CLINICALTRIALS.GOV PROTOCOL
REGISTRATION SYSTEM AND RESULTS
ENTRY ISSUES

School of Medicine Research Support Services
OVERVIEW

- This presentation goes screen-by-screen during the registration process. It is designed to simply show the way clinical trials must be entered into the clinicaltrials.gov system to facilitate ease and understanding. There are other sources of information as well:


- ClinicalTrials.gov PRS Test system [https://prstest.nlm.nih.gov/](https://prstest.nlm.nih.gov/) you can practice with this link
  - When using the above test system:
    - The Organization is UCaliforniaIrvin
    - Test site Username: the same one for your department/account in the real system
    - Test site password: change
IMPORTANT THINGS TO REMEMBER

- The status that is listed at the top of the Edit Protocol screen refers to the protocol entry status, not the study itself. When you have entered all the info into the PRS that is needed, remember to change the record status to “completed.”

- When entering the different “arms” of a study, remember to enter the intervention methods for each “arm.” If one arm doesn’t get an intervention, that is the info that would be entered under the “intervention” label (i.e. “control group,” “none” or “N/A”).

- The more areas that have information entered in them, the better. Records that are more complete, even if some of the data entered seems redundant, are better for the safety of the potential/current participants and oversight. Also, the more information left out, the less likely it is that the record will be published and compliance standards met.

- Remember to check the Quality Assurance Review comments at the top of the Edit Record screen and take care of the issues cited by the QA team, as well as address error messages before setting its entry status to “complete.”

- Clinical trials must be posted within 21 days of the enrollment of the first patient…better to get it listed early.
RATIONALE FOR COMPLIANCE

- Federal Public Law 110-85, section 801:
  
  + If the clinical trial protocol or the results are not posted in the legally sanctioned time, there is a 30-day correction period.

  + After the 30-day correction period, there may be a fine up to $10,000 per day per infraction assessed to the “responsible party” – the Principal Investigator.
SIGN IN AT REGISTER.CLINICALTRIALS.GOV

- **Organization:** UCalifornialrvine
- **Username:** Dept Specific
- **Password:** Dept Specific
MAIN MENU: CREATE NEW PROTOCOL

One or more of this organization's records requires administrator attention.

Our records show that your current email address is "ngibson@uci.edu". If this is not correct, please update your account.

U.S. Public Law 110-85
About Results Data Entry

- Standard Functions
- Protocol Records
  - Create
  - Modify
  - QA Review Comments
  - View
  - Check my records
  - Undelete
- User Account
  - Change password
  - PRS Administrator(s)
- Help
  - Quick Start Guide
  - Frequently Asked Questions
  - What's New: Apr 9, 2009
  - User's Guide
  - Data Element Definitions
  - Results Data Element Definitions
  - FDAMA 113 Requirements
- Session
- Logout

- Administrative Functions
- Protocol Records
  - Check all records
  - Validate all records
  - Release all records
  - Check release status
  - Change owner
  - Publication Report
- User Accounts
  - Create
  - Modify
  - Enable/disable
- Organization Account
  - View
  - Groups
  - Email Addresses
  - Product Information
- Help
  - Admin Quick Reference
- XML Upload
  - Upload protocol records
  - Check upload status
  - Document Type Definition
  - Results XML Schema
PROTOCOL ID# & BRIEF TITLE

The ID# could be the internal dept ID# or the IRB Protocol ID#...the IRB ID# is desirable for inter-departmental Standard Operating Procedures.
Include as much info as possible. If the study is not FDA regulated, there are certain other pieces of info that must be included later on. Official title shouldn’t be a cut/paste of the brief title…makes the system unhappy.
Be sure to keep the approval status updated, especially if you’re registering the trial before the approval process has been completed.
Collaborators are organizations, not individuals.
BRIEF SUMMARY & DETAILED DESCRIPTION

Keep the “Brief Summary” just that; brief. It should be fairly easy for medically untrained people to understand.

The detailed description is where you can go into further detail about what the study entails.
Remember to update the "recruitment status" and the completion dates as they change or expire.
Name and explain what the study is intending to measure in regards to the intervention or observation.

<table>
<thead>
<tr>
<th>Primary Outcome Measure</th>
<th>Outcome Measure: Investigators feel confident in using PRS</th>
<th>Time Frame: One (1) day</th>
<th>Safety Issue?: No</th>
</tr>
</thead>
</table>

Key Secondary Outcome Measures

<table>
<thead>
<tr>
<th>Outcome Measure: Investigators trust OCRT through use of PRS demo, and make use of OCRT services.</th>
<th>Time Frame: Investigative career</th>
<th>Safety Issue?: No</th>
</tr>
</thead>
</table>

* Required by ClinicalTrials.gov
  - Required to comply with US Public Law 110-85, Section 801
  - May be required to comply with US Public Law 110-85, Section 801
  [Secondary outcomes must be specified, if any are to be measured.]
**ARMS & INTERVENTIONS**

Here is where control and intervention groups can be specified, as well as what the intervention(s) will be.
The conditions that the study is assessing (whether recognized or not), and search terms to help potential volunteers and other researchers find the study.
Eligibility Criteria:

Inclusion Criteria:
- Is an investigator or someone who needs to know how to enter study information into the clinicaltrials.gov PRS

Exclusion Criteria:
- Someone who doesn't need to know how to enter study info in the clinicaltrials.gov PRS, or doesn't need assistance.

Gender: Both

Age Limits:
- Minimum: 18 Years
- Maximum: N/A (No limit)

Accepts Healthy Volunteers?: Yes

* Required by ClinicalTrials.gov
* Required to comply with US Public Law 110-85, Section 801
* May be required to comply with US Public Law 110-85, Section 801
The “Locations” tab has a lot of information that is entered throughout different screens...be sure to go all the way through, and complete as much as possible.
Add citations to already-published studies and/or research, and links in the following section to doctor’s/investigator’s websites and places to find further information about topics included in the study.
Once all the fields are filled in, click the “next action” which will be “complete” meaning that the entry of data into the PRS has been completed. The administrator will take it from there, and either approve and release the record or let you know if items need attention. Also, enter the “Record Verification Date” to keep things current.
When you are editing a record, remember to check for reviewer comments in the top box underneath the dates and owner section. If there are comments, you can choose “Latest Comments” to go straight to the most recent set of editorial comments or “History” to see the last 24 months of comments posted.
If you choose the “History” link in Comments, you will come to this screen which gives you all the dates that comments were recorded from the reviewers at ClinicalTrials.gov. If there is more than one date that hasn’t been addressed, remember to go through all the recent comments and make sure all the requirements are being met.
Note the General Comments first, and if there are any dates listed as unaddressed comments, be sure to revisit those dates on the previous screen.

You can click on the “Show Only..” link and get rid of sections without comments. Be sure to note all the comments, and address them before Completing the record. The “Expand All” link is also helpful by allowing you to see all the sections with the comments underneath.
Once the study has been completed and record updated, the “Results” section can be created, and data can be entered. Preliminary results must be entered within 1 year from the primary date of completion.
These first two sections are pretty straightforward: person to contact about the results, and what agreements may or may not be in place between sponsors and investigators.
Pre-study information (i.e. did the subjects need clearance through a physical, diagnosis, etc.)

In the “Arm/Group” area, the arms should have a somewhat descriptive label; avoid “arm A” or “Arm 1”, in favor of labels such as the labels below.
These measures are really setting the context for interpreting the study data.
This is where the initial findings of the outcome measures are entered. Notice the “Posted” box at the top... at least one outcome measure must be posted in order to release the record with results. That means at least one outcome measure will be published/available publicly.
The arm/group names import from the study information, and the general outcome measure info are the beginnings of the actual results entry.
The more descriptive and specific the limitations and caveats are, the more complete the record will be. This section is important to help determine the context in which the study data is to be interpreted and evaluated.
**RESULTS**

This top set of info boxes should be filled in if you have the information available. The more terms and info is entered, as with initial protocol entry, the better.

These two lower boxes are a little more complicated. The best way to cover all the bases is to enter the total #’s in the first “edit” row, then enter the names of all the adverse events in the second “edit” row.

<table>
<thead>
<tr>
<th>Source Vocabulary for Table Default</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment Type for Table Default</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Add Serious Adverse Event</th>
<th>5 Affected out of 180 At Risk (2.78%)</th>
<th>14 Affected out of 175 At Risk (8%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add Other Adverse Event</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
This is the adverse event screen, where you would enter the names and organ systems related to all of the adverse events.

Systematic/non-systematic assessment refers to how the adverse events were diagnosed/reported to the PI/study team. Systematic would be checkups planned in the Protocol. Non-systematic could be an ED visit, something reported during a checkup that happened another time, etc.
RESULTS

This screen shows what the data looks like for Adverse Events after data entry. The next screenshot is an example of the data entry itself. “Edit” takes you to the next screen...

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Smaller Stapler</th>
<th>Larger Stapler</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute renal failure</td>
<td>1 Event</td>
<td>0 Event</td>
</tr>
<tr>
<td>Anastomotic leakage</td>
<td>5 Events</td>
<td>14 Events</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>5 Events</td>
<td>0 Event</td>
</tr>
<tr>
<td>GI obstruction</td>
<td>5 Events</td>
<td>14 Events</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>0 Event</td>
<td>14 Events</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>0 Event</td>
<td>14 Events</td>
</tr>
<tr>
<td>GI hemorrhage</td>
<td>0 Event</td>
<td>14 Events</td>
</tr>
</tbody>
</table>
After clicking Edit on the previous screen, you are brought here to enter the data from the Adverse Event reports. Once this is done, click “OK” and on the next screen, click Adverse Event Overview and you have completed the AE/SAE entry.
Any strange issues? Questions? Contact the UCI School of Medicine ClinicalTrials.gov administrator: somrss@uci.edu or 714.456.8708