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

- Good Clinical Practice
- Single IRB
- Clinical Trial Review Criteria
- Registration & Reporting
- 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**?

✅ **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/](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>Who:</th>
<th>All NIH-funded investigators involved in the conduct, oversight or management of clinical trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>What:</td>
<td>Investigators are expected to receive Good Clinical Practice training</td>
</tr>
<tr>
<td>Why:</td>
<td>To assure the safety, integrity, and quality of clinical trials</td>
</tr>
<tr>
<td>How:</td>
<td>Through a class or course, academic training program, or certification from a recognized clinical research professional organization</td>
</tr>
<tr>
<td>When:</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.**

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

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)

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