ClinicalTrials.gov Registration User’s Guide

January 2018
ClinicalTrials.gov Assistance and Training at WCM

• Contact the WCM ClinicalTrials.gov Administrator at registerclinicaltrials@med.cornell.edu to:
  
  – Schedule a one-on-one to review these slides and ClinicalTrials.gov responsibilities
  
  – Obtain a ClinicalTrials.gov account for yourself or a designee

• Visit the WCM ClinicalTrials.gov site at http://researchintegrity.weill.cornell.edu/clinicaltrialsdotgov.html
Caveats

This user guide is a collaborative effort on the part of ClinicalTrials.gov administrators at 11 academic medical centers around the nation to share efficient, best practices for most registrations based on our experience within our institutions. The recommendations within it should not be seen as necessarily required by law in all cases. The vast variety of circumstances for different registrations cannot be fully encompassed within a single slide set.
Tips and Recommendations

✓ Chrome and Firefox are more likely to let you “expand” text boxes to see more
✓ Use MS Word to create and edit these fields carefully
✓ Do not use first or second person. Replace “I” and “we” with “the investigator”; replace “you” with “participants”
✓ Typos and spelling errors are not acceptable
✓ Define all acronyms
✓ Use notes provided by PRS system to guide you (suggestions/reminders; not mandatory)
✓ The Draft Receipt function provides a copy of your record as it appears in PRS
Validation Messages

- 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 (based on information entered for other data elements).
- Finish by addressing all remaining validation messages.
- Complete all required fields before checking/stressing on validation.
Public Site

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 264,317 research studies in all 50 states and in 203 countries.

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

Before participating in a study, talk to your healthcare provider and learn about the risks and potential benefits.

Find a study

Recruitment status
- Recruiting and not yet recruiting studies
- All studies

Condition or disease (For example: breast cancer)

Other terms (For example: NCT number, drug name, investigator name)

Country

Search

Advanced Search
Protocol Registration and Results System

Organization Name: WeillMC. To obtain a new ClinicalTrials.gov user account, please contact registerclinicaltrials@med.cornell.edu
To create a new record, click the **New Record** link **or** use the **Records** drop down menu.

The system flags records with problems to be addressed.
IRB Protocol #

This title will be displayed in search results

Expanded Access records should only be created by the product manufacturer

More explanations for this stage on next screen
The Help link contains examples and data entry tips

The Definitions link contains the meaning of terms and useful information about field lengths

* Organization’s Unique Protocol ID: Pro00000123

* Brief Title: A 24-Week Double Blind Trial of Remuverol in Adults with Condition A

[*] Acronym: (if any) If specified, will be included at end of Brief Title in parentheses.

* Study Type:  
  - **Interventional** (or clinical trial) — participants assigned to intervention(s) based on a protocol
  - **Observational** participants not assigned to intervention(s) based on a protocol; typically in context of routine care
  - **Expanded Access** availability of an experimental drug or device outside of a clinical trial protocol

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)
After you click “Continue”, you will see this dialog box

Select OK
If the clinical study is funded in whole or in part by a U.S. Federal Government agency, the complete grant or contract number must be submitted as a Secondary ID. NIH grants should have an activity code (3 or 4 numbers and letters, such as R01), institute code (2 letters), and a 6 digit serial number. They may have a dash (-) and suffix.

Choose Quit to save work from previous screens, then Continue.

Required by ICMJE; should be consistent with formal IRB title.
After you click “Quit”, you will see this dialog box
The Record Owner is the primary contact for the record. Only an administrator can change the Record Owner.

PI can now share access with study team members and support staff. PI is legally responsible for accuracy and veracity of the record, and for ensuring proper maintenance.
Click Open to edit information section by section.
As you fill in more information, the Record Summary will show your progress.
Update this date every time the record is updated and review for accuracy. This is how compliance is tracked.

Only use “Active, not recruiting” if data are still being collected. If data collection is complete, the status should be Completed or Terminated.

Save button is always at bottom of each page

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Record Verification Date</td>
<td>Month: March Year: 2016</td>
<td></td>
</tr>
<tr>
<td>Overall Recruitment Status</td>
<td>Not yet recruiting</td>
<td></td>
</tr>
<tr>
<td>Study Start Date</td>
<td>Month: April Day: 1 Year: 2016 Type: Actual</td>
<td>Select Actual once date has occurred</td>
</tr>
<tr>
<td>Primary Completion Date</td>
<td>Month: December Day: 15 Year: 2020 Type: Anticipated</td>
<td>Select Anticipated for projections</td>
</tr>
<tr>
<td>Study Completion Date</td>
<td>Month: --Select-- Day:    Year:     Type: --Select--</td>
<td></td>
</tr>
</tbody>
</table>
Primary and Study Completion Dates

* Primary Completion Date:
  - Month: --Select--
  - Day: [ ]
  - Year: [ ]
  - Type: --Select--
  - Final data collection date for primary outcome measure.
  - ERROR: Primary Completion Date has not been entered.

* § Study Completion Date:
  - Month: --Select--
  - Day: [ ]
  - Year: [ ]
  - Type: --Select--
  - Final data collection date for study.
  - WARNING: Study Completion Date has not been entered.

Completion Dates are based on data collection.
They are NOT based on:

- data analysis
- database lock
- publication
- IRB closure

If you use these as Completion Dates, you may have LATE RESULTS.
Primary and Study Completion Dates

**Remember:** Results for the primary outcome measure(s) are due within one year of the Primary Completion Date. Results for the secondary outcome measures are due one year after the completion date for that outcome.

<table>
<thead>
<tr>
<th>* Primary Completion Date:</th>
<th>Month: September</th>
<th>Day: 15</th>
<th>Year: 2019</th>
<th>Type: Anticipated</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Final data collection date for primary outcome measure.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* § Study Completion Date:</td>
<td>Month: March</td>
<td>Day: 15</td>
<td>Year: 2020</td>
<td>Type: Anticipated</td>
</tr>
<tr>
<td></td>
<td>Final data collection date for study.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In this example, Primary Outcome results are due by **September 15, 2020**. All study results must be entered by **March 15, 2021**. Some secondary results may be due earlier depending on data collection time frames.
Choosing sponsor

If the study is NIH funded, include the NIH Institute or Center as a Collaborator. Collaborators include other funders, etc. Add as many as necessary.

- Responsible Party must be listed as “Sponsor”
- Sponsor should be “Weill Medical College of Cornell University”
Refer to definitions and linked Checklist for these sections.

If this is “Yes”, the IND/IDE information is required.

For “Human Subjects Protections Review,” provide the IRB information outlined in the WCM ClinicalTrials.gov Requirements for Posting.

You may leave this blank unless the protocol specifies if a data monitoring committee was established.

Neither of these questions is required. Section 801 Clinical Trial = ACT; FDA-regulated intervention/Section 801 clinical trial are optional; will likely eventually be phased out. We recommend NOT answering it unless your institution has a specific policy.
Provide the IRB information outlined in the WCM ClinicalTrials.gov Requirements for Posting.

Register **before** any enrollment begins.
This field is optional and can be left blank. It does not have to be in lay language.
It can be adapted from the background or aims section of the protocol, but do not copy and paste the entire protocol. This field cannot contain promotional language.
Where applicable, explain uncertainties or exploratory nature of study. If there are any parts of the trial, which the public cannot know about while the study is ongoing without affecting scientific integrity, such as deception research or inclusion/exclusion criteria which could be easily faked in order to join a study (e.g. pain levels in order to have access to a controlled substance), it would be good to explain here, e.g. “Some inclusion/exclusion criteria are purposely omitted at this time to preserve scientific integrity. They will be included after the trial is complete.”
Enter each study condition, one per line. Use Search MeSH link to verify the correct condition term

Keywords help users find studies in the database
Give an honest estimate for anticipated enrollment (based on consent, not completion).

Check the "definitions" link.
Arms may not pre-exist based on how many arms you defined in the previous section. You must add each arm. Do not title your arm as Intervention or Arm 1. Arm title should be more descriptive.
List Placebo as a Drug intervention

<table>
<thead>
<tr>
<th>Interventions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>* Intervention Type:</td>
<td>Drug</td>
</tr>
<tr>
<td>* Intervention Name:</td>
<td>Remuverol</td>
</tr>
<tr>
<td>[*] Other Names:</td>
<td></td>
</tr>
<tr>
<td><em>(if any)</em></td>
<td>Add Other Name</td>
</tr>
<tr>
<td>* § Intervention Description:</td>
<td>15 mg tablet</td>
</tr>
<tr>
<td>* § Intervention Description:</td>
<td>Remuverol placebo tablet</td>
</tr>
</tbody>
</table>

Frequent PRS Comment: The preferred format is to include *all* interventions that were pre-specified to be administered as part of the protocol, even if a particular intervention is not "of interest"
Errors must be fixed to move on. Click **edit** to resolve these Errors.

Cross-Reference tables will not exist for single arm studies. For multiple arm studies, you must link arms and interventions even when it seems that it’s obvious that Arm A does intervention A and Arm B does intervention B.
Outcome Measures

• Protocol/statistical analysis plan must be submitted with results and will be public for studies with a primary completion date of 1/18/2017 or later
  – Ensure coherence among protocol and registration for primary, secondary and “other” outcomes
  – PRS reviewers may assume all outcomes are primary or secondary unless they are specified in the protocol as other or exploratory

• Include all PRIMARY and SECONDARY outcomes (tertiary/exploratory are optional)

• Label outcomes as “primary” or “secondary” per the protocol
  – Can list more than one primary if applicable
Outcome Measures

• More registrations get rejected for inadequate Outcome Measure precision or inaccurate or multiple time frames than anything else.

• Outcome Measures should be specific and indicate what is being measured and is (or planned to be) reported.

• Remember the mantra: *Outcome Measures must be measurable outcomes.*
Outcome Measure Tips: Title

• Include the metric (i.e. scale, score, number, percentage)
  - Ex: Safety
  - ✔ Ex: Safety, as measured by number of subjects with at least one AE

• Be clear and concise; omit verbs
  - ❌ Ex: To determine the maximum tolerated dose of Drug A in patients with breast cancer.
  - ✔ Ex: Maximum Tolerated Dose of Drug A in patients with breast cancer

• List outcomes separately
  - ❌ Ex: All-cause mortality, hospitalizations, ER visits
  - ✔ Ex: Number of hospitalizations, Number of ER visits, Number of ER visits. *Should be listed as 3 separate outcomes*

• Exception: if a composite score of multiple measures will be used
  - Example: Count of individuals who experience any of the following: all-cause mortality, hospitalizations, and emergency room visits
Outcome Measure Tips: Time Frame

• Be specific (e.g. # of minutes, weeks, months)
  – Ex: Baseline, week 2
  – Ex: During hospitalization, approximately 5 days
  – Ex: Post-intervention, week 12

• If multiple time points are included:
  – If measuring change between the time points, add the word “change” to the title
  – If not measuring change, each time point needs to be listed as a separate outcome measure

• Remember that completion dates should reflect completion of data collection for your outcome measures. Refer back to study status section.

Average time, expected average time, or max assessment time would all be acceptable when the protocol cannot specify precise time frame
Outcome Measure Tips: Description

• If a scale will be used, include the range and meaning of the scores
  – Example: The Hamilton Depression Rating Scale is used for rating the severity of depressive symptoms. Scores range from 0 to 50, with higher scores indicating greater severity of depression.

• If a scale is not linear (e.g. logarithmic), that would be good to note as well.
Outcome Measures: Example 1

There are 2 time points, so the word “change” is added to the title.

The Title includes the scale that will be used to assess change in pain.

The Description includes the range of the scale and what the scale means.
**Outcome Measures: Example 2**

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
<th>Time Frame</th>
</tr>
</thead>
<tbody>
<tr>
<td>To assess the safety of Remuverol</td>
<td></td>
<td>End of study</td>
</tr>
<tr>
<td>Number of participants with at least one adverse event</td>
<td>Adverse events will only include those that are determined to be related to the study drug.</td>
<td>End of study (24 weeks)</td>
</tr>
</tbody>
</table>

- The title includes the metric
- The Time Frame includes the specific length of time
- The Description defines “adverse events”
Use Inclusion / Exclusion Criteria with colon followed by dashed list format

No paragraphs

| * Sex: All |
| Biological sex of eligible participants. |
| [ ] Gender Based: No |
| If applicable, indicate if participant eligibility is based on self-representation of gender identity. |
| * Age Limits: Minimum: 18 Years Maximum: N/A (No limit) |
| * Accepts Healthy Volunteers: No |
| * Eligibility Criteria: |

**Inclusion Criteria:**
- Outpatients
- At least 18 years old
- Diagnosed with Condition A for at least 6 months

**Exclusion Criteria:**
- Any cardiovascular, hepatic, or renal disease
- Pregnancy
- Current use of narcotics

Make sure that all criteria you post are appropriate for the public to see.

Match informed consent more than protocol, if something might need to be masked from participants.

If necessary, use Detailed Description field to flag that the eligibility criteria are deliberately incomplete to preserve the scientific integrity of the study.
### Edit Overall Contacts

**Help Definitions**

<table>
<thead>
<tr>
<th><strong>Central Contact Person:</strong></th>
<th><strong>Central Contact Backup:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name: Kathy</td>
<td>First Name:</td>
</tr>
<tr>
<td>MI: A.</td>
<td>MI:</td>
</tr>
<tr>
<td>Last Name: Coordinator</td>
<td>Last Name:</td>
</tr>
<tr>
<td>Phone: 919-123-4567</td>
<td>Phone:</td>
</tr>
<tr>
<td>Ext:</td>
<td>Ext:</td>
</tr>
<tr>
<td>Email:</td>
<td>Email:</td>
</tr>
<tr>
<td>Degree: BA</td>
<td>Degree:</td>
</tr>
</tbody>
</table>

**Either Central Contact or Facility Contacts are required.**

The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).

<table>
<thead>
<tr>
<th><strong>Overall Study Officials:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name: Joe</td>
</tr>
<tr>
<td>MI:</td>
</tr>
<tr>
<td>Last Name: Investigator</td>
</tr>
<tr>
<td>Degree: MD</td>
</tr>
<tr>
<td>Organizational Affiliation: Duke University Medical Center</td>
</tr>
<tr>
<td>Official's Role: Study Principal Investigator</td>
</tr>
</tbody>
</table>

**NOTE: Study Official is required by the WHO and ICMJE.**

- **Add the PI as a Study Official**
Overall contact may be used to differentiate a study coordinator or administrator from the study official.

All sites should be added for multi-site studies, only after the IRB has approved that location.
Site recruitment status must be consistent with overall recruitment status; if overall recruitment is not recruiting, no site can be recruiting.
Studies available in PubMed are linked automatically if the NCT# was included in the publication. Others need to be added manually.

Indicate if the reference provided reports results from this study.
The Record Summary

Click the **Spelling** link to review spelling errors and unexpanded acronyms.

- **Errors** must be addressed before releasing the record.
- **Warnings** indicate potentially serious issues that should be reviewed and addressed as needed.
- **Notes** indicate other potential issues; address as needed.

NOTE: Study Official is required by the WHO and ICMJE.

When the Record Summary shows all green checks, the PI should carefully review the record. False statements are criminal under the regulations! For new registrations, the PI should read each section carefully.
The Record Summary – to complete

Record Summary

Record Status

In Progress ➔ Entry Completed ➔ Approved ➔ Released ➔ PRS Review ➔ Public

Next Step: Confirm data entry complete

Entry Complete

Record Owner: Test User
Last Update: 01/23/2017 11:53 by Test User
Initial Release: [Not yet released]

Access List: [] Edit
Upload: Allowed Edit
PRS Review: [Not yet released]
Public Site: [Not yet registered]

FDAAA: ACT

Click Entry Complete to send the record to the Responsible Party for Approval and Release

This study appears to be an ACT and is subject to federal regulations. The reasons why your trial is considered ACT will be displayed.
The Record Summary – User Information

The Record Owner is the primary contact for the record. Only an administrator can change the Record Owner.

Add the PI and anyone else who should have edit rights. The Record Owner can do this.

Initial Release date displays on the public site. This is important for FDAAA and ICMJE.
Can a Study Record be Deleted?

• Only if the study record has never been published on ClinicalTrials.gov

• Otherwise, No.

• ClinicalTrials.gov serves as a long-term public registry. Once a study record is published, it remains in the system even after a trial has closed.

• If you find a duplicate, contact ClinicalTrials.gov at register@clinicaltrials.gov.
PRS Review

Once the record is released, ClinicalTrials.gov conducts a manual review
• If major issues are identified, the record owner and RP will receive notification from ClinicalTrials.gov with comments
• The study will be reset to In Progress
• Study Owner/RP must correct the issues and re-release it within 15 calendar days (new in 42 CFR 11)
• If no major issues are identified, the study is assigned an NCT number and published on the public side of the database (clinicaltrials.gov)
• This process takes about 2-5 business days
• Even if its published, advisory comments may be posted. Corrections are not mandatory
Ongoing Responsibilities of Record Owners

• Records can be transferred to other user accounts as staff change

• Records must be updated every 12 months and within 30 days of Recruitment Status changes or amendments that affect information in clinicaltrials.gov record, especially recruitment status, location and contact information

• Always update the Record Verification Date to indicate that you have updated or reviewed the record

• Records must be updated within 30 days after the completion date (last data collection)

• Failure to update information on ClinicalTrials.gov can result in penalties. There are more specific update requirements in 42 CFR 11.64
Checking your Problem Records

PRS System identifies current ‘Problem Records’

- Records that have not been marked as completed
- Active studies that have not been updated (or the Record Verification Date has not been updated)
- Records missing one or more FDAAA-required data elements:
  - Responsible Party
  - Study Start Date
  - Primary Completion Date
  - Primary Outcome Measure
- Records that appear to be overdue for FDAAA results reporting
Do You Need to Submit Results?

• All Applicable Clinical Trials (ACTs) are required to submit results
• All NIH-funded trials begun on after 1/18/2017 and applied for on or after 1/18/2017 must report results, whether ACTs or not
• Other grantors may require results submission

Based on registration information entered, the system will assess whether the trial appears to be:
1) An ACT with results required by law
2) A Non-ACT: results ARE not required by law, though NIH policy (if so funded) or other funders’ policies may still require results reporting
3) Older trials may be designated Probable ACT or Probable Non-ACT

Note: There is no reminder flag for NIH-funded trials.
Acknowledgements

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