New NIH Guidelines for Human Subjects Research and Clinical Trial Requirements for Grants and Contracts

NIH is launching a series of initiatives that are rolling out in 2017-2018 to enhance the accountability and transparency of clinical research. These initiatives target key points along the whole clinical trial lifecycle from concept to results reporting. The following are links to useful information about these changes.

Clinical Trial Requirements for Grants and Contracts
https://grants.nih.gov/policy/clinical-trials.htm

Video Overview of new NIH policies on human subjects research

Clinical Trial Requirements for Grants and Contracts
https://grants.nih.gov/policy/clinical-trials.htm

Why Changes to Clinical Trial Policies?

Determine if your research meets the NIH definition of a clinical trial

NIH Definition of Clinical Trial Case Studies

Expect the case studies and related guidance to evolve over the upcoming year.

New Human Subjects and Clinical Trial Information Form

Clinical Trial-Specific Funding Opportunities
https://grants.nih.gov/policy/clinical-trials/specific-funding-opportunities.htm
Clinical Trial-Specific Review Criteria
https://grants.nih.gov/policy/clinical-trials/review-criteria.htm

Updated Appendix Policy

Clinical Trials Protocol Template

Single IRB Policy for Multi-site Research

Certificates of Confidentiality

Requirements for Registering & Reporting NIH-funded Clinical Trials in ClinicalTrials.gov

Good Clinical Practice Training

Steps to Compliance for NIH Awardees
https://grants.nih.gov/policy/clinical-trials/reporting/steps.htm

Frequently Asked Questions