Creating a clinicaltrials.gov Record

When you are entering your study into clinicaltrials.gov (CT.gov) please be aware of a few things.

1. Confirm that the study needs to be registered. COMIRB determines FDAAA applicability, but if the PI intends to publish the findings [regardless of applicability], many journals require posting on a website like CT.gov before the first patient is enrolled. If there is NO intent to publish, applicable clinical trials must be posted with 21 days of the first patient being enrolled. Also, if you are using the CTRC for your study, it will need to be posted on CT.gov due to a change in CCTSI/UCD policy effective 01 January 2014. For trials that COMIRB does not determine to be FDAAA applicable, only the fields marked with a red asterisk are required; FDAAA applicable studies need to provide more information.

2. You can save your work in progress and go back to it. Click ‘Continue’ on the bottom left of the screen and the data entered will be saved. If you do not enter everything required (as indicated by red asterisk or green lettering with or without parentheses), you can still click ‘Continue’ and the data will be saved. You can then go back into a section and add or change information by clicking ‘Edit’ to the far left of the relevant section. Once you have saved you data and left the entry screens the first time, you will be doing all of your editing from the main ‘Edit Protocols/Results Record’ screen for that particular study, so you will not be automatically directed to the next required section. The system works like most databases, when you move between web pages your content is automatically saved (you do not need to click ‘complete’ to save periodically).

3. If you click on the words/titles in the left lavender column, a glossary will open in another window that includes some definitions and examples. For a more complete list, review the data elements found here: http://prsinfo.clinicaltrials.gov/definitions.html

4. About the symbols CT.gov uses:
   - Red asterisks * indicate that the compulsory field is required for registering a protocol on CT.gov.
   - Green superscript FDAAA or (FDAAA) indicate it a field is or may be required for applicable clinical trials. COMIRB determines applicability.
   - Any red ‘ERROR’ stop signs need to be corrected those before you click ‘Complete’ in the top left. To correct them, ‘Edit’ the section and follow the instructions/review the examples to fix the problem (it may involve going into other sections).
   - Yellow ‘ALERT’s need to be addressed; they appear when there is a compulsory field [red asterisk] left blank.
   - Yellow ‘WARNING’s need to be addressed; they appear when there is an applicable compulsory field [green writing] left blank.
   - Blue ‘NOTE’s are to help you improve your protocol entry but are not required by CT.gov.

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Here are some things we look/expect for certain sections (sections are based on the ‘Edit’ buttons to the far left of the study screen):

### Section 1: Study Identification (starts with Unique Protocol ID)

- The Unique Protocol ID is your **COMIRB study number**
- The brief title can be the official title or it can be simpler and shorter for the general public
- The official title must be entered
- If this trial is sponsored by an NIH grant enter the grant number here following the formatting examples. Also enter the granting institute in section 3 under ‘collaborators’ (Note, the ClinicalTrials.gov system communicates directly with NIH RePORTER)
- Other IDs may be entered here as well
- If you receive NIH funding for a study that uses the CTRC, there will be at least one secondary ID: The CTSA grant **UL1 TR001082**

### Section 2: Study Status

- ‘Record Verification Date’ **MUST** be updated whenever you verify or update the record, even if no changes are made. This date is displayed in the public record and lets the public and any funders know that the study information, status and contact information especially, are current.
- Keep recruitment status current within 30 days of changes.
- The Primary Completion Date is when the last subject reaches a primary outcome. Results **must** be posted within 12 months of this date if the study is applicable.
- The Study Completion Date is when the last patients has met all the secondary outcomes.

### Section 3: Sponsor/Collaborators

- **Sponsor = University of Colorado Denver**
- **Responsible Party = Sponsor.** Do not change this to PI or Sponsor-Investigator. This allows the CT.gov administrators at the University to review the record before being send to CT.gov national for review.
- Collaborators are optional

### Section 4: Oversight

- To answer the ‘FDA Regulated’ question refer to your initial COMIRB approval letter.
- If your initial COMIRB approval letter indicated that “this study meets FDAAA applicability criteria” then you must select ‘yes’ for ‘FDA Regulated’ and ‘yes’ for the subsequent question ‘Section 801 Clinical Trial?’ even if the COMIRB letter states it is not FDA regulated.
  - If you are registering your study for publication purposes, i.e. it is not FDAAA
If your initial COMIRB approval letter indicated that “this study meets the requirements for posting on clinicaltrials.gov under the FDA Modernization Act of 1997 (FDAMA)”, then you must select ‘yes’ for ‘FDA Regulated’ and ‘no’ for the subsequent question ‘Section 801 Clinical Trial?’.

‘Section 801 Clinical Trial?’ determination is made by COMIRB in the initial minor mods or approval letter.

- Approval Number = COMIRB # again, not approval date
- Board Name = Colorado Multiple Institutional Review Board
- Board Affiliation = University of Colorado Denver
- COMIRB contact info = 303.724.1055, comirb@ucdenver.edu, Campus mail Box F490, 13001 E. 17th Place, Room N3214, Aurora, CO 80045
- Data Monitoring Committee? = this will be in the protocol or application
- Copy and paste the ‘Oversight Authorities’ from the list in CT.gov

**Section 5: Study Description**

- Brief Summary = you could use the information from the consent section ‘Why is this study being done?’ because it is for the general public audience.
- Do not use ‘you’ and ‘we’; use ‘patients’ and ‘investigators’ instead.
- The detailed description is optional but you will get a note if you do not enter it.

**Section 6: Conditions**

- Use the link to ‘Search MeSH’ to find conditions
- Keywords allow the public to search for studies related to a condition or treatment so be clear.

**Section 7: Study Design**

- This should be found in your protocol
- ‘Study Phase’ is always compulsory; we recommend reading their instructions as ‘Use “N/A” for trials that do not involve *investigational* drug or biologic products.’
- There are different fields depending on whether or not you selected ‘Interventional’, ‘Observational’, or ‘Expanded Access’ for ‘Study Type’ in Section 1.
- Clinicaltrials.gov public site has more information on ‘Observational’ and ‘Expanded Access’ studies under ‘How to Register Your Study’ under ‘Submit Studies’.
Section 8: Arms/Groups and Interventions

- Review the ‘Help’ and ‘Definitions’ links
- The ‘Arm’ and ‘Intervention’ labels should be identical for at least one of each [example: arms = ‘liver transplant’ and ‘no liver transplant’; intervention = ‘liver transplant’]
- If one arm does not get an intervention per protocol, you will need to create an intervention: for ‘Intervention Type’ select ‘Other’ and name the intervention ‘None’ or ‘N/A’ or ‘SOC’ or ‘Control Group’
- If there are multiple arms and/or multiple interventions, you will need to complete the ‘Cross-Reference’ portion.
- This section frequently has errors initially, play around with different wording and combinations to try to resolve them, and try not to get frustrated.

Section 9: Outcome Measures

- Limit the Outcome Measure title to WHAT was measured, not why it was measured. There should be no verbs or prepositional phrases in the outcome title; use the Description free text for that elaboration.
- The title and time frame must be concise and exact; for example if your primary outcome is to measure glucose, triglycerides, and testosterone in blood after 12 weeks of treatment, you may need to break that down into a single outcome for each of the three, resulting in more than one outcome.
- Be prepared to pick just one primary outcome if the QA reviewers request it.
- The Time Frame refers to how long it would take a single patient to reach that outcome (this may correspond to the length of participation in the study from the consent form) and not how long it will take to reach that outcome for the anticipated enrollment.

Section 11: Eligibility

- These can be copied from the protocol or application but they need to be in a bulleted list, not numbered or in paragraph form.
- If you are doing an Observational study, there will be other fields to complete including ‘Study Population’ and ‘Sampling Method’

Sections 12 and 13: Contacts/Locations and References

- The Central Contact should be the person handling recruitment and daily activities, if that person is the PI that’s fine but it will more likely be a coordinator.
- Only enter the PI in the ‘Study Officials/Investigators’ section
- Add to the References as there are publications.

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When you believe everything is entered, please click the ‘Spelling’ link near the top and check for spelling errors and unexplained acronyms. The system will tell you there are unexpanded acronyms unless you put the acronym in parentheses after the spelled out term. This is the case for medication names as well as seemingly well-known acronyms like CBC and BP.

Once you check the spelling and click ‘Complete’ the Clinical Research Support Center is automatically notified by CT.gov and will review it prior to approving and releasing it. When it is released, it is reviewed by the QA team for CT.gov and they can respond with comments or post it. You will get an NCT number when it is posted for the first time. Every six months, until the overall study status is ‘Complete’, you will get a reminder email from CT.gov to update your posting. Even if there are no changes to make, UPDATE the ‘Record Verification Date’ at least annually. You must update the ‘Overall Status’, ‘Recruitment Status’, and contact information within 30 days of any changes though. This cannot be postponed until you get a reminder email from CT.gov.