Doing Human Subjects Research?

Changing NIH Policies May Impact You
NIH Initiatives to Enhance Clinical Trial Stewardship

- Good Clinical Practice
- Single IRB
- Registration & Reporting
- Clinical Trial Review Criteria
- Clinical Trial FOAs
- New Application Forms

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**?
- Involve one or more **interventions**?
- **Prospectively assign** human subject(s) to intervention(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/](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

<table>
<thead>
<tr>
<th><strong>Who:</strong></th>
<th>All NIH-funded investigators involved in the conduct, oversight or management of clinical trials</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What:</strong></td>
<td>Investigators are expected to receive Good Clinical Practice training</td>
</tr>
<tr>
<td><strong>Why:</strong></td>
<td>To assure the safety, integrity, and quality of clinical trials</td>
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<tr>
<td><strong>How:</strong></td>
<td>Through a class or course, academic training program, or certification from a recognized clinical research professional organization</td>
</tr>
<tr>
<td><strong>When:</strong></td>
<td>Effective January 2017. Training should be refreshed every 3 years</td>
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</tbody>
</table>

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.**

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

**Who:** All NIH-funded awardees and investigators conducting clinical trials

**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 January 2017

See [https://grants.nih.gov/policy/clinical-trials/reporting/steps.htm](https://grants.nih.gov/policy/clinical-trials/reporting/steps.htm)
Single Institutional Review Board (sIRB) Policy for Multi-site Research

Domestic multi-site clinical trials 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)