NIH-funded Human Subjects Research/Clinical Trials and the Transition to Forms E

The National Institutes of Health (NIH) has instituted new requirements for studies involving clinical trials and human subjects, as well as new forms that go into effect for NIH applications with deadlines on or after January 25, 2018. To enhance the stewardship of research involving human subjects, NIH is implementing the following:

All Research Involving Human Human Participants	Research that Meets the NIH Definition of a Clinical Trial
New forms to collect human subjects Information	Training in Good Clinical Practice (GCP)
Use of a single Institutional Review Board (IRB) for multi- site studies	Clinical trial-specific Funding Opportunity Announcements (FOAS)
Certificates of confidentiality for all research That uses "indentifiable, sensitive information"	New review criteria
	Expanded registration and results Reporting in ClinicalTrials.gov

NIH Might Consider Your Human Subjects Research to be a Clinical Trial
Does your study…

- ✓ **Involve one or more human subjects?**
- ✓ **Prospectively assign human subjects(s) to interventions(s)**
- ✓ **Evaluate the effects of intervention(s) on the human subject(s)?**
- ✓ **Have a health-related biomedical or behavioral outcome?**

If "Yes" to ALL of these questions, your study is considered a clinical trial

Unsure how to answer the questions? NIH has a tool that can help

https://grants.nih.gov/ct-decision/index.htm

Two Short Videos to Explain the Changes

- Overview of New NIH Policies on Human Subjects Research - **15 Minute Video**
  - o Overview (3:37 minutes)
  - o Part I: Changes for All Research Involving Human Subjects (4:52 minutes)
  - o Part II: Changes for Clinical Trials (6:18 minutes)

- PHS Human Subjects and Clinical Trials Information Form Walk-through - **9 Minute Video**

NIH Resources

- Single IRB Policy for Multi-site Research - Frequently Asked Questions related to Grant Proposal Preparation https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm
- High-level Summary of Form Changes in FORMS-E Application Packages