IRBNet Guidance for using the Wizard/SMART Application Form:

The guidance in this document is intended to help you navigate through completing the IRBNet Wizard/SMART application form (i.e., the IRB application form for a new study). The Wizard application form is a smart form that uses a logic-tree design. The form will prompt you to enter information that is relevant to your specific study and needed to facilitate the IRB review process. As such, the Wizard application form will function as a replacement for previous application documents (i.e., Exempt application form, Expedited application form, Full/Convened Board application form). These documents will no longer need to be submitted with new projects.

The Wizard application form does **NOT** replace the study-related Protocol Synopsis or Site-Specific Protocol Information (for Sponsored Clinical Trials), consent/HIPAA Authorization forms, recruitment materials, waiver requests, or any other applicable, study-related documents.

The North Texas Regional IRB recommends that you complete the Wizard application form first, as it will provide you with a list of other documentation that is needed to complete your submission (based on your responses).

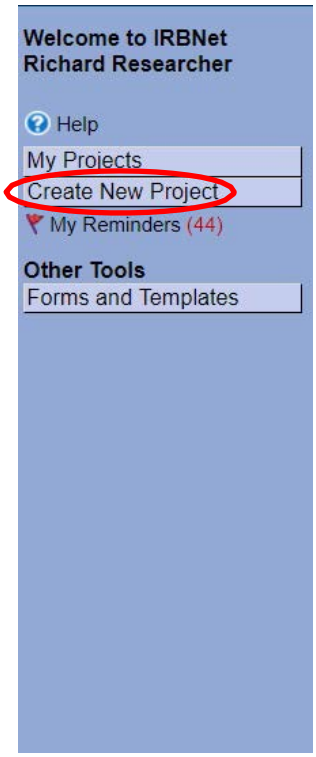
Please feel free to contact Itzel Pena Perez (Itzel.Pena@unthsc.edu, 817-735-0673) or Tania Ghani (Tania.Ghani@unthsc.edu, 817-735-2038) if you have any questions about how to complete the Wizard application form.

How to Create a New Project and Access the Wizard Application Form in IRBNet:

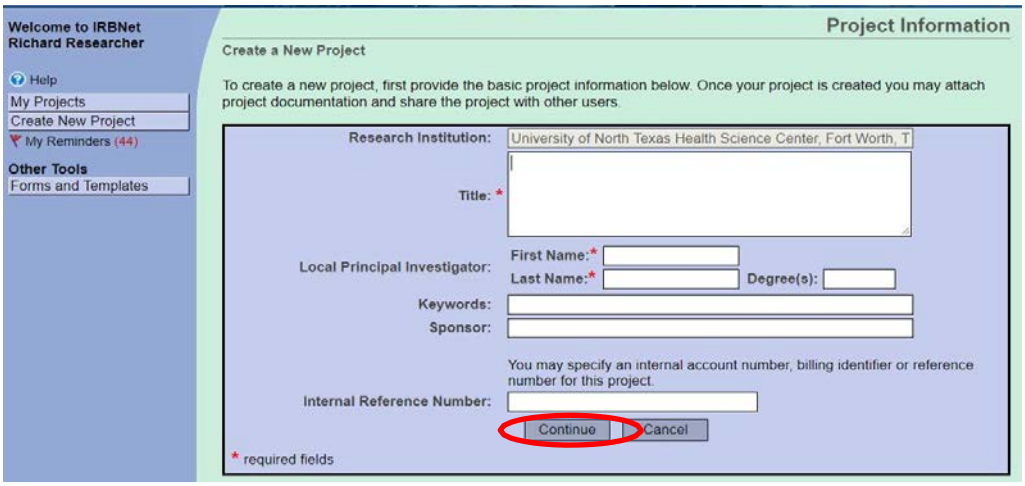
1. Navigate to www.irbnet.org and login using the username and password you created from the previous section. If you have not created an account, please follow the necessary steps to register for an account.

   Please note that IRBNet sessions will time out. Ensure you are saving changes/refreshing the page frequently in order to avoid losing work.

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

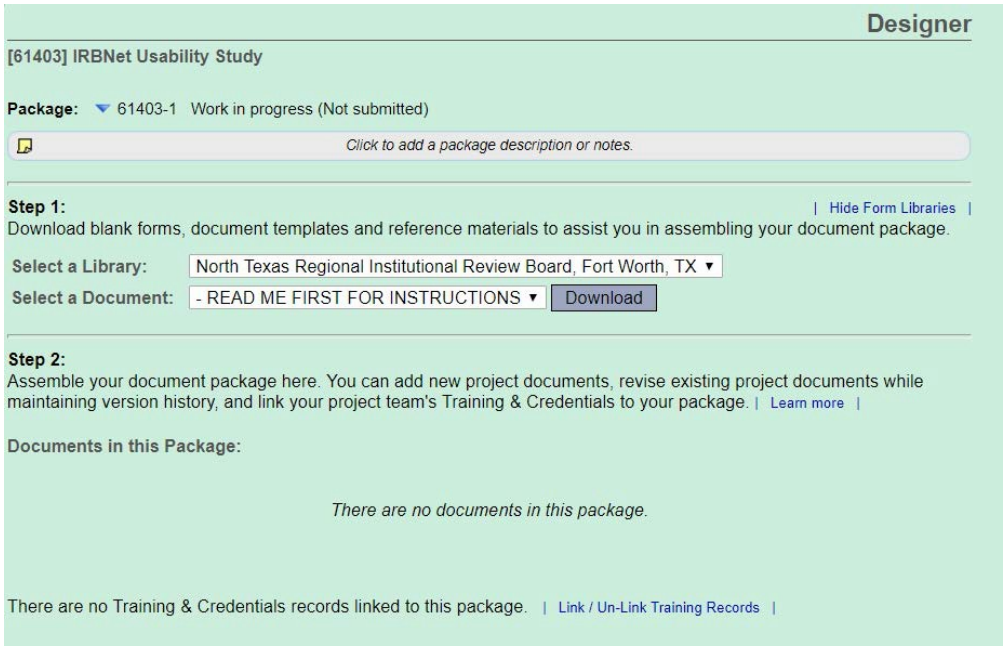


3. The following screen will appear:

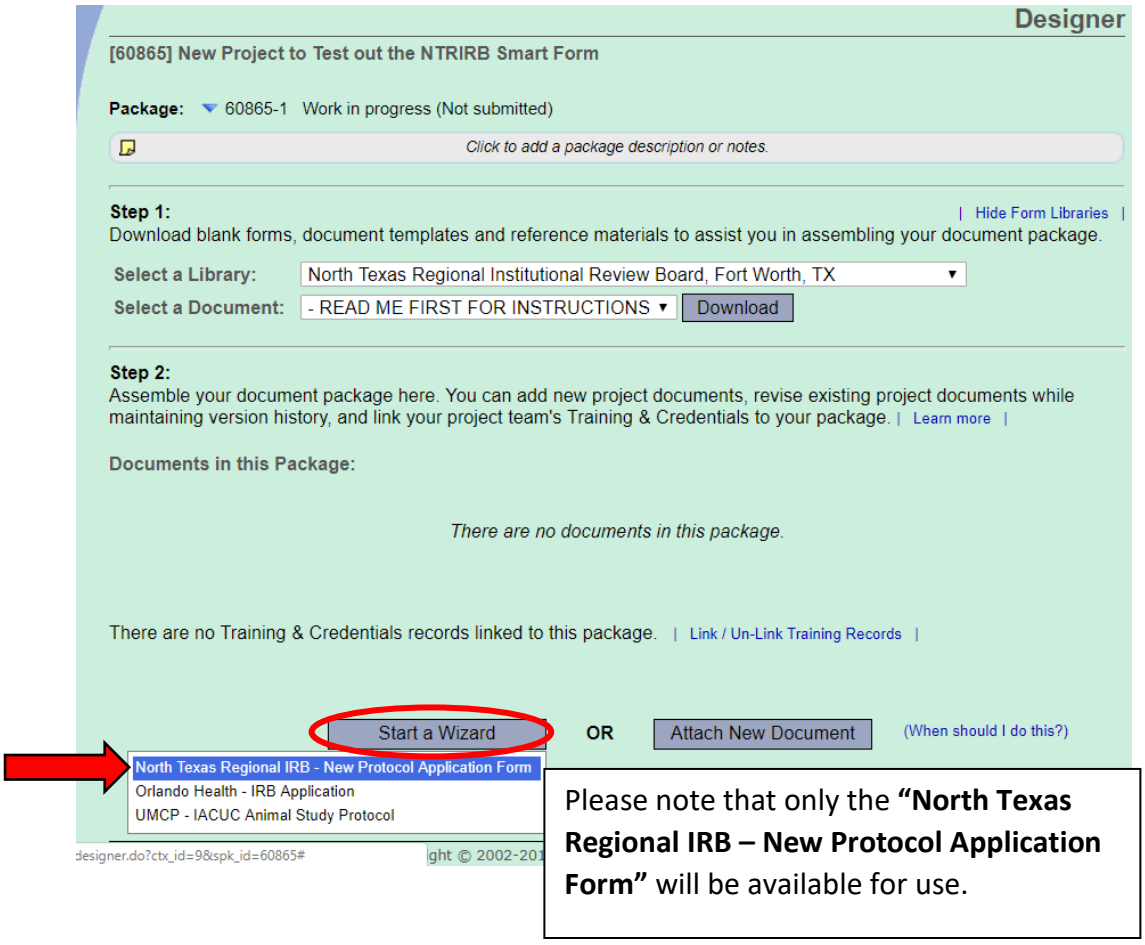


4. Enter the title of the project and your name. If the study is sponsored, please enter the sponsor / funding agency's name in the sponsor box. The keywords box may be useful for you if you have several studies and need to find this study at a later time based upon a specific keyword. Once you have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

5. You will be taken to the Designer page and this screen. The "Read Me First" document will provide IRBNet guidance specific to the North Texas Regional IRB. Please note that the IRB recommends downloading the necessary blank forms, document templates and reference materials *after* completing the Wizard application form as your responses to the Wizard application form will guide you on what will need to be submitted.



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



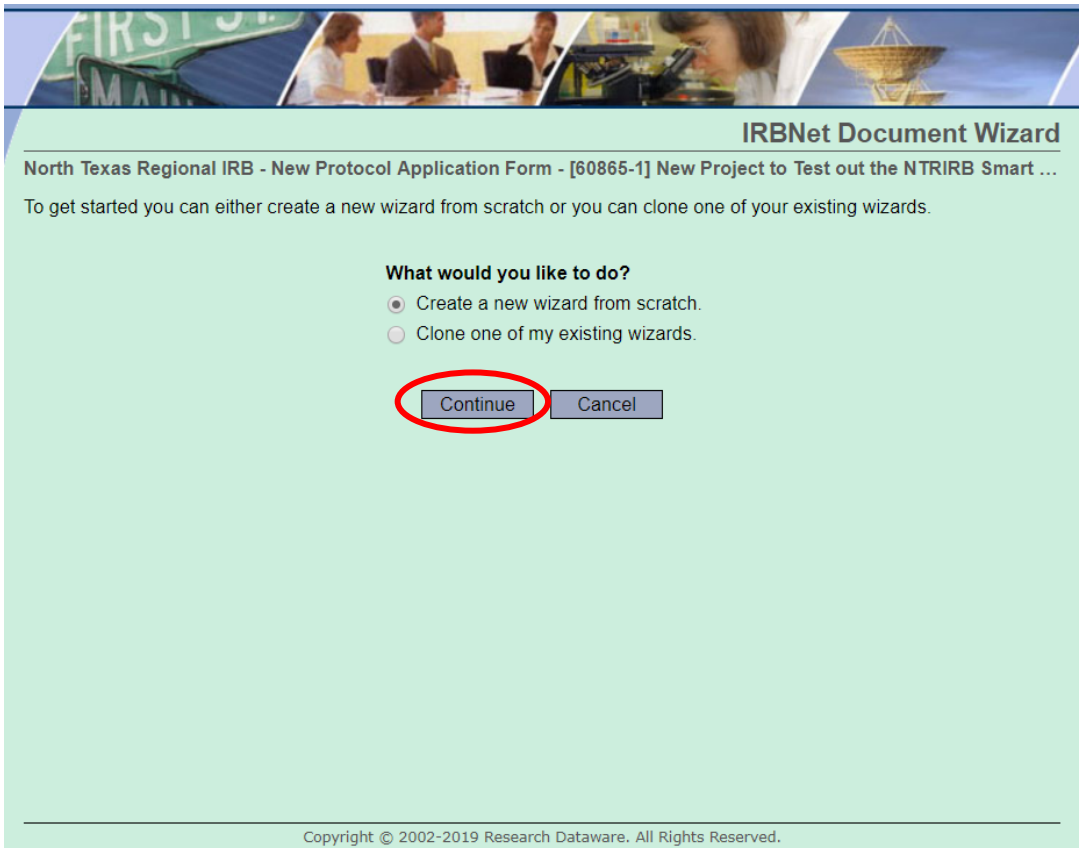
Please note that only the **"North Texas Regional IRB – New Protocol Application Form"** will be available for use.

How to Complete the Wizard Application Form in IRBNet:

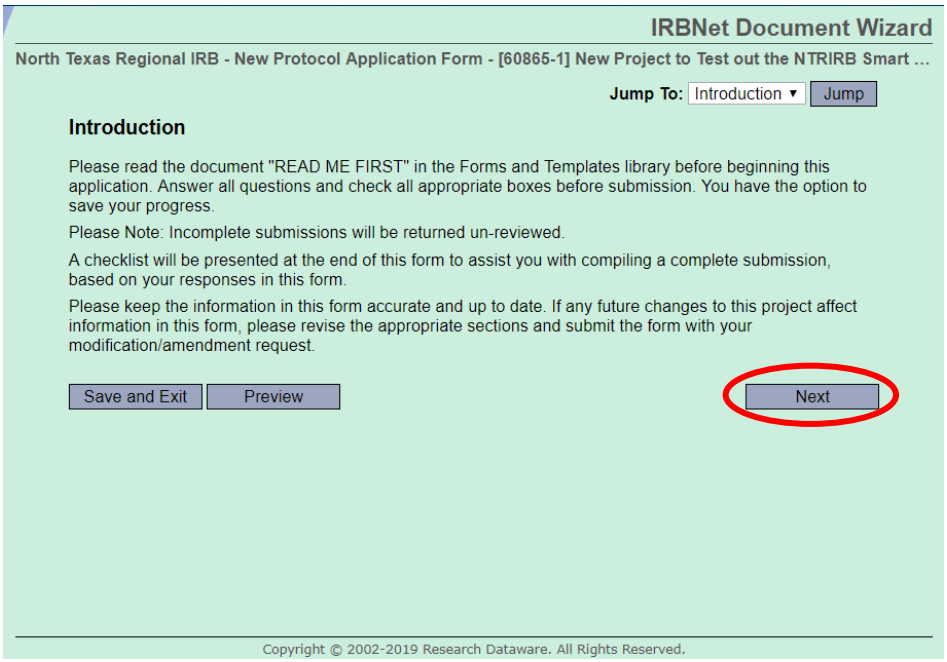
7. If this is the first project you are submitting in IRBNet, select “Create a new wizard from scratch”.

   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.

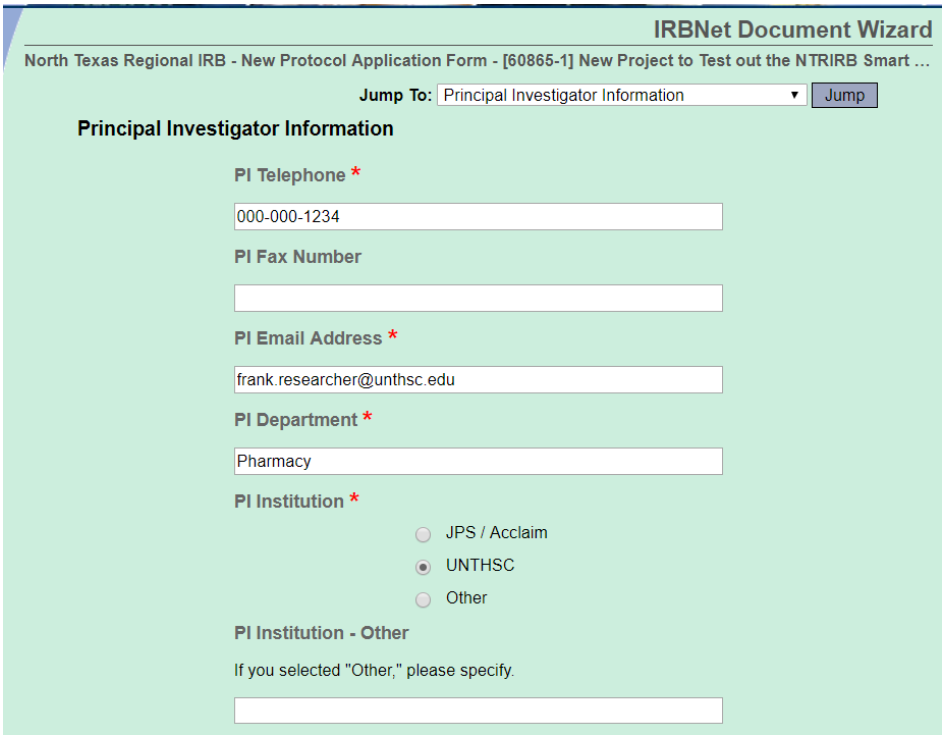
   For this example, we will “Create a new wizard from scratch”, then select “Continue”.



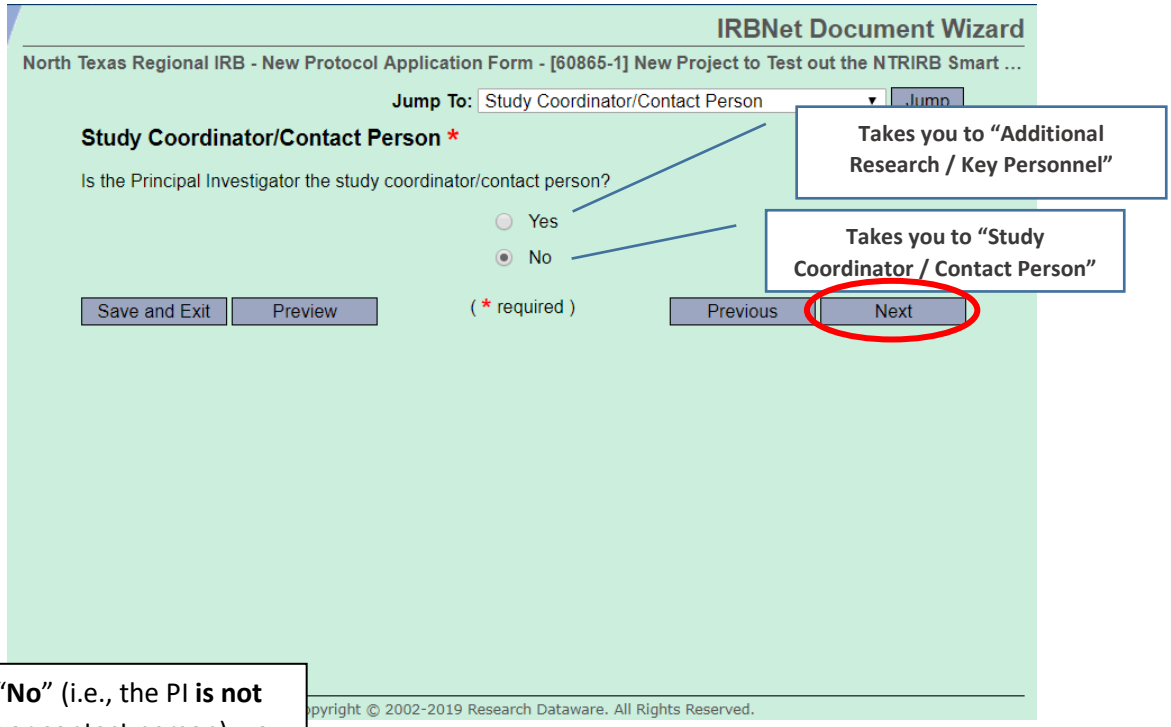
8. You will be taken to the Introduction page. Please follow the instructions provided, then click "Next":



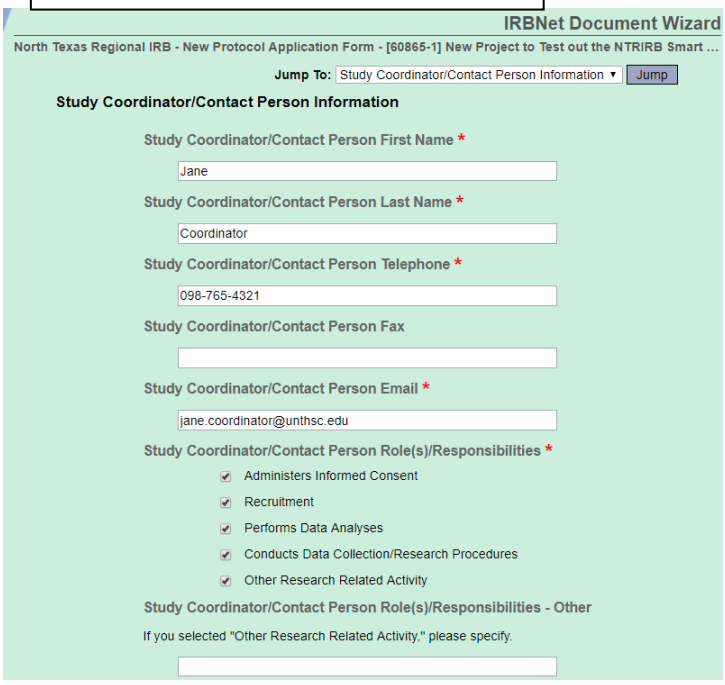
9. Please fill in the applicable information about the principal investigator (PI):



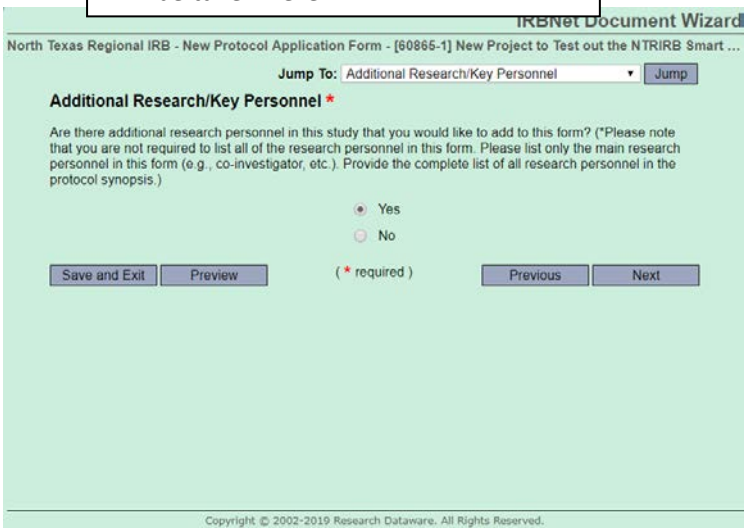
10. If the Principal Investigator is the study coordinator/contact person for the study, please select “Yes”. After hitting “Next”, you will be taken to the “Additional Research / Key Personnel Information” page.
    However, if the PI is ***not*** the study coordinator/contact person, please select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



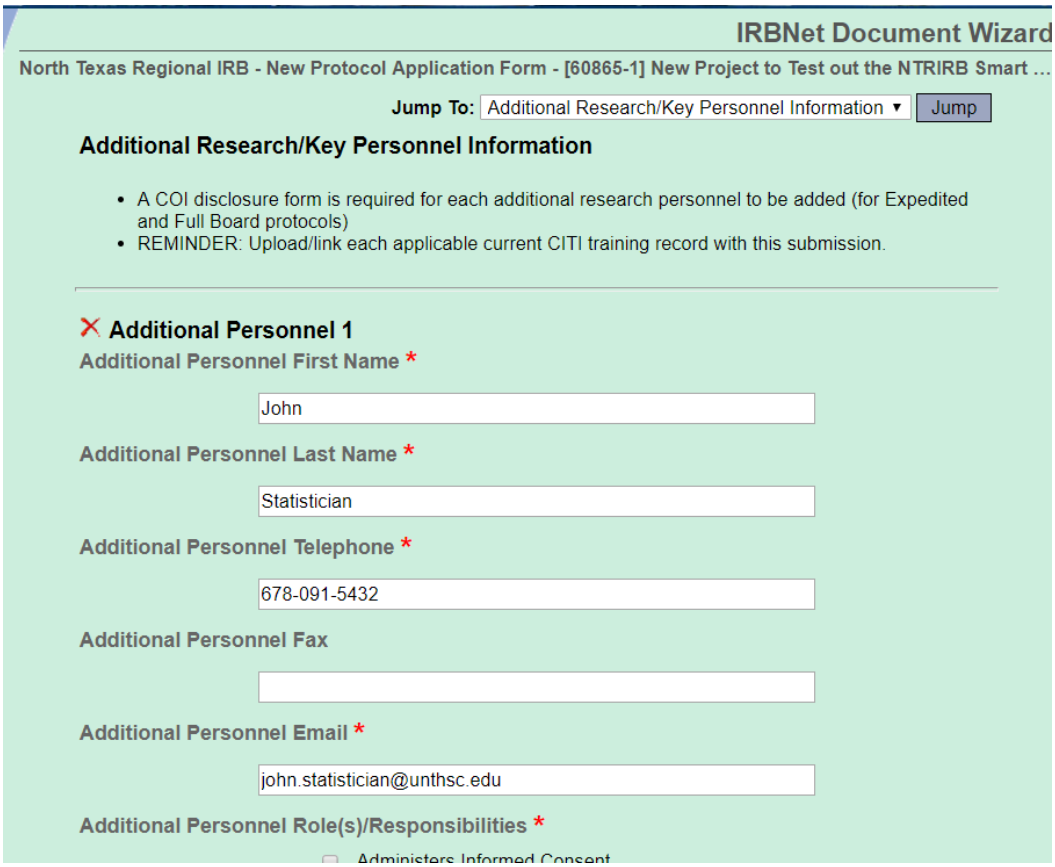
If you selected “**No**” (i.e., the PI **is not** the coordinator or contact person), you will be taken here:



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



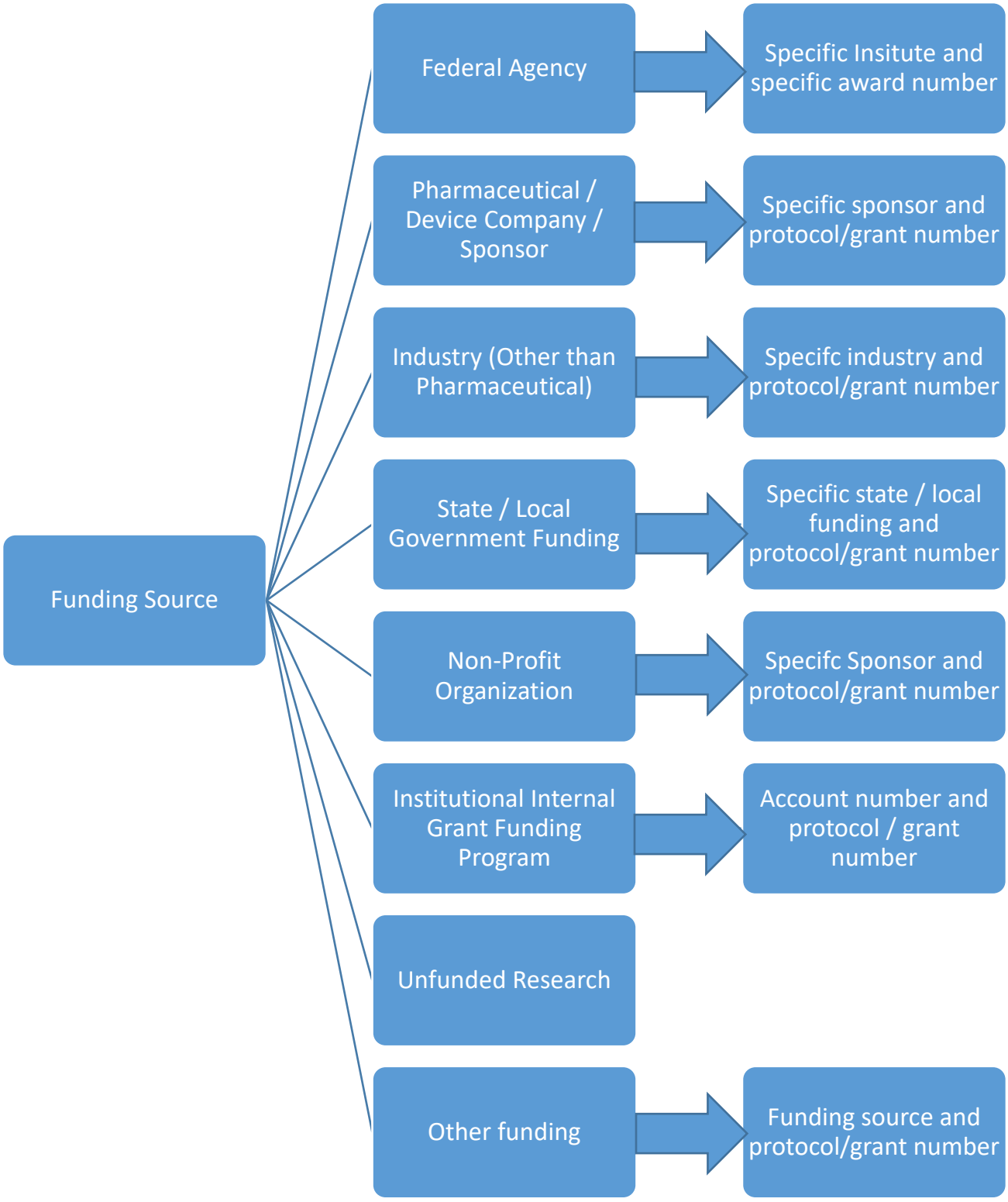
11. Please provide information about other pertinent Research/Key Personnel. The IRB recommends listing ***only the main personnel*** in the Wizard application form and providing a complete list of research personnel in the protocol synopsis, as this will prevent the need to update the form whenever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



12. 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.

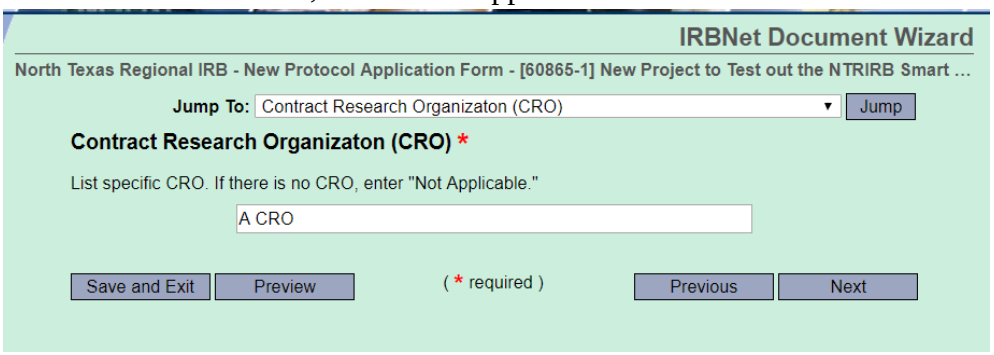
a. First, you will be asked to provide information about the project's Funding Source(s). Please note that you may select multiple funding sources, as applicable.

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".

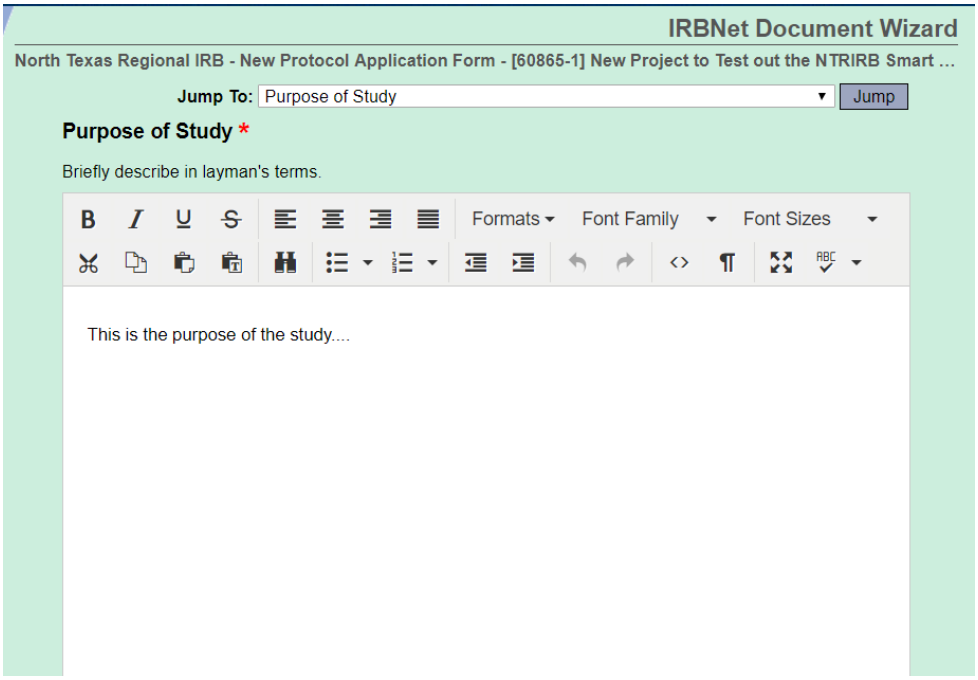


13. In the next section, you will be asked to enter information about the Contract Research Organization (CRO).

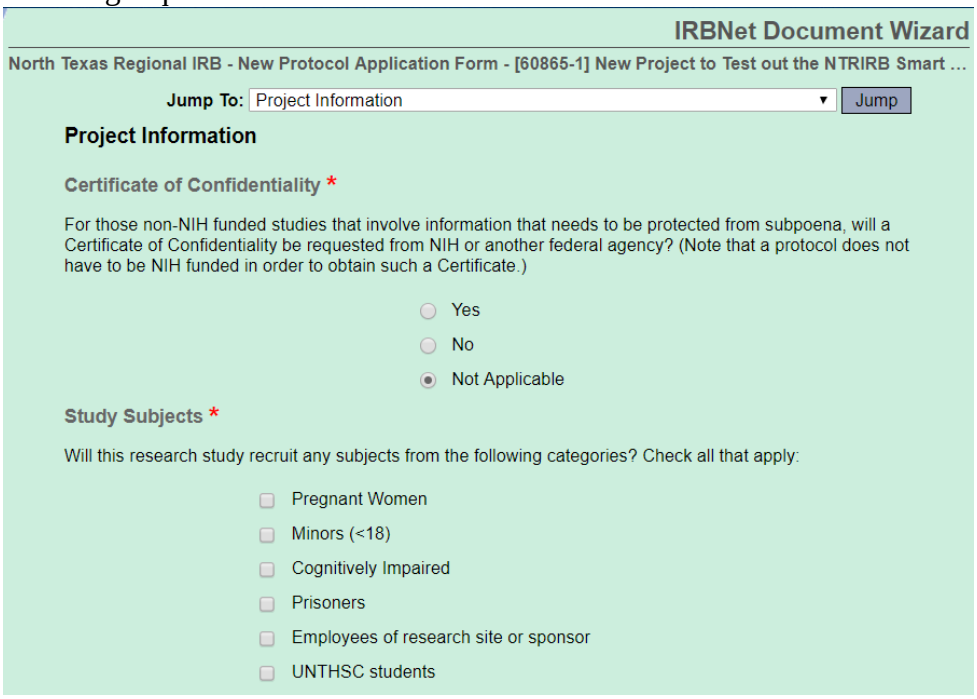
i. If there is no CRO, enter “Not Applicable”



14. 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.



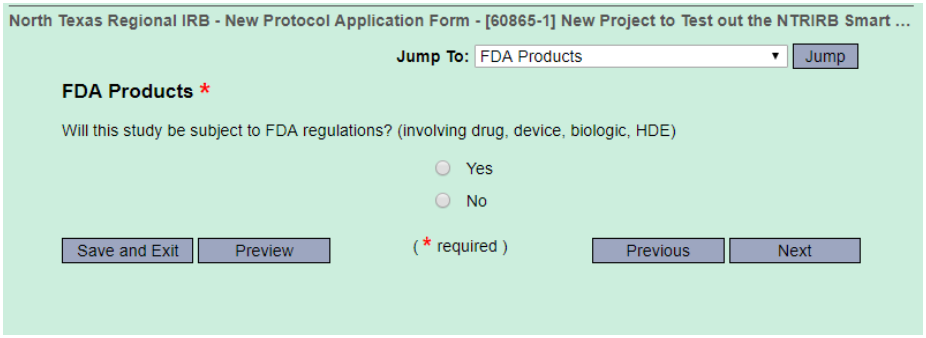
15. The Project Information page will ask you to provide information about Certificate of Confidentiality, the subject population to be included in the study, recruitment of subjects, and any waivers being requested.



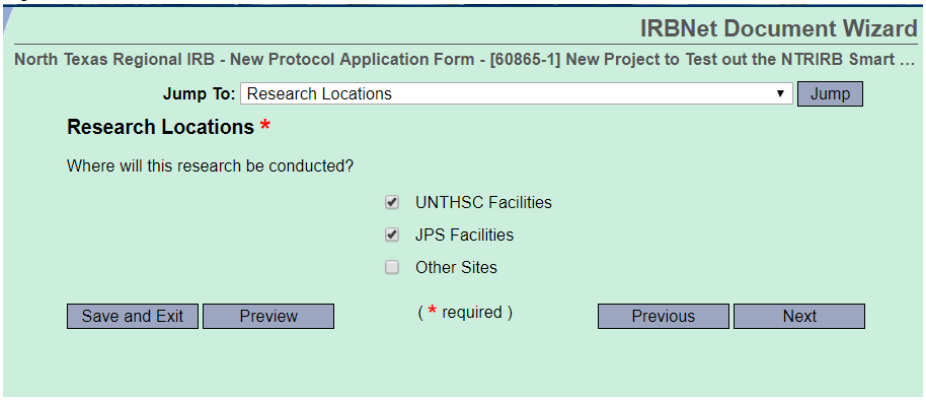
16. On the next page, you will select the Type of Review, which will be followed by a page that asks you about the Type of Research Project. Your selections on these pages will generate the information that is requested on subsequent pages. The screenshots and charts (below) outline the type of information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

17. 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.

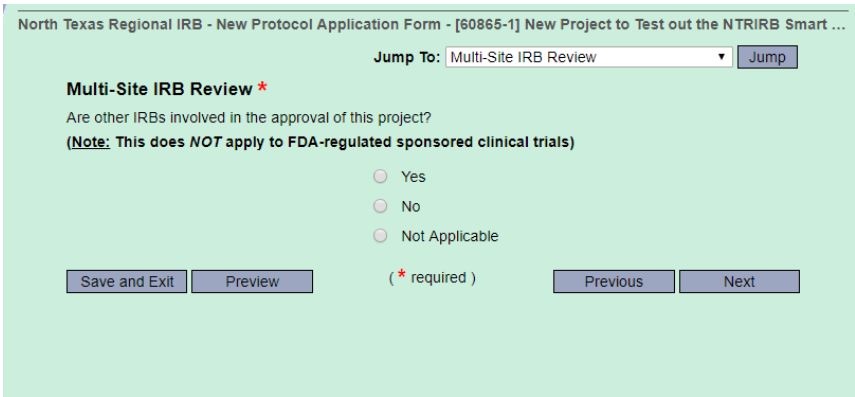
18. Then, you will be asked if the study is subject to FDA Regulations. Please note this page will appear regardless of the type of review or type of research project selected.



19. 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.

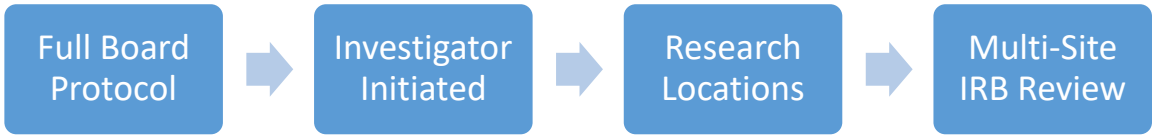


20. Following the Research Locations, the form will ask if other IRBs are involved in the approval of the project. Please note this page will appear regardless of the type of review or type of research project selected.

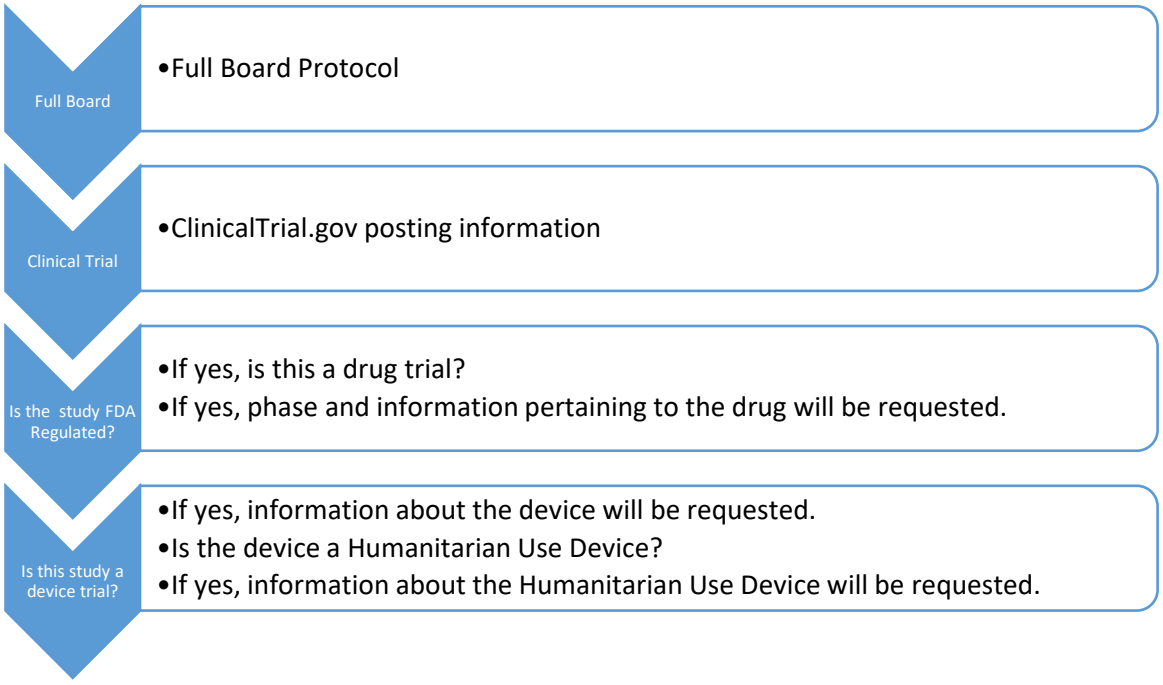


21. Based on your responses to items 16 & 17 above (Type of Review & Type of Research Project pages), a series of questions will appear for you to complete.

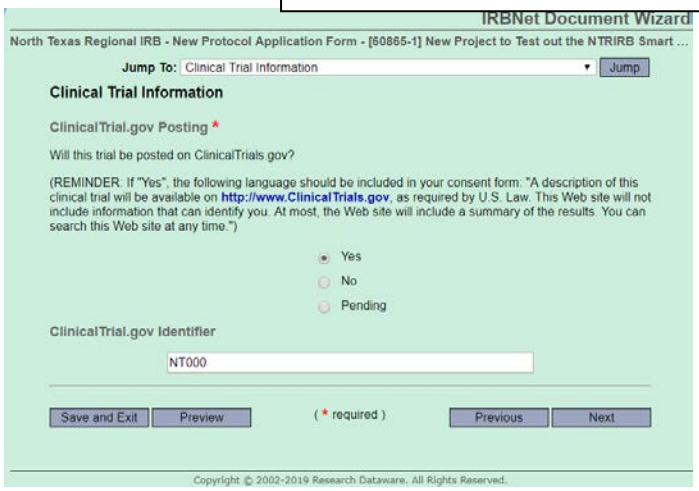
a. For example, if "Full Board Protocol" is selected (on the Type of Review page) followed by "Investigator Initiated" (on the Type of Research Project page), the following pages will be generated:

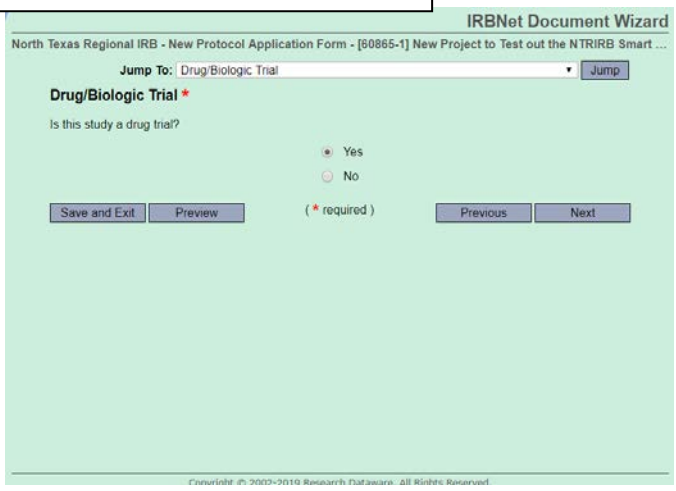


b. If “Full Board Protocol” followed by “Clinical Trial” is selected, the following pages will be generated:

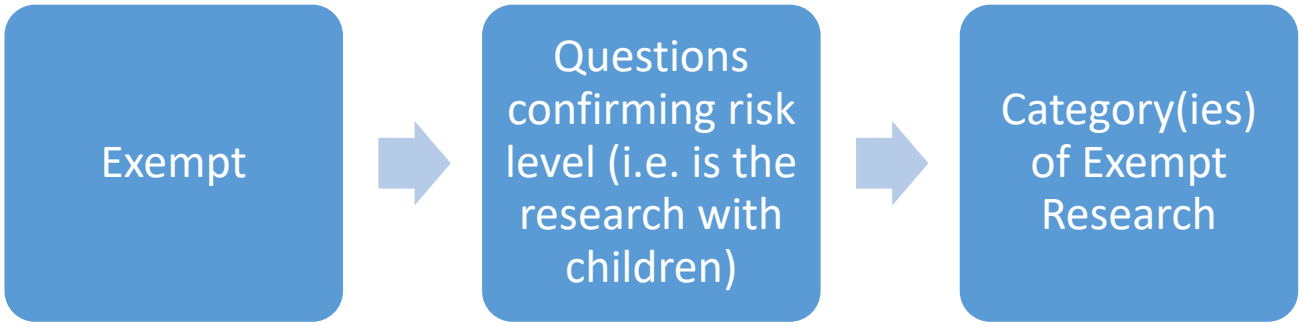


Some screenshots relevant to FDA studies are provided below. Note: These will only generate if you have previously selected “Yes,” when asked if the study is regulated by the FDA.



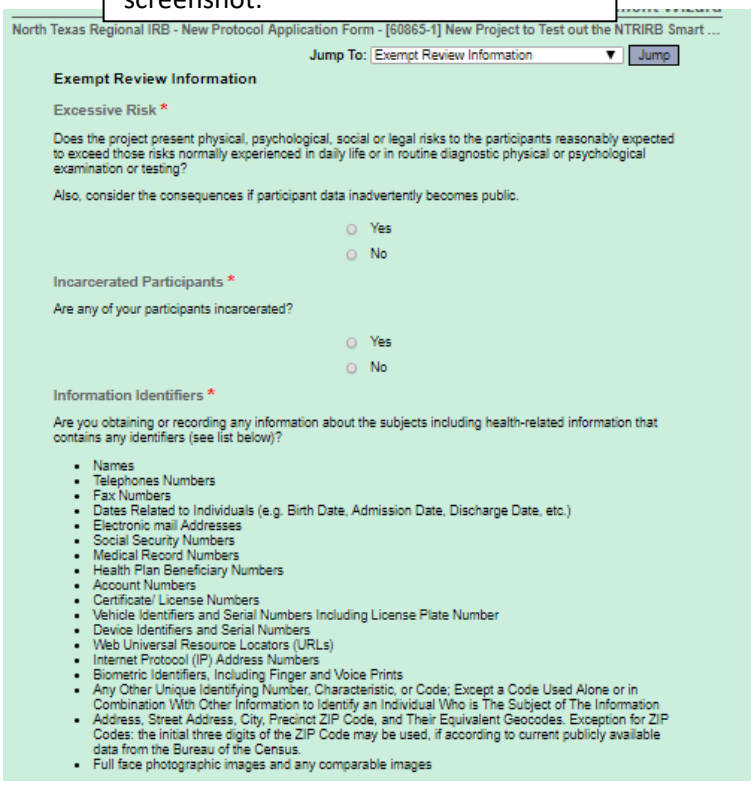


c. If the “Type of Review” selected is “Exempt”, subsequent pages will ask for information related to risk and category. See the graphic below for an example scenario:



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?

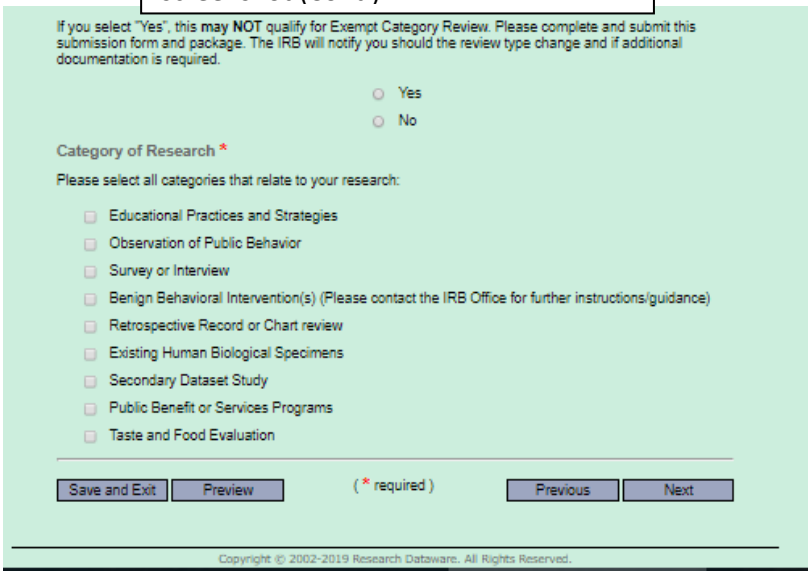
○ Yes
○ No

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:

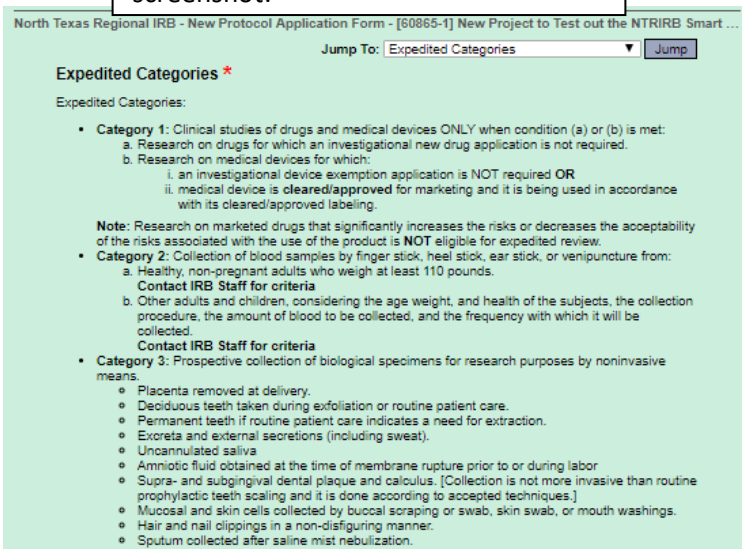
- ☐ Educational Practices and Strategies
- ☐ Observation of Public Behavior
- ☐ Survey or Interview
- ☐ Benign Behavioral Intervention(s) (Please contact the IRB Office for further instructions/guidance)
- ☐ Retrospective Record or Chart review
- ☐ Existing Human Biological Specimens
- ☐ Secondary Dataset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

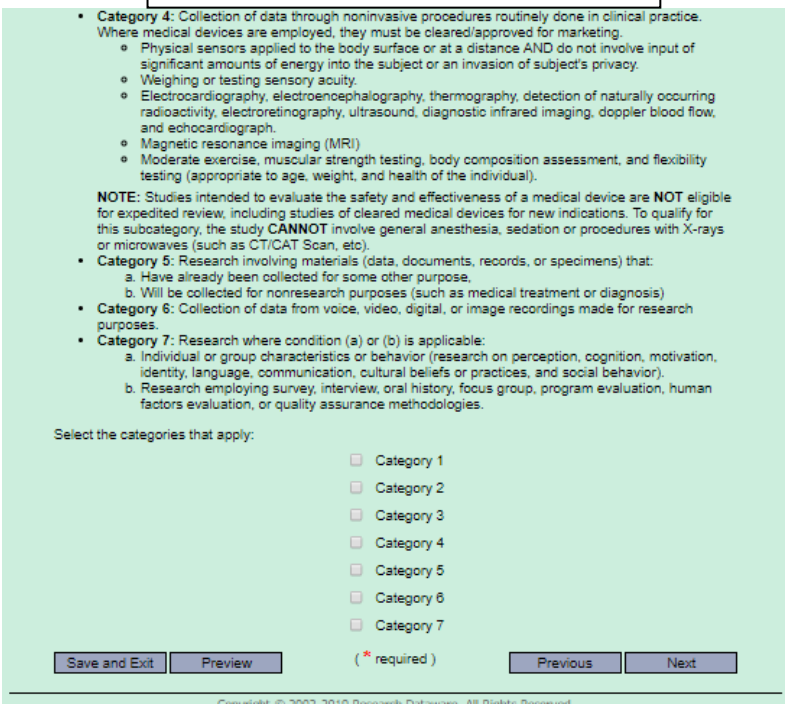
Expedited Categories *

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).

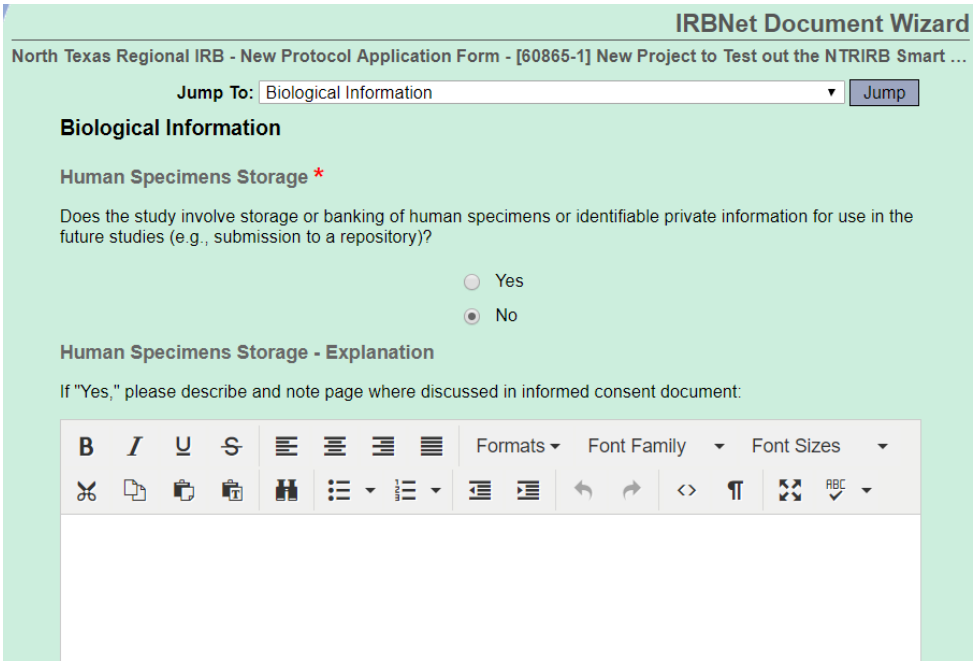
  NOTE: Studies intended to evaluate the safety and effectiveness of a medical device are **NOT** eligible for expedited review, including studies of cleared medical devices for new indications. To qualify for this subcategory, the study **CANNOT** involve general anesthesia, sedation or procedures with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

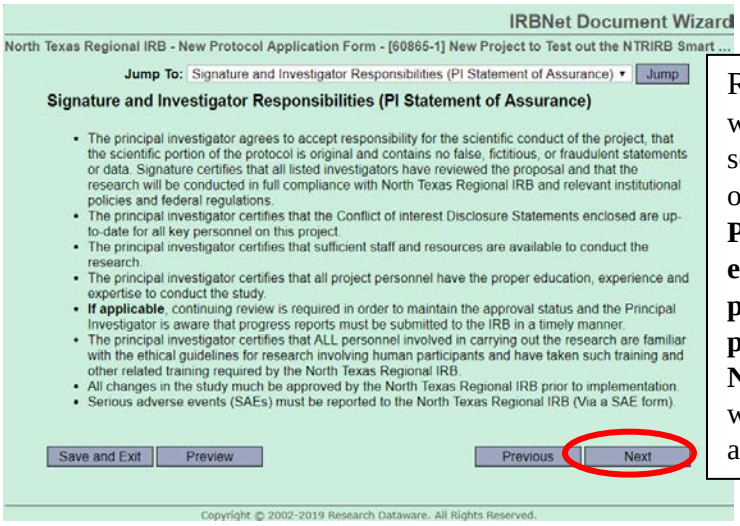
☐ Category 1
☐ Category 2
☐ Category 3
☐ Category 4
☐ Category 5
☐ Category 6
☐ Category 7

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

22. 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).

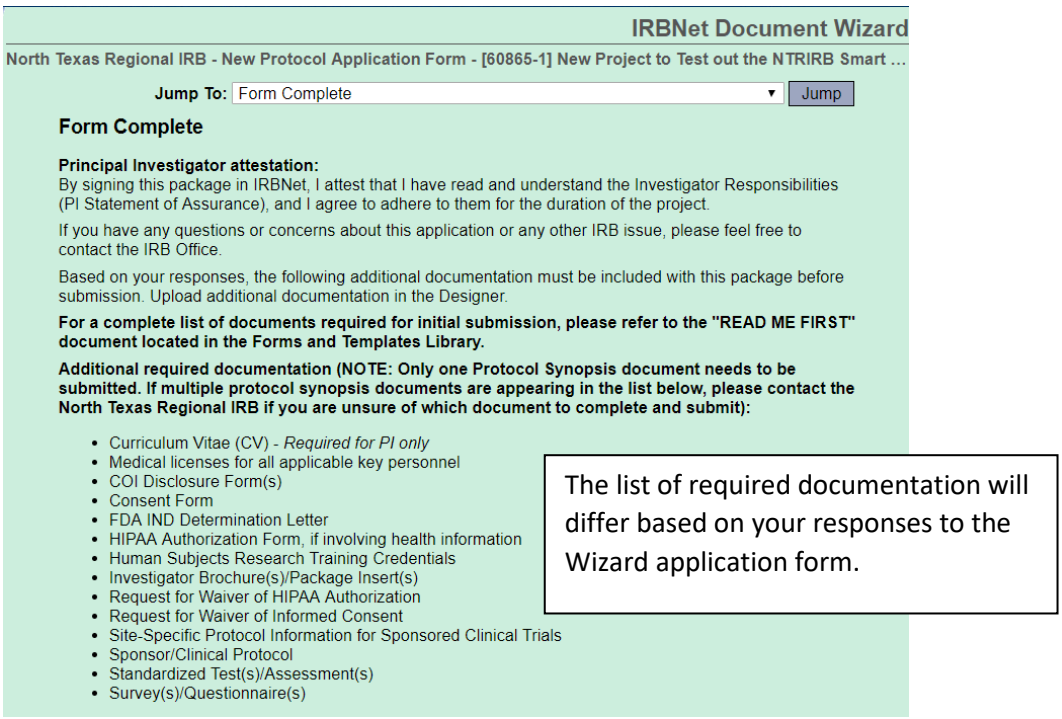


23. Signature and Investigator Responsibilities: This page will appear for all studies. The PI/investigator should read this page, and ensure they understand each item as written (or contact IRB staff with any questions). Clicking "Next" will take you to the last page of the application form.

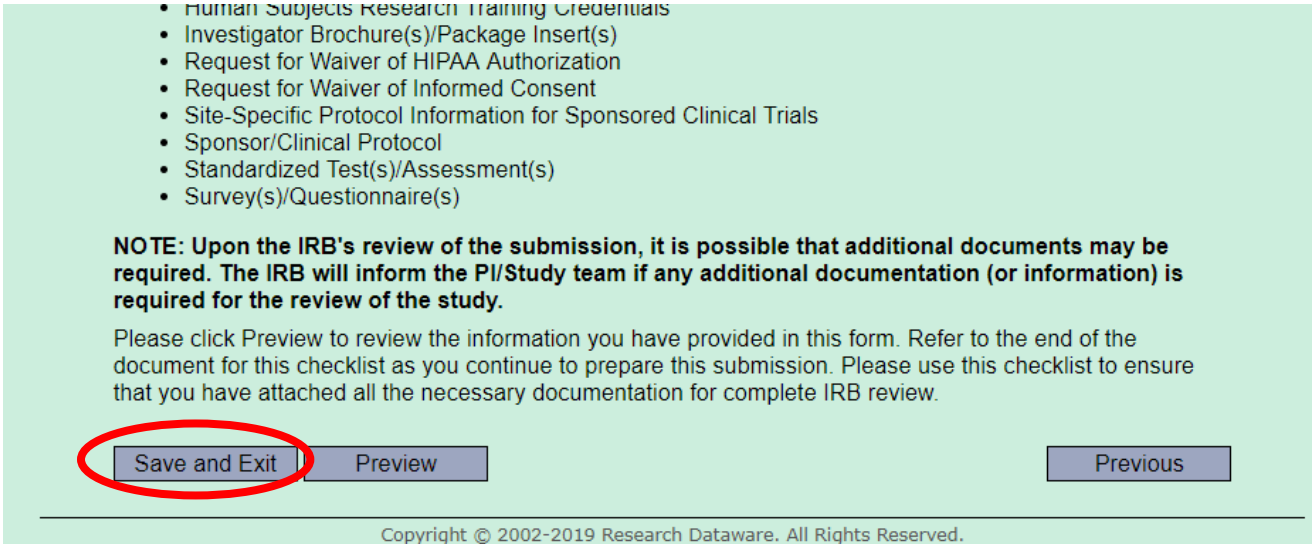


REMINDER: Please note that there will not be a specific place in this section/page to provide an electronic, or physical signature. **Therefore, the Principal Investigator (PI) must electronically sign the submission package in IRBNet before the project is formally submitted to the North Texas Regional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

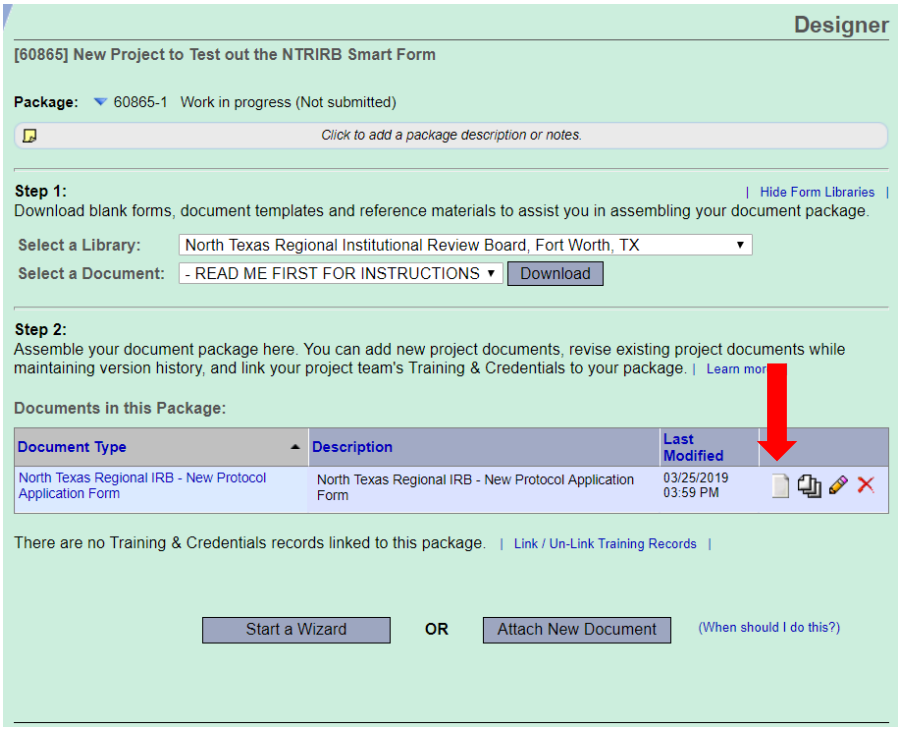
24. The last page includes instructions and a list of all applicable documents/forms that need to be submitted in IRBNet in addition to the study application. The items on this page generate based on the investigator's responses within the Wizard application form (NOTE: If the investigator goes back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



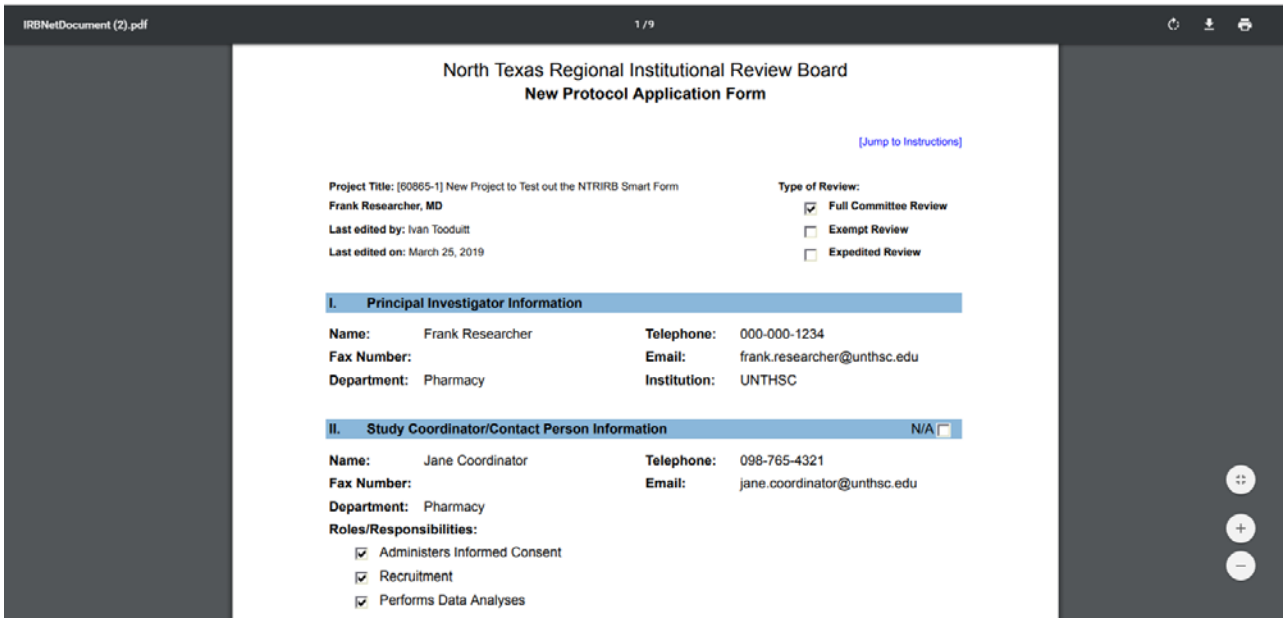
25. Once the investigator hits the "Save/Exit" button, they will be taken back to the Designer page.



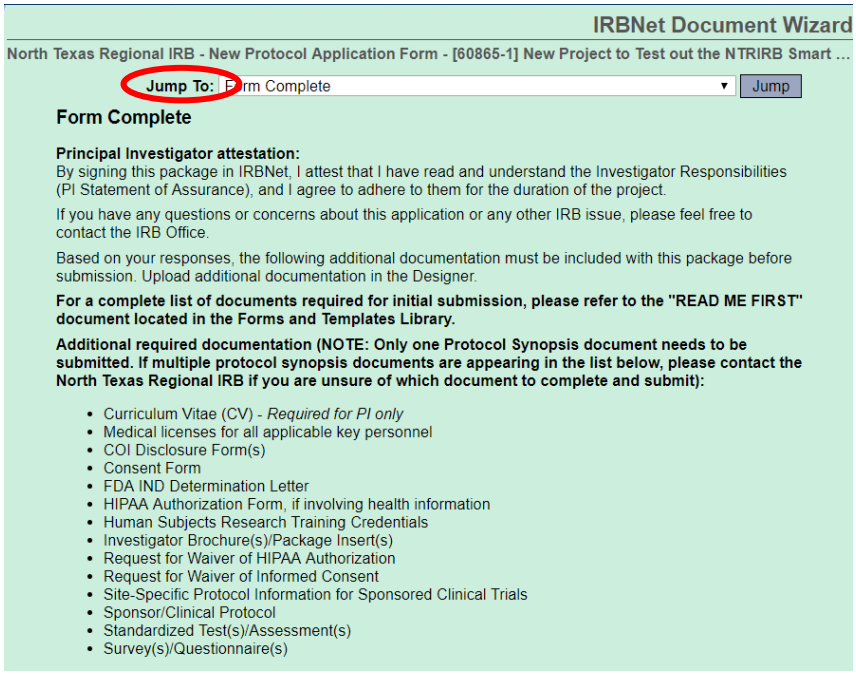
26. On the Designer page, the Wizard application form (titled “North Texas Regional IRB – New Protocol Application Form”) will now appear as a new document in the package:



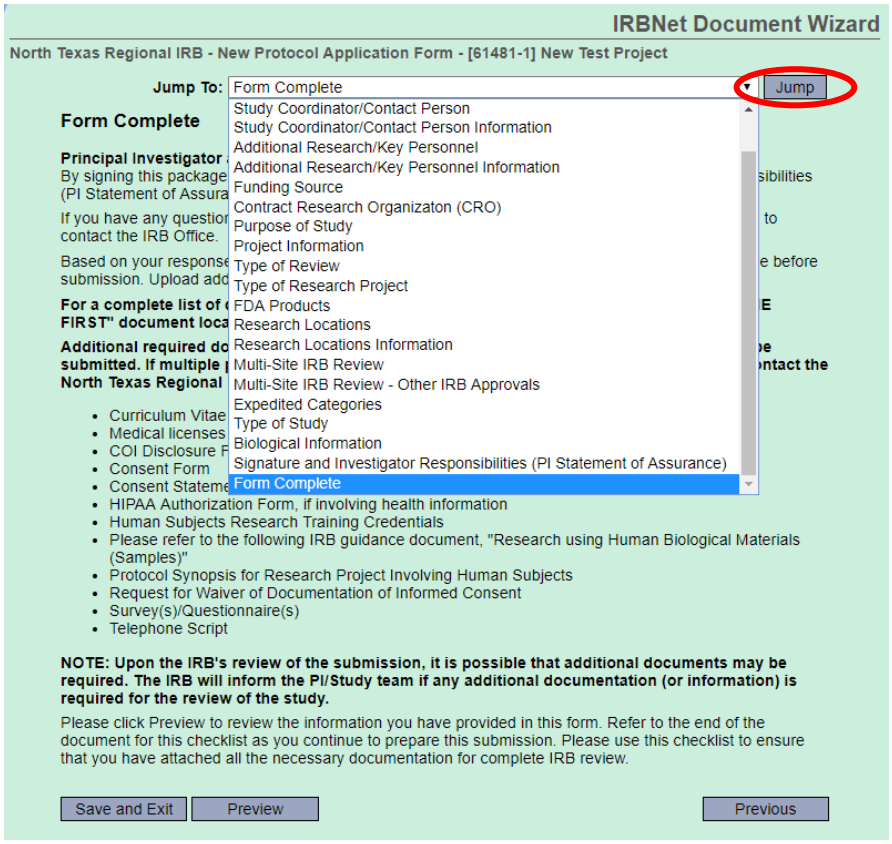
27. By clicking the “View this Document” button (document icon, as shown in screenshot above), the investigator can download a PDF version of their completed Wizard application Form.



28. 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”.



A few reminders:

(1) Researchers must still upload and submit a study-related Protocol Synopsis (e.g., Site-Specific Protocol- Information for Sponsored Clinical Trialss, Protocol Synopsis for Chart Review studies, Protocol Synopsis for Survey Research, etc.). The IRBNet Wizard (SMART) Application form does **NOT** replace the Protocol Synopsis or any other study document. The Wizard Application form is the general application that is submitted with every new study.

(2) Given this new electronic application form, there is no longer a traditional place for the Principal Investigator to provide a 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.

(3) Researchers do NOT need to fill out the IRBNet Wizard Application form for projects that have already been approved by the IRB (i.e., existing projects). Researchers are only required to use the IRBNet Wizard Application form for any NEW projects that are submitted on, or after, May 1, 2019.

(4) Post-IRB Approval: If you request an amendment/modification to the protocol, and the proposed amendment/modification will affect ***critical*** information found in the Wizard Application form, then you will need to update/modify the information in the Wizard Application form. Please note that the "track changes" / redline feature is not available within the Wizard Application form; therefore, you will need to describe the modifications (that you make to the Wizard Application form) in the memo accompanying your Amendment/Modification.

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.

Contact Itzel Pena Perez (Itzel.Pena@unthsc.edu, 817-735-0673) or Tania Ghani (Tania.Ghani@unthsc.edu, 817-735-2038) if you have any questions on completing the Wizard application form.

CONGRATULATIONS!! You have completed the IRBNet Wizard application form! ☺