Doing Human Subjects Research?

Changing NIH Policies May Impact You

Reforms & Initiatives

To enhance the stewardship of research involving human subjects, NIH is implementing the following:

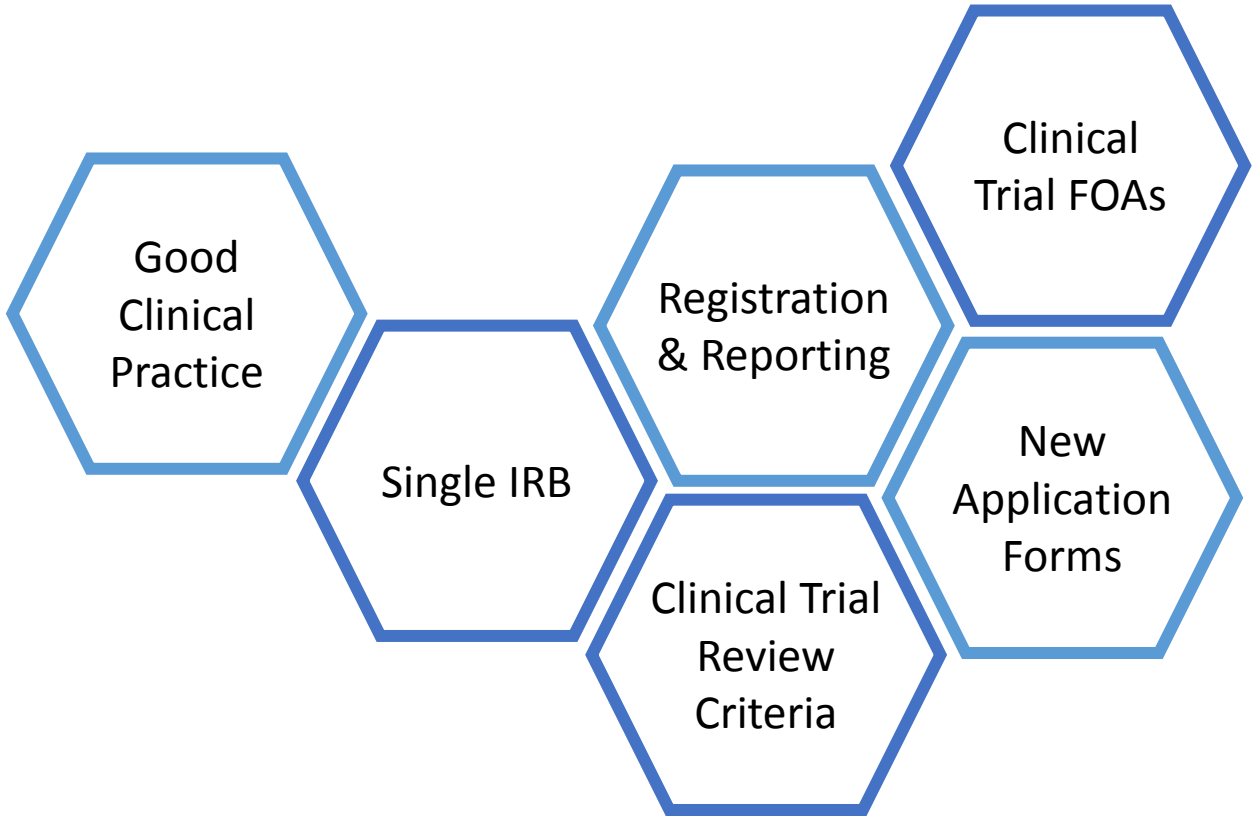
All Research Involving Human Participants

- ✓ New forms to collect human subjects information
- ✓ Use of a single Institutional Review Board (IRB) for multi-site studies
- ✓ Certificates of confidentiality for all research that uses “identifiable, sensitive information”

Research that Meets the NIH Definition of a Clinical Trial

- ✓ Training in Good Clinical Practice (GCP)
- ✓ Clinical trial-specific Funding Opportunity Announcements (FOAs)
- ✓ New review criteria
- ✓ Expanded registration and results reporting in ClinicalTrials.gov

NIH Initiatives to Enhance Clinical Trial Stewardship



Enhancing Clinical Trial Stewardship at NIH

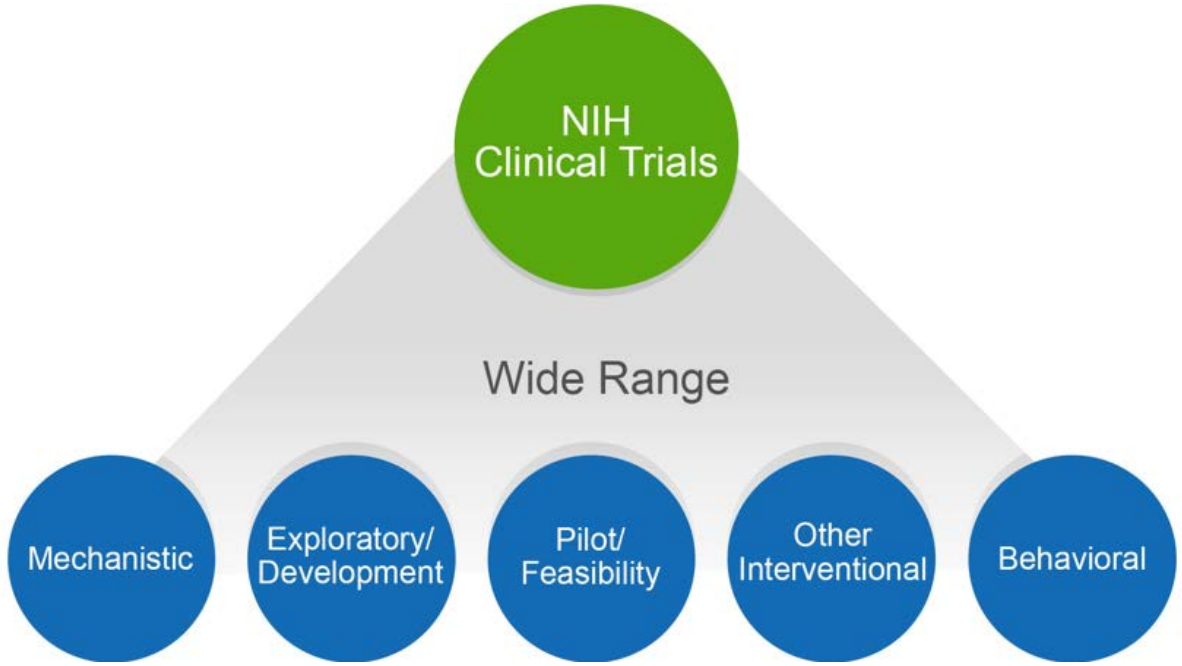
- ✓ Accountability
- ✓ Transparency
- ✓ Efficiency
- ✓ Dissemination

Learn more at https://grants.nih.gov/policy/clinical-trials.htm

NIH Might Consider Your Human Subjects Research to be a Clinical Trial

Does your study…

- ✓ Involve one or more **human subjects**?
- ✓ **Prospectively assign** human subject(s) to intervention(s)?
- ✓ Evaluate the **effect 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? We have a tool that can help! https://grants.nih.gov/ct-decision/

Identifying Whether NIH Considers Your Study to be a Clinical Trial is Crucial

It impacts whether you need to:

- ✓ Respond to a **clinical trial-specific FOA**
- ✓ Address additional **review criteria** specific for clinical trials
- ✓ **Register and report** your clinical trial in ClinicalTrials.gov

Identifying the Right Funding Opportunity Announcement (FOA) is Key

Due Dates on or after January 25, 2018	All clinical trial applications **MUST** be submitted to an FOA that allows clinical trials

How to determine if an FOA accepts clinical trials?

1. Refer to Section II. Award Information
2. Indicated in FOA title (new FOAs only)

Tip: Check your FOA at least 30 days before the due date for any updates

Good Clinical Practice (GCP) Training

Who: All NIH-funded investigators involved in the conduct, oversight or management of clinical trials

What: Investigators are expected to receive Good Clinical Practice training

Why: To assure the safety, integrity, and quality of clinical trials

How: Through a class or course, academic training program, or certification from a recognized clinical research professional organization

When: Effective January 2017. Training should be refreshed every 3 years

See https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm

Clinical Trial Specific Review Criteria

FOAs will include additional criteria:

Scored Review Criteria

- ✓ Significance
- ✓ Investigator
- ✓ Innovation
- ✓ Approach
- ✓ Environment

Additional Review Criteria

- ✓ Study Timeline & Milestones

Read the FOA carefully and be sure your application addresses the review criteria appropriately

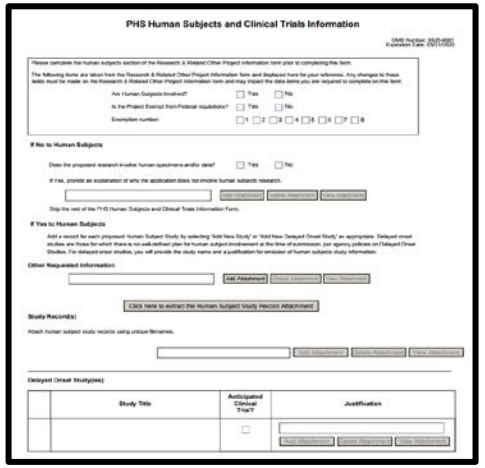
New Application Packages (FORMS-E)

Due Dates on or after January 25, 2018

FORMS-E Application Packages is **REQUIRED** (including new Human Subjects and Clinical Trials form)

PHS Human Subjects and Clinical Trials Information Form

- ✓ Consolidates information from multiple forms
- ✓ Incorporates structured data fields
- ✓ Collects information at the study-level



Be sure you are using the correct application forms for your due date.

FORMS-E will be available October 2017.

See https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm

Changes to the Appendix Policy

Due Dates on or after January 25, 2018

Since the new Human Subjects and Clinical Trials Information form collects key elements from the protocol, the **optional protocol submission will be removed from the Appendix Policy.**

Parent FOAs

- ✓ Will **NEVER** allow inclusion of the protocol in the application
- ✓ If the protocol is included, the application will be sent back

IC issued FOAs

- ✓ Protocols and other materials allowed only when specified as required in the FOA

See NIH Guide Notice: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-098.html

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

Who: All clinical trial applications requesting support for a trial that will be initiated on/after January 18, 2017

What: Register and report the results of trials in ClinicalTrials.gov

Why: Increase the availability of information about clinical trials and their results to the public in a timely manner

When: Effective for applications due on/after January 18, 2017

See https://grants.nih.gov/policy/clinical-trials/reporting/steps.htm

Single Institutional Review Board (sIRB) Policy for Multi-site Research

Domestic multi-site non-exempt human subjects research studies will require a single IRB of record

Key Dates

- **Grants:** Applications due on or after January 25, 2018
- **Contracts:** Solicitations published starting January 25, 2018

Exceptions

- sIRB not applicable for Career Development (K), Research Training (T), or Fellowship (F)

See https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm

Updated Certificates of Confidentiality (CoC) Policy

Effective October 1, 2017 - CoCs will be issued automatically for any NIH-funded project using identifiable, sensitive information that was on-going on/after December 13, 2016

- ✓ Eliminates the need for NIH funded investigators to apply for a CoC
- ✓ Enhances the privacy protections of individuals participating in NIH-funded research
- ✓ Requires investigators to only disclose information under specific circumstances
- ✓ Applies to NIH awards funded wholly, or in part, by NIH
- ✓ Disclosure restrictions also apply to anyone who receives a copy of identifiable sensitive information protected by the policy, even if they are not funded by NIH
- ✓ CoC is issued as a term and condition of award (no physical certificate)

Learn more at https://humansubjects.nih.gov/coc/index