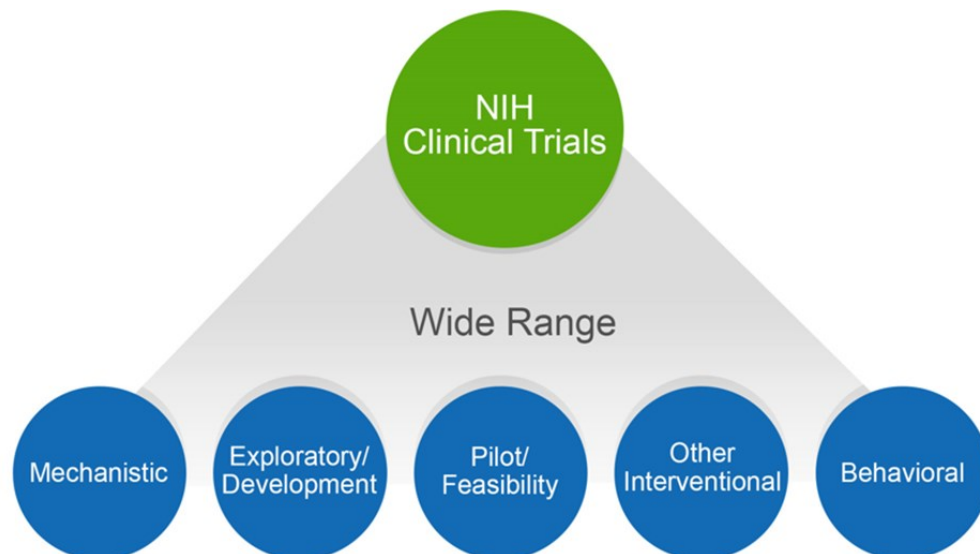




# Doing Human Subjects Research?

## Changing NIH Policies May Impact You



### Does your study...

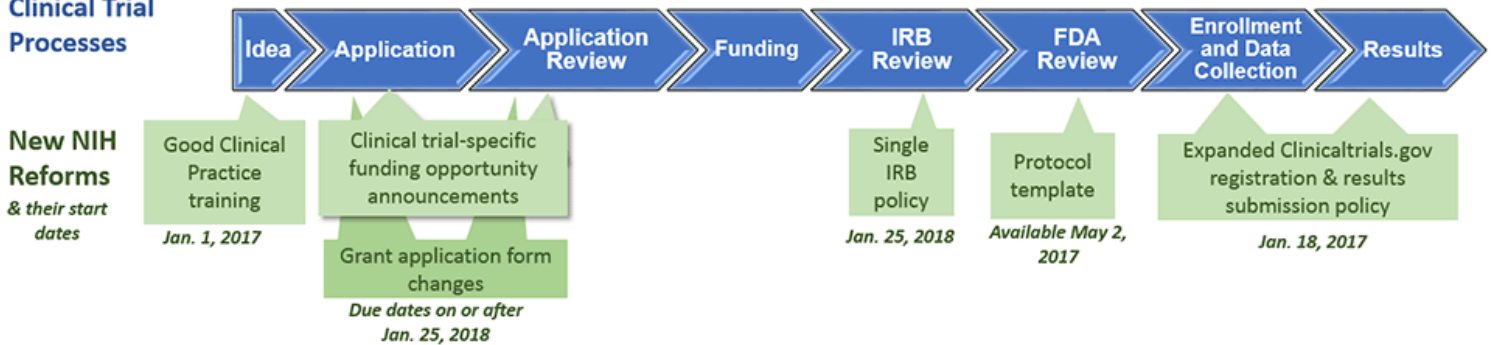
- ⇒ Involve one or more human subjects?
- ⇒ Prospectively assign human subjects to interventions?
- ⇒ Evaluate the effect of interventions on the human subjects?
- ⇒ Have a health-related biomedical or behavioral outcome?

**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/>

## Clinical Trial Processes



## 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>