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, guidance, 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 LSU Health New Orleans, including the Health Sciences Center (HSC), the Stanley S. Scott Cancer Center (SSSCC) and the Healthcare Network (HN), hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research.

SOP 2.17 describes the process for the registration and results reporting of clinical trials to ClinicalTrials.gov.

2. RESPONSIBILITY

The HSC, SSSCC and HN Clinical Trials Offices develop, implement, and maintain 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)	Other Research Staff
Clinical Research Nurse Coordinator (CRNC)	Administrative and Support Staff

3. DEFINITIONS

Please refer to the SOP Glossary document for detailed definitions of commonly used clinical research terminology.

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.

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.

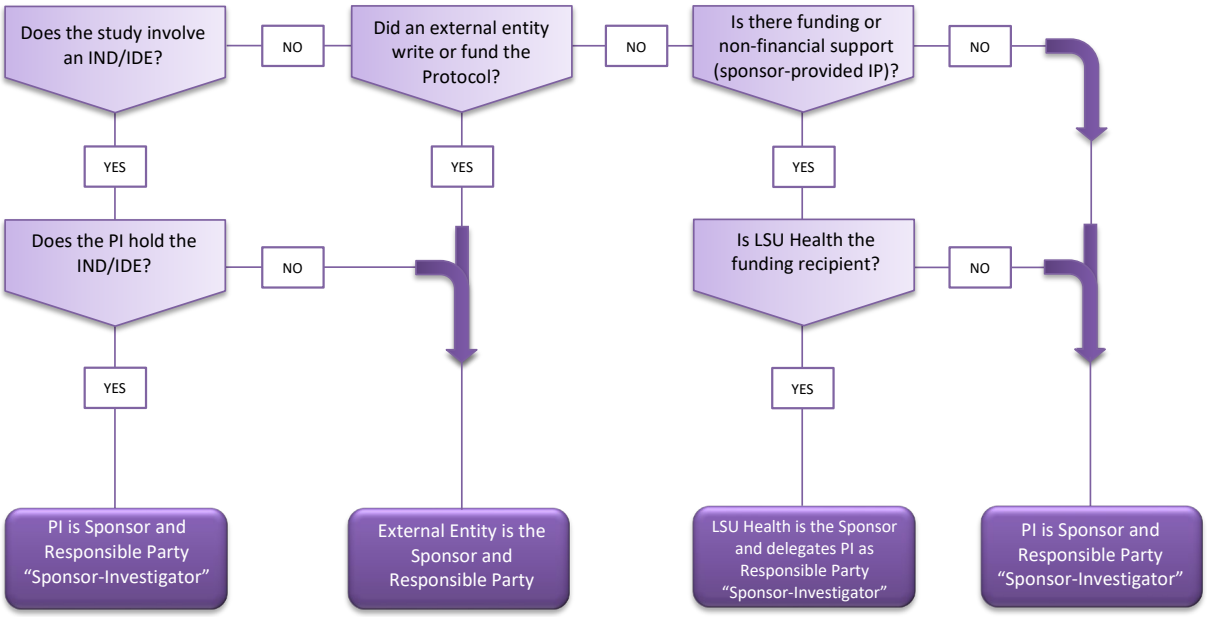
If the study was approved by OSU's Cancer IRB, the PI will be instructed to work with appropriately delegated ClinicalTrials.gov Administrator within the Comprehensive Cancer Center to ensure research studies are registered appropriately.

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

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 email 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(s)

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

Registration

Federal regulations require that registration be complete no later than 21 days after the first subject has been enrolled. ICMJE requires that registration be complete prior to the first subject's enrollment. A study is considered registered once the responsible party releases the record to PRS for review.

Actively Enrolling Studies

Every 6 months, the study registration should be updated and verified. Even if no changes are being made, the record must still be verified.

Studies Closed to Enrollment, Pending Results

Annually, the study registration should be updated and verified. Even if no changes are being made, the record must still be verified.

Change in the Study Status

Study registration must be updated within 30 days where there is a change in study status.

Posting the Clinical Trial Informed Consent Form

After the trial is closed to recruitment and no later than 60 days after the last study visit by any subject, one IRB-approved informed consent form must be posted.

Results Submission

Study Registration must be updated no later than 1 year after the primary completion date. Delayed submission of results is permitted in certain circumstances. See 42 CFR 11.44 for details.

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.

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 AND GUIDANCE

LSU Health Guidance/Policy	Title
LSUHSC HRP Policies & Procedures	4.07 Guidance on ClinicalTrials.gov Registration

LSUHSC Clinical Trials Office	Registration and Report of Clinical Trial Results

Federal/International Regulation/Guidance/Policy	Title
45 CFR 11	Clinical Trials Registration and Results Information Submission
45 CFR 46.116(h)	General Requirements for Informed Consent
ClinicalTrials.Gov	Data Element Definitions for Interventional and Observational Studies
NIH Policy on Clinical Trial Registration and Results Reporting	Policy on the Dissemination of NIH-Funded Clinical Trial Information
Food and Drug Administration Amendments Act (FDAAA) Section 801	Expanded Clinical Trial Registry Data Bank
Elaboration of Definitions for FDAAA Section 801	Elaboration of Definitions of Responsible Parties and Applicable Clinical Trials
Declaration of Helsinki	Ethical Principles for Medical Research Involving Human Subjects
World Health Organization (WHO)	International Clinical Trials Registry Platform (ICTRP)
International Committee of Medical Journal Editors	Clinical Trial Registration

6. MATERIALS

6.1. None

Approved by:

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