Clinical Trials.gov PRS

Protocol Registration and Results System

NIH Requirements for Clinical Trials Registration and Reporting Resources

To learn more about the topics in the NIH Requirements for Clinical Trials Registration and Reporting video, visit these resources:

 Good Clinical Practice Training: Find training options available to NIH-funded clinical investigators and clinical trial staff to meet the Good Clinical Practice training requirement. (Source: NIH Grants & Funding)

Related resource:

- Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials: Read the policy statement, background, and scope and applicability information, and find the effective date and contact information for inquiries about NOT-OD-16-148.
- Clinical Trial Requirements for Grants and Contracts: Find key resources and tips for applicants and grantees on a series of NIH initiatives to enhance the accountability and transparency of clinical trial research throughout the clinical trial life cycle, from concept to results reporting. (Source: NIH Grants & Funding)
- Clinical Trial-Specific Funding Opportunities: Learn about the requirement for applicants proposing clinical trials to submit their applications through a funding opportunity announcement (FOA) designated specifically for clinical trials. (Source: NIH Grants & Funding)

Related resources:

- Policy on Funding Opportunity Announcements (FOA) for Clinical Trials: Read about the purpose of these FOAs, and find the effective date and contact information for inquiries about NOT-OD-16-147.
- Update on Clinical Trial Funding Opportunity Announcement Policy: Read about updates to the clinical trial FOA policy, and find contact information for inquiries about NOT-OD-17-043.
- Posting Clinical Trial Informed Consent Forms: Learn about the requirement that clinical trials post informed consent documents to a public federal government website. (Source: NIH Grants & Funding)

Related resource:

 Guidance on Posting Informed Consent Forms for NIH-Funded Clinical Trials: Read about the purpose of this requirement, and find resources and contact information for inquiries about NOT-OD-19-110. Requirements for Registering & Reporting NIH-funded Clinical Trials in ClinicalTrials.gov: Find resources for understanding and complying with the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information and the federal regulations in FDAAA 801 as implemented by 42 CFR Part 11 (the Final Rule). (Source: NIH Grants & Funding)

Related resource:

- NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information: Read about the purpose of this policy, and find the effective date and contact information for inquiries about NOT-OD-16-149.
- Basic Experimental Studies Involving Humans (BESH): Find resources to help differentiate between a measurement and an intervention, learn about answering the four clinical trial questions for BESH, and more.

Related resource:

- Continued Extension of Certain Flexibilities for Prospective Basic Experimental Studies With Human Participants: Read about the purpose of this extension, and find the effective date and contact information for inquiries about NOT-OD-21-088.
- Does Your Human Subjects Research Study Meet the NIH Definition of a Clinical Trial?: Use a decision tool to determine whether your research study meets the NIH definition of a clinical trial.
- Final NIH Policy for Data Management and Sharing: Read about the purpose of this
 policy, and find the effective date, resources, and contact information for inquiries
 about NOT-OD-21-013.
- Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality: Read about the purpose, background, and scope and applicability of this policy, and find resources and contact information for inquiries about NOT-OD-17-109.
- Amendment: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research: Read about the purpose of this policy, its background, its scope and applicability, guidelines for reporting results of valid analyses on ClinicalTrials.gov, and related definitions, and find resources and contact information for inquiries about NOT-OD-18-014.
- Inclusion Across the Lifespan: Learn about the Inclusion Across the Lifespan policy and how to comply with it in applications and progress reports. (Source: NIH Grants & Funding)
- General Application Guide for NIH and Other PHS Agencies: Learn about the PHS Human Subjects and Clinical Trials Information form used to collect information on

human subjects research, clinical research, and/or clinical trials, including study population characteristics, protection and monitoring plans, and a protocol synopsis. This form accommodates the full spectrum of all types of clinical trials.

Related resource:

- Video tour of the Human Subjects and Clinical Trials Information Form: View a video walk-through of the form. (Source: NIH Grants & Funding)
- NIH Policy for Data and Safety Monitoring: Read about the policy, its background, principles of monitoring data and safety, and practical and implementation issues.

Related resource:

- Further Guidance on a Data and Safety Monitoring for Phase I and Phase II Trials: Read about this further guidance, its background, and the monitoring plan.
- Clinical Trials Frequently Asked Questions: Read about the multiple policies that have been put in place to enhance clinical trial stewardship and what these policies mean for you.
- How to Register Your Study: Review the steps for registering a clinical study on the ClinicalTrials.gov website. (Source: ClinicalTrials.gov)
- How to Submit Your Results: Learn about the ClinicalTrials.gov results database, and review the steps for submitting the results of a study to ClinicalTrials.gov. (Source: ClinicalTrials.gov)
- Human Subjects Research Home page: Find information about proposing and conducting NIH extramural research involving human subjects. Learn about the considerations related to human subjects research when planning and submitting a research application or contract proposal and throughout the extramural funding cycle. (Source: NIH Grants & Funding)