



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:

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, TX

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.

Continue Cancel

* required fields

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

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

Designer

[61403] IRBNet Usability Study

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

Click to add a package description or notes.

Step 1: | Hide Form Libraries |
Download blank forms, document templates and reference materials to assist you in assembling your document package.

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

Select a Document: - READ ME FIRST FOR INSTRUCTIONS | Download

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

Documents in this Package:
There are no documents in this package.

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

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

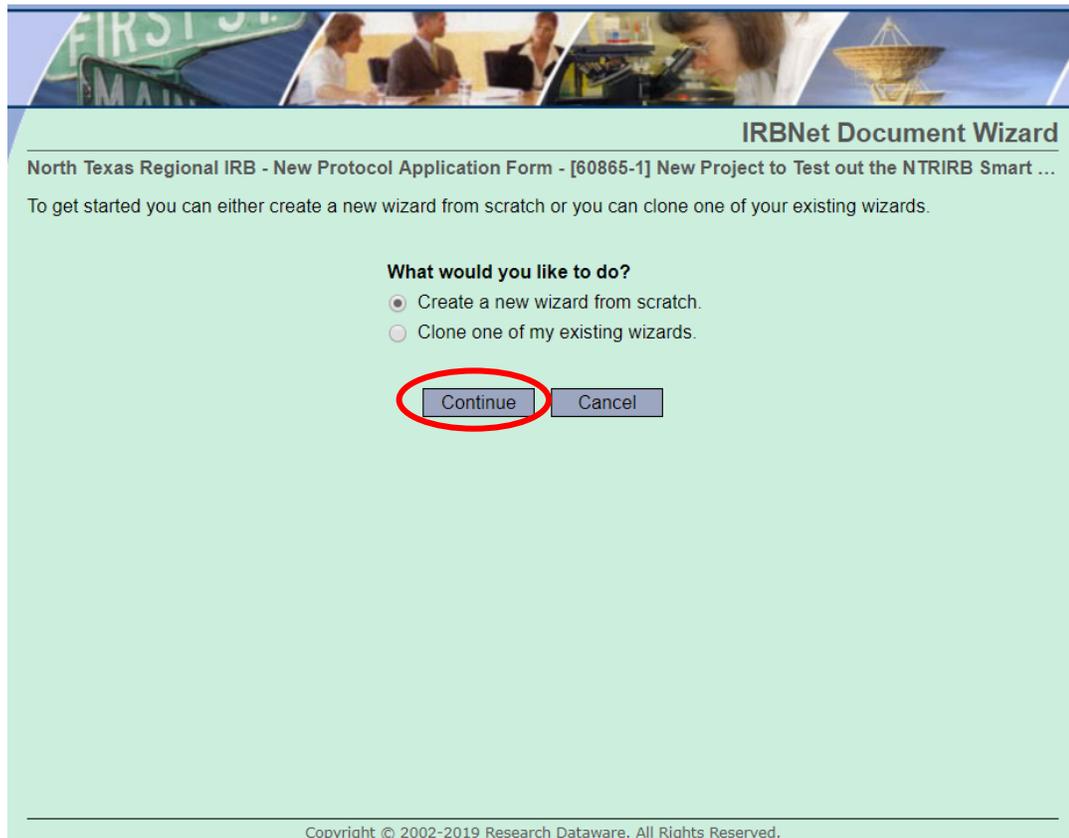
The screenshot shows the 'Designer' interface for a new project. At the top right, the word 'Designer' is displayed. Below it, the project title is '[60865] New Project to Test out the NTRIRB Smart Form'. The 'Package' section shows '60865-1 Work in progress (Not submitted)' and a button to 'Click to add a package description or notes.' The 'Step 1' section includes a 'Hide Form Libraries' link, a 'Select a Library' dropdown menu set to 'North Texas Regional Institutional Review Board, Fort Worth, TX', and a 'Select a Document' dropdown menu set to '- READ ME FIRST FOR INSTRUCTIONS' with a 'Download' button. The 'Step 2' section provides instructions on assembling the document package and includes a 'Learn more' link. Below this, it states 'Documents in this Package:' followed by 'There are no documents in this package.' and 'There are no Training & Credentials records linked to this package.' At the bottom, there are two buttons: 'Start a Wizard' (circled in red) and 'Attach New Document' (with a '(When should I do this?)' link). A dropdown menu is open under 'Start a Wizard', showing three options: 'North Texas Regional IRB - New Protocol Application Form' (highlighted in blue), 'Orlando Health - IRB Application', and 'UMCP - IACUC Animal Study Protocol'. A red arrow points to the first option. A text box on the right contains the instruction: '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”.



The screenshot shows the IRBNet Document Wizard interface. At the top, there is a banner with a collage of images including a person at a computer, a microscope, and a satellite. Below the banner, the title "IRBNet Document Wizard" is displayed. The main content area has a light green background and contains the following text: "North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...". Below this, it says "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 small copyright notice: "Copyright © 2002-2019 Research Dataware. All Rights Reserved."

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

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

Jump To: Principal Investigator Information ▾ Jump

Principal Investigator Information

PI Telephone *
000-000-1234

PI Fax Number

PI Email Address *
frank.researcher@unthsc.edu

PI Department *
Pharmacy

PI Institution *

JPS / Acclaim
 UNTHSC
 Other

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

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.

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:

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: 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.

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

Jump To: Additional Research/Key Personnel [Jump]

Additional Research/Key Personnel *

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

Yes

No

Save and Exit Preview (* required) Previous Next

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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:

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 Information ▾ Jump

Additional Research/Key Personnel Information

- A COI disclosure form is required for each additional research personnel to be added (for Expedited and Full Board protocols)
- REMINDER: Upload/link each applicable current CITI training record with this submission.

✘ Additional Personnel 1

Additional Personnel First Name *

Additional Personnel Last Name *

Additional Personnel Telephone *

Additional Personnel Fax

Additional Personnel Email *

Additional Personnel Role(s)/Responsibilities *

Administers Informed Consent

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.

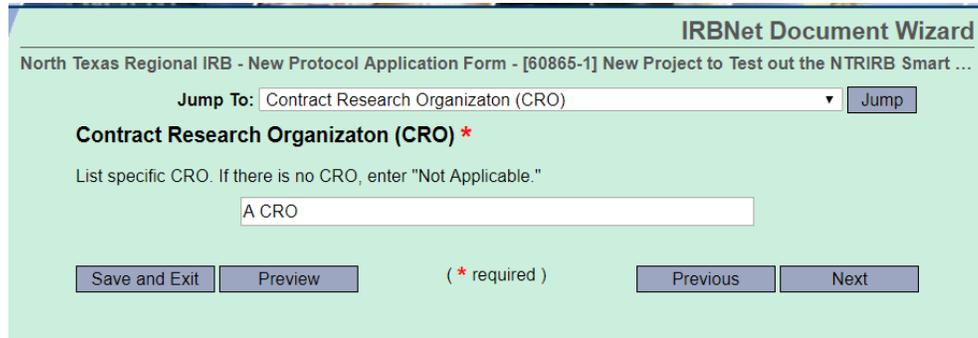
The screenshot shows the 'IRBNet Document Wizard' interface. At the top right, the title 'IRBNet Document Wizard' is displayed. Below it, the page title reads 'North Texas Regional IRB - New Protocol Application Form - [60865-1] New Project to Test out the NTRIRB Smart ...'. A 'Jump To:' dropdown menu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

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



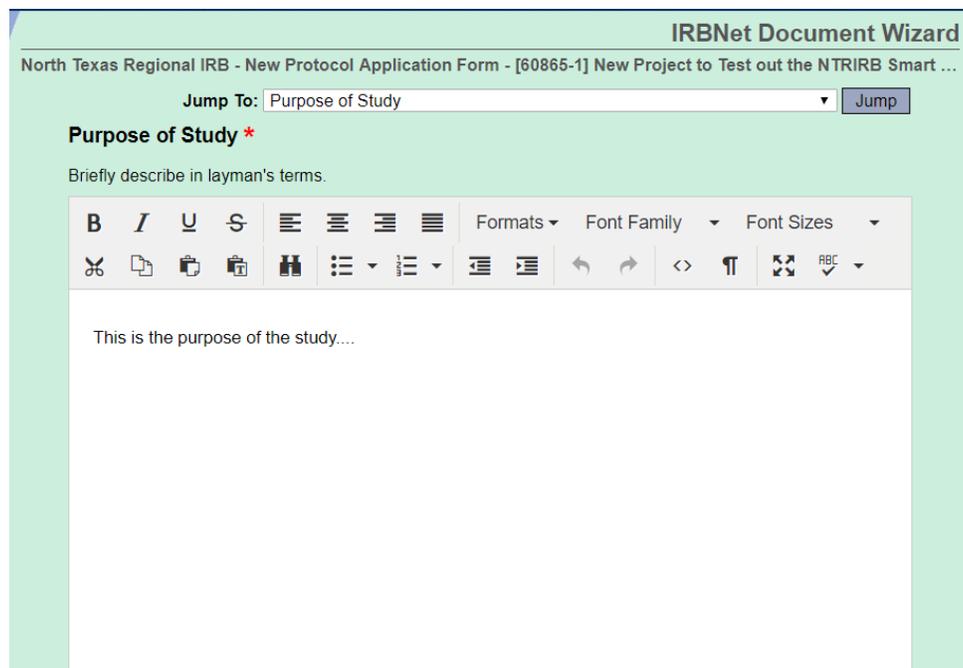
13. In the next section, you will be asked to enter information about the Contract Research Organization (CRO).

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



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 with 'Contract Research Organizaton (CRO)' selected and a 'Jump' button. The main heading is 'Contract Research Organizaton (CRO) *'. Below the heading is the instruction 'List specific CRO. If there is no CRO, enter "Not Applicable."' and a text input field containing 'A CRO'. At the bottom, there are buttons for 'Save and Exit', 'Preview', 'Previous', and 'Next', along with a note '(* required)'.

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.



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 with 'Purpose of Study' selected and a 'Jump' button. The main heading is 'Purpose of Study *'. Below the heading is the instruction 'Briefly describe in layman's terms.' and a rich text editor. The rich text editor has a toolbar with various formatting options like bold, italic, underline, strikethrough, bulleted list, numbered list, link, unlink, undo, redo, source code, and ABC. The text area contains the placeholder text 'This is the purpose of the study...'

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.

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

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.

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

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.

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)'.

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.

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)'.

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.

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)'.

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.

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

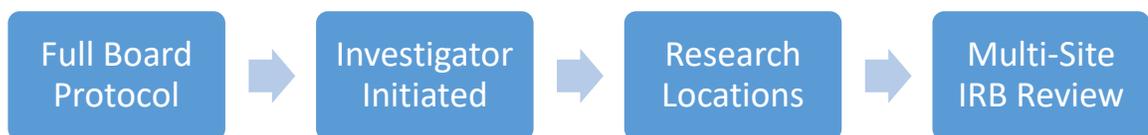
No

Not Applicable

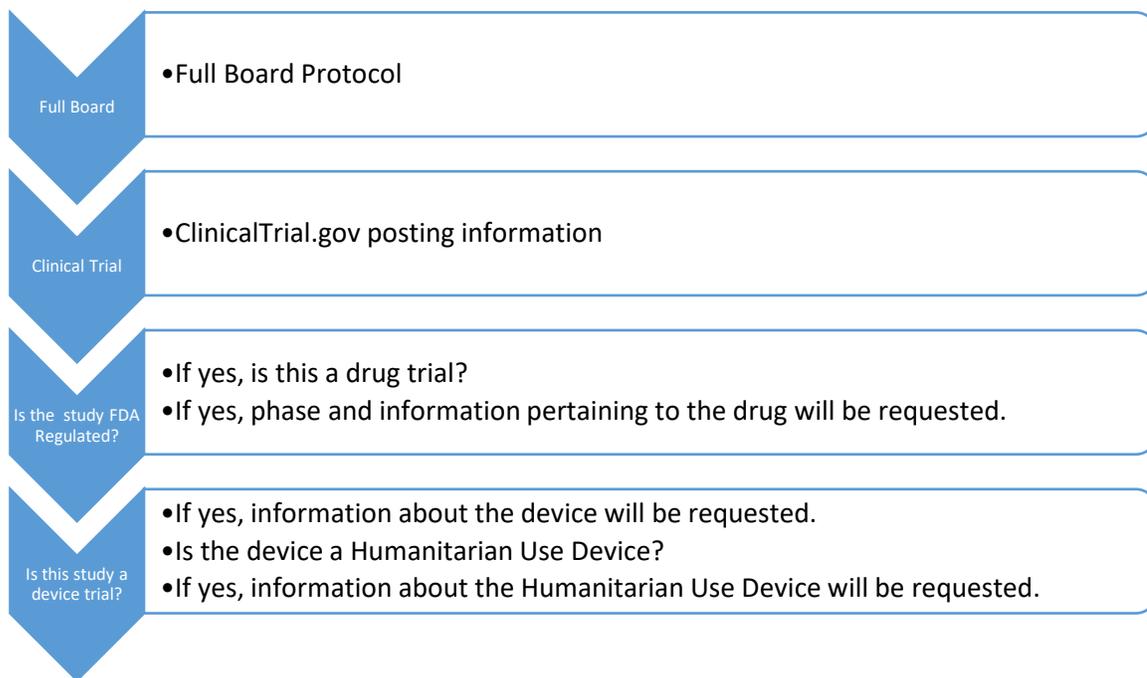
Save and Exit Preview (* required) Previous Next

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.

IRBNet Document Wizard

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

Jump To: Clinical Trial Information

Clinical Trial Information

ClinicalTrial.gov Posting *

Will this trial be posted on ClinicalTrials.gov?

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

Yes
 No
 Pending

ClinicalTrial.gov Identifier

NT000

(* required)

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IRBNet Document Wizard

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

Jump To: Drug/Biologic Trial

Drug/Biologic Trial *

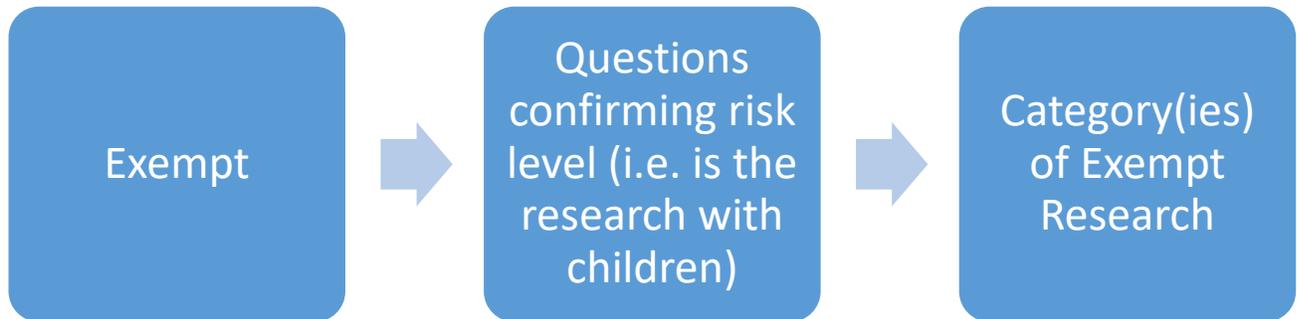
Is this study a drug trial?

Yes
 No

(* required)

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



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

Exempt Review Category example screenshot:

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

Jump To: Exempt Review Information

Exempt Review Information

Excessive Risk *

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

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

Yes
 No

Incarcerated Participants *

Are any of your participants incarcerated?

Yes
 No

Information Identifiers *

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

- Names
- 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
- Certificate/ License Numbers
- Vehicle Identifiers and Serial Numbers Including License Plate Number
- Device Identifiers and Serial Numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) Address Numbers
- Biometric Identifiers, Including Finger and Voice Prints
- Any Other Unique Identifying Number, Characteristic, or Code; Except a Code Used Alone or in Combination With Other Information to Identify an Individual Who is The Subject of The Information
- Address, Street Address, City, Precinct ZIP Code, and Their Equivalent Geocodes. Exception for ZIP Codes: the initial three digits of the ZIP Code may be used, if according to current publicly available data from the Bureau of the Census.
- Full face photographic images and any comparable images

Exempt Review Category example screenshot (Cont.):

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

Yes
 No

Category of Research *

Please select all categories that relate to your research:

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

(* required)

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



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

Expedited Review Category example screenshot:

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

Jump To: Expedited Categories [Jump]

Expedited Categories *

Expedited Categories:

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

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

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

Expedited Review Category example screenshot (cont.):

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

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

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

Select the categories that apply:

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

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

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.

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:

Designer

[60865] New Project to Test out the NTRIRB Smart Form

Package: 60865-1 Work in progress (Not submitted)

Click to add a package description or notes.

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

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

Select a Document: - READ ME FIRST FOR INSTRUCTIONS [Download](#)

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	
North Texas Regional IRB - New Protocol Application Form	North Texas Regional IRB - New Protocol Application Form	03/25/2019 03:59 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?)

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.

IRBNetDocument (2).pdf 1/9

North Texas Regional Institutional Review Board
New Protocol Application Form

[\[Jump to Instructions\]](#)

Project Title: [60865-1] New Project to Test out the NTRIRB Smart Form
 Frank Researcher, MD
 Last edited by: Ivan Toodult
 Last edited on: March 25, 2019

Type of Review:
 Full Committee Review
 Exempt Review
 Expedited Review

I. Principal Investigator Information

Name: Frank Researcher Telephone: 000-000-1234
 Fax Number: Email: frank.researcher@unthsc.edu
 Department: Pharmacy Institution: UNTHSC

II. Study Coordinator/Contact Person Information N/A

Name: Jane Coordinator Telephone: 098-765-4321
 Fax Number: Email: jane.coordinator@unthsc.edu
 Department: Pharmacy

Roles/Responsibilities:
 Administers Informed Consent
 Recruitment
 Performs Data Analyses

28. Note that throughout the application form, you have the option to “Jump” to another section.

The screenshot shows the 'IRBNet Document Wizard' interface. At the top, 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 with 'Form Complete' selected. A red circle highlights the 'Jump' button next to the dropdown. The main content area is titled 'Form Complete' and contains instructions for the Principal Investigator, including a list of required documents such as Curriculum Vitae, Medical licenses, COI Disclosure Form, Consent Form, FDA IND Determination Letter, HIPAA Authorization Form, etc.

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

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

A few reminders:

- (1) **Researchers must still upload and submit a study-related Protocol Synopsis (e.g., Site-Specific Protocol- Information for Sponsored Clinical Trials, 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! ☺