



# 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.

Creating New: IRB Submission	Go to forms menu	😯 He
1.0 Intake Questions / Basic Study Information		
* 1. Study Title:		
Non-Human Submission		
* 2. Short Title:		
Non-Human Submission		
* 3. Principal Investigator: [None] •••		
* 4. What type of project is this? If you are unsure, click here to help you decide [Link to external url decision tree] :	7	,
Human Research or Clinical Investigations includes clinical thats, studies interacting/intervening with participants to collect specimens, data, or conduct, specimens.	procedures. This also includes <u>secondary research</u> use o	T
O Exempt Human Research This includes research on educational techniques in an educational setting; studies involving surveys of adults (not children or	r prisoners); chart reviews; or benign behavioral intervent	ons.
• Non-Human Research Research involving only anonymous data/specimens provided by an honest broker and/or data/specimens of deceased individua.	ls, anonymous surveys where no PHI is collected.	
O Non-Regulated Research Projects such as Quality Improvement, Health Surveillance, Case reports of 3 or fewer cases, etc. Typically, these projects are an immediate change in procedures/processes at the local institution. These projects are not considered to be generalizable beyond the institution.	e designed to describe a condition/treatment/etc. or used	o mak
O Non-Research, Treatment Protocols(Compassionate Use/Expanded Access) These protocols are intended for treatment with unapproved drugs or device are regulated by the FDA and require IRB review and approval.	es. These protocols are not considered clinical investigat	ions b
Clear		



 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 the

\* 1.1 Will the UTSW or an affiliated institution receive a direct federal (DHHS) award to 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 <u>Clear</u>

\* 1.2. Does the project involve a drug or device used outside of usual medical practice administered to one or more humans?

○ Yes ● No <u>Clear</u>

\* 1.3. Will the safety and/ or effectiveness of a drug (FDA approved or non-FDA appro that of another?

○ Yes ● No <u>Clear</u>

\* 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 e 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

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 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?

O Yes No Clear

\* 1.3 Will the safety and/ or effectiveness of a drug (FDA approved or non-FDA approved) or i compared to that of another?
 O 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 <u>Clear</u> • Continue to the next section, provide a concise summary of your project and upload any relevant or supporting documents.

\* **2. Concise Summary of Project**: Provide a brief description of the study design. applicable, include a brief description of outcome variables and study endpoints:

#### 5. Upload the study protocol documentation:



There are no items to display



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

Pre-Submission
Last updated: 7/24/2024 10:10 PM
Next Steps
Edit Study
Printer Version
A Submit



## Non-Human and Non-Regulated Research – WORKFLOW

### STUDY00001148: Non-Human Submission



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