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| **Areas/Depts:** | *Research* |
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# Registration of Clinical Trials

## DEFINITIONS:

1. **Applicable Clinical Trial** (FDAAA 801 definition) is a trial that generally includes interventional studies (with one or more arms) of FDA-regulated drugs, biological products, or devices that meet one of the following conditions:
   a. the trial has one or more sites in the United States;
   b. the trial is conducted under a FDA investigational new drug application (IND) or investigational device exemption (IDE); or
   c. the trial involves a drug, biologic, or device that is manufactured in the United States or its territories and is exported for research.

   The following trials are generally excluded unless funded either in whole or in part by NIH:
   a. Non-serious/life-threatening Phase 1 drug trials, including studies in which drugs are used as research tools
   to explore biological phenomena or disease processes
   b. Small clinical trials to determine the feasibility of a device or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes
   c. Trials that do not include drugs, biologics, or devices (e.g., behavioral interventions)
   d. Non-interventional (observational) clinical research, such as cohort or case control studies
   e. Trials that were ongoing as of September 27, 2007, and reached the Completion Date before December 26, 2007
2. **ClinicalTrials.gov** is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world; service provided and maintained by the NIH.
3. **Clinical Trial (NIH definition)** is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
   a. "Prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

b. "Intervention" is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

c. "Health-related biomedical or behavioral outcome" is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

4. **Clinical Trial (ICMJE definition)** is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.
   a. Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes).
   b. Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.
5. **Ongoing Clinical Trial** is any Clinical Trial that has enrolled one or more subjects and the final subject has not been examined or received an intervention for the purpose of collecting data on the primary outcome.
6. **Primary Completion Date** is the date that the final participant is examined or receives an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concludes according to the pre-specified protocol or is terminated. In the case of clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all of the primary outcomes.
7. **Protocol Registration and Results System (PRS)** is a web-based data entry system used to register the clinical studies and submit results information for registered studies. Researchers must have a PRS account to register study information on ClinicalTrials.gov.
8. **Qualifying Clinical Trial** is a clinical trial qualified for coverage by the Center for Medicare and Medicaid Services (CMS) as specified in the "Medicare National Coverage Determination (NCD) Manual," Section 310.1.
9. **Record Verification Date** is the date on which the responsible party last verifies the clinical study information in the entire ClinicalTrials.gov record for the clinical study, even if no additional or updated information is being submitted.
10. **Responsible Party** refers to the entity or individual who is responsible for registering a clinical trial and submitting clinical trial information to the Clinical Trial Registry Data Bank, according to FDAAA 801.
11. **Study Completion Date** is date the final participant is examined or receives an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (for example, last participant's last visit), whether the clinical study concludes according to the pre-specified

protocol or is terminated.

# PURPOSE:

To promote consistency within OSF Healthcare System (OSF) in meeting the requirements for registering and reporting the results of clinical trials in ClinicalTrials.gov, the clinical trial registry and results data bank operated by the National Library of Medicine (NLM) of the National Institutes of Health (NIH).

# POLICY:

## Requirements

It is the policy of OSF that new or Ongoing Clinical Trials which meet any of the following criteria are registered on http://www.clinicaltrials.gov/ :

a. Applicable Clinical Trials (ACTs) as defined in the Department of Health and Human Services (HHS) regulation "Clinical Trial Registration and Results Information Submission", at 42 CFR Part 11.

b. Trials funded in whole or in part by the National Institutes of Health (NIH) that meet the clinical trial definition in the "NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information".

c. Trials that meet the clinical trial definition in the International Committee of Medical Journal Editors (ICMJE) clinical trial registration policy.

d. Qualifying Clinical Trials, as defined in the "Medicare National Coverage Determination (NCD) Manual," Section
310.1, which will render claims for items and services to the Center for Medicare and Medicaid Services (CMS).



## Responsibility

For each clinical trial subject to this Policy, OSF Principal Investigators (PIs) are responsible for:

a. ensuring the clinical trial is registered on ClinicalTrials.gov in a timely manner by the Responsible Party (Sponsor or PI);

b. reviewing the content of the clinical trial record posted on ClinicalTrials.gov for accuracy;

c. notifying the Responsible Party (Sponsor or PI) and the OSF Healthcare PRS Administrator of any inconsistencies and/or errors in the clinical trial record;

d. reviewing the clinical trial record to verify that required information is submitted timely; and

e. assisting the Responsible Party (Sponsor or PI) in reporting clinical trial results as appropriate.

## Oversight

1. To serve in the oversight capacity, OSF has appointed an Institutional PRS Administrator ("Administrator"). The Administrator assists Responsible Parties with:
    a. establishing user accounts and temporary passwords;
    b. resetting a password when the original is lost or forgotten;
    c. changing ownership of a study; or

d. transferring a study to another institution.

2. The Administrator monitors the system and notifies Responsible Parties when updates and/or problems are not addressed in a timely manner.
3. The Administrator offers basic training on the use of the PRS interface and assists with basic tasks of clinical trial registration.
4. The Administrator is not responsible for reviewing, editing, or verifying the accuracy of the clinical trial record posted on ClinicalTrials.gov.

# PROCESS:

## Identifying a Clinical Trial Needing Registration

Use the following criteria to assess a new or Ongoing Clinical Trial to determine whether it must be registered:

a. Clinical Trials funded either in whole, or in part by NIH. Apply this criteria to all NIH-funded studies independent of whether the study meets the definition of an Applicable Clinical Trial.
b. Clinical Trials that meet the clinical trial definition of The International Committee of Medical Journal Editors (ICMJE) that the investigator may wish to publish.
c. Qualifying Clinical Trials which will render claims for items and services to the Center for Medicare and Medicaid Services (CMS).
d. "Applicable Clinical Trials (ACT)" which include the following:
    i. Trials of Drugs/Biologics: Controlled, clinical investigations of a product subject to FDA regulations. This includes preliminary studies or phase I trials to be published in an ICMJE journal.
    ii. Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric post-market surveillance.
    iii. Applicable Clinical Trials generally include interventional studies (with one or more arms) of FDA regulated drugs, biological products, or devices that meet one of the following conditions:
        1. the trial has one or more sites in the U.S.;
        2. the trial is conducted under an FDA Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) application; or
        3. the trial involves a drug, biologic, or device that is manufactured in the U.S. or its territories and is exported for research.

## Determining the Responsible Party for Registering a Clinical Trial

1. The Responsible Party is either:
    a. The Sponsor of a clinical trial; or
    b. The PI of such clinical trial, if so designated by a sponsor, grantee, contractor, or awardee, so long as the PI is:
        i. responsible for conducting the trial;
        ii. has access and control over the data from the clinical trial;

iii. has the right to publish the results of the trial; and

iv. has the ability to meet all of the FDAAA's requirements for the submission of clinical trial information.

2. For clinical trials that are being performed at multiple institutions, the lead sponsor is responsible for registering the trial. If the OSF PI is not the lead sponsor, he or she works with the other investigators and sponsors to ensure that the trial is registered only once for the entire project.
3. For investigator-initiated trials, OSF delegates the responsibilities of the "Responsible Party" to the PI, who is designated as the "Sponsor."

## Registering a Clinical Trial

Clinical Trials subject to this policy are registered in ClinicalTrials.gov by the designated Responsible Party prior to enrollment of the first participant.

## Updating a Registered Clinical Trial

1. Once a trial is registered, registrations are updated regularly by the Responsible Party.
2. ClinicalTrials.gov notifies the Principal Investigator (PI) or designee account when trials are due for updates.
3. General updates to clinical trial registration information are made at the following times:
   a. Update the Primary Completion Date at least once every 12 months.
   b. Update clinical trial registration with any changes in recruitment status or to the estimated completion date within 30 calendar days.
   c. Update clinical trial registration with any changes in device approval status within 15 calendar days.
   d. Update clinical trial registration to correct errors, deficiencies, and/or inconsistencies within 15 calendar days of being informed of them by the Agency.
   e. Unless there have been no changes, update Record Verification Date at least every 6 months.
   f. Regardless of whether there are any changes, general updates to clinical trial registration information are made at least once per year.

## Submitting Results for a Registered Clinical Trial

Submit results for all registered clinical trials no later than 12 months after the Primary Completion Date.

- Update results reporting to correct errors, deficiencies, and/or inconsistencies to results within 25 calendar days of being informed of them by the Agency.

# REFERENCES:


1. Clinical Trials Registration and Results Information Submission. 42 CFR Part 11. (September 21, 2016). https://www.ecfr.gov/
2. National Institutes of Health (NIH) Policy on the Dissemination of NIH-Funded Clinical Trial Information. NOT-OD-16-149. (September 16, 2016). https://grants.nih.gov/
3. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) Manual. Routine Costs in Clinical Trials Section 310.1. https://www.cms.gov/

# HYPERLINKS:

1. https://prsinfo.clinicaltrials.gov/prs-users-guide.html
2. https://clinicaltrials.gov/ct2/manage-recs/faq
3. https://prsinfo.clinicaltrials.gov/definitions.html
4. https://www.gpo.gov/fdsys/pkg/FR-2016-09-21/pdf/2016-22379.pdf
5. http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/
6. https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/SE1344.pdf
7. ACT Wizard: http://grants.nih.gov/clinicaltrials_fdaaa/docs/Flow_chart-ACT_only.pdf

*This policy is in effect for OSF Healthcare System, OSF Healthcare Foundation and all OSF Healthcare System subsidiaries and affiliates, except as limited in the header or body of this policy. For purposes of this policy, the terms "subsidiaries" and "affiliates" mean facilities or entities wholly owned or wholly controlled by OSF Healthcare System. The hospitals covered by this policy are:*

| | | **Name as listed with Medicare:** |
|---|---|---|
| X | OSF St. Mary Medical Center | ST MARY MEDICAL CENTER |
| X | OSF Saint Francis Medical Center | SAINT FRANCIS MEDICAL CENTER |
| X | OSF Saint James – John W. Albrecht Medical Center | SAINT JAMES HOSPITAL |
| X | OSF St. Joseph Medical Center | ST JOSEPH MEDICAL CENTER |
| X | OSF Saint Anthony's Health Center | OSF HEALTHCARE SYSTEM |
| X | OSF Saint Anthony Medical Center | SAINT ANTHONY MEDICAL CENTER |
| X | OSF St. Francis Hospital & Medical Group | ST FRANCIS HOSPITAL |
| X | OSF Holy Family Medical Center | OSF HEALTHCARE SYSTEM |
| X | OSF Saint Elizabeth Medical Center | Ottawa Regional Hospital & Healthcare Center |
| X | OSF Saint Luke Medical Center | OSF HEALTHCARE SYSTEM |
| X | OSF Saint Paul Medical Center | Mendota Community Hospital |
| X | OSF Heart of Mary Medical Center | OSF HEALTHCARE SYSTEM |
| X | OSF Sacred Heart Medical Center | OSF HEALTHCARE SYSTEM |
| X | OSF Little Company of Mary Medical Center | OSF HEALTHCARE SYSTEM |
| X | OSF Saint Clare Medical Center | OSF HEALTHCARE SYSTEM |



## Attachments

No Attachments

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| Education/Communication Step | Stephanie Madrigal: Dir Clin Rsrch Admin/Ops | 5/25/2023 |
| Executive Steering Committee | Amy Olsen: Coord Clinical Policy RN [MT] | 5/25/2023 |
| President, OSF Healthcare | Sister Diane Marie: President-Sister | 5/10/2023 |
| System Chief Medical Officer | Ralph Velazquez: System CMO | 5/10/2023 |
| Regulatory/Policies Council | Michael Theisen: Resource Document Spec | 5/10/2023 |
| Executive Director, Research Administration | Stephanie Madrigal: Dir Clin Rsrch Admin/Ops | 5/1/2023 |
| Notification | Heidi Vermillion: Coord Research Admin | 5/1/2023 |