Clinical Research FAQs for:

- Study Type Assessment and Regulatory Tracking (START) Form
- Data Project
- CDA/NDA

What studies need to be entered into START?

- The START Form is required for any prospective clinical research, including Observational and Registry studies, that are based at UTRGV, UT Health RGV, or any UTRGV facility (main campus or any outpatient clinic), AND involves any interaction with the human participant after the consent is obtained. UTRGV uses the NIH definitions for clinical research and clinical trials.

What is the definition of clinical research?

- UTRGV uses the NIH definition of Clinical Research. Here is the link to that definition: https://orwh.od.nih.gov/toolkit/nih-policies-inclusion/definitions

Do all clinical research studies need to be entered into START?

- No, if there is no interaction with a human participant after consent is obtained AND no service(s) needed from the Office of Clinical Research for your study, it does not need to be entered into START.

What types of services does START provide?

- Participant Compensation – if your study is using participant stipends or reimbursements, this will be initiated by filling out the START Form.
- Operational Feasibility – The Office of Clinical Research will help you determine what resources are needed for your research and then to ensure those resources are available for you during the conduct of your study. If you have already done this, this step will merely be a formalization of that process.
- Qualifying Clinical Trial Analysis – If you are doing a clinical trial, the Office of Clinical Research will assess your study to see if it requires a Medicare coverage analysis.
- Coverage Analysis/Budget builds – If your study requires one, the Office of Clinical (OCR) Research will do a coverage analysis. OCR will help you determine an accurate budget for the assessments included in your study.
- Study Billing and Invoice Support - The OCR offers tailored support for billing and invoicing within EPIC based on the specific needs of your study. This includes ensuring that all study-related services are accurately billed and appropriately allocated to the correct payer source (e.g., patient, insurance, or grant).
- Study Builds within EPIC – The Office of Clinical Research will assess whether your study requires integration into the EPIC EMR system. A study build in EPIC is required for all prospective human subject research that includes *billable services*. *Billable services* are

defined as any procedures or services provided during the course of the research study that are eligible for billing to patients, insurers, or grants.

- Communication with Research Contracts and Industry Agreements – The Office of Clinical Research will help you determine if you need a contract or agreement for any element of your study, and then facilitate agreement(s), when applicable.
- Registration and Reporting Requirements for Clinicaltrials.gov – The Office of Clinical Research (OCR) will help you determine if your study should be registered on clinicaltrials.gov and if you are responsible for the registration and reporting. If you are, the OCR will help you through the process.
- Assessment of Regulatory Requirements – The Office of Clinical Research (OCR) will help you identify what regulations and policies apply to your study. This can be federal, state, institutional or other. OCR will help you fulfill the applicable requirements.
- Providing a "Green Light" for commencement of research – The Office of Clinical Research will identify and track all necessary approvals for the commencement of your research on an Activation Checklist. When your study's activation checklist is completed, it will be distributed to:
    - The Principal Investigator
    - The person who submitted the study to START (if different than the PI)
    - The IRB
    - Any other applicable committee (IBC, Radiation Safety, etc.)
    - Research Contracts and Industry Agreements, if applicable
    - The departmental approver for each affected department.

  Thus, informing all stakeholders to expect your study to begin participant enrollment.

What if I don't need any of the services within START?

- If you don't need any of these services but your study is prospective clinical research, including Observational and Registry studies, based at UTRGV, UT Health RGV, or any UTRGV facility (main campus or any outpatient clinic), AND involves any interaction with the human participant after the consent is obtained, you will still enter into START. UTRGV is collecting information about all clinical research conducted at the university in order to move toward R1 status.

Is START another approval for my study?

- No. START is a central intake platform that identifies all required approvals for your study. Using the Study Activation Checklist, the OCR will then track the progress of all the approvals and provide the "Green Light" once they've all been met.

How long does it take to fill out the START form for a new submission?

- It depends. If you have a complex clinical trial, it will likely take you 30 to 45 minutes to complete the form and upload all your documents. If you have a simpler study that does not require many resources, it will take closer to 15 minutes to complete.

Who can enter a study into START?

- Anyone on your team who is familiar with or will be involved in the conduct of the study enough that they can answer questions accurately. The Principal Investigator, a Sub-Investigator, a research coordinator or research assistant are examples of who can enter the study into START.

When should I enter my study into START?

- For unfunded, department funded or seed funded studies: enter your study into START after you have any applicable approvals from your department. Refer to your own department SOPs for what approvals are required.
- For grant funded/studies seeking grant funding: enter your study into START after your funding is secured.
- For industry funded or federal non-grant funded studies: enter your study into START after you have all the study documents from the sponsor.

What documents should I upload with my START submission?

- Protocol
- Informed Consent
- Investigator Brochures/Package Inserts
- Device Reports
- Case Report Forms
- Any/***All*** Study Related Manuals or Materials
- Study budget materials
- IRB communications
- Anything else that would contain information about the conduct of your study

What if I already discussed operational feasibility with service providers?

- The Office of Clinical Research recognizes that some researchers may have already reached out to service providers to see if elements of their studies are feasible. If that is the case, this process will merely be a formalization of the discussions already had.

What do you mean by "service providers"?

- We mean any department, other than your own, that will conduct or aid in the conduct of your research. For example, if your study involves the UTRGV Laboratory drawing, processing, storing or shipping labs, the UTRGV Laboratory would be considered a "service provider". Other service providers can include, but are not limited to, radiology (scans, x-rays, etc.), pathology, infusion, and pharmacy.

How long are service providers allowed for review?

- We are giving service providers two weeks to begin the review process.

What if I already uploaded some of these documents into ARGO?

- Communicate this with the Office of Clinical Research. There may be a way for us to find the documents internally.

After I submit my new study into START, how long will it be before I hear anything?

- You will receive an automated email immediately after your submission. Depending on the needs of your study, you will receive additional communication from the Office of Clinical Research within 10 business days of your submission.

What is NHSR (Non-Human Subjects Research) determination?

- Non-regulated research refers to studies not covered by the HHS Regulations. Activities are non-regulated research if they do not involve a systematic approach involving a predetermined method for studying a specific topic, answering a specific question, testing a hypothesis, or developing theory.
- Researchers may request a determination that an activity is "Non-regulated research," but the final determination will be made by the Office of Research Compliance
- Examples of Non-Regulated Research:
    - Quality Improvement
    - Health Surveillance
    - Program Evaluation
    - Instructions for Submission:
- Complete the **Request for Determination Non-Regulated Research Form**
- Submit the completed form by email to irb@utrgv.edu
- The Office of Research Compliance will review your request and will issue a determination letter within 3-7 business days or upon completion of required items.

What documents should I upload with my Data Project/QA/QI submission?

- If you submitted your project to the IRB for NHSR determination, and it was determined not to be research, please upload the determination letter along with a copy of the form you submitted to the IRB.
- If your project was determined to be research, please upload the IRB approval letter.

When will I hear anything about my Data Project/QA/QI submission?

- You should receive an autogenerated email from the system as soon as you complete your submission.
- You may or may not receive additional communications and follow up questions from the Office of Clinical Research.
- You will receive an autogenerated email as soon as a member of the Office of Clinical Research approves your data request.

How long will it take to get my data?

- It depends on the complexity of your request.
    - Once the Office of Clinical research approves your request, it is submitted on your behalf to IT.
    - IT is instructed to contact you/the person requesting the data directly for any additional information/follow up questions they may have.
    - Your IT ticket number is recorded by the Office of Clinical Research within your submission.
    - Should you need an update on the status of your data after the Office of Clinical Research has submitted it to IT, contact IT directly.

What is a CDA/NDA?

- A Confidential Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA) is a legal contract that protects the exchange of confidential information between two or more parties. It's often used in research and development, and in industry-sponsored clinical studies.

Which studies need a CDA/NDA?

- You will need a CDA/NDA if your project is funded/sponsored by an outside organization that requires one.
- You may also need one if your project is using information or technology provided from an outside organization.

What if I believe my project needs a CDA/NDA but I do not have one?

- Reach out to either the Office of Clinical Research at clinicalresearch@utrgv.edu or Research Contracts and Industry Agreements at rcia@utrgv.edu.

What happens after I submit my CDA/NDA?

- The PI and the Research Contracts and Industry agreements will receive autogenerated emails indicating the submission was complete.
- Research Contracts and Industry agreements will communicate directly with the submitter/PI for the completion of the agreement.