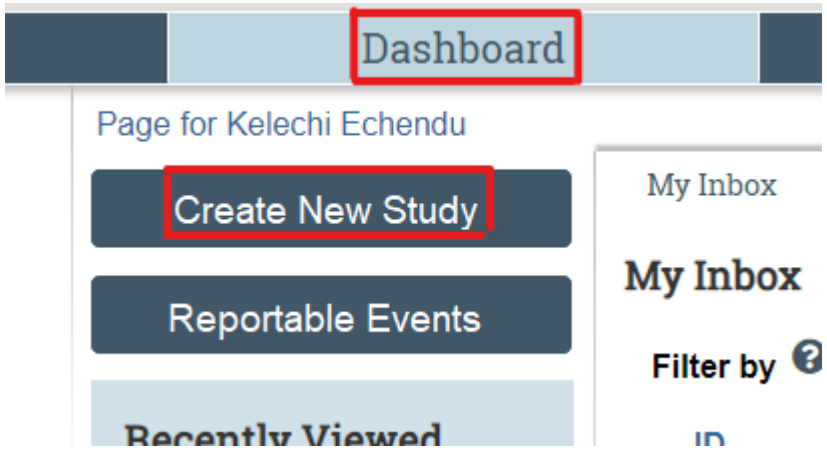
UTSW ETHOS
Electronic Tracking And Human Research Oversight System

UT Southwestern Medical Center

# Create and Submit a Non-Human and Non-Regulated Research Submission

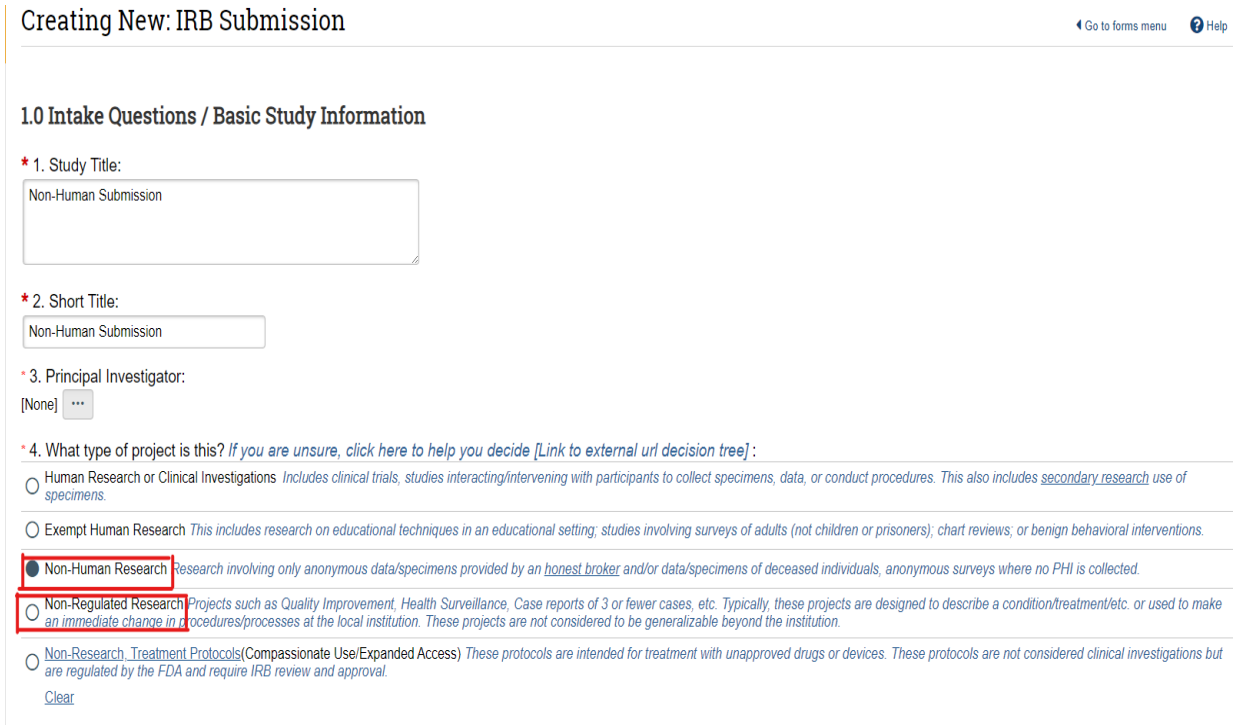
*Human Research Protection Program*

- When you log in with your UTSW credentials, your landing page will be your Dashboard.
- From the Dashboard, click on "**Create New Study**".

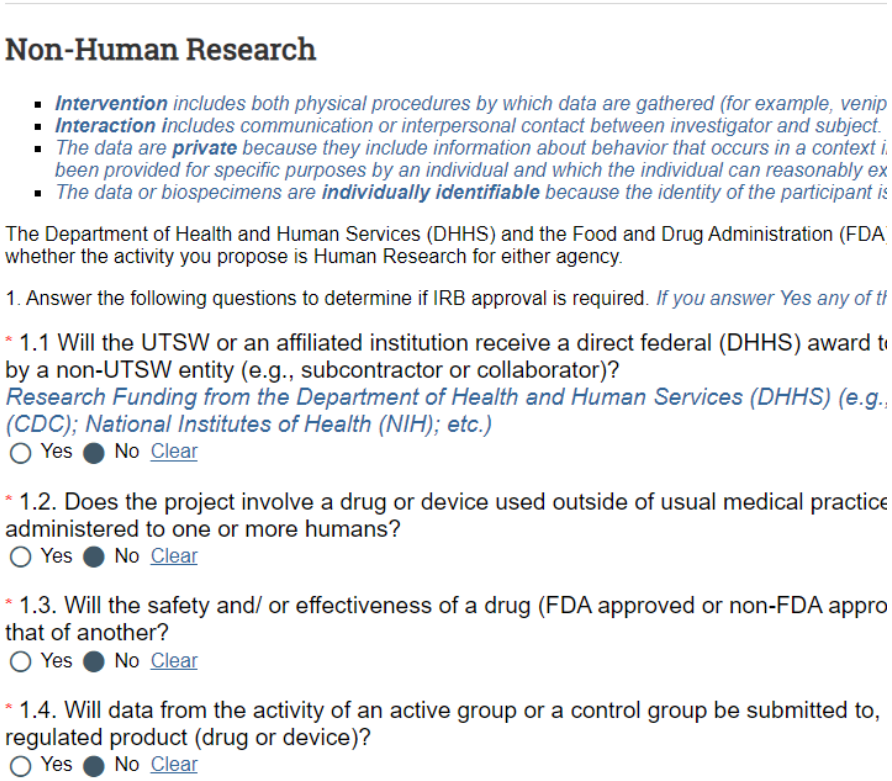


- Complete the Intake Questions / Basic Study Information page.

- In the Study type section (Item 4), select “non-human research” or “non-regulated research” and complete the rest of the intake questions as is applies.



- Non-Human and Non-regulated questions are the same as the contents of former Y1 and Y2 form. The contents are embedded in the new UTSW ETHOS system).



## Non-Human Research

- ***Intervention*** *includes both physical procedures by which data are gathered (for example, venip*
- ***Interaction*** *includes communication or interpersonal contact between investigator and subject.*
- *The data are* ***private*** *because they include information about behavior that occurs in a context i*
  *been provided for specific purposes by an individual and which the individual can reasonably ex*
- *The data or biospecimens are* ***individually identifiable*** *because the identity of the participant is*

The Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA
whether the activity you propose is Human Research for either agency.

1. Answer the following questions to determine if IRB approval is required. *If you answer Yes any of th*

* 1.1 Will the UTSW or an affiliated institution receive a direct federal (DHHS) award t
by a non-UTSW entity (e.g., subcontractor or collaborator)?
*Research Funding from the Department of Health and Human Services (DHHS) (e.g.,*
*(CDC); National Institutes of Health (NIH); etc.)*
○ Yes ● No Clear

* 1.2. Does the project involve a drug or device used outside of usual medical practice
administered to one or more humans?
○ Yes ● No Clear

* 1.3. Will the safety and/ or effectiveness of a drug (FDA approved or non-FDA appro
that of another?
○ Yes ● No Clear

* 1.4. Will data from the activity of an active group or a control group be submitted to,
regulated product (drug or device)?
○ Yes ● No Clear

## Non-Regulated Research

- ***Intervention*** *includes both physical procedures by which data are gathered (for example, venipuncture)*
- ***Interaction*** *includes communication or interpersonal contact between investigator and subject.*
- *The data are* ***private*** *because they include information about behavior that occurs in a context in which a*
  *been provided for specific purposes by an individual and which the individual can reasonably expect will*
- *The data or biospecimens are* ***individually identifiable*** *because the identity of the participant is or may*

The Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) regulati
whether the activity you propose is Human Research for either agency.

1. Answer the following questions to determine if IRB approval is required. *If you answer Yes any of the followi*

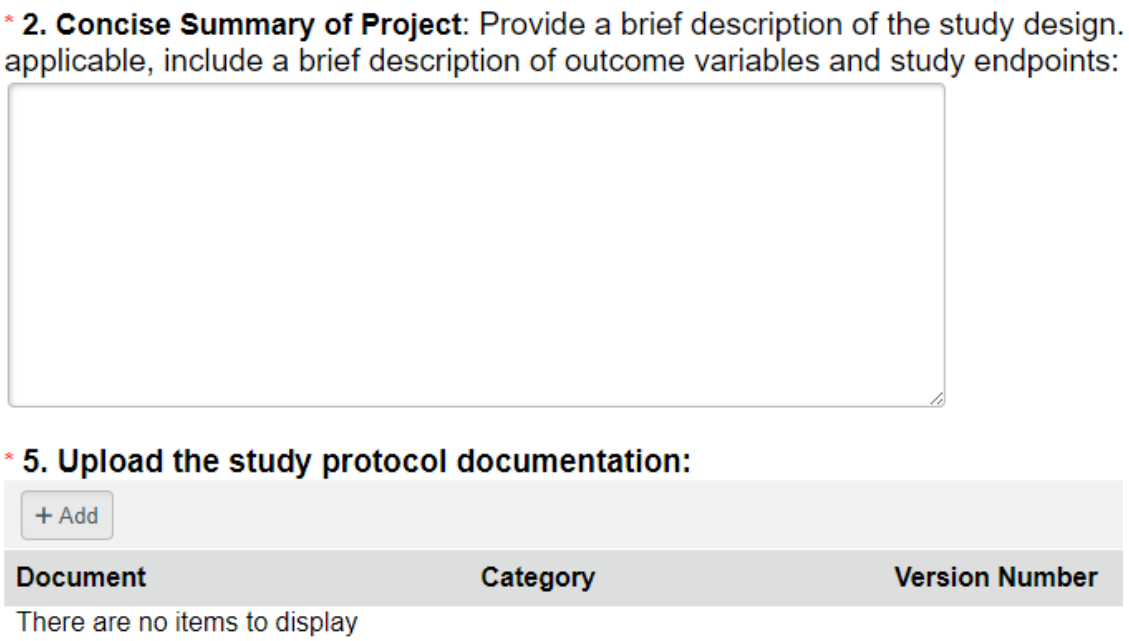
* 1.1. Will the UTSW or an affiliated institution receive a direct federal (DHHS) award to condu
by a non-UTSW entity (e.g., subcontractor or collaborator)?
*Research Funding from the Department of Health and Human Services (DHHS) (e.g., Agenc*
*(CDC); National Institutes of Health (NIH); etc.)*
○ Yes ● No Clear

* 1.2 Does the project involve a drug or device used outside of usual medical practice, includi
administered to one or more humans?
○ Yes ● No Clear

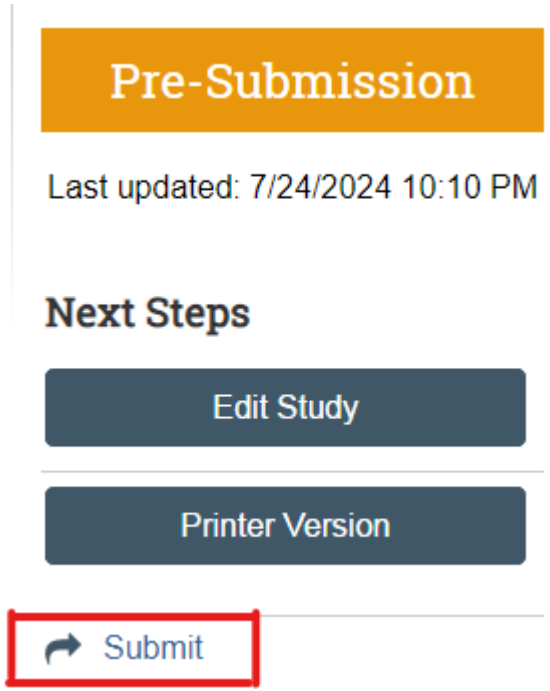
* 1.3 Will the safety and/ or effectiveness of a drug (FDA approved or non-FDA approved) or
compared to that of another?
○ Yes ● No Clear

* 1.4 Will data from the activity of an active group or a control group be submitted to, or held f
FDA-regulated product (drug or device)?
○ Yes ● No Clear

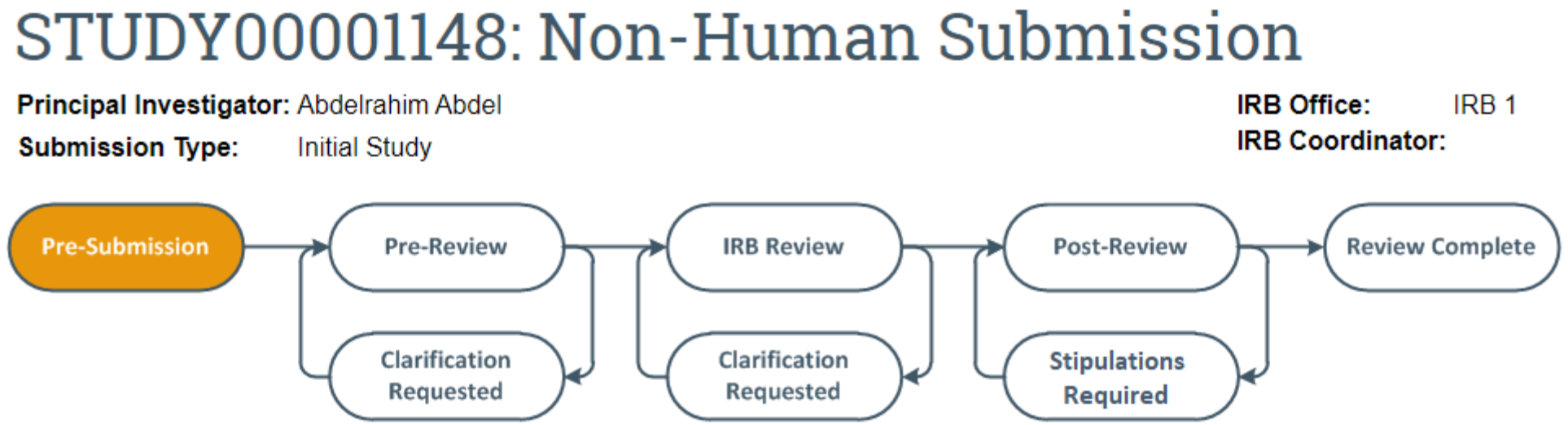
- Continue to the next section, provide a concise summary of your project and upload any relevant or supporting documents.



- After you have completed all the pages, you may submit the submission.
- When the study is submitted, it routes to the HRPP for review.



# Non-Human and Non-Regulated Research – WORKFLOW




***The Non-Human and Non-Regulated Research workspace has the same workflow as initial study workspace.***