NIH-funded Human Subjects Research/Clinical Trials and the Transition to Forms E

The National Institutes of Health (NIH) has instituted new requirements for studies involving clinical trials and human subjects, as well as new forms that go into effect for NIH applications with deadlines on or after January 25, 2018. To enhance the stewardship of research involving human subjects, NIH is implementing the following:

All Research Involving Human
Human Participants

<table>
<thead>
<tr>
<th>Research that Meets the NIH</th>
<th>Definition of a Clinical Trial</th>
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<tbody>
<tr>
<td>New forms to collect human subjects Information</td>
<td>Training in Good Clinical Practice (GCP)</td>
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</table>

Use of a single Institutional Review Board (IRB) for multi-site studies

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<td>Clinical trial-specific Funding Opportunity Announcements (FOAS)</td>
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Certificates of confidentiality for all research That uses “indentifiable, sensitive information”

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<tr>
<td>New review criteria</td>
<td>Expanded registration and results Reporting in ClinicalTrials.gov</td>
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NIH Might Consider Your Human Subjects Research to be a Clinical Trial

Does your study…

✓ Involve one or more human subjects?
✓ Prospectively assign human subjects(s) to interventions(s)
✓ Evaluate the effects 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? NIH has a tool that can help


Two Short Videos to Explain the Changes

- Overview of New NIH Policies on Human Subjects Research - 15 Minute Video
  - Overview (3:37 minutes)
  - Part I: Changes for All Research Involving Human Subjects (4:52 minutes)
  - Part II: Changes for Clinical Trials (6:18 minutes)

- PHS Human Subjects and Clinical Trials Information Form Walk-through - 9 Minute Video

NIH Resources

- High-level Summary of Form Changes in FORMS-E Application Packages