LSU HEALTH COORDINATOR COMPETENCIES

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PROTOCOL COMPLIANCE

ClinicalTrials.gov Registration & Result Submission Overview

Objectives

- Describe what ClinicalTrials.gov is
- Discuss how you should register your study (FDA, NIH & ICMJE)
- Identify FDA required informed consent language
- Identify who is responsible for registration (Responsible Party)
- Discuss results reporting requirements
- Describe how registration works at LSU Health New Orleans
- Identify Helpful Resources

What is ClinicalTrials.gov?

A publicly available registry and results database of federally and privately supported clinical trials conducted in the United States and around the world.

- Purpose: to **disclose to the public** key information about clinical trials that are currently available or were previously conducted.
- **Captures summary protocol information** before and during the trial, as well as **summary results and adverse event information** of a completed trial.

Federal laws, regulations and editors of prominent medical journals require registration of a clinical trial, as described below.

Definitions of a Clinical Trial

	Definition
FDA	• Controlled clinical investigations (other than phase 1 investigations) of any U.S. Food and Drug Administration (FDA)-regulated drug or biological product for any disease or condition • Certain studies of FDA-regulated medical devices, excluding small clinical trials to determine feasibility and certain clinical trials to test prototype devices, but including FDA-required pediatric post-market surveillances of a device product
NIH	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.
ICMJE	Any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome.

Registering a Study with ClinicalTrials.gov

All clinical trials, *including investigator-initiated trials*, must register on ClinicalTrials.gov to comply with federal FDA requirements outlined in FDA 42 CFR 11 (Final Rule) and/or other federal agencies and department's policy or requirements.

The information posted on ClinicalTrials.gov must be updated throughout the course of the trial, verified at least every 12 months, and the results must be provided when the study ends.

Important note: Even if your investigator-initiated clinical trial does not meet the NIH or FDA clinical trials registration requirements, you are strongly advised to read and consider registering your trial to comply with the following additional requirements:

- International Committee of Medical Journal Editors (ICMJE) for publications purposes
- Center for Medicare & Medicaid (CMS) for research billing claims for qualifying clinical trials
- Research funders now requiring registration and results reporting

Registering a Study with ClinicalTrials.gov

Required By:	Types of Studies:	When to Register
FDA	Studies that meet the definition of an "applicable clinical trial" and were initiated after 9/27/07, or initiated on/before that date and were ongoing as of 12/26/07	No later than 21 days after enrollment of the first participant
NIH	All NIH-funded clinical trials submitted for funding on or after 1/18/17	No later than 21 days after enrollment of the first participant
ICMJE	Clinical trials that plan to publish within medical journals	Must register at or before the time of first participant enrollment

Studies that fall under multiple registration requirements only need to be registered once.

ClinicalTrials.gov Informed Consent Language

[Include the following paragraphs if this is an applicable clinical trial of a drug, device, biologic or other product regulated by the FDA; otherwise delete.]

Public information about this study:

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

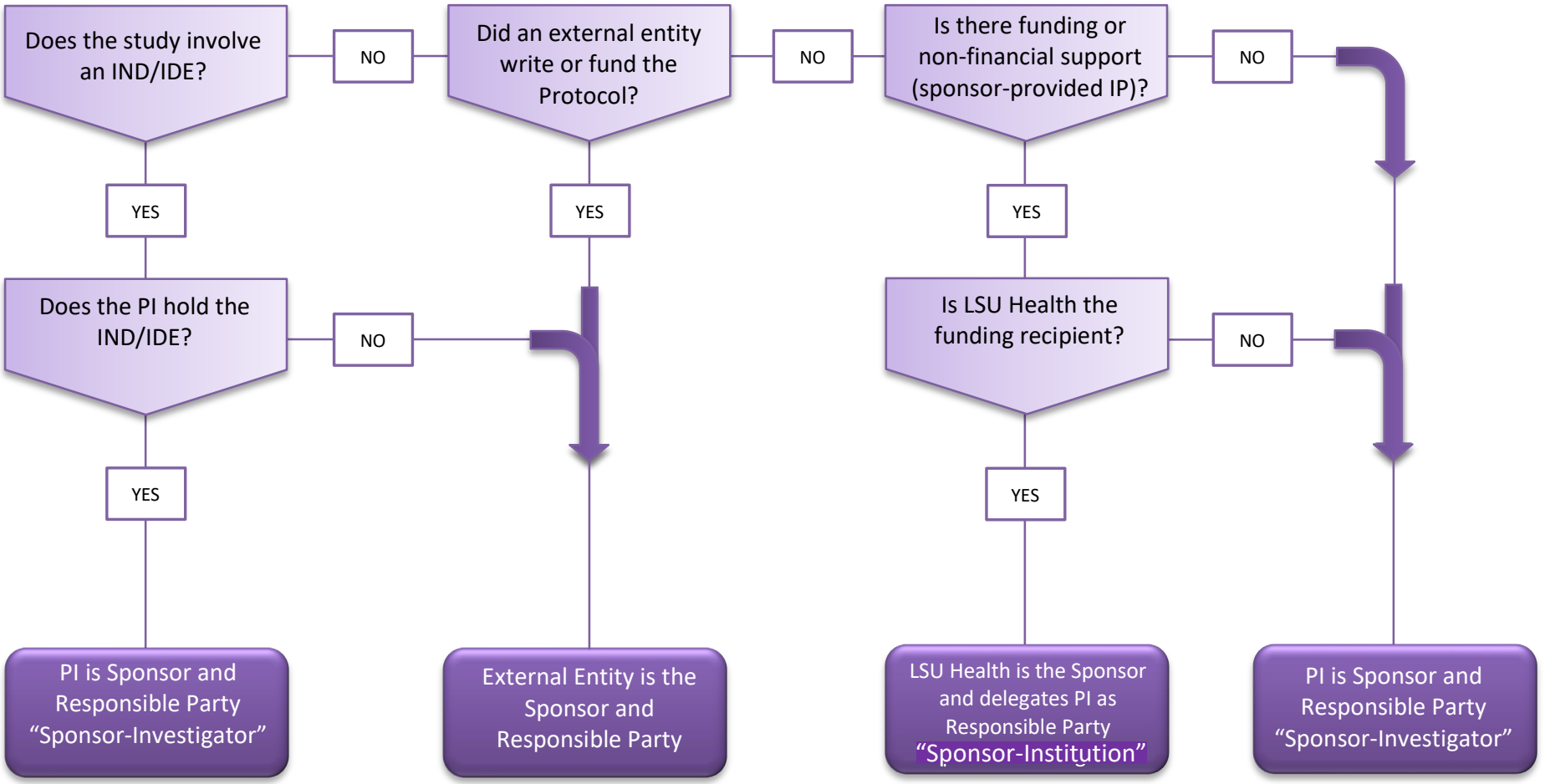
The National Clinical Trials number for this study is NCT .

Posting the Informed Consent on ClinicalTrials.gov

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.

- The form must be posted **after recruitment closes**, and **no later than 60 days after the last study visit**.
- Upload an IRB approved ICF in the Document section within the ClinicalTrials.gov record.
- *Contact the CTO when you are ready to upload your Consent to discuss the proper format.*

Responsible Party



LSU Health NEW ORLEANS
Office of Research Services

Timeline Requirements

Registration

- FDA & NIH - no later than 21 days after the first subject has been enrolled.
- ICMJE - Complete prior to the first subject's enrollment.

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.

Change in the Study Status

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

Timeline Requirements

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.

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.

Results Submission

- Must be updated no later than 1 year after the primary completion date. *Delayed submission of results is permitted in certain circumstances.*

Registration at LSU Health

1. **Obtain an Account**

Requests for a ClinicalTrials.gov account can be made by contacting the Clinical Trials Office.

2. **Create, Update and Maintain Study Records**

It is the responsibility of the PI and any delegated study team members to keep the ClinicalTrials.gov record up to date and to ensure all required submissions are made in the appropriate amount of time.

3. **Submit Results**

Resources

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

LSU Health Coordinator Competencies

- ✓ Onboarding
- ✓ Ethical Standards
- ✓ Protocol Compliance
- ❑ Informed Consent
- ❑ Patient Recruitment & Retention
- ❑ Management of Patients
- ❑ Documentation & Document Management
- ❑ Data Management & Information Technology
- ❑ Financial Stewardship
- ❑ Leadership & Professional Development