THE UNIVERSITY OF UTAH®

Office of Quality Compliance
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University of Utah ClinicalTrials.gov Guidelines

Regulations, Policies, Accounts, Registration, and Results Reporting

1. Scope

This document establishes guidelines and expectations for managing ClinicalTrials.gov study registration, maintenance, results reporting, and document uploads for University of Utah Sponsor Investigators, Lead Principal Investigators, and other University ClinicalTrials.gov users to ensure compliance applicable federal regulations.

a. **Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801)** requires Responsible Parties to register and submit summary results of clinical trials. Registration is required for trials that meet the FDAAA 801 definition of an “applicable clinical trial (ACT).”

   i. Section 801 of the Food and Drug Administration Amendments Act of 2007

   ii. ACT Determination Checklist.pdf

b. **Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR 11)** The Final Rule clarifies and expands the requirements for submitting clinical trial registration and results information to ClinicalTrials.gov in accordance with FDAAA 801. In general, the final rule requires the submission of results information not later than 1 year after the completion date (referred to as the "primary completion date") of the clinical trial, which is defined as the date of final data collection for the primary outcome measure.

   i. Final Rule Clinical Trials Registration and Results Information Submission

c. **The National Institutes of Health (NIH) Policy on Dissemination of NIH-funded Clinical Trial Information** applies to all NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the Clinical Trial Registration and Results Information Submission regulation of 42 CFR Part 11.

   i. NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information

   ii. NIH Clinical Trial Definition

d. **Revised Common Rule (45 CFR Part 46)** requires that any clinical trial conducted or supported by a Common Rule department or agency, post one IRB approved consent form used in enrolling participants on a publicly available Federal website (i.e., ClinicalTrials.gov).

   i. Revised Common Rule (45 CFR Part 46) Informed-Consent Posting

e. **The International Committee of Medical Journal Editors (ICMJE)** requires registration of any human research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome.

   i. ICMJE Clinical Trial Registration

f. **Medicare (CMS)** qualifying trials, including some phase I and device feasibility trials, are required to be registered into the ClinicalTrials.gov database. A ClinicalTrials.gov identifier (NCT number) is required on clinical trial related claims in order to receive payment.

i. Medicare National Coverage Determination Mandatory Reporting of a Clinical Trial Identifier Number

2. ClinicalTrials.gov Registration

Principal Investigators (PIs) or a delegated research team members are responsible for registering and maintaining their study records on ClinicalTrials.gov, verifying the completeness and accuracy of uploaded information, and ensuring all data-entry activities occur within the required time frames. See 'Roles and Responsibilities' on page X for details.

The following registration requirements apply:

a. **FDAAA 801**: The PI or delegate must register, and input required clinical trial information through the Protocol Registration System (PRS) at the ClinicalTrials.gov website no later than 21 days after enrollment of the first participant.

b. **NIH**: The PI or delegate must register, and input required clinical trial information at the ClinicalTrials.gov website no later than 21 days after enrollment of the first participant.

c. **ICMJE**: The PI or delegate must register with an ICMJE-qualified publicly accessible registry at or before the first patient is enrolled in the study as a condition for publication in a participating journal.

d. **CMS**: The PI or delegate must register, and input required clinical trial information and obtain an NCT# at the ClinicalTrials.gov website before submitting claims for such services to CMS.

3. ClinicalTrials.gov Account

To register on ClinicalTrials.gov PRS, the PI and those assisting with the study record must set up an account by contacting the PRS Administrators in the Office of Quality Compliance.

a. Complete Account Request Form here: U of U ClinicalTrials.gov New Account Request Form

b. The OQC PRS Administrators will provide account information and a temporary password to the email address provided. Once the user receives their account information and temporary password, they can log in to http://register.clinicaltrials.gov and enter their username and password.

c. When prompted for the Organization by ClinicalTrials.gov, enter the following information:
   i. **Organization**: UUtah

4. Roles and Responsibilities

a. **Responsible Party:** FDAAA 801 and the Final Rule states that as long as the PI is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet the requirements for the submission of clinical trial information, the PI should be designated as the responsible party for registering a clinical trial and submitting results to clinicaltrials.gov.

i. The University of Utah designates PIs as the Responsible Party for *all* records. Unless otherwise specified (I.e., HCI – CTO).

ii. Although the PI may delegate clinicaltrials.gov record responsibilities to members of their research team, the PI retains the ultimate responsibility of accuracy and compliance.

iii. The PI must 'Approve' and 'Release' records for ClinicalTrials.gov PRS Administrator review.

b. **Record Owner:** Whoever enters the initial record information in ClinicalTrials.gov will be assigned as the Record Owner. PRS Administrators can change the Record Owner to another user within the institution. Contact OQC@utah.edu assistance.

i. Additional users can be added to the record through the 'Access List'. Contact OQC@utah.edu for assistance.

c. **Department PRS Administrators:** The primary role of PRS administrators is to oversee department record compliance.

i. Department PRS administrators should **not** create ClinicalTrials.gov user login accounts and/or transfer records to other institutions/organizations without the assistance of the institutional PRS Administrators.

ii. If you would like to establish a PRS Administrator for your department, contact OQC@utah.edu for assistance.

d. **Internal PRS Administrators:** There are institutional PRS Administrators in the OQC who provide ClinicalTrials.gov oversight, compliance support, and account request for PIs and research teams. Some departments assign departmental PRS Administrators.

5. Updating Records

Principal Investigators or delegated research team members are responsible for updating clinical trials records registered on ClinicalTrails.gov, reviewing the record for accuracy, and ensuring data entry occurs within the required timeframes linked below:

a. ClinicalTrial.gov Registration and Update Requirements

i. All active ClinicalTrials.gov records are required to be reviewed and verified no less than once every twelve (12) months, even if there are no changes to recruitment or study status. At this time, the "Verification Date" must be updated in the Protocol Section of the record.

b. Protocol Amendments should be reflected in the ClinicalTrials.gov record after IRB approval.

6. Results Reporting

Principal Investigators or a delegated research team member are responsible for reporting results and Informed Consent document upload of clinical trials registered on ClinicalTrials.gov, as applicable. Results reporting is voluntary if the study does not qualify as a clinical trial under FDAAA 801 or NIH definition.

a. **FDAAA 801**: Aggregate results, and adverse event reporting on ClinicalTrials.gov must occur within 12 months of the Primary Completion Date.

b. **NIH**: Aggregate results, and adverse event reporting on ClinicalTrials.gov must occur within 12 months of the Primary Completion Date.

c. **ICMJE**: If the study qualifies as a clinical trial under FDAAA or NIH, results and event reporting must occur within 12 months of the Primary Completion Date. The ICMJE does not consider results data posted in the tabular format required by ClinicalTrials.gov to be prior publication.

d. **Revised Common Rule Requirements – ICF Posting:** The informed consent form must be posted after the trial is close to enrollment, but no later than 60 days after the last study visit by a participant.

e. If a clinical trial is subject to registration requirements by more than one entity—FDAAA, NIH, ICMJE, or CMS- it must only be registered once on ClinicalTrials.gov. Registration and results reporting must occur within the timeframe set by the applicable entities, whichever is sooner.

7. Non-Compliance

Internal escalation procedures for noncompliance or outstanding record updates and maintenance are as followed:

a. The OQC PRS Administrator will request the Department PRS Administrator and/or Responsible Party to address issues within 15 business days.

    i. Record Owners and users listed on the record Access List may be contacted for corrective actions as well.

b. If any issue remains unaddressed, the OQC PRS Administrators will notify the applicable Departmental Chair and/or Research Manager to request support to address outstanding issues within 15 business days or an agreed-upon time frame.

c. Any issues that remain unaddressed after the additional 15 business days or agreed-upon time frame, will escalate to the Office of Vice President of Research (VPR) in an effort to achieve final resolution.

Internal procedures may be in concurrence with the following:

d. **FDAAA 801:** Penalties may include civil monetary fines up to $13,237 for failing to submit or for submitting fraudulent information to ClinicalTrials.gov. After notification of noncompliance, the fine may be applied daily until resolved.

e. **NIH:** Penalties may include the withholding or recovery of grant funds.

f. **ICMJE**: Journals can refuse to publish data from studies that are noncompliant or unregistered.

The FDA and/or NIH will send written notification of potential non-compliance to the Responsible Party and request corrective action within 30 days of receiving notification. Forward all notifications of potential non-compliance to OQC@utah.edu.

g. Outstanding noncompliance with University of Utah guidelines, and/or federal requirements could result in corrective actions that may include reporting noncompliance to the IRB.

8. Responsible Party Leaving Institution

When a PI is leaving the University of Utah, they are responsible for notifying the OQC to coordinate record transition and responsibilities as applicable:

a. If the research is continuing at the University of Utah under a new PI, the new PI must be assigned to the ClinicalTrials.gov study record as the Responsible Party.

b. If the research continues at the PIs new institution, the OQC will assist in transferring the record(s) to the new institution.

9. Education and Training

ClinicalTrials.gov training and education is only required for the role of Department PRS Administrators. Training and education are not required for PIs and other research team members, but available through a self – paced course provided by the Research Education Department (REd).

a. RED 743 | Introduction to ClinicalTrials.gov

10. ClinicalTrials.gov Entry Guidance

*The guidance below is **not** inclusive of all ClinicalTrials.gov entry sections or requirements.*

ClinicalTrials.gov	**Entry Guidance**
Unique Protocol ID	IRB Number
Secondary IDs	Grant/Contract Number(s)
Sponsor	University of Utah
Responsible Party	Principal Investigator
Collaborators	Other organizations (if any) providing support. Support may include funding, design, implementation, data analysis or reporting
Brief Title	Written in language intended for the lay public Avoid technical study design terms
Study Description – Brief Summary	Written in language intended for the lay public Clearly state the study's hypothesis and purpose
Conditions/Keywords	List each condition and keyword individually, one per line.
Eligibility	Use bullet point or number list to record criteria Enter 'Maximum Age' even if N/A
IPD Sharing Statement (ICMJE requirement)	University of Utah ICMJE and IPD Guidelines
Outcome Measure Titles and Descriptions	**Titles**: specific measurement that will be reported. Avoid using study Aims in the title. **Descriptions**: description of what will be measured, avoid descriptions the goal or objective of an assessment or of the study.

	Define all scales/questionnaires and scores in the Outcome Measure Descriptions

Other Guidance:

a. Record should be written in third person
b. Acronyms and abbreviations are spelled out, with the acronym or abbreviation provided in parentheses, at least the first time they are used in the Protocol and Results sections
c. Symbols are spelled out
d. A caret (^) is used to indicate exponents (e.g., kg/m^2)
e. Use of 'participants' rather than 'subjects' or "patients" in descriptions and summary sections

ClinicalTrials.gov PRS Review Criteria:

a. Registration: ClinicalTrials.gov Protocol Registration Quality Control Review Criteria
b. Results: ClinicalTrials.gov Results Quality Control Review Criteria

11. References and Resources

a. ACT Determination https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf
b. NIH Clinical Trial Decision Tree https://grants.nih.gov/ct-decision/index.htm
c. PRS Registration Review Criteria https://prsinfo.clinicaltrials.gov/ProtocolDetailedReviewItems.pdf
d. PRS Results Review Criteria https://prsinfo.clinicaltrials.gov/ResultsDetailedReviewItems.pdf
e. PRS Guided Tutorial for Entering Results https://prsinfo.clinicaltrials.gov/tutorial/content/index.html#/ -
f. CMS Clinical Trial Policies https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies
g. ICMJE Clinical Trial Registration https://www.icmje.org/about-icmje/faqs/clinical-trials-registration/
h. FDA Guidance: Civil Money Penalties https://www.fda.gov/media/113361/download
i. ClinicalTrials.gov Public Database https://clinicaltrials.gov/
j. PRS Website https://register.clinicaltrials.gov/

Please contact OQC@utah.edu for any questions, comments, or concerns related to ClinicalTrials.gov