SOP-20: ClinicalTrials.gov Study Registration and Record Management

1. Objective
   To ensure that the Principal Investigator (PI) and all research team members assisting in the conduct of clinical research are informed about their obligations and responsibilities as they pertain to Good Clinical Practices (GCP), the investigational plan, applicable regulations, guidances, and institutional policies. This Standard Operating Procedure (SOP) applies to the written procedures followed by all members of a clinical research team involved in the conduct of human subjects’ research at The Ohio State University Wexner Medical Center (OSUWMC), hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research.

SOP-20 describes the process for the registration and results reporting of clinical trials to ClinicalTrials.gov. Attachments include:

   A: Creating a New Study Record for ClinicalTrials.gov
   B: Maintaining Study Records on ClinicalTrials.gov

2. Responsibility
   The College of Medicine Clinical Trials Management Organization (COM-CTMO) develops, implements, and maintains SOPs. The need to write a new or revise an existing SOP is based upon changes to federal regulations, guidelines, institutional policies, or procedures. These documents will be provided to departments and research teams conducting human subjects’ research. Departments or research teams may develop additional research SOPs or a Research Procedure Addendum (RPA) to expand on an existing SOP, however this need should be limited.

The PI is ultimately accountable for all clinical research activities and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks. It is the responsibility of all members of the clinical research team involved in supervising, managing, or conducting study-related activities to follow the SOPs. The clinical research team may include but is not limited to the following members:

   Research Team Members
   
   Principal Investigator (PI)            Clinical Research Coordinator (CRC)
   Sub-Investigator (Sub-I)               Clinical Research Assistant (CRA)
   Clinical Research Manager (CRM)       Other Research Staff as appropriate
   Clinical Research Specialist (CRS)     Administrative and Support Staff

3. Definitions (as they pertain to registering a trial on ClinicalTrials.gov)
   A. Applicable Clinical Trial (ACT): Registration is required for trials that meet the FDAAA 801 or 42 CFR 11 definition of an “Applicable Clinical Trial” and were either initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007. Trials that were ongoing as of September 27, 2007 and reached their completion date (see Primary Completion Date data element on ClinicalTrials.gov) before December 26, 2007 are excluded.
Applicable Clinical Trials include the following:

1. **Trials of drugs and biologics:** Controlled clinical investigations, other than phase 1 clinical trials, of drugs or biological products subject to U.S. Food and Drug Administration (FDA) regulation.

2. **Trials of devices:** 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies where the primary outcome measure relates to feasibility and not to health outcomes, and 2) **Pediatric Post market Surveillance** required by FDA.

**B. Responsible Party:** The individual or entity with complete access to trial data and rights to publish. The Responsible Party for Investigator Initiated studies in the College of Medicine is the **Principal Investigator.** The Responsible Party may designate individuals to help complete the ClinicalTrials.gov record; however, the final responsibility of review and approval lies with the Responsible Party. **The Responsible Party has the sole authority to release a record.**

**C. Record Owner:** This individual can be the Principal Investigator or a designated research team member who is responsible for updating the ClinicalTrials.gov record and ensuring that it is updated in a timely manner. The owner must maintain communication so that the protocol record is released by the PI (Responsible Party) in the required time frame.

**D. International Committee of Medical Journal Editors (ICMJE):** A group of general medical journal editors and representatives of selected related organizations working together to improve the quality of medical science and its reporting.

**E. Protocol Registration and Results System (PRS):** Website for entering and updating ClinicalTrials.gov records. [https://register.clinicaltrials.gov/](https://register.clinicaltrials.gov/)

**4. Procedures**

**A. Determining Study Registration Requirements:**

The PI is responsible for determining if the study is an ACT, thus requiring registration and results information on ClinicalTrials.gov. To determine if a study is an applicable clinical trial per 42 CFR 11, please use the checklist available on the ClinicalTrials.gov website [https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf](https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf).

In addition to federal requirements (42 CFR 11), **NIH Policy,** journals (i.e., ICMJE), funding sources, and insurance companies (i.e., Medicare/Medicaid) may require registration and submission of results information.

If the study was approved by OSU’s Cancer IRB, the PI will be instructed to work with appropriately delegated ClinicalTrials.gov Administrator within the Comprehensive Cancer Center to ensure research studies are registered appropriately.

Studies with approved consent language stating the study will be registered to ClinicalTrials.gov must register their study to ClinicalTrials.gov. If it is determined that the study does not require registration per regulations and the PI decides not to register the study for publication or other purposes, then an amendment removing the ClinicalTrials.gov language must be approved by the IRB and consented subjects must be notified.
Studies with human subjects that are not required per regulations or publication requirements may still be registered to ClinicalTrials.gov per the PI’s discretion.

B. Determining Responsible Party

Please use the flow diagram below, the NIH’s flow sheet, and information on the ClinicalTrials.gov website to determine who should be listed as the Responsible Party and what option should be selected. For studies initiated and written by an investigator at OSU, the PI of the study should be listed as the Responsible Party, whether listed as “Principal Investigator” or “Sponsor-Investigator.” The Responsible Party has the sole authority to approve and release the record; all records must be reviewed and released by the Principal Investigator. In the event that the PI leaves OSU, please contact the administrators to determine who should become the new Responsible Party.

C. Obtain an Account

The College of Medicine has separate ClinicalTrials.gov administrators for cancer and non-cancer clinical research studies.

1. Requests for a ClinicalTrials.gov account can be made by contacting the appropriate organizational ClinicalTrials.gov administrator.

2. The requestor must provide full name and preferred institutional e-mail address. Please note that the PI of the study will need to have a ClinicalTrials.gov account in order to approve and release the record. You may request that at the same time if the PI does not have an account yet.

3. Once an account is created, you will be notified by the administrator and will receive an automated e-mail from the Protocol Registration and Results System (PRS) with login instructions.
D. Create, Update and Maintain Study Records

Instructions for creating, editing, approving, and releasing a study record are available on the main ClinicalTrials.gov website.

1. Creating and updating submissions: For new records please refer to Attachment A: Creating a New Study Record for ClinicalTrials.gov.

2. Maintaining record: please refer to Attachment B: Maintaining Study Records on ClinicalTrials.gov.

3. Records release: All records must be reviewed and released by the PI.

E. Post Clinical Trial Consent Form

ClinicalTrials.gov can be used to fulfill the Common Rule requirement (45 CFR 46.116(h)) to post a consent form used to enroll study subjects into a clinical trial conducted or supported by a Federal department or agency. Upload an IRB approved ICF in the document section within the ClinicalTrials.gov record. The help link in the document section provides instructions.

F. Submit Results

Instructions for submitting results are available on the ClinicalTrials.gov website.

G. Timeline Requirements

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<tr>
<th>Event</th>
<th>Timeline requirements</th>
<th>Notes</th>
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<tr>
<td>Registration</td>
<td>No later than 21 days after the first subject is enrolled</td>
<td>A study is considered registered once the responsible party releases the record to PRS for review.</td>
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<td>ICMJE requires that registration is complete prior to first subject enrollment.</td>
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<tr>
<td>Actively enrolling studies</td>
<td>Update/verification every 6 months</td>
<td>The record must be verified even if no changes need to be made.</td>
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<tr>
<td>Studies closed to enrollment or pending results</td>
<td>Update/verification annually</td>
<td>The record must be verified even if no changes need to be made.</td>
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<td>Change in study status</td>
<td>Within 30 days of status change</td>
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<td>Posting of clinical trial consent form</td>
<td>After the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject</td>
<td>Only one IRB-approved informed consent form used to enroll subjects must be posted.</td>
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<tr>
<td>Results submission</td>
<td>No later than 1 year after the primary completion date</td>
<td>Delayed submission of results is permitted in certain circumstances. See 42 CFR 11.44 for details.</td>
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H. Protocol Record Management

1. The Responsible Party is ultimately responsible for ensuring the studies are registered with ClinicalTrials.gov and updated appropriately at required intervals and released to the public database. Refer to Section G above for timeline requirements for updates.

2. The PI and protocol Record Owner should be contacted by the appropriate ClinicalTrials.gov administrator if their protocol record is delinquent and needs to be updated.

3. If the protocol record remains delinquent two weeks after the first notice, a second notification should go out to the PI, protocol Record Owner and department chair.
4. If the protocol record remains delinquent one month after the initial contact without acceptable activity/progress, alternative management of the account by another party should be arranged. The cost of these services may be billed to the department.

5. Records that are entered into the ClinicalTrials.gov database, but are not released, should get one notification and if left incomplete at 30 days post notification, the record should be deleted from the database.

6. **Please note that records cannot be deleted once they have been issued an NCT number, even after the study has been completed.** There are limited circumstances when a record can be removed from the public site – please contact the administrator for assistance.

### I. Transferring a Record:

1. If the Record Owner or Responsible Party is leaving the Institution, they should inform their ClinicalTrials.gov Administrator to ensure the record is appropriately monitored or transferred. The Record Owner or PI can either be reassigned to another Record Owner or PI within the university, or the record can be transferred to a new institution.

2. If the PI (Responsible Party) is moving studies from another institution please contact your designated ClinicalTrials.gov administrator to help facilitate the record transfer.

### J. Penalties

1. Under 42 CFR 11, civil and monetary penalties exist for noncompliance. Monetary penalties can be up to 10,000 US dollars a day.

2. Grant funding can be withheld until the required information has been submitted.

3. Journals can refuse to publish data from records that are noncompliant.

4. Noncompliance with OSU policies, 42 CFR 11, and other requirements could result in corrective actions that may include reporting of noncompliance to the IRB.

### 5. Applicable Regulations, Guidances and Policies

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<th>Regulation/Guidance/Policy</th>
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<td>42 CFR 11</td>
<td>Clinical Trials Registration and Results Information Submission</td>
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<td>Center for Clinical and Translational Science (CCTS)</td>
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<td>Data Element Definitions for Interventional and Observational Studies</td>
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<td>NIH Policy on Clinical Trial Registration and Results Reporting</td>
<td>NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information</td>
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<td>Organization</td>
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<td>World Health Organization</td>
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<td>Elaboration of Definitions for FDAAA Section 801</td>
<td>[Elaboration of Definitions of Responsible Party &amp; Applicable Clinical Trial]</td>
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<td>[Office of Responsible Research Practices Guidance on Clinical Trial Registration]</td>
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