ClinicalTrials.gov PRS
Protocol Registration and Results System

NOTE: THROUGHOUT THIS DOCUMENT, Times Roman is the Clinicaltrials.gov Administrator's Quick Reference most recent edition –

Calibri shows UM- specific instructions

To contribute to continuous quality improvement, send any questions, concerns or recommendations to Diane Wilson (dlehman) or Amy Lum (aelux) in UMMS Office of Regulatory Affairs.

Problem Resolution Guide

This guide explains each type of problem that may appear on the PRS Home page, or in a PRS Problem Report, and lists steps for problem resolution.

Tips:

- Record Owner steps may also be performed by any User who is on the record's Access List or by an organization's Administrator.
- Administrator/Responsible Party steps must be performed by the Investigator when Responsible Party is Principal Investigator or Sponsor-Investigator.
- For more information on responsibilities of PRS Record Owners, Users and Administrators, see the Quick Start Guide and Administrator's Quick Reference (Administrators only).

Problem Resolution Responsibility Allocation Chart	
Problem	**Problems Addressed by…**
PRS Review Comments	Reviewed by Group Administrator, but PI needs to resolve; either party can consult with UMMS Regulatory Affairs
Entry Not Completed	Resolved by Group Administrator – usually PI (or study team) needs a gentle reminder
Not Recently Updated	Resolved and prevented by Group Administrator – review and remind at 11 months (note: problems in the 6- 11 month range can be left alone for now)
Record Has Errors	Reviewed by Group Administrator, - PI needs to resolve; either party can consult with UMMS Regulatory Affairs
Missing FDAAA Information	Refer to UMMS Regulatory Affairs
Late Results – per FDAAA	Refer to UMMS Regulatory Affairs
Ready for Review and Approval	Resolved by Group Administrator- usually PI needs a gentle reminder
Never Released	Resolved by Group Administrator – usually PI needs a gentle reminder
Update Not Released	Resolved by Group Administrator – usually PI needs a gentle reminder

Data Entry Issues

PRS Review Comments

UM: If the PRS review comments arrived less than 14 days ago, the chances are the person is still working on the record and you can leave it/them alone. If it is more than that, a quick phone call or email to check if they noticed that PRS sent back comments that need addressing – or if they need help is probably in order.

The study has not yet been made public (or has not yet been updated) on ClinicalTrials.gov because issues were identified during ClinicalTrials.gov PRS Review. The PRS Review Comments must be addressed and the record Released before the study can be made public (or updated).

Problem resolution:

1. Record Owner: Read the PRS Review Comments. Comments can be accessed from the Record Summary page.
2. Record Owner: Modify the record as needed to fully address the comments.
3. Record Owner: Mark the record as Entry Completed.
4. Administrator/Responsible Party: Review, edit as needed, Approve and Release the record.

Entry Not Completed

UM: If the last update is less than 14 days ago, the chances are the person is still working on the record and you can leave it/them alone. If it is more than that, a quick phone call or email to check if they intended to complete it, if it's just not ready to be posted (e.g. they are waiting on funding or IRB approval of a set of conditions), if they wish to delete the record because the study won't happen or another site is doing it, or if they need help is probably in order.

The record has not been marked as Entry Completed, following initial data entry or modification of the record. A record must be marked as Entry Completed, Approved and Released in order to be reviewed by Clinicaltrials.gov PRS and made public (or updated) on the ClinicalTrials.gov website.

Problem resolution:

1. Record Owner: Review the record and modify it if necessary.
2. Record Owner: Mark the record as Entry Completed.
3. Administrator/Responsible Party: Review, edit as needed, Approve and Release the record.

Tip: If the study does not need to be made public (registered) on ClinicalTrials.gov and the record has never been Released**, check with the RP to see if you can** delete the record.

Not Recently Updated

UM: Currently the legal requirement is for updating records annually or within 30 days of a change in enrollment status. If the record has not been updated within 11 months, send a reminder to the RP and updater.

The record for a Recruiting (or Not yet recruiting) study has not been updated in more than six months, or the record for an Active, not recruiting (or Enrolling by invitation) study has not been updated in more than one year.

Problem resolution:

1. Record Owner: Review the record and modify it as needed, including update of the Verification Date.
2. Record Owner: Mark the record as Entry Completed.
3. Administrator/Responsible Party: Review, edit as needed, Approve and Release the record.

Record Has Errors

UMichigan Administrators: If you wish to be helpful, enter the record to see what the nature of the error is to explain in a quick reminder email to the RP and updater. If you don't understand the error, please consult with UMMS Office of Regulatory Affairs.

The record has one or more Error messages. Note that errors can arise due to the passage of time (e.g., anticipated primary completion date in the past).

Problem resolution:

1. Record Owner: Review the record and modify it as needed, including update of the Verification Date.
2. Record Owner: Mark the record as Entry Completed.
3. Administrator/Responsible Party: Review, edit as needed, Approve and Release the record.

FDAAA 801 Issues

The FDAAA 801 issues report is for informational purposes only. The report identifies trials that may be "applicable clinical trials" subject to Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) and that are missing required information or appear to be overdue for results submission. It is recommended that the data elements used to identify trials

for the report be reviewed for accuracy and updated, as needed: Study Type, Intervention Type(s), Study Phase, Facility Locations, IND/IDE Protocol?, Primary Completion Date, Study Completion Date and Overall Recruitment Status. For additional information see the FDAAA Issues information page in the PRS and the FDAAA 801 Requirements page on the ClinicalTrials.gov website.

Records for older studies that are not subject to FDAAA 801 (completed before December 26, 2007) may show FDAAA 801 related issues if a completion date is not provided. Entering the actual completion date for an older study will remove it from the report.

Missing FDAAA Information

The record is missing one or more data elements required by FDAAA 801, such as: Responsible Party, Study Start Date, Primary Completion Date and Primary Outcome Measure.

Problem resolution:

1. Record Owner: Review the record and modify it as needed, ensuring that all WARNING messages have been resolved.
2. Record Owner: Mark the record as Entry Completed.
3. Administrator/Responsible Party: Review, edit as needed, Approve and Release the record.

Late Results - per FDAAA

The record appears to be overdue for results submission per FDAAA 801.

UMichigan: If you don't believe that results are required, check with UMMS Regulatory Affairs, before or rather than submitting a certification or extension request. These rules are likely to change with the final regulations in 2016, so we will handle these on a case-by-case basis until then.

Problem resolution:

Determine whether (A) results are required to be submitted; or (B) it is appropriate to submit a Certification or Extension Request to delay results submission. For more information, read When Do I Need to Register and Submit Results? on the ClinicalTrials.gov website.

(A) Results:

1. Administrator/Responsible Party: Identify the appropriate individual within the organization to enter results information for the study. If necessary, create a User account for the individual and change record ownership (or update the record's Access List).
2. Record Owner: If submitting Results for the first time, refer to Help: Results Data Entry for the full set of instructional resources.

3. Record Owner: Enter Results information using the Enter Results link on the Record Summary page.
4. Record Owner: Mark the record as Entry Completed.
5. Administrator/Responsible Party: Review, edit as needed, Approve and Release the record.

(B) Certification or Extension Request:

1. Administrator/Responsible Party: Identify the appropriate individual within the organization to enter a Certification or Extension Request. If necessary, create a User account and change record ownership (or update the record's Access List).
2. Record Owner: Enter Certification or Extension information using the "Delay Results" link on the Record Summary page.
3. Record Owner: Mark the record as Entry Completed.
4. Administrator/Responsible Party: Review, edit as needed, Approve and Release the record.

This problem will continue to be listed for the record until Results information is entered and passes ClinicalTrials.gov PRS Review.

Administrator Issues

Ready for Review and Approval

UMichigan – send the Mini PPT reminding of the review and approve and release process to RP as well as updater, so that RP will review, approve and release. Check back 1 week later to see that it has been released, then try a phone call to RP.

The Record Owner (or other User) has marked a record as Entry Completed, following initial data entry or modification of the record. The record must be Approved and Released in order to be reviewed by ClinicalTrials.gov PRS and made public on the ClinicalTrials.gov website.

Problem resolution:

1. Administrator/Responsible Party: Review, edit as needed, Approve and Release the record.

Never Released

UM: If the last update is less than 14 days ago, the chances are the person is still working on the record and you can leave it/them alone. If it is more than that, a quick phone call or

email to check if they intended to complete it, if it's just not ready to be posted (e.g. they are waiting on funding or IRB approval of a set of conditions), if they wish to delete the record because the study won't happen or another site is doing it, or if they need help is probably in order.

A record has been created, but has never been Released. A record must be marked as Entry Completed, Approved and Released in order to be reviewed by ClinicalTrials.gov PRS and made public on the ClinicalTrials.gov website.

Problem resolution:

1. Administrator/Responsible Party: Determine whether the study should be made public on ClinicalTrials.gov and who should finish data entry.
2. Administrator/Responsible Party: Change record ownership or update the record Access List, if necessary.
3. Record Owner: Finish initial data entry or update the record, as appropriate.
4. Record Owner: Mark the record as Entry Completed.
5. Administrator/Responsible Party: Review, edit as needed, Approve and Release the record.

Tip: If the study does not need to be made public (registered) on ClinicalTrials.gov and the record has never been Released, delete the record.

Update Not Released

UMichigan – send the Mini PPT reminding of the review and approve and release process to RP as well as updater, so that RP will review, approve and release. Check back 1 week later to see that it has been released, then try a phone call to RP.

A record that has been made public on ClinicalTrials.gov has been updated, but has not been Released. A record must be marked as Entry Completed, Approved and Released in order to be reviewed by ClinicalTrials.gov PRS and updated on the ClinicalTrials.gov website.

Problem resolution:

1. Administrator/Responsible Party: Determine who should finish updating the record.
2. Administrator/Responsible Party: Change record ownership or update the record Access List, if necessary.
3. Record Owner: Review and update the record, as appropriate.
4. Record Owner: Mark the record as Entry Completed.
5. Administrator/Responsible Party: Review, edit as needed, Approve and Release the record.