ClinicalTrials.gov Registration and Results Reporting Guidance for Sponsor-Investigators

Department: Office of Research Integrity and Compliance (ORIC)

Purpose

The purpose of this guidance document is to support standardized processes for the registration and results reporting of clinical trials on ClinicalTrials.gov.

ClinicalTrials.gov is an online clinical study registry and results database for participants, their families, health-care professionals, researchers, and the public to access information about research studies involving human volunteers.

Scope

The guidance applies to all Sponsor-Investigators and Principal Investigators (PI) serving as the responsible party for clinical studies conducted at the Stanley Manne Children's Research Institute at Ann & Robert H. Lurie Children's Hospital of Chicago. Clinical studies conducted under the oversight of the institution that meet criteria for registration and/or results reporting on ClinicalTrials.gov include but are not limited to:

- Applicable Clinical Trials (ACTs) subject to the 2007 Food and Drug Administration Administrative Amendments Act (FDAAA) requirements
- NIH-*funded* clinical trials subject to NIH policy on dissemination of clinical trial information
- Qualifying Clinical Trial (QCT) subject to Centers for Medicare and Medicaid Services (CMS) requirements for inclusion of a clinical trial identifier on billing claims, in accordance with Medicare National Coverage Determination (NCD) Manual Section 310.1 (Pub. 100-03)
- Clinical Trials subject to International Committee of Medical Journal Editors (ICMJE) requirements for trial registration, as outlined in *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals* (December 2016)

For additional resources in determining if a study meets registration and/or results reporting criteria, please refer to the "Policies, References, and Literature" and "Helpful Tools and Resources" sections at the end of this document.

Roles and Responsibilities

- **Responsible Party:** is the term used in Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA)(PL 110-85) to refer to the entity or individual who is responsible for registering a clinical investigation and submitting Clinical Trial Information to the Clinical Trial Registry Data Bank. As the responsible party, the Sponsor-Investigator or PI determines whether a study meets criteria for registration and/or results reporting in ClinicalTrials.gov. The responsible party is responsible for the accuracy, completeness,

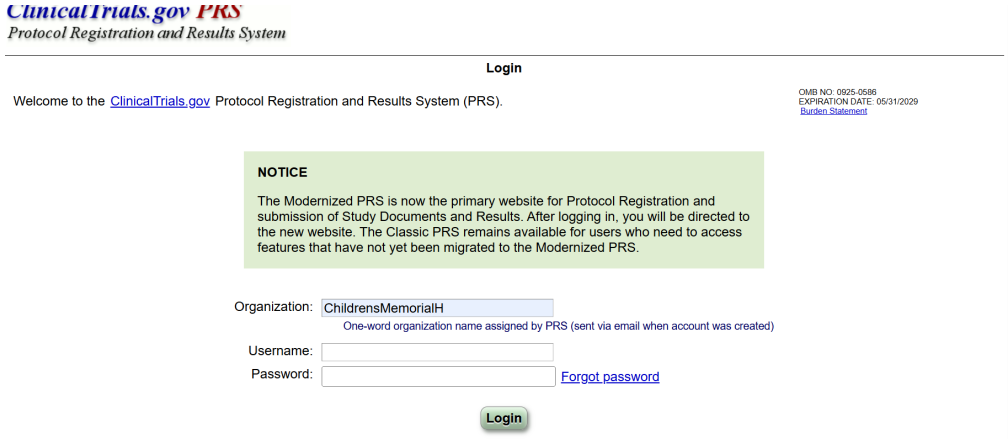
approval, and timely submission of all study records and requirements within ClinicalTrials.gov.

- **Record Owner:** individual that creates the study record in ClinicalTrials.gov. The Record Owner may be the responsible party or the responsible party's delegate.
- **Study Team (e.g. Study Coordinators, Clinical Research Managers, Research Nurse):** If delegated by the responsible party, the study team may be granted access to help prepare and maintain ClinicalTrials.gov registration records. This includes supporting data entry, tracking key study milestones and reporting deadlines, addressing comments and errors, and coordinating with stakeholders to ensure data accuracy and completeness.
- **Research Compliance Officer:** Serves as a liaison for escalations or complex compliance issues.
- **ORIC Director of Regulatory/Quality Assurance**: Serves as support for compliance program manager and serves as a first line for escalations or complex compliance issues.
- **ORIC Compliance Program Manager**: Provides guidance to the responsible party, the record owner, and/or delegates on clinical trial registration and reporting requirements. Conducts quality assurance reviews of records, as applicable. Monitors institutional compliance and identifies gaps or risks. Develops and delivers training and educational resources.
- **Data Management / Biostatisticians (if applicable):** Supports preparation of results data tables and analyses. Ensures consistency between reported results and statistical analysis plans. Assists in validating outcome measures and reported data.
- **Office of Clinical and Community Trials (OCCT):** Provides support in determining CMS requirements for qualifying clinical trials.

Accessing ClinicalTrials.gov

In order to register a study and enter information into ClinicalTrials.gov, the responsible party or their delegate will need a Protocol Registration System (PRS) user account. To request a PRS account, complete the PRS Account Request Form on the Research Regulatory and Quality Assurance Page. Once an account request is received, a PRS Administrator will review and provide unique login information.

With the login information, users can now access ClincialTrials.gov.

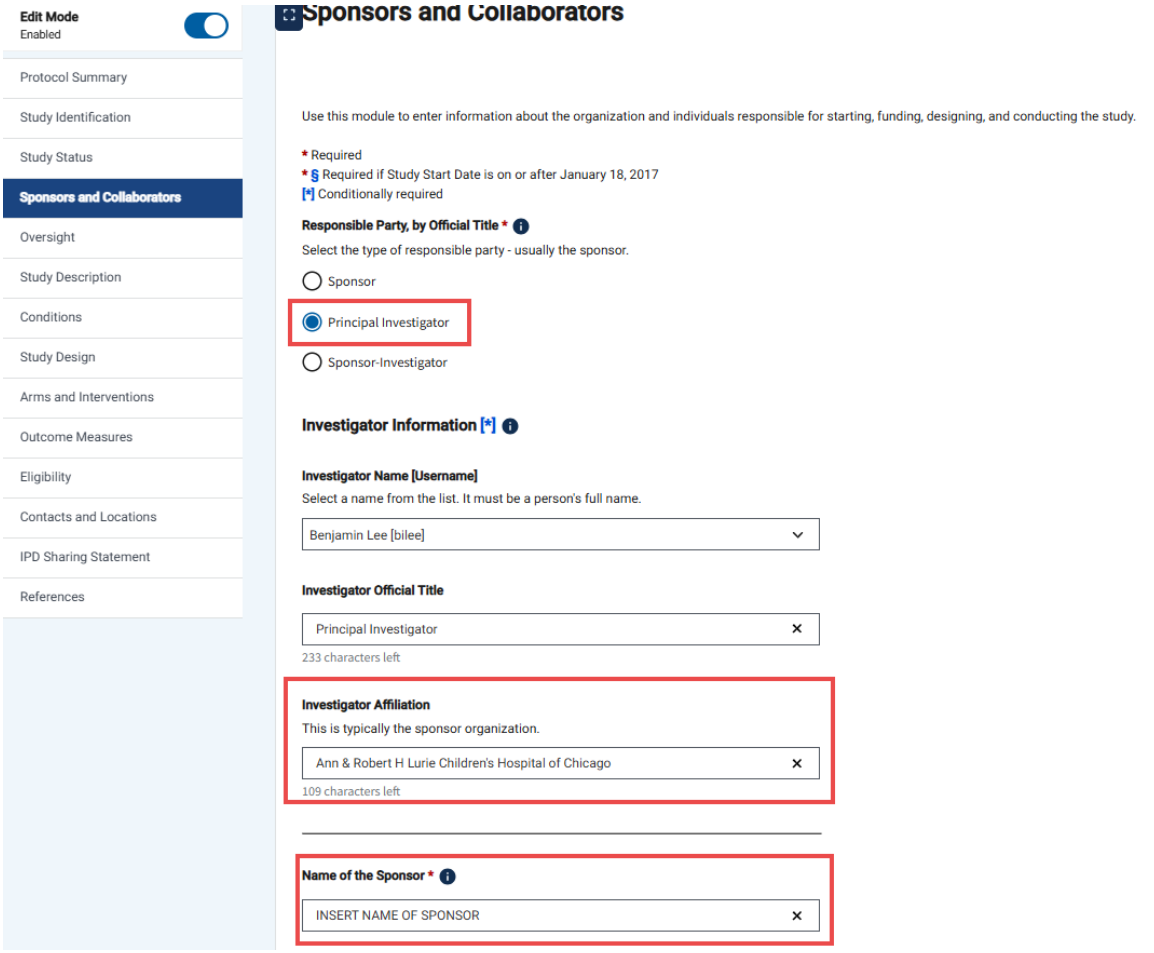


Responsible Party for a Registered Study

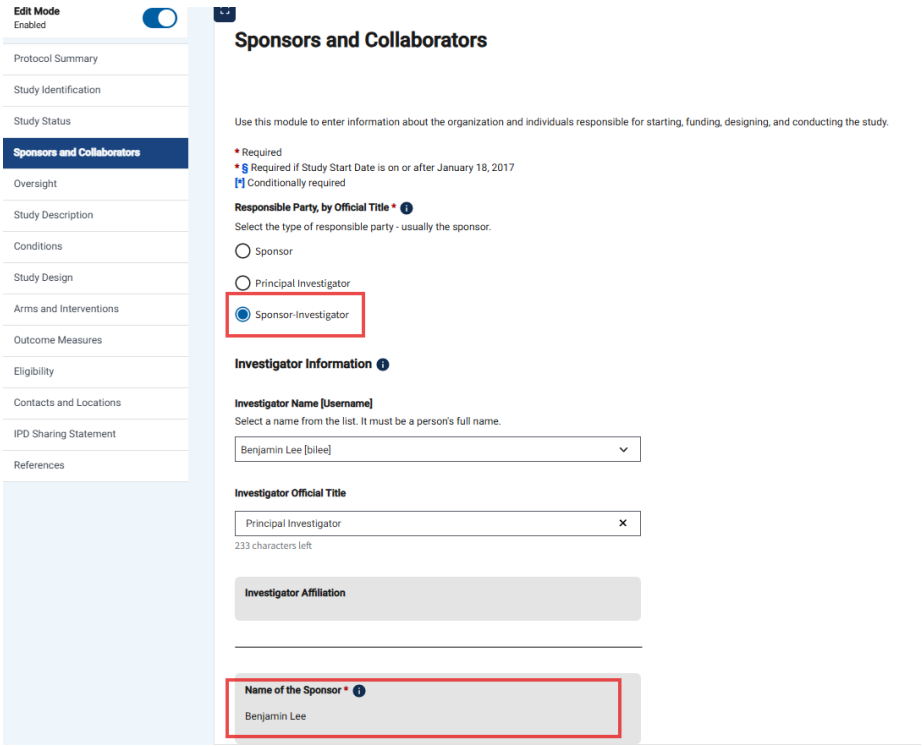
When registering a study in ClinicalTrials.gov, it is important to properly designate the responsible party. The responsible party oversees the accuracy, completeness, approval, and timely submission of all study records and requirements within ClinicalTrials.gov. There are two options that may be applicable to Lurie Children investigators.

- **Principal Investigator:** select when the PI is designated as responsible party by the sponsor. The sponsor may designate a PI as the responsible party if such PI meets all of the following requirements: is responsible for conducting the study; has access to and control over the data from the study; has the right to publish the results of the study; and has the ability to meet all of the requirements for submitting and updating clinical study information. During registration, the investigator's institutional affiliation and the overall sponsor of the protocol should also be completed.

  If a sponsor has delegated a PI as the responsible party, please reach out to Ctgov@luriechildrens.org to confirm appropriateness of this sponsor delegation.



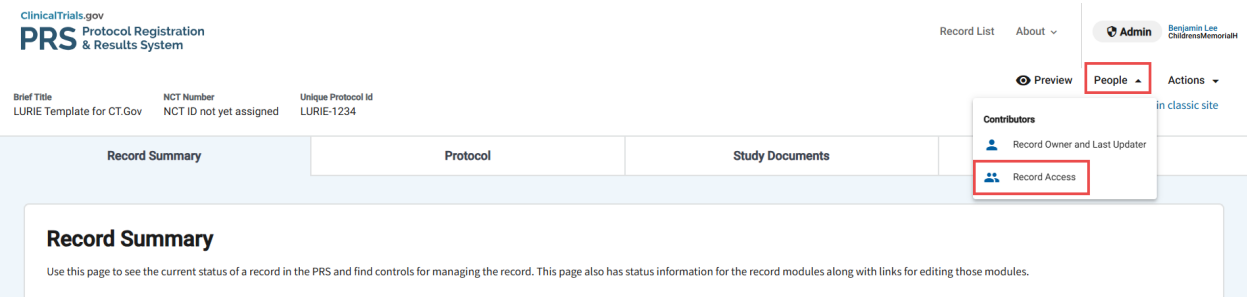
- **Sponsor-Investigator:** select when the PI both initiates and conducts the study. The PI serves as both sponsor and investigator. No additional fields need to be completed.



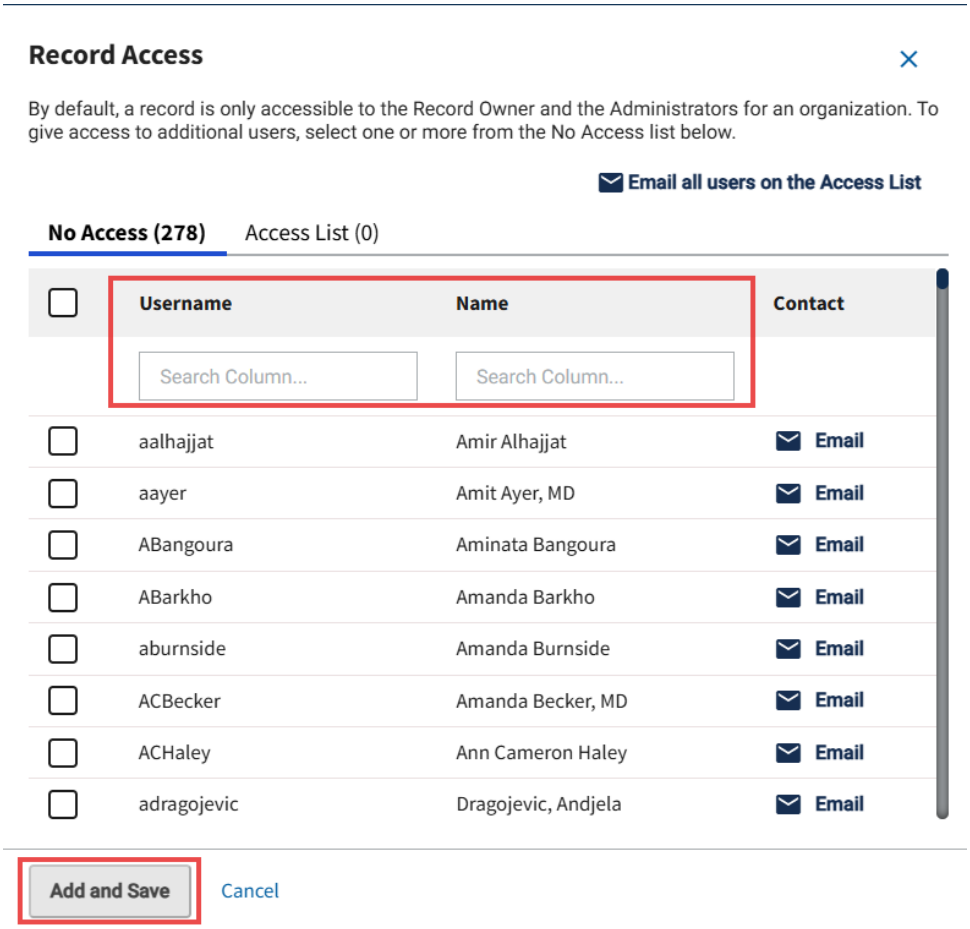
Record Access List

By default, a study record is only accessible to the Record Owner and the PRS Administrators for an organization. To give access to additional users follow these steps:

1) In the Record Summary, select **People** and then **Record Access**



2) A Record Access list will populate. The Record Owner may add users by searching for their username or Name. Once additional user access has been granted, select **Add and Save**.



3) Record Owner privileges may now be performed by a User who is delegated by the responsible party and on the record's Access List or by any Lurie Children's PRS Administrator.

Registration Requirements

For clinical trials subject to the NIH Policy and Final Rule, the responsible party or the responsible party's delegate must:

- Register the study on ClinicalTrials.gov no later than **21 days** after the first subject enrollment.
- Update registration information no less than **once every 12 months** with the understanding that certain information may be required to be updated more frequently.
- Complete an **Expanded Access registration** if an investigational drug product studied in an applicable drug clinical trial is available through an expanded access protocol.
    - For expanded access records, the responsible party who is both the manufacturer of the drug product and the sponsor of the trial should only create one expanded access record for each investigational drug product, however, multiple ACTs can be linked to the same record if they study the same product.
- CMS requires registration of QCTs **before** claims are submitted to Medicare. The National Clinical Trial (NCT) number must be included on claims for items and services provided in

clinical trials that are qualified for coverage. For more information on CMS requirements please refer to the "Policies, References, and Literature" section at the end of this document.

- ICMJE requires, and recommends that all medical journal editors require, registration of clinical trials in a public registry **at or before the time of first participant enrollment** as a condition of consideration for publication. The ICMJE accepts registration in any registry that is a primary register of the WHO International Clinical Trials Registry Platform (ICTRP) or ClinicalTrials.gov. For more information on ICMJE requirements please refer to the "Policies, References and Literature" section at the end of this document.

Study Maintenance Requirements

Study records within ClinicalTrials.gov must be updated at least once every 12 months even if no other updated information is submitted at the time. Other data elements that require more frequent updating include:

Table. Clinical Trial Registration Data Elements for More Frequent Updating

Data Element	**Deadline for Updating (i.e., not later than the specified date)**
Study Start Date	30 calendar days after the first subject is enrolled (if the first human subject was not enrolled at the time of registration).
Intervention Name(s)	30 calendar days after a nonproprietary name is established.
Availability of Expanded Access	30 calendar days after expanded access becomes available (if available after registration); and 30 calendar days after a National Clinical Trial number is assigned to a newly created expanded access record.
Expanded Access Status	30 calendar days after a change in the availability of expanded access.
Expanded Access Type	30 calendar days after a change in the type(s) of available expanded access.
Overall Recruitment Status	30 calendar days after a change in overall recruitment status.
Individual Site Status	30 calendar days after a change in status of any individual site.
Human Subjects Protection Review Board Status	30 calendar days after a change in status.
Primary Completion Date	30 calendar days after the clinical trial reaches its actual primary completion date.
Enrollment	At the time the primary completion date is changed to "actual," the actual number of participants enrolled must be submitted.

Study Completion Date	30 calendar days after the clinical trial reaches its actual study completion date.
Responsible Party, by Official Title	30 calendar days after a change in the responsible party or the official title of the responsible party.
Responsible Party Contact Information	30 calendar days after a change in the responsible party or the contact information for the responsible party.
Device Product Not Approved or Cleared by U.S. FDA	15 calendar days after a change in approval or clearance status has occurred.
Record Verification Date	Any time the responsible party reviews the complete set of submitted clinical trial information for accuracy and not less than every 12 months, even if no other updated information is submitted at that time.

Results Reporting Requirements

For clinical trials subject to the Final Rule and NIH Policy:

- Summary results for primary outcome measure(s) must be entered by the RP or their delegate **no later than twelve months after the study's Primary Completion Date.**
- Results for secondary outcome measures must be entered by the RP **one year after the date on which the final research participant is examined or receives intervention for the purposes of final collection for the secondary outcome measure.**
- Other information in the ClinicalTrials.gov record may be required to be updated more frequently, such as responding to required actions.

Data Entry

- For assistance on data entry in ClinicalTrials.gov, please refer to the linked PRS User Guides in "Helpful Tools and Resources" sections at the end of this document.

Change in Responsible Party

If there is a change in the RP for a study registered on ClinicalTrials.gov, the following steps should be completed prior to the change to ensure continued compliance:

- Notify ORIC at Ctgov@luriechildrens.org.
- Identify eligible new RP and ensure that the new RP accepts all associated responsibilities including study registration, maintenance, and results reporting requirements.
- Submit a modification via RASCAL documenting the change in study PI.
- Old RP or delegate to update the study record in the PRS ClinicalTrials.gov system to reflect the new RP.
- The new RP must review, approve, and release the updated study record in ClinicalTrials.gov to reflect the new changes.

Transfer of ClincialTrials.gov Records to Another Institution

When a clinical study is transferred to another institution, the RP must ensure that the ClinicalTrials.gov record is appropriately updated to reflect the change in oversight and maintain compliance with all applicable requirements. Study transfers do not change registration and reporting timelines.

For assistance with study transfers please reach out to ORIC and PRS Administrators at Ctgov@luriechildrens.org.

Notifications from ClinicalTrials.gov

ClinicalTrials.gov notifies record owners and responsible parties of issues through a combination of automated PRS system alerts and manual quality control review comments from National Library of Medicine (NLM) staff:

- **Notifications from ClinicalTrials.gov**
    - Automated PRS validation messages: As data are entered into the Protocol Registration and Results System (PRS), the system generates **Errors, Warnings, and Notes** to identify missing, inconsistent, or potentially incorrect information. Errors must be corrected before a record can be released for review, while warnings and notes should be evaluated because they may result in reviewer comments.
    - Email notifications: After a record is released for PRS review, NLM staff review it for apparent errors, deficiencies, or inconsistencies. If issues are identified, the Record Owner and Responsible Party receive an email directing them to log into PRS to review the comments.
    - PRS Review Comments: Reviewer feedback is available within the study record and is categorized as major comments (requiring corrections that must be addressed before the record can proceed through the review process) and advisory comments (recommendations to improve the clarity or completeness of the record)

Compliance and Monitoring

ORIC may conduct periodic reviews of ClinicalTrials.gov records to ensure compliance with applicable regulatory and institutional requirements, and to support continuous quality improvement efforts. The scope of the reviews may include but are not limited to, assessment of the timeliness of study registration, accuracy and completeness of records, submission and completion of results reporting, and responsiveness to ClinicalTrials.gov administrator quality control comments.

In the event that possible errors, deficiencies, inconsistencies, or potential noncompliance are identified, ORIC will implement the following remediation and escalation process:

- **Notifications of Upcoming Annual Deadlines**
    - ORIC will issue reminder notifications to the responsible party and delegates approximately 30 days prior to the ClinicalTrials.gov record update due date to support timely completion of required annual record updates.
- **Initial Notification of Errors, Deficiencies, or Inconsistencies**

    - Initial Notification will be sent to the responsible party and delegates on the study record's access list. The responsible party, delegates, and Clinical Operation Managers will be notified of any issues from CT.gov that have been flagged and reported and need correction in the study record(s). Applicable deadlines or regulatory expectations will be provided, and the responsible party must provide acknowledgement within 10 business days.
    - If no response is received following the initial notification, ORIC will send one follow up reminder. The follow up reminder is intended to serve as a courtesy notification and opportunity to resolve outstanding issues prior to formal escalation. The responsible party must provide acknowledgement within 5 business days of the follow up reminder.
    - Failure to respond or resolve the issue(s) within the requested timeframe may result in escalation to operational/administrative leadership.
- **Formal Warning**
    - If errors, deficiencies, and inconsistencies remain unresolved or repeated noncompliance is identified, ORIC may issue a formal warning to the responsible party.
    - ORIC may also require a written corrective and preventative action (CAPA) plan, mandatory retraining on Clinicaltrials.gov requirements, and increased monitoring of study records.
- **IRB Escalation**
    - Continued failure to address errors, deficiencies, inconsistencies, significant or repeated noncompliance, failure to submit required results information, or failure to respond to federal notices or institutional directives may be reported to institutional leadership and/or the IRB for further review and action.
    - The IRB or institutional officials may implement additional corrective ramifications including:
        - Suspension or restriction of study activities
        - Withholding of IRB approvals or continuing review approvals
        - Restrictions on submission and/or approval of new protocols
- **Federal Enforcement Considerations**
    - PIs and study teams are reminded that failure to comply with ClinicalTrials.gov requirements may result in federal regulatory enforcement actions including:
        - Civil monetary penalties
        - Withholding or loss of federal funding
        - Public posting of noncompliance determinations by federal agencies

Policies, References, and Literature

- **Lurie Children Clinical Trial Registration and Reporting Policy**
  Clinical Trials Registration and Reporting Policy.
- **Final Rule for Clinical Trials Registration and Results Information Submission**
  FDAA 42 CFR Part 11

- **Office for Human Research Protections**
  Revised Common Rule 42 CFR 46
- **NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information**
  NIH Policy NOT-OD-16-149
- **Basic Experimental Studies in Humans (BESH) Will No Longer Be Considered Clinical Trials by the NIH**
  NIH Policy NOT-OD-26-032
- **Implementation of Changes for Basic Experimental Studies with Humans**
  NIH Policy NOT-OD-26-067
- **Centers for Medicare and Medicaid Services**
  Medicare National Coverage Determination (NCD) Manual, Section 310.1-Pub. 100-03
- **ICMJE**
  Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (December 2016)

Helpful Tools and Resources

- Identifying an Applicable Clinical Trial under FDAA
- Checklist for Evaluating if your Study is an Applicable Clinical Trial
- Decision Tool: Does Your Human Subjects Study Meet the NIH Definition of a Clinical Trial? | Grants & Funding
- PRS Help Resources | ClinicalTrials.gov
- PRS User's Guide | ClinicalTrials.gov

VERSION/REVISION HISTORY:

The table below documents the version/revision history for this guidance document.

Approval Date	Version	Version/Revision Summary
9/23/2026	V1	