Tips for Study Registration in UPittsburgh ClinicalTrials.gov PRS

If you determined that your study is an Applicable Clinical Trial (ACT), but do not see the “FDAAA: ACT” label on the study Record Summary page after following the tips below, contact ctgov@pitt.edu for assistance.

General Tips

- As you enter information, system validation (error, warning and note) messages may appear and disappear. Start by entering information for all required data elements. Note that some data elements are required, while others are conditionally required. Finish by addressing all remaining validation messages.

- Use the “Definitions” links to find exactly what information is being requested and guidance on how to answer. Assumptions are often not reality in the world of ClinicalTrials.gov.

- The Record Owner is roughly equivalent to the OSIRIS Coordinator role. PRS automated e-mails are sent to the Record Owner and Responsible Party. The user who creates the record is the Record Owner by default and can grant other users access by editing the Access List on the Record Summary page. To change the Record Owner, send your request to ctgov@pitt.edu.

- Be sure to also consult the Protocol Review Criteria. There is a “Help” dropdown list at the top of your PRS homepage and a “Help” link at the top of each page within the study record. You may also consult https://clinicaltrials.gov/ ➔ Submit Studies ➔
  - How to Register Your Study
  - FAQs
  - Support Materials
  - Training Materials

Create New Record/Study Identification

- Unique Protocol ID: recommend IRB PRO# or department assigned ID

- Study Type:
  - Interventional versus Observational: Would the target study population not routinely encounter the study intervention(s)/exposure(s), in the manner specified by the study, outside the context of the study? If yes, the study is likely interventional.

  - Expanded Access:
    - 42 CFR 11.28(c): If expanded access is available for an investigational drug product (including a biological product) studied in an applicable drug
clinical trial, and an expanded access record for that investigational product has not been submitted, the responsible party, if both the manufacturer of the investigational product and the sponsor of the applicable clinical trial, must submit an expanded access record for that investigational product.

- An expanded access record may otherwise be created for expanded access to an investigational product. For example, creation of a new expanded access record may be required in some cases to satisfy Medicare requirements. Please contact Sharon Ralph at UPMC OSPARS for further guidance on that matter.
- In all cases, the same rules for determining the Sponsor Organization PRS account and Responsible Party of the record apply to all three Study Types (i.e., Interventional, Observational, Expanded Access). In addition, an individual Sponsor should register expanded access for any one investigational product no more than once.

- Secondary IDs: If the study receives funding from a U.S. Federal Government agency (including the NIH), the grant or contract number must be included. This is essential for monitoring compliance with the NIH Policy.

**Important Note:** This guidance document does not cover all modules and data elements required for a study record. Generally, it is recommended that you complete the modules addressed in this document in the order in which they appear below. The modules not addressed here may be completed in any order. It is recommended that the Study Status module be completed last.

**Study Design**
- Enrollment (anticipated): This is the number of participants that you expect to participate following informed consent and confirmation of eligibility.
  - More restrictive than the Pitt IRB’s definition of enrollment
  - Generally, should match the “number of subjects to undergo research related procedures” in OSIRIS 3.11

**Arms & Interventions** (“Groups & Exposures” for Observational studies)
Create an intervention entry for each intervention being evaluated in the study. Some examples:
- If the study of a procedure/surgery intervention includes the evaluation of a drug (e.g. nerve block) or device (e.g. surgical instrument), be sure to add the drug or device intervention.
- If the study of a radiation intervention includes the evaluation of a device (e.g. X-ray device), be sure to add the device intervention.
Outcome Measures

• If your study meets the requirements for submission of results information, results will need to be reported for all pre-specified primary and secondary outcome measures. Select other pre-specified outcome measure for outcomes of third-level or lesser importance (e.g. outcome measure that is exploratory in nature).

• All outcome measure components must be specific and precise:
  ➢ The title is what is being measured (e.g., Pain Level).
  ➢ The description is how it is being measured (e.g., XYZ Pain Scale, a participant reported rating of pain level ranging from 0 = no pain to 10 = severe pain).
  ➢ The time frame is the timepoints at which, or the time span over which, the outcome is being assessed (e.g., At 6 months from study start).
  ➢ Explanation of why it was measured or what you expected to find (hypothesis/prediction statements) is not allowed and will result in QC review comments requiring corrections.

Contacts/Locations: List all site locations that will recruit participants.

Oversight

• U.S. FDA-regulated Drug (including biologics) / U.S. FDA-regulated Device:
  ➢ Important Note: This is not asking if the study is conducted under an IND application or IDE (separate data element).

      ➢ Select “Yes” for the appropriate data element(s) if any of the interventions being evaluated as part of the study design: (a) are FDA approved, licensed or cleared, or (b) would require FDA approval, licensing or clearance as a drug, biologic or device product to be legally marketed in the United States.

      ➢ A product may be used in a clinical trial even though it is not the intervention studied or experimental variable of interest. Consider whether (a) the study is designed to examine the effect, performance or differences in the intended use of an FDA-regulated drug or device product, and/or (b) at least one pre-specified primary or secondary outcome measure reflects a characteristic, an effect, or the performance of an FDA-regulated drug or device product.

      ➢ A study with an intervention of type other than drug, biologic or device may still be an Applicable Clinical Trial evaluating an FDA-regulated drug or device product. Some examples include:
        ▪ Dietary supplement being studied for the treatment of cancer
        ▪ Genetic trial studying a gene therapy or genetic test
        ▪ Radiation trial studying an X-ray device
        ▪ Procedure/surgery trial studying a surgical instrument
➢ To help you determine whether you are studying an FDA-regulated device, refer to the FDA website. Particular sections of interest may include:
  ▪ Premarket Requirements (How to Market Your Device)
  ▪ In Vitro Diagnostics
  ▪ Digital Health

➢ For further guidance, refer to the Applicable Clinical Trial (ACT) Checklist.

- Post Prior to Approval/Clearance:
  ➢ Displays when U.S. FDA-regulated Device = Yes and Unapproved/Uncleared Device = Yes.
  ➢ You must select “Yes” if you intend to comply with the International Committee of Medical Journal Editors (ICMJE) clinical trial registration policy. However, consider any potential implications of posting full registration information in the public domain prior to approval/clearance of the studied device product.

- Product Exported from U.S.:
  ➢ Displays when U.S. FDA-regulated Drug (or Device) = Yes and U.S. FDA IND/IDE = No.
  ➢ If your study has at least one recruiting site in the United States (as specified in the Contacts/Locations module), leave this data element unspecified.

- Availability of Expanded Access:
  ➢ Displays when U.S. FDA IND/IDE = Yes.
  ➢ Select “Unknown” unless the Responsible Party of the study is both the Sponsor-Investigator of the study and the manufacturer of the unapproved drug or device product (also see above: Study Type → Expanded Access).

Sponsor/Collaborators
- Responsible Party:
  ➢ FDA-regulated study: select Sponsor-Investigator
    ▪ Note: If Sponsor and Investigator are different individuals, contact ctgov@pitt.edu for guidance
  ➢ Not FDA-regulated study: select Principal Investigator

- Collaborators: Include the name of the agency (including the NIH) matching the grant or contract number entered as a Secondary ID in the Study Identification module, if applicable. This is essential for monitoring compliance with the NIH Policy.

Study Status
- Study Start Date: provide month/year only (leave day unspecified) while “anticipated” so that less frequent updating is required