.**



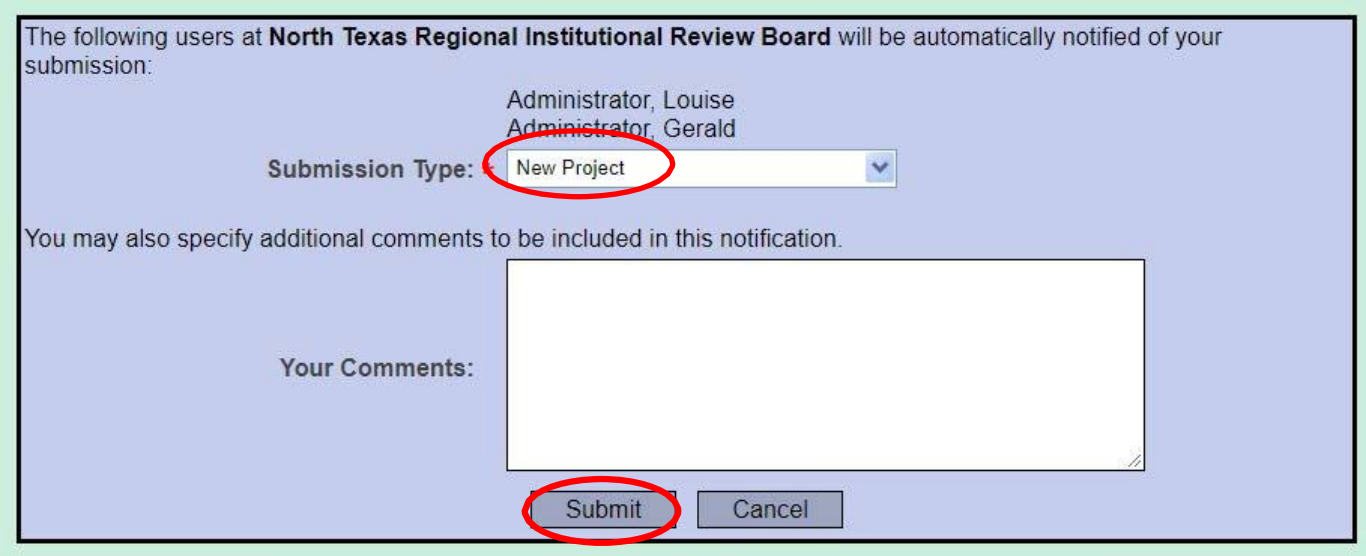
The IRB will not proceed with the review of projects that are incomplete, unclear or inconsistent. If any revisions are needed, you will be notified with an email from IRBNet.

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

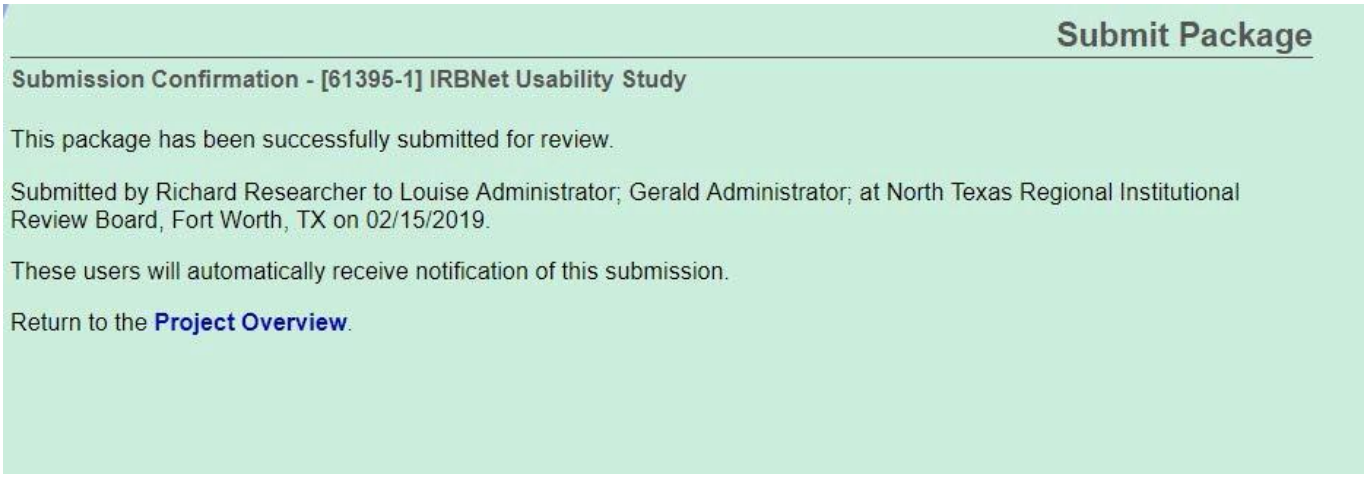
25. The page below will appear. Make sure to select **North Texas Regional IRB** and click **Continue.**



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.**



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



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

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

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

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

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

Project Title:

Lock Status: Unlocked - Revisions Pending
Date:

Message from

Hi Dr

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

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

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

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

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

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

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

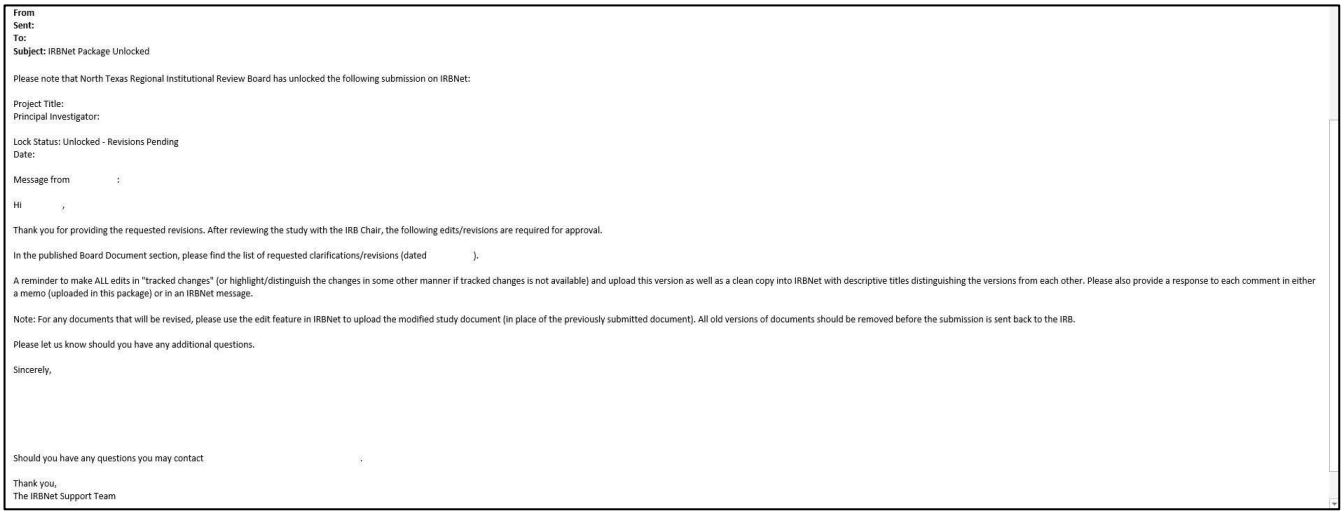
Sincerely,

Should you have any questions you may contact

Thank you,
The IRBNet Support Team

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

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



From
Sent:
To:
Subject: IRBNet Package Unlocked

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

Project Title:
Principal Investigator:

Lock Status: Unlocked - Revisions Pending
Date:

Message from :

Hi ,

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

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

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

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

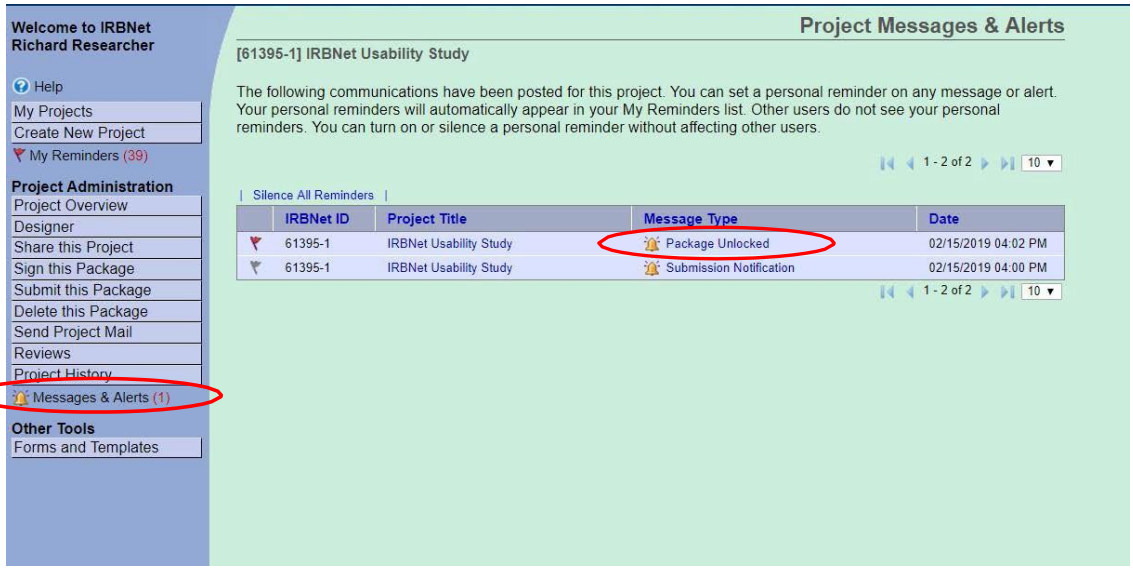
Please let us know should you have any additional questions.

Sincerely,

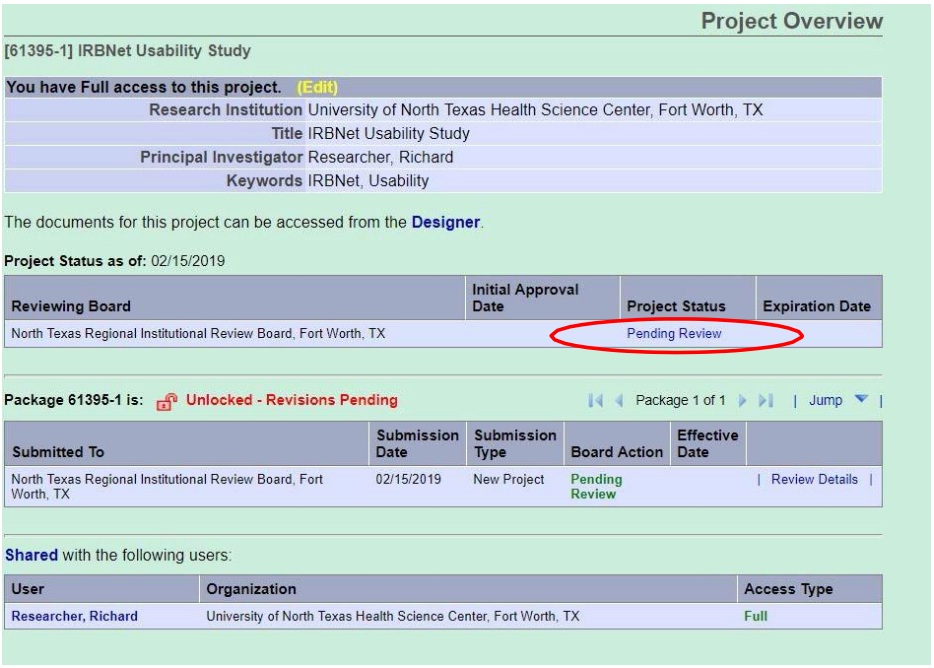
Should you have any questions you may contact .

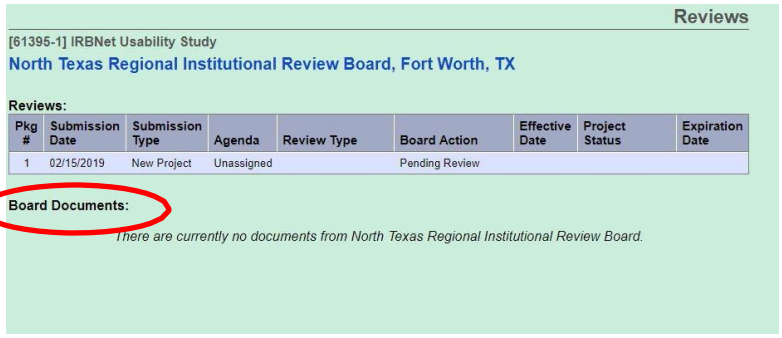
Thank you,
The IRBNet Support Team

1. In IRBNet, you can access the IRB's requested revisions (and other communication) in the following places:
   a. Under "Messages and Alerts" in the "Package Unlocked" message.



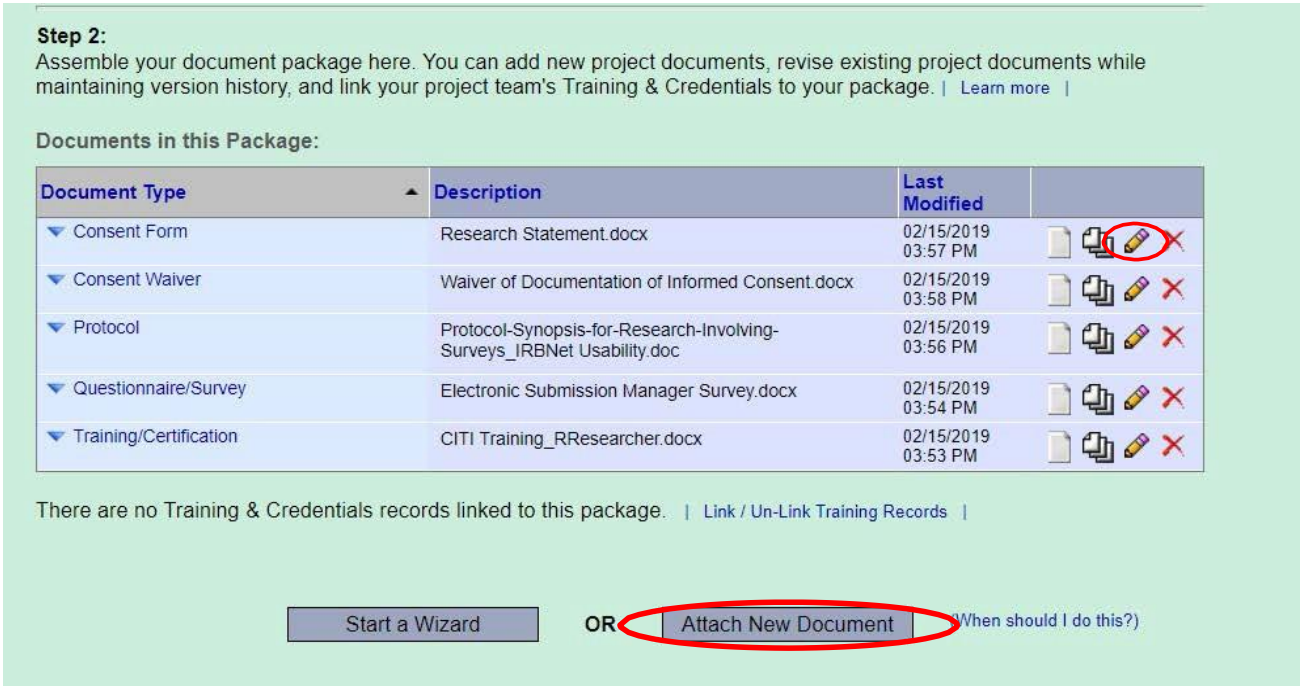
   b. Under "Board Documents" which can be accessed by clicking, "Pending Review".





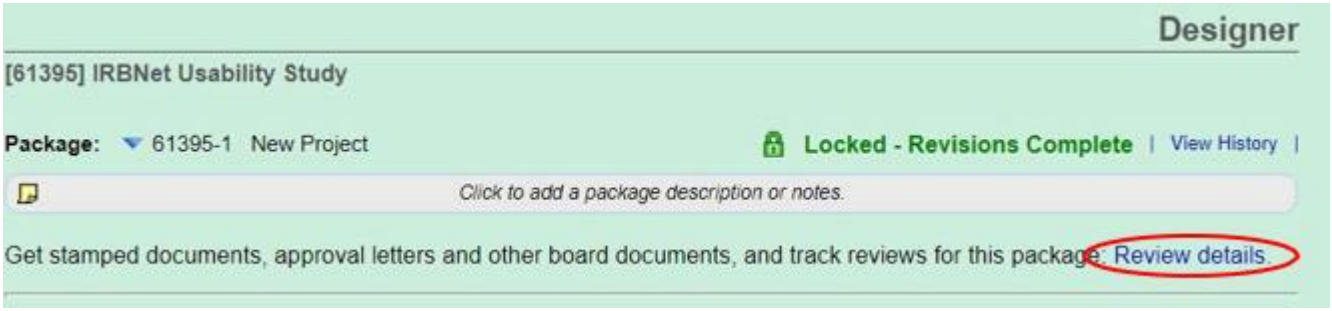
2. To make requested revisions, return to the Designer to edit, upload or delete documents.

If you are revising a previously submitted document, you can use 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".

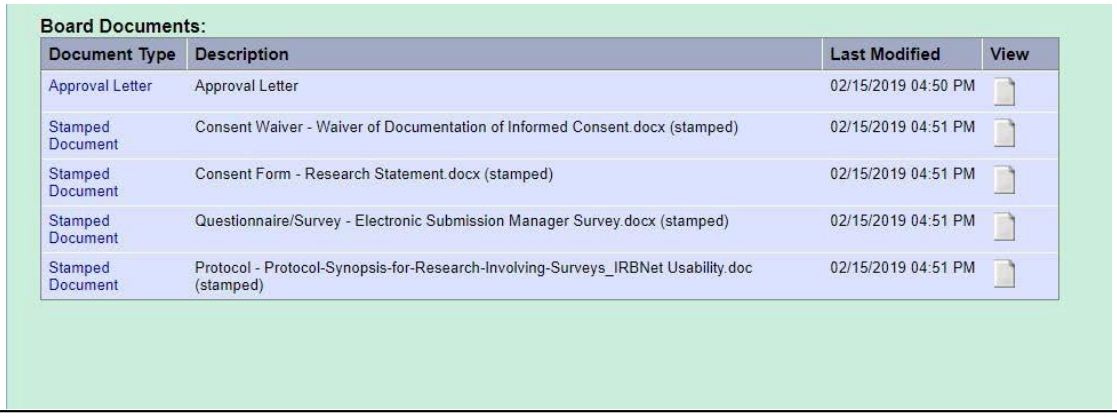


3. Once all appropriate/requested changes are made, click **Mark Revisions Complete** to resubmit the revised submission. Keep in mind that your project will be locked and you will be unable to make any further changes after **Mark Revisions Complete** is clicked. If additional revisions are needed,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

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



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



V. How to Proceed After Receiving an IRB Determination

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

Determination	Next Steps
Approved	• No further action needed until one of the following: ○ Submission of Continuing Review (if / when applicable), Amendment/Modifications and SAEs by using "Create New Package" (see Section VI of this manual)
Exempt	• 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	• 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) ○ 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	• Review IRB findings provided in the Determination (found in "Board Documents") • Address the comments by "Creating New Package" (see Section VI of this manual) ○ 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	• 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). *No new packages should be submitted for projects that are Disapproved.* • Please note the new submission will need to address the IRB's findings
Not Human Subjects Research	• 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	• 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

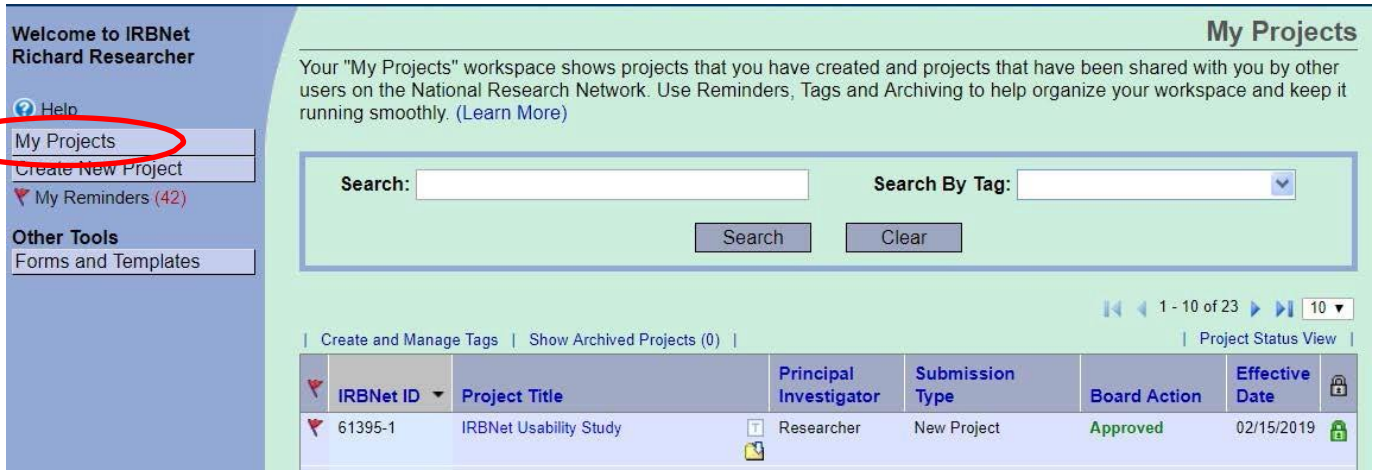
After receiving a determination, a few different scenarios will apply. As discussed in the previous section, how to proceed will vary based on the determination. This section will guide you on how to **"Create a New Package"**.

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

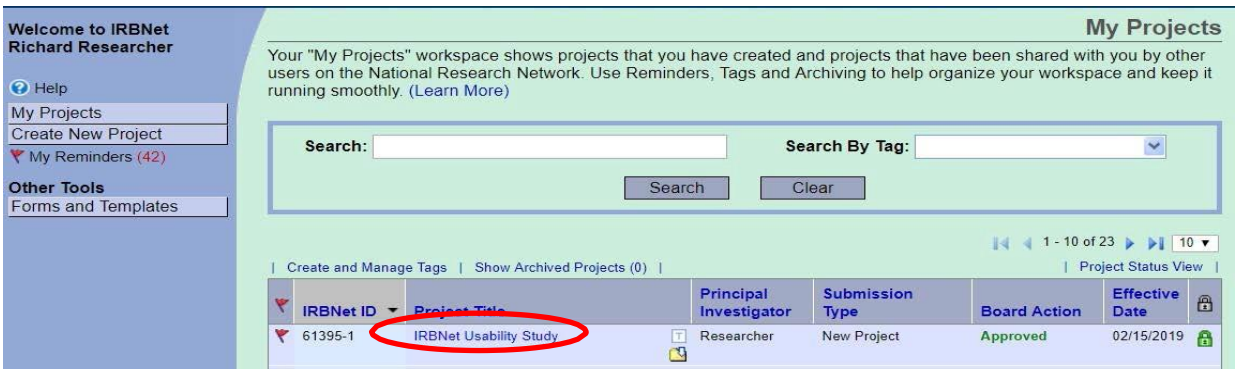
- Amending/Modifying a Project (i.e. adding key personnel, updating study documents)
- Responding to modifications when a project has been Deferred or Approved with Modifications
- Submitting a Continuing Review

Steps to Create a New Package:

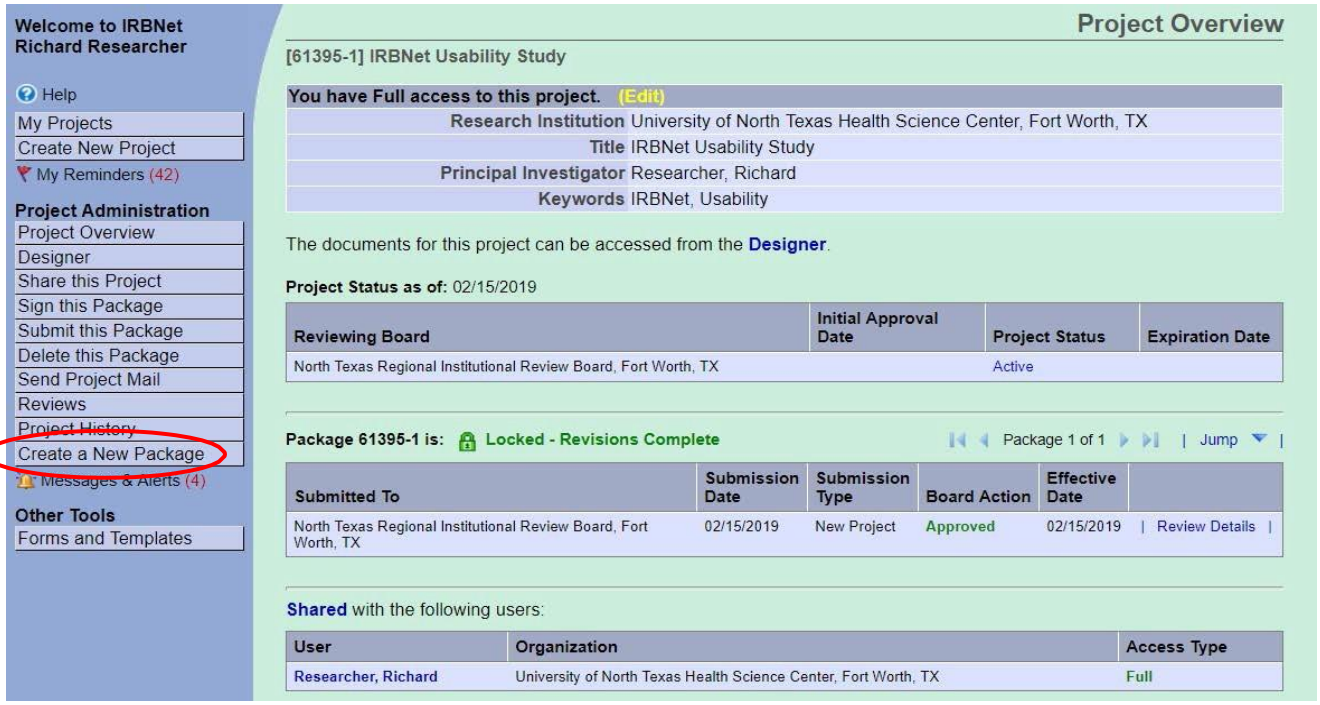
1. Login to www.irbnet.org using your username and password.
2. Select **My Projects** on the left side of the screen.



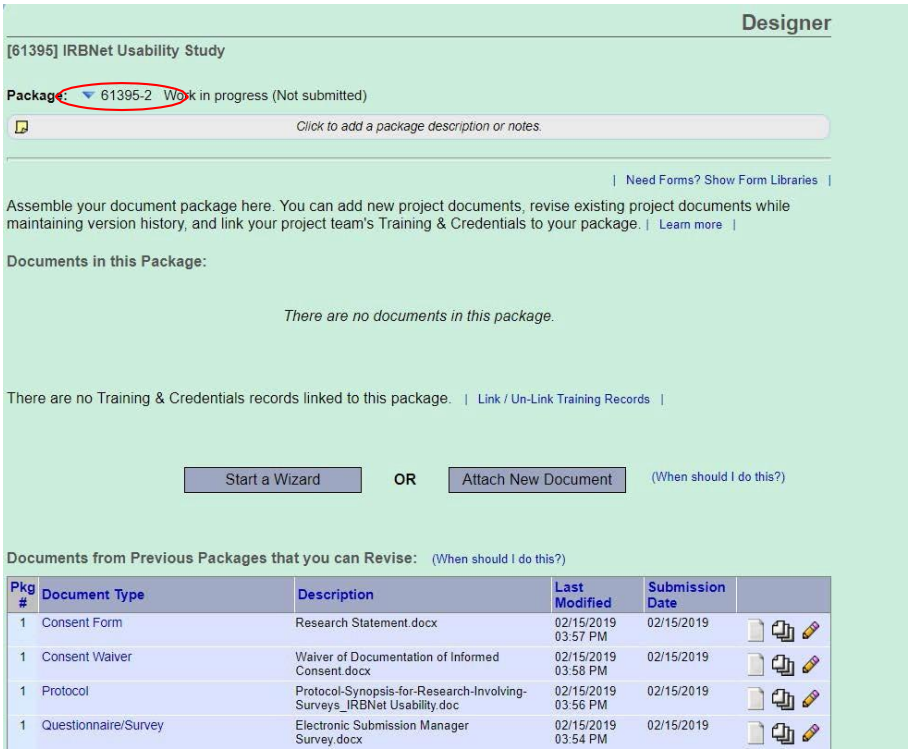
3. Select the project you wish to modify.



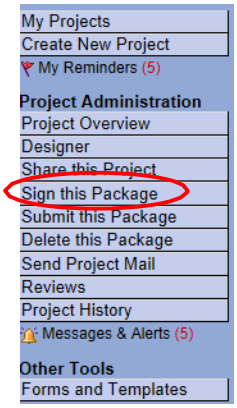
4. Once you click into the study, click on the **Create a New Package** tab.



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

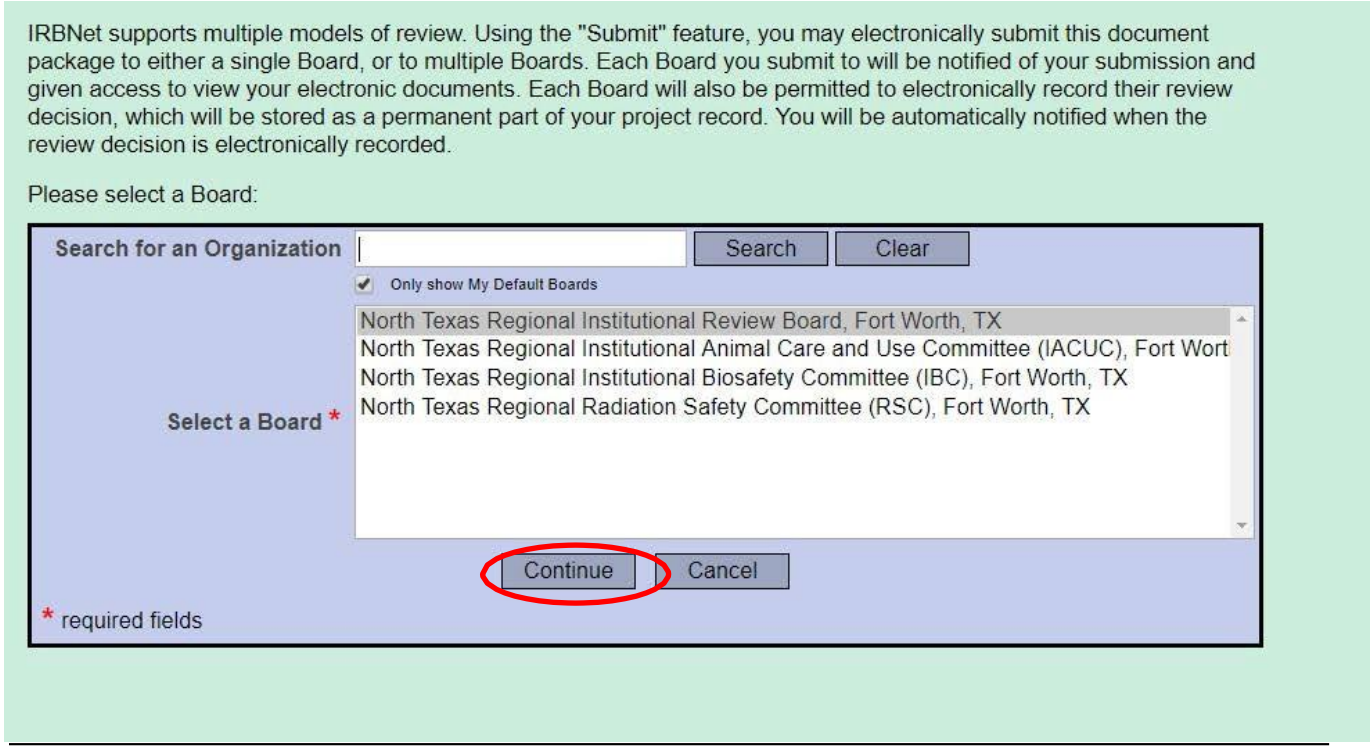


6. When all necessary documents have been uploaded, click **Sign this Package** on the left-hand side of the screen. This process will be the same as when you initially submitted a new project.

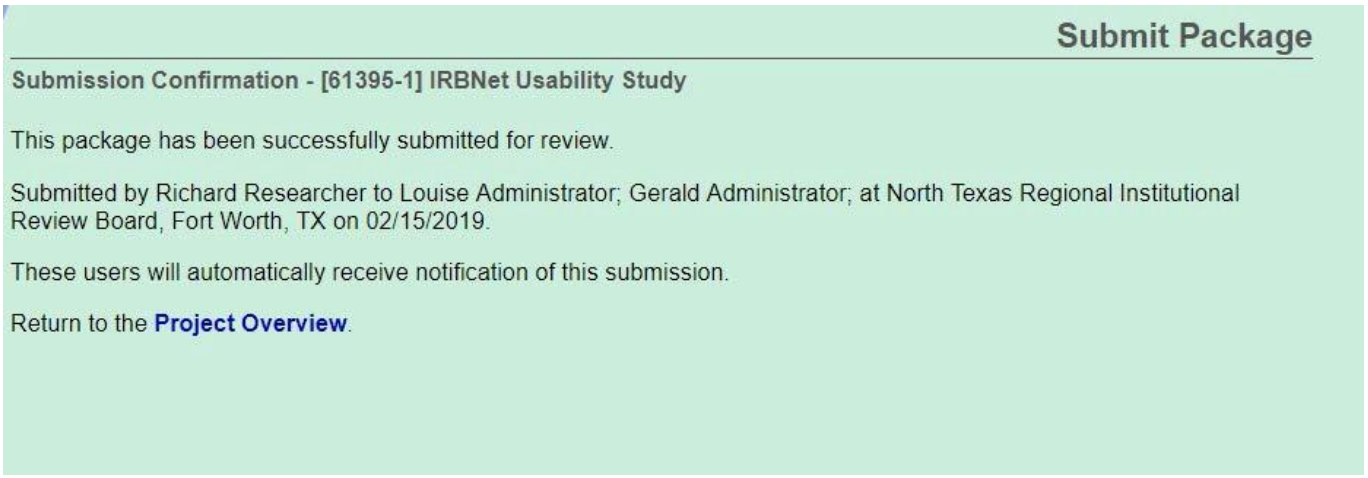


7. Once signed, click **Submit this Package** on the left-hand side of the screen. This process will be the same as submitting a new project with the exception of selecting the appropriate "Submission Type". "Response/Follow-Up" should be used in situations where study teams are responding to feedback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

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



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



Appendices

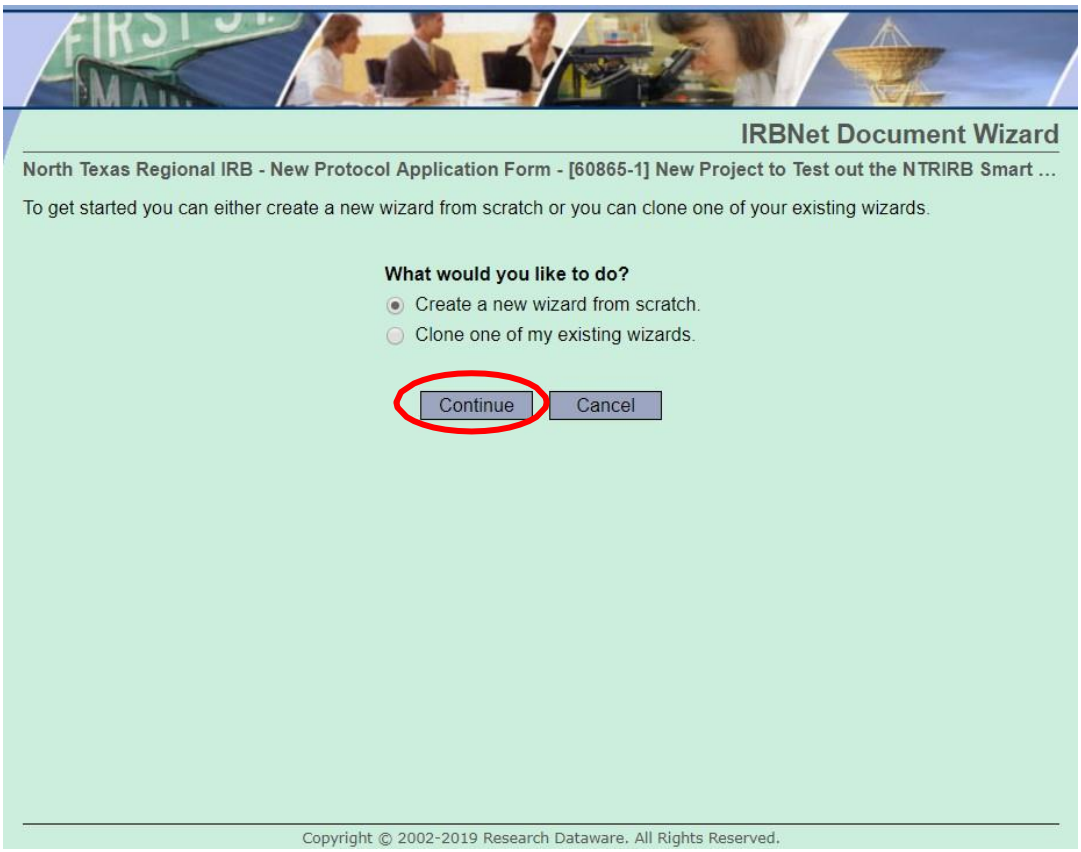
A. Wizard Form Guidance 31
B. Developing Descriptive File Names 48
C. Linking CITI Training 49

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

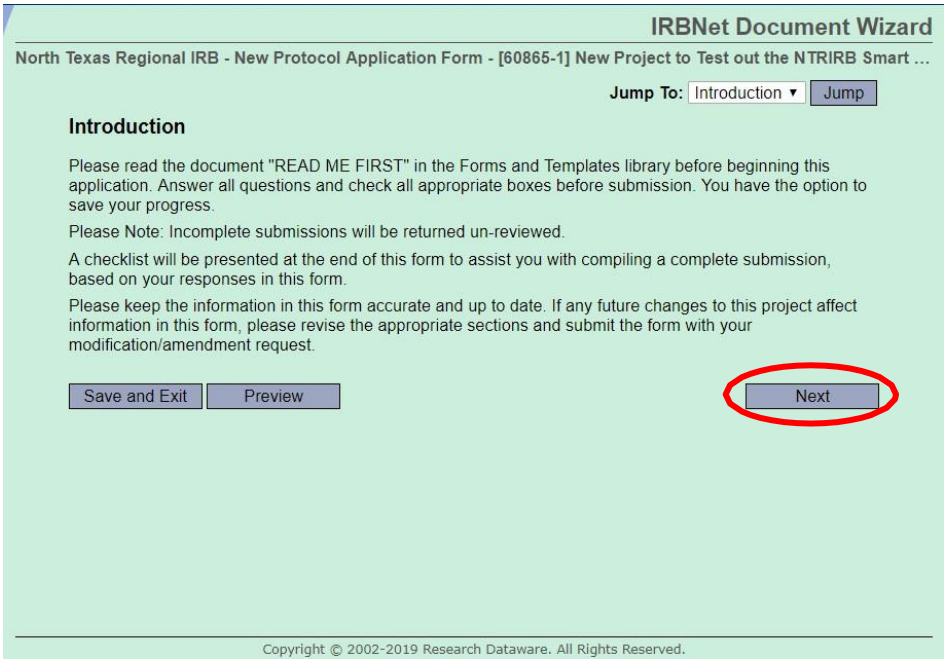
1. If this is the first project you are submitting in IRBNet, select "Create a new wizard from scratch".

   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.

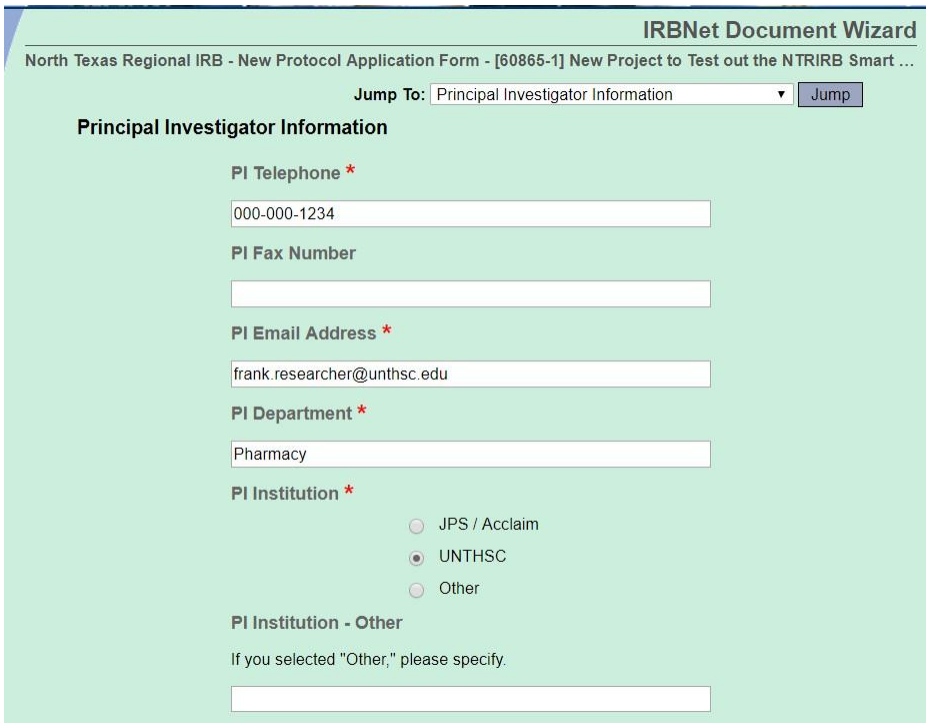
   For this example, we will "Create a new wizard from scratch", then select "Continue".



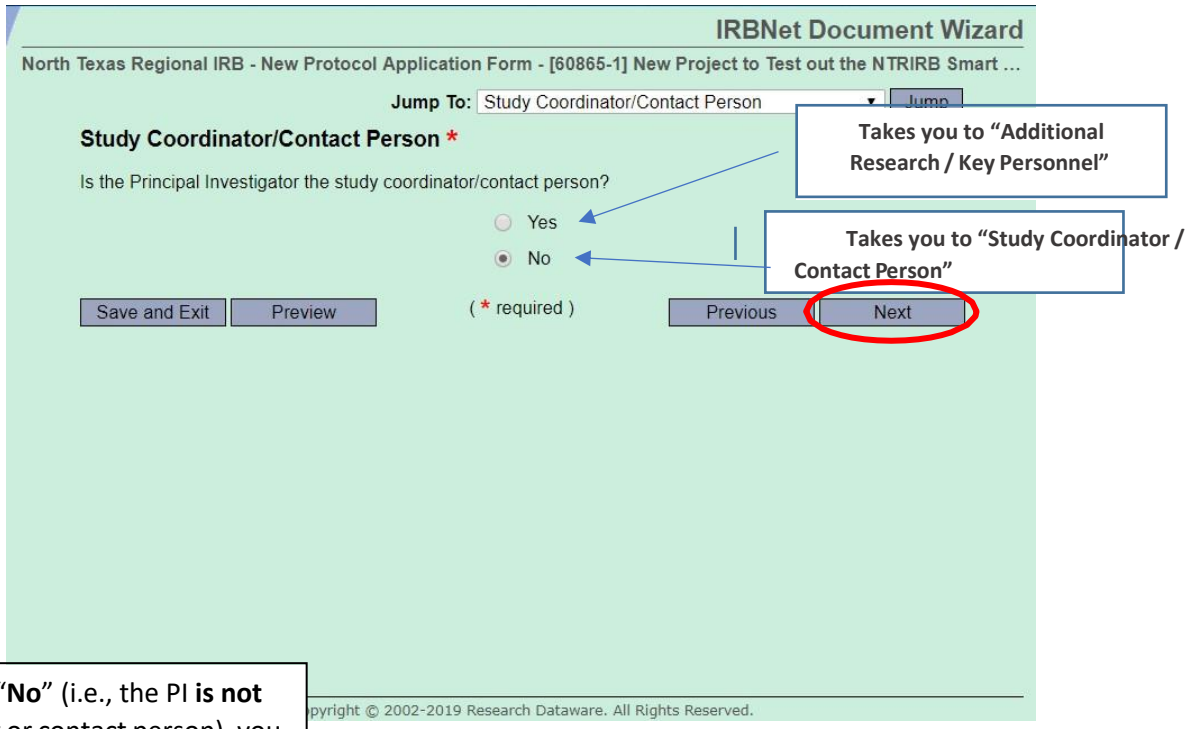
2. You will be taken to the Introduction page. Please follow the instructions provided, then click "Next":



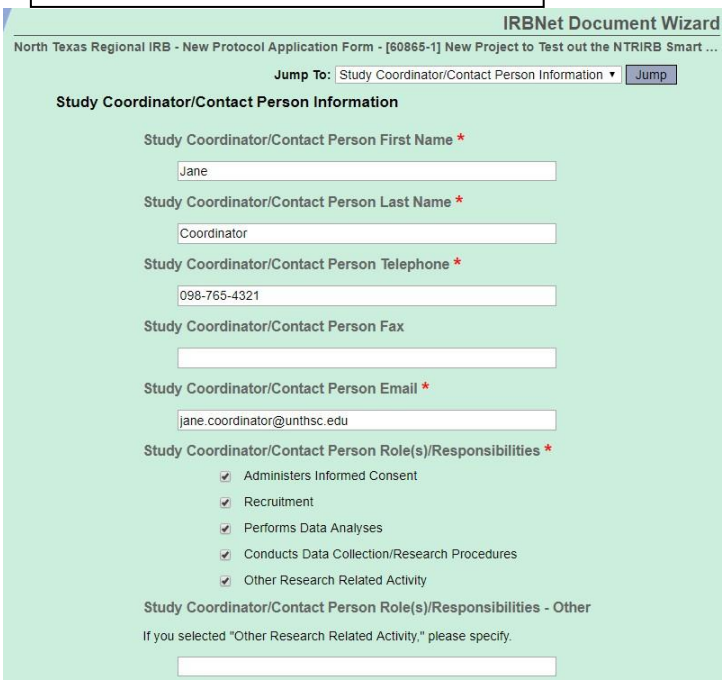
3. Please fill in the applicable information about the principal investigator (PI):



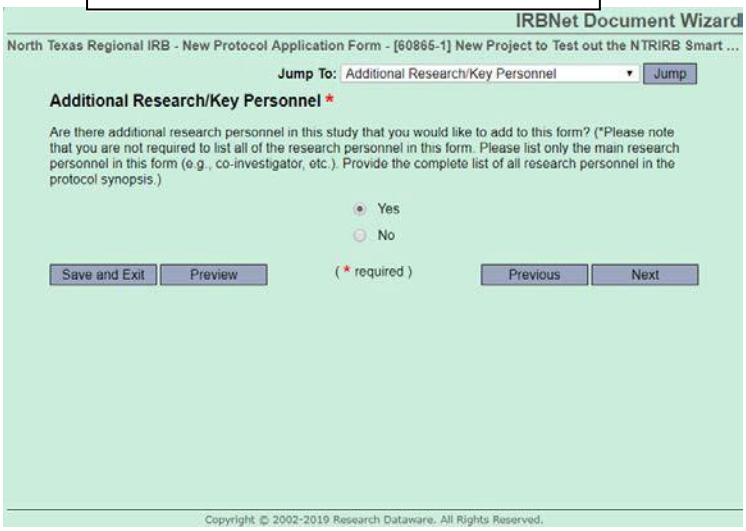
4. If the Principal Investigator is the study coordinator/contact person for the study, please select "Yes". After hitting "Next", you will be taken to the "Additional Research / Key Personnel Information" page.
   However, if the PI is ***not*** the study coordinator/contact person, please select "No". After hitting, "Next", you will be taken to the "Study Coordinator / Contact Person" page.



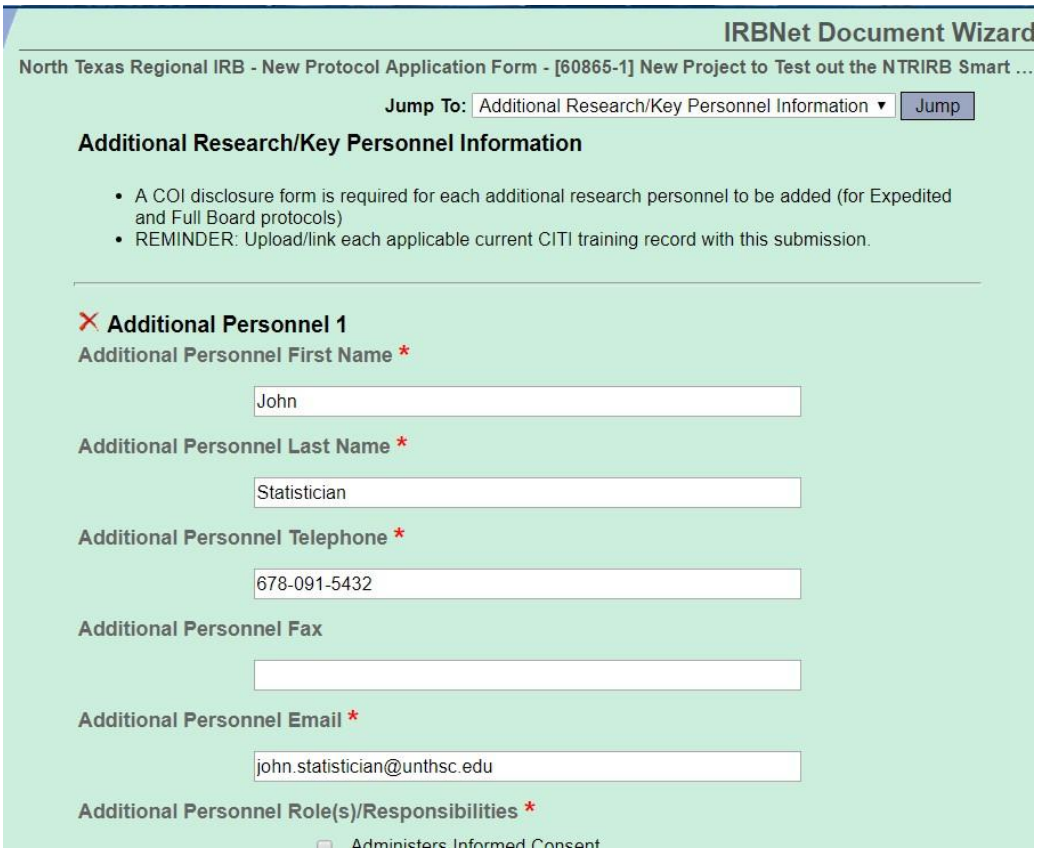
If you selected "**No**" (i.e., the PI **is not** the coordinator or contact person), you will be taken here:



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



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



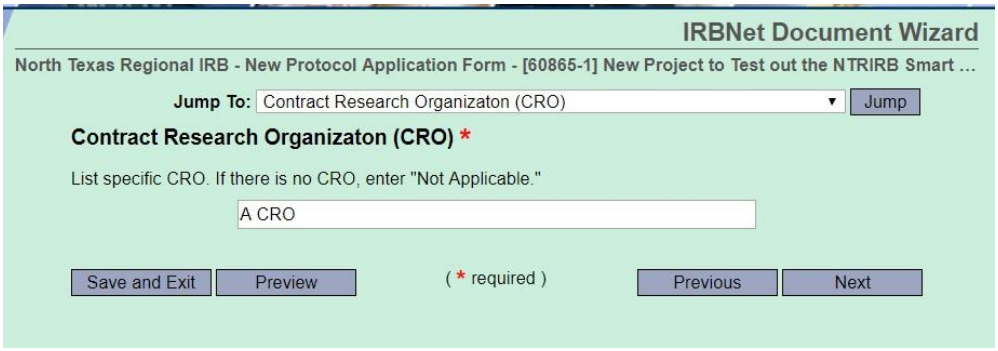
6. The Wizard application form will guide you through questions about the study. Based on answers to certain questions, the Wizard application form will generate the appropriate additional pages that need to be completed. Not all of the additional pages will be generated for every project.

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

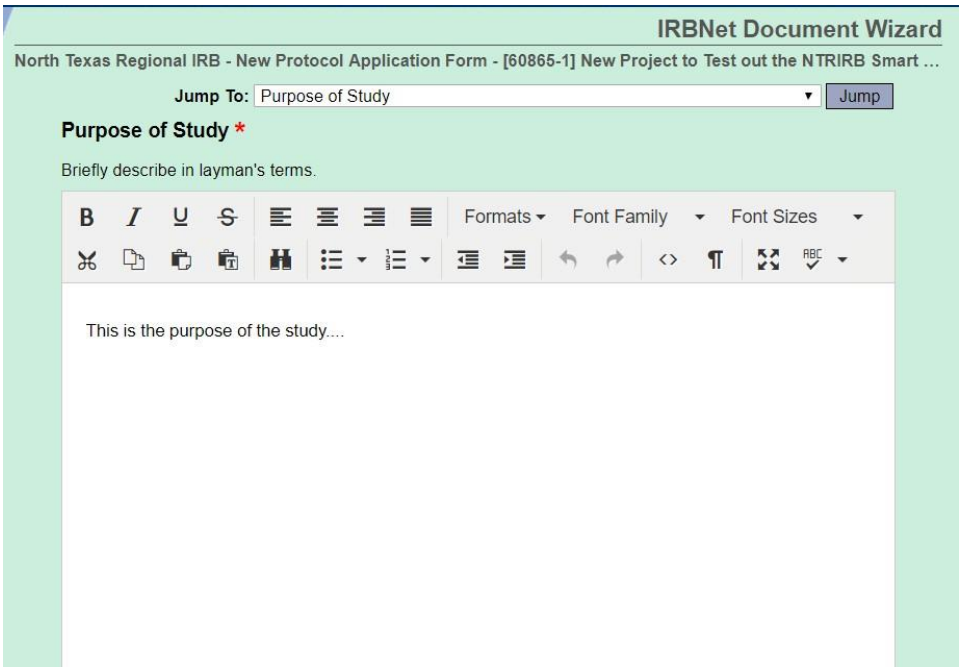
b. Listed below are all of the possible "funding source" options, which are followed by the type of information that will be requested on the subsequent page after you click "Next".

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

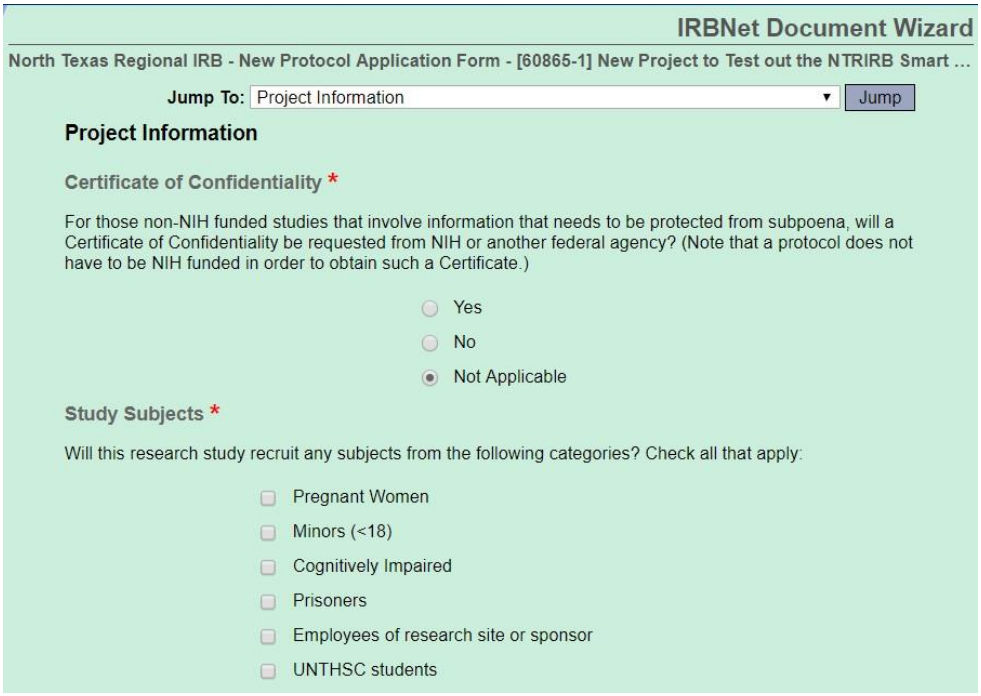
   a. If there is no CRO, enter "Not Applicable"



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.

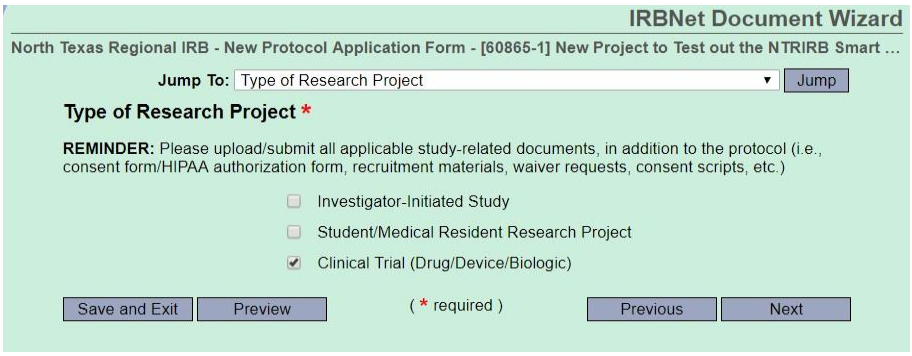


9. The Project Information page will ask you to provide information about Certificates of Confidentiality, the subject population to be included in the study, recruitment of subjects, and any waivers being requested.

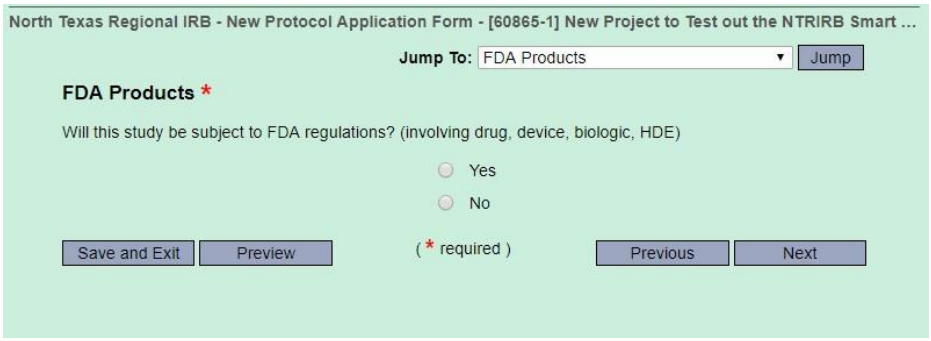


10. On the next page, you will select the Type of Review, which will be followed by a page that asks you about the Type of Research Project. Your selections on these pages will generate the information that is requested on subsequent pages. The screenshots and charts (below) outline the type of information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

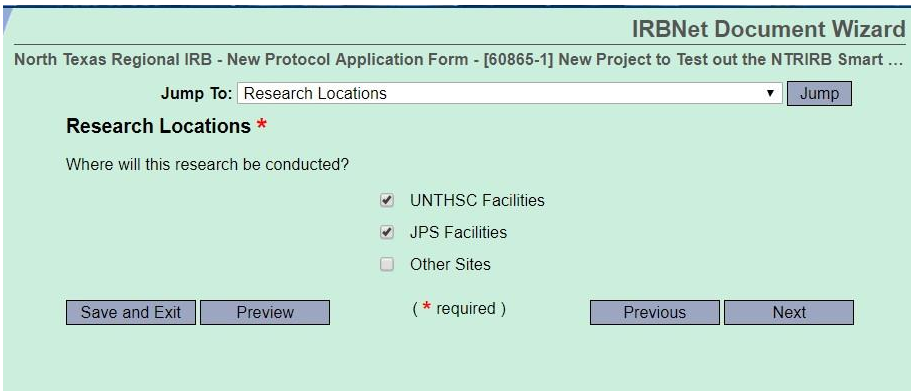
11. The Type of Research Project section will ask you to indicate if this is an Investigator-Initiated Study, Student / Resident Research Project, or a Clinical Trial.



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



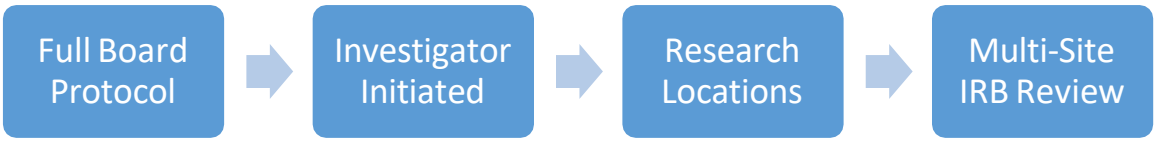
13. The Wizard application form will then request the location where the research will be taking place. Please note this page will appear regardless of the type of review or type of research project selected.



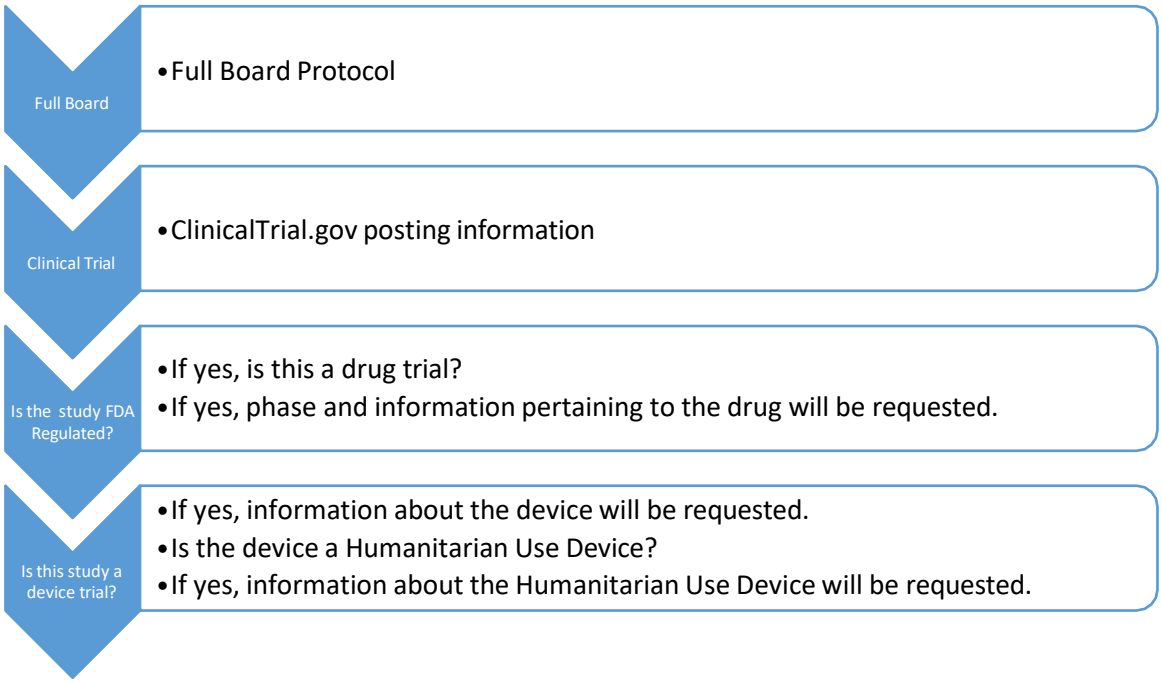
14. Following the Research Locations, the form will ask if other IRBs are involved in the approval of the project. Please note this page will appear regardless of the type of review or type of research project selected.

15. Based on your responses to items 10 & 11 above (Type of Review & Type of Research Project pages), a series of questions will appear for you to complete.

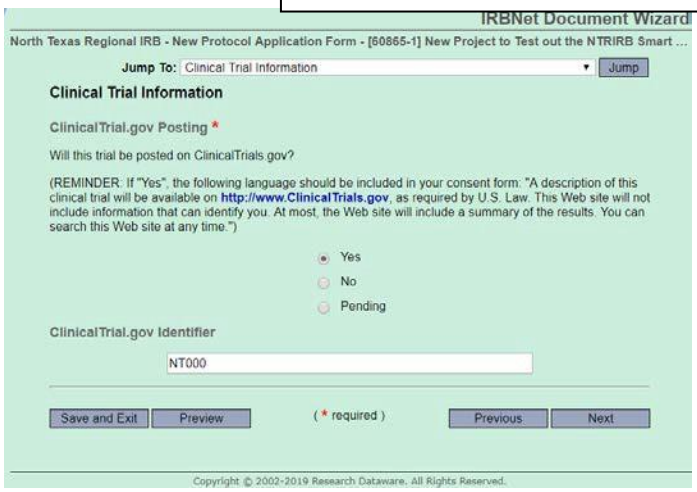
    a. For example, if "Full Board Protocol" is selected (on the Type of Review page) followed by "Investigator Initiated" (on the Type of Research Project page), the following pages will be generated:

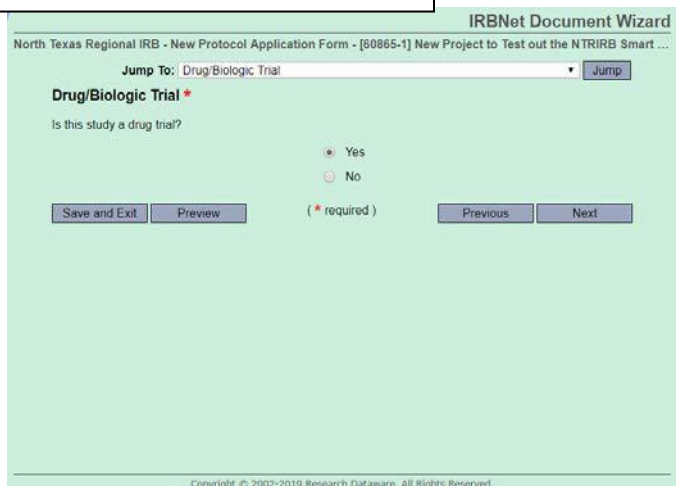


b. If "Full Board Protocol" followed by "Clinical Trial" is selected, the following pages will be generated:

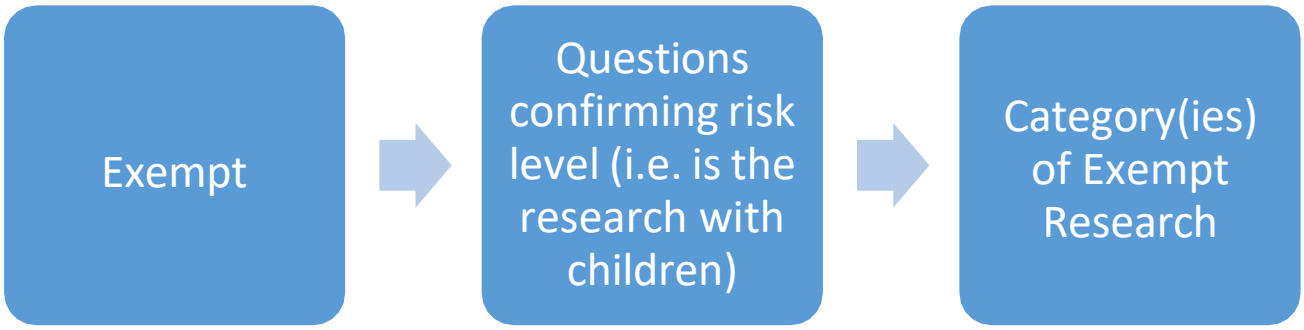


Some screenshots relevant to FDA studies are provided below. Note: These will only generate if you have previously selected "Yes," when asked if the study is regulated by the FDA.



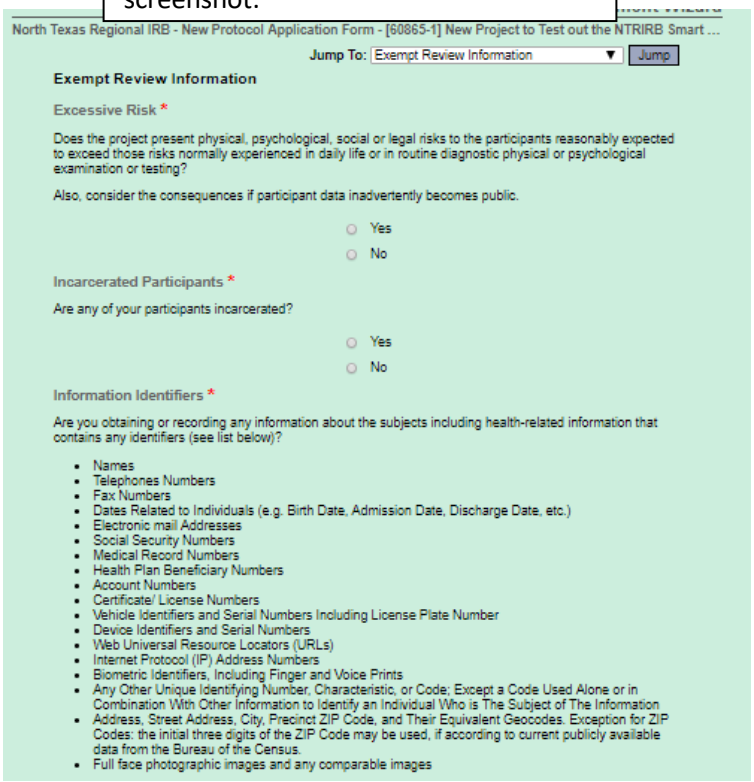


c. If the "Type of Review" selected is "Exempt", subsequent pages will ask for information related to risk and category. See the graphic below for an example scenario:



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?

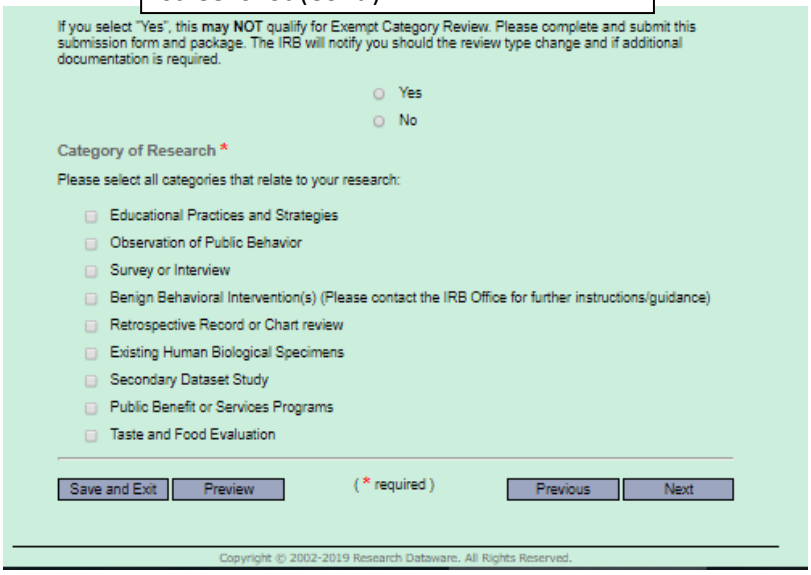
○ Yes
○ No

Information Identifiers *

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

- Names
- 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:

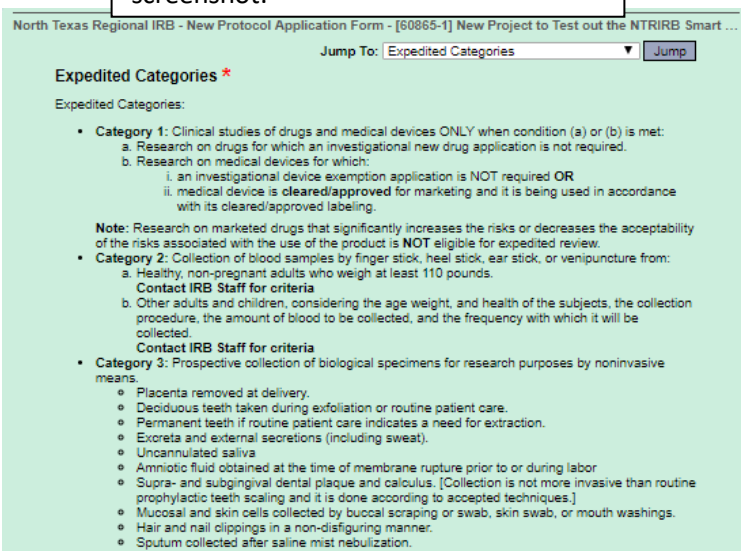
- ☐ Educational Practices and Strategies
- ☐ Observation of Public Behavior
- ☐ Survey or Interview
- ☐ Benign Behavioral Intervention(s) (Please contact the IRB Office for further instructions/guidance)
- ☐ Retrospective Record or Chart review
- ☐ Existing Human Biological Specimens
- ☐ Secondary Dataset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

Save and Exit | Preview | (* required) | Previous | Next

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

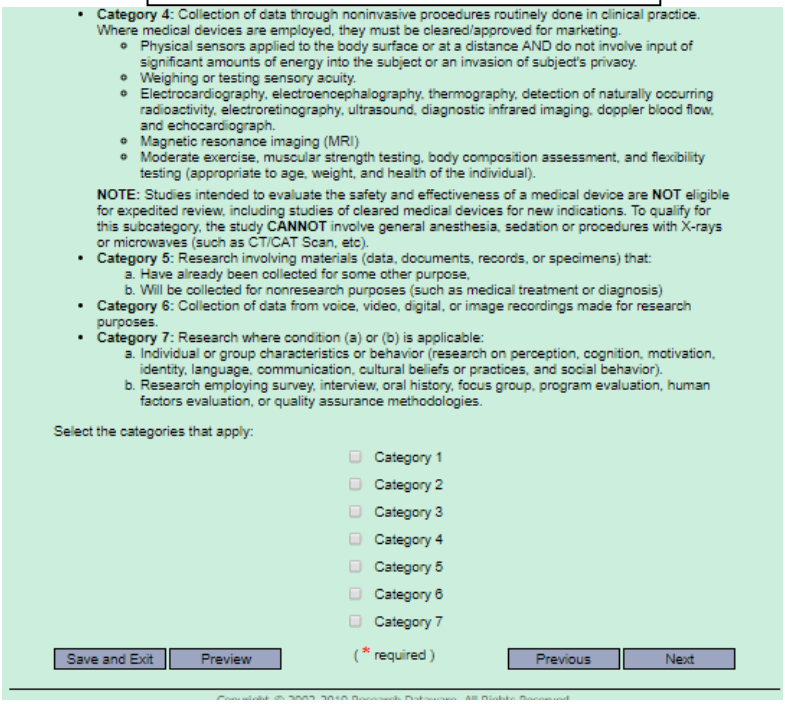
Expedited Categories *

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).

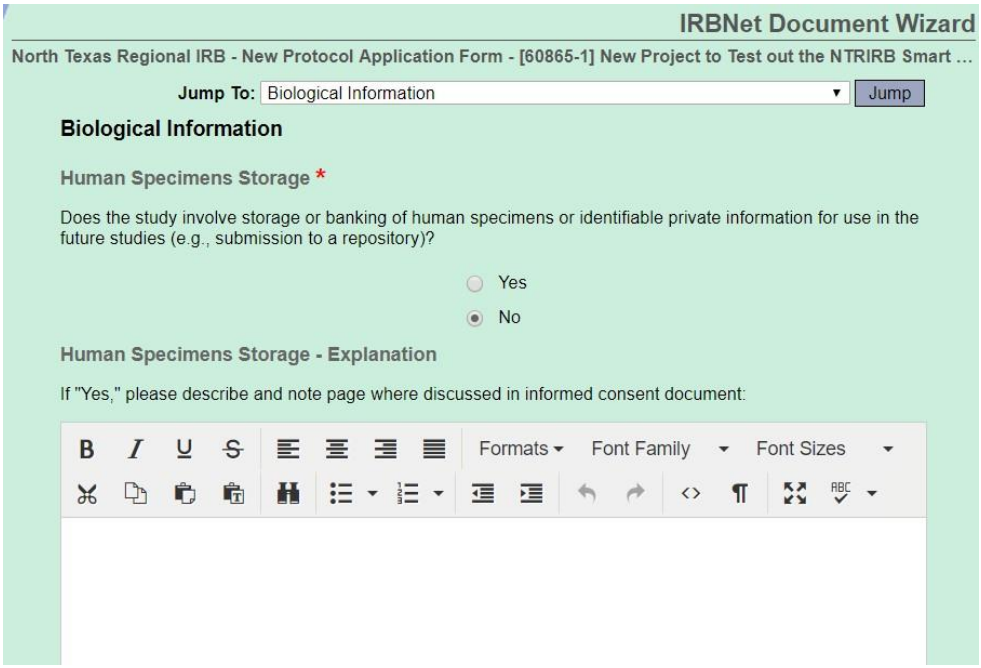
  NOTE: Studies intended to evaluate the safety and effectiveness of a medical device are **NOT** eligible for expedited review, including studies of cleared medical devices for new indications. To qualify for this subcategory, the study **CANNOT** involve general anesthesia, sedation or procedures with 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:

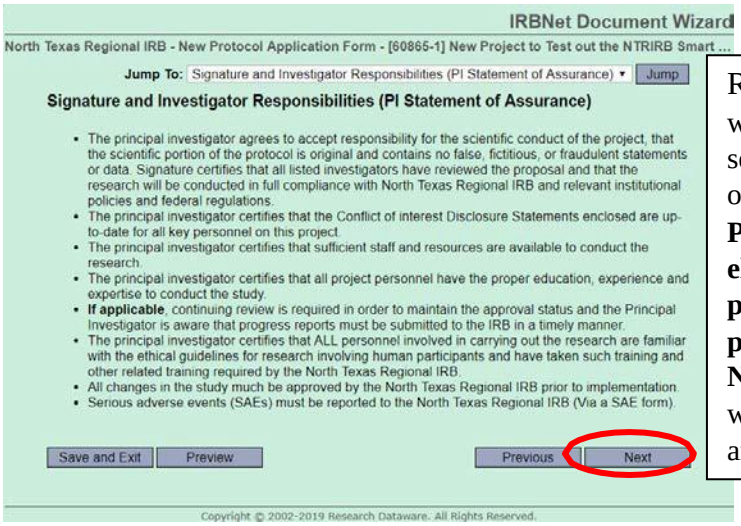
☐ Category 1
☐ Category 2
☐ Category 3
☐ Category 4
☐ Category 5
☐ Category 6
☐ Category 7

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).

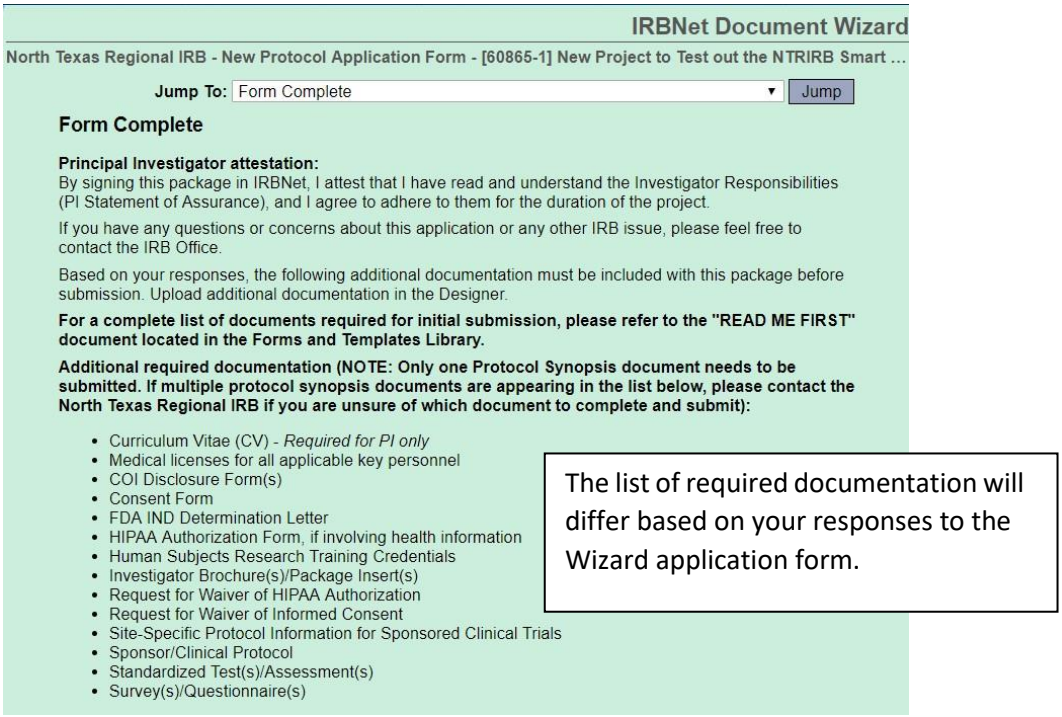


17. Signature and Investigator Responsibilities: This page will appear for all studies. The PI/investigator should read this page, and ensure they understand each item as written (or contact IRB staff with any questions). Clicking "Next" will take you to the last page of the application form.

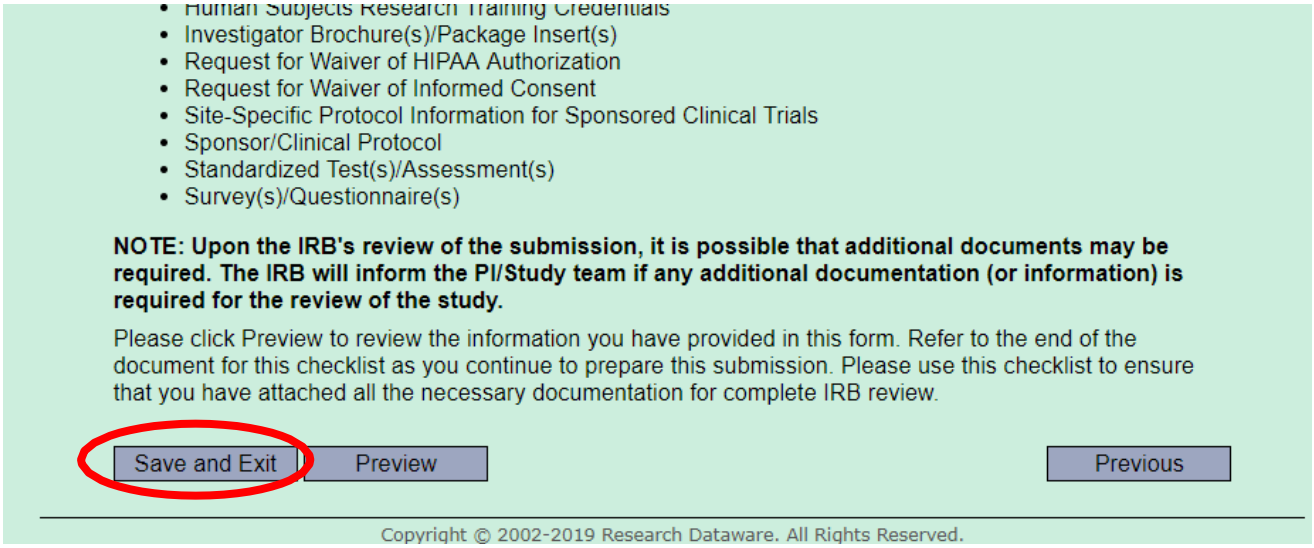


REMINDER: Please note that there will not be a specific place in this section/page to provide an electronic, or physical signature. **Therefore, the Principal Investigator (PI) must electronically sign the submission package in IRBNet before the project is formally submitted to the North Texas Regional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

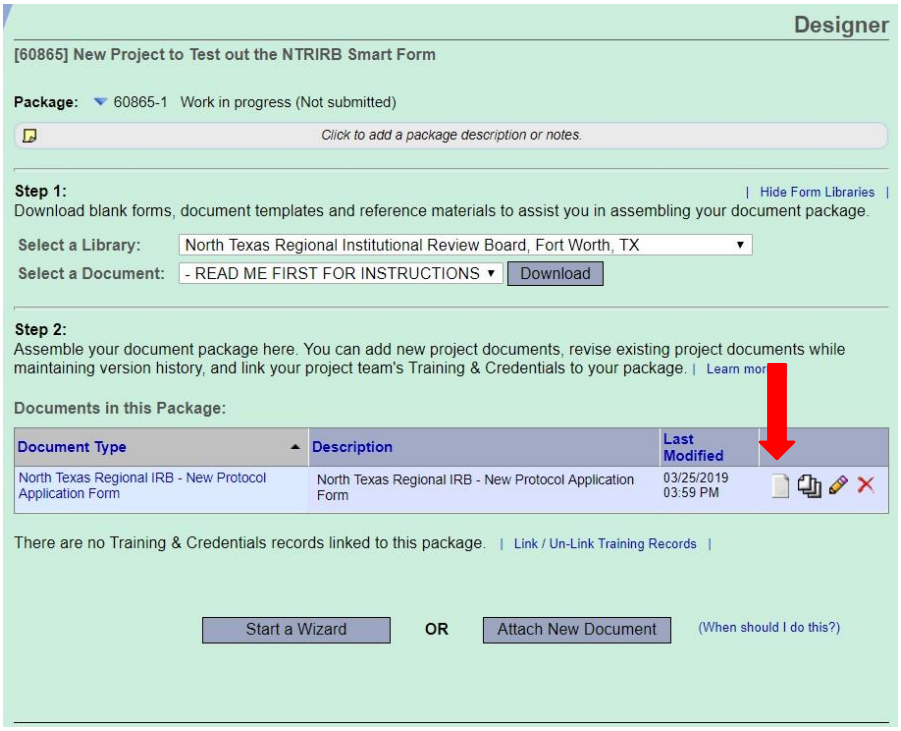
18. The last page includes instructions and a list of all applicable documents/forms that need to be submitted in IRBNet in addition to the study application. The items on this page generate based on the investigator's responses within the Wizard application form (NOTE: If the investigator goes back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



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

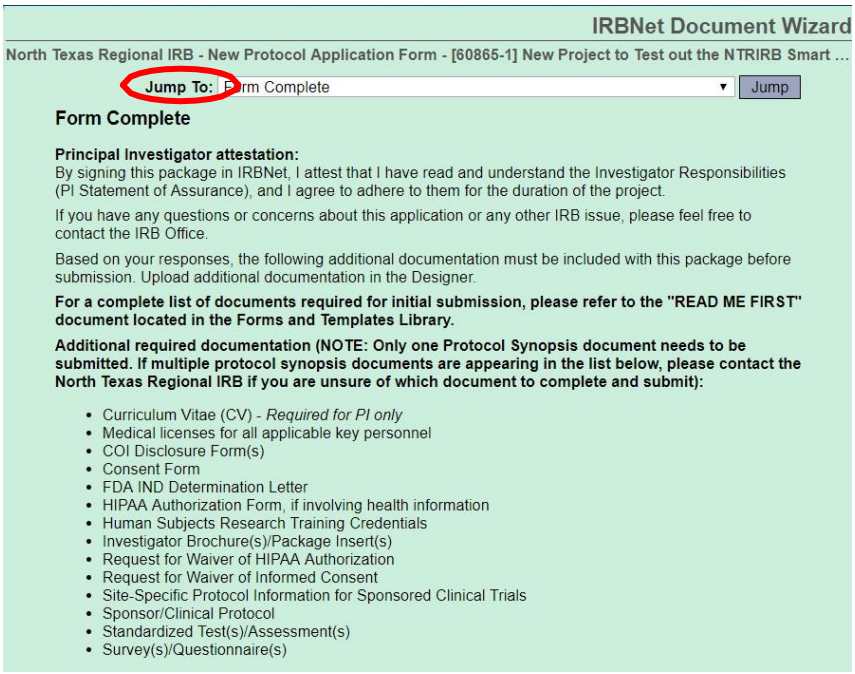


20. On the Designer page, the Wizard application form (titled "North Texas Regional IRB – New Protocol Application Form") will now appear as a new document in the package:

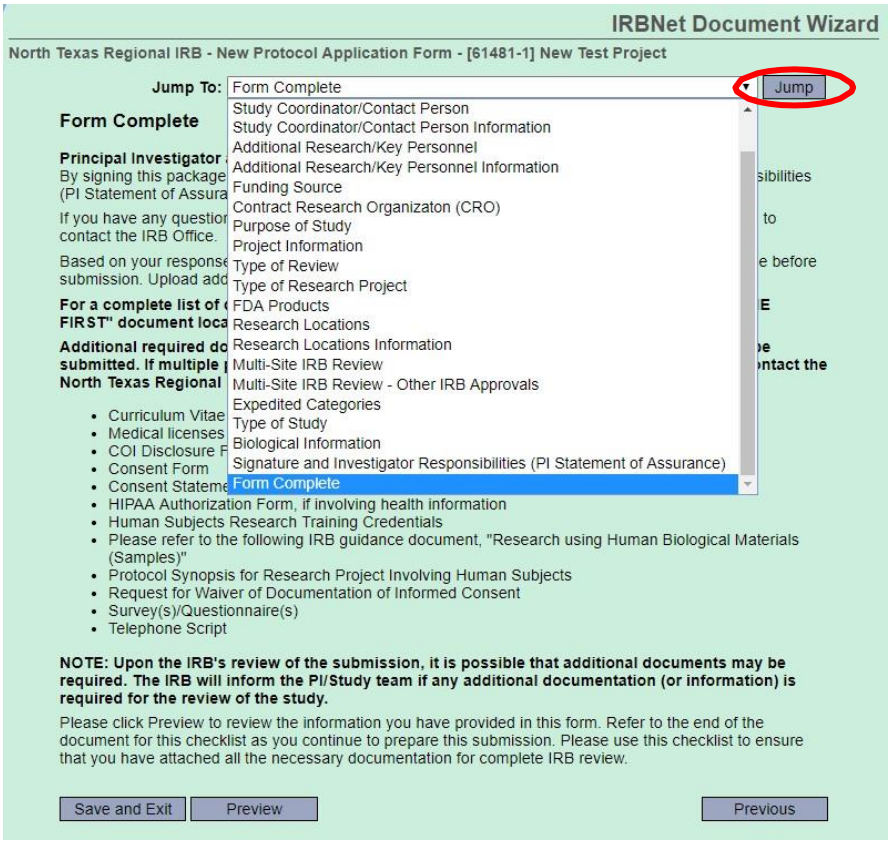


21. By clicking the "View this Document" button (document icon, as shown in screenshot above), the investigator can download a PDF version of their completed Wizard application Form.

22. Note that throughout the application form, you have the option to "Jump" to another section.



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



B. Developing Descriptive File Names

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

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

For trainings and COIs, the IRB recommends:

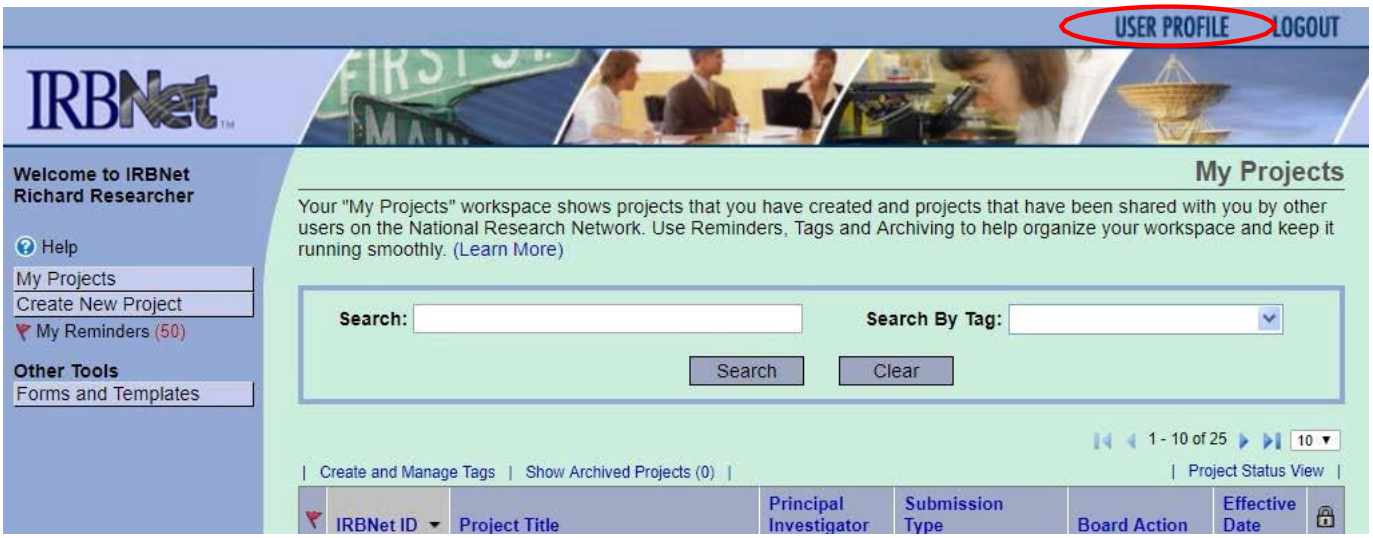
-Title of training
-First initial and last name of key personnel to which the training belongs.

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

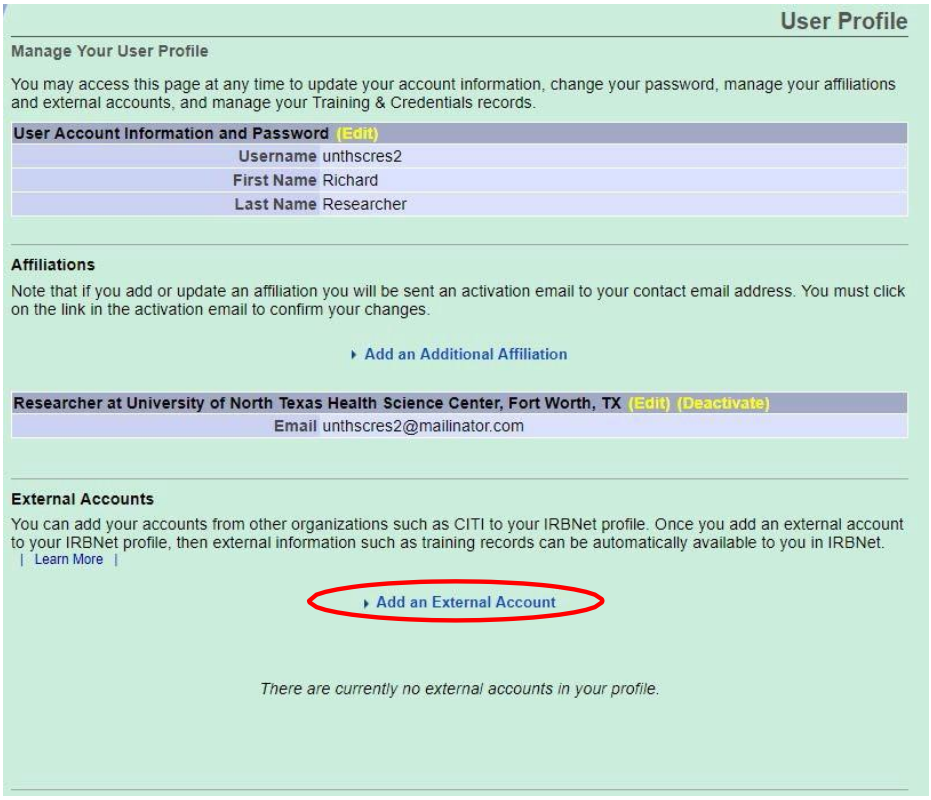
C. Linking CITI Training to User Profile

IRBNet can link your CITI training to your User Profile, which, in turn, can be linked to individual projects. To do this, follow the screenshots below.

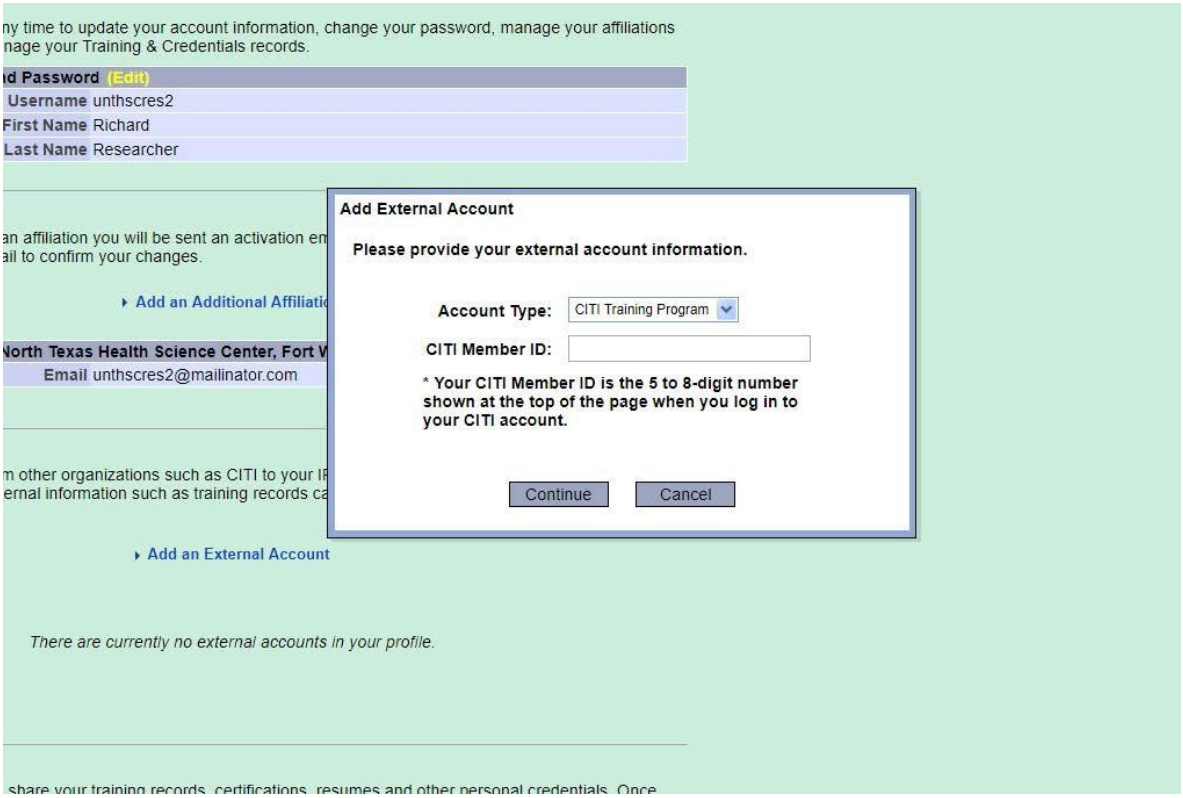
1. After logging in, select "User Profile" at the top of the page.



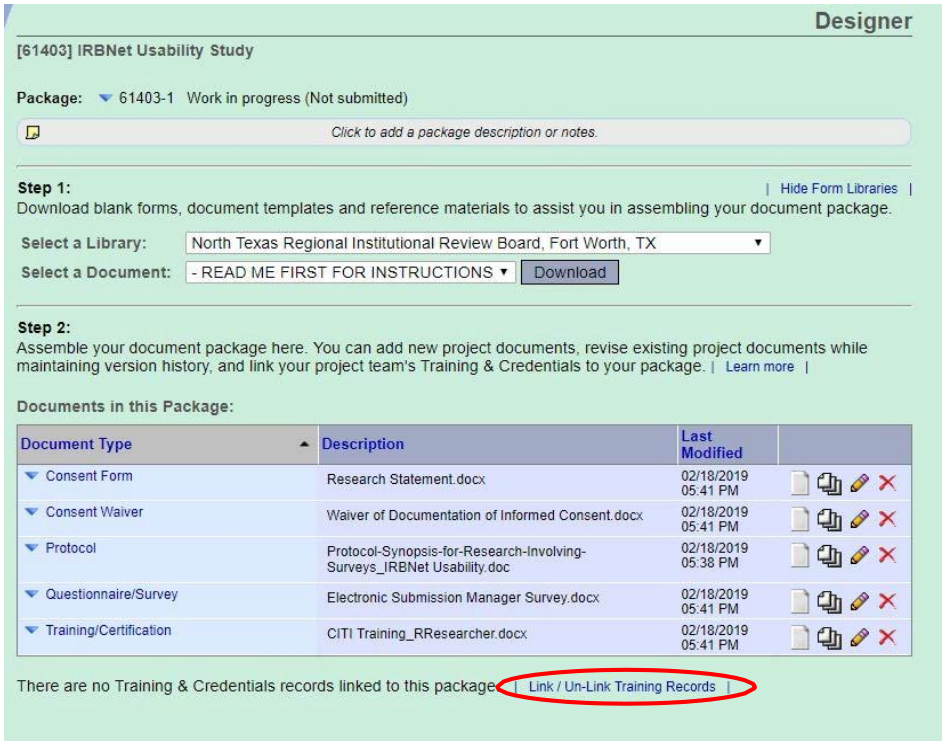
2. In your "User Profile", find the "External Accounts" section. Click "Add an External Account".



3. The system will prompt you to insert your CITI Member ID.



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



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.