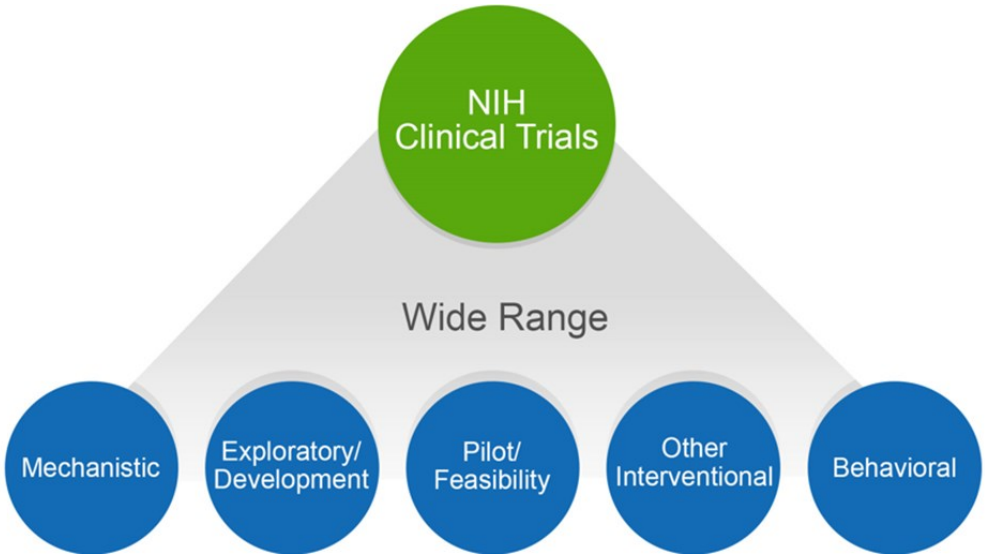
National Institutes of Health
Office of Extramural Research

Doing Human Subjects Research?

Changing NIH Policies May Impact You

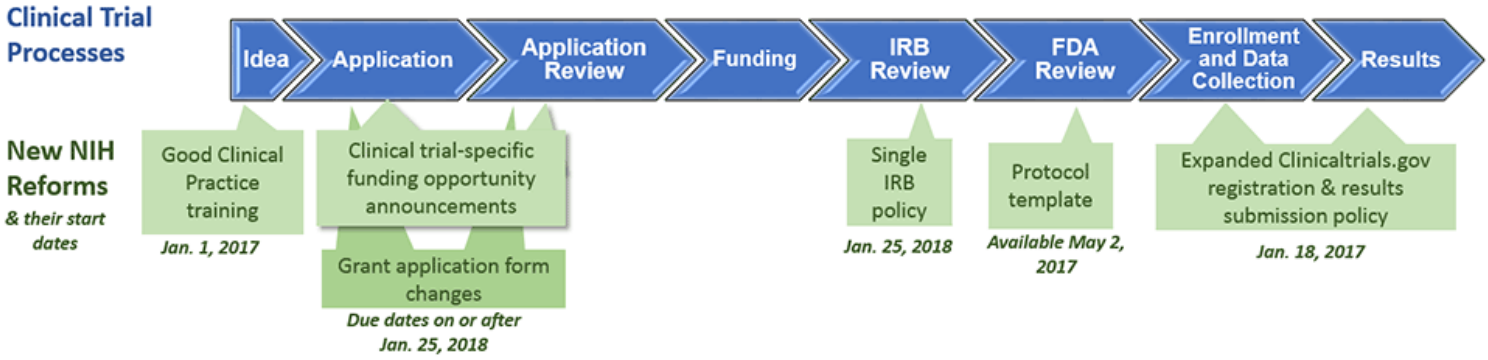


Does your study…

- ⇒ Involve one or more human subjects?
- ⇒ Prospectively assign human subjects to interventions?
- ⇒ Evaluate the effect of interventions on the human subjects?
- ⇒ 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/



Why Changes to Clinical Trial Policies?

To increase efficiency, accountability, and transparency of clinical trials throughout the lifespan of grant applications and contract proposals.

Good Clinical Practice Training

Effective January 1, 2017 NIH expects all NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP).

Clinical Trial-specific Funding Opportunities

Beginning for January 25, 2018 due dates, all applications proposing clinical trials must be submitted through a funding opportunity announcement (FOA) designated specifically for clinical trials.

New Human Subjects and Clinical Trial Information Form

A new Human Subjects and Clinical Trial Information form will be required for all human subjects and/or clinical trial research beginning for January 25, 2018 due dates. The new form will be included in FORMS-E application packages posted this fall.

Single IRB Policy for Multi-site Research

Do you conduct multi-site studies? The new policy requires use of single IRB for grant applications with due dates January 25, 2018 and beyond, and for contract solicitations published starting January 25, 2018.

Clinical Trials Protocol Template

If your application includes phase 2 or 3 clinical trials that require Investigational New Drug application (IND) or Investigational Device Exemption (IDE) applications, a NIH-FDA template with instructional and sample text can help you write your protocols. Use of this template is optional. Exemption (IDE) applications, a NIH-FDA template with instructional and sample text can help you in writing your protocols.

Clinicaltrials.gov Registration and Reporting

A new regulation and NIH policy has expanded Clinicaltrials.gov registration and reporting to all NIH-funded clinical trials.

Want more information?

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