NIH Clinical Trial Initiatives: How it Impacts NLM Data Science and Biomedical Informatics Research

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**Overview**

To enhance the stewardship of research involving human subjects, NIH is implementing the following:

<table>
<thead>
<tr>
<th>All Research Involving Human participants</th>
<th>Research that Meets NIH Definition of a Clinical Trial</th>
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</thead>
<tbody>
<tr>
<td>✓ New human subject information forms</td>
<td>✓ Training in Good Clinical Practice (GCP)</td>
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<tr>
<td>✓ Single IRB for multi-site studies</td>
<td>✓ Clinical trial specific FOAs</td>
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<tr>
<td>✓ Certificates of confidentiality for all research that uses “identifiable, sensitive info”</td>
<td>✓ New review criteria</td>
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<td></td>
<td>✓ Expanded registration and reporting in ClinicalTrials.gov</td>
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Why are changes being made?

Ensure public trust in...

Scientific rigor
Transparency
Ethical oversight
NIH stewardship of public funds
Changes for All human subject research

New PHS Human Subjects and Clinical Trials Information Form

✓ FORMS-E Application Package is required for due dates on or after January 25, 2018

✓ Consolidates human subject data that used to be spread over several forms

✓ Collects information at the study level and incorporates new structured data fields
Changes for All Human Subject Research

Single IRB for multi-site research involving human participants

✓ Applies to grant applications with due dates on or after January 25, 2018.
All human subject research that involves multiple sites will require a single Institutional Review Board to be used in the ethical review of non-exempt human subjects research protocols funded by NIH. The goal is to streamline the IRB process and enable IRBs to concentrate their efforts on the review of single site protocols.
Changes for All human subject research

Certificates of Confidentiality

These certificates are designed to protect research participants by limiting the disclosure of identifiable, sensitive information.

In the past there was a process for obtaining these certificates. **Beginning October 1, 2017** all NIH funded research that collects identifiable, sensitive information and began or was ongoing on or after December 13, 2016 is considered to have been issued a certificate of confidentiality as part of the terms of award.
Changes that apply to clinical trials research

- Training in Good Clinical Practice (GCP)
- Clinical trial Specific FOAs
- New review criteria
- Expanded registration and reporting in ClinicalTrials.gov
Is my study a clinical trial?

NIH Definition of a Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
Is my study a clinical trial?

1. Does the study involve human subjects?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on participants?
4. Is the effect that will be evaluated health-related biomedical or behavioral outcome?

FAQs and Case Studies available to help applicants decide
Is my study a clinical trial?

1. Does the study involve human subjects? Yes
2. Are the participants prospectively assigned to an intervention? Yes
3. Is the study designed to evaluate the effect of the intervention on participants? Yes
4. Is the effect that will be evaluated health-related biomedical or behavioral outcome? Yes

If ALL 4 answers are YES then your study is considered a clinical trial

FAQs and Case Studies available to help applicants decide
Good Clinical Practice (GCP) Training

✓ All NIH – funded investigators involved in the conduct, oversight or management of clinical trials must receive Good Clinical Practice training

✓ The goal is to ensure the safety, integrity, and quality of clinical trials

✓ Policy is effective January 1, 2017. Training should be refreshed every 3 years
All clinical trials MUST be submitted to a funding opportunity announcement that allows clinical trials

**Beginning January 25, 2018**
All clinical trials MUST be submitted to a funding opportunity announcement that allows clinical trials

Review the Related Notices in the Funding Opportunity Announcement
Clinical trial review criteria

FOAs will include additional criteria:

**Scored Review Criteria**
- Significance
- Investigator
- Innovation
- Approach
- Environment

**Additional review Criteria**
- Study Timeline
Registering and reporting results on Clinical Trials.gov

<table>
<thead>
<tr>
<th>WHO</th>
<th>All clinical trial applications requesting support for a trial that will be initiated on/after January 18, 2017</th>
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<tbody>
<tr>
<td>WHAT</td>
<td>Register and report the results of trials in ClinicalTrials.gov</td>
</tr>
<tr>
<td>WHY</td>
<td>Increase the availability of information about clinical trials and their results to the public in a timely manner</td>
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</table>
Registering and reporting results on Clinical Trials.gov

In order to comply with the NIH Policy on Clinical Trial Dissemination, awardees must:

- Submit a statement in the application that outlines a plan to comply with the expectations of the policy
- Register the clinical trial no later than 21 days after enrolling the first participant
- Update the trial with submitted information at least once a year
- Submit summary results no later than one year after primary completion date
The study involves the recruitment of research participants suspected to have disease X. It is designed to compare the ability of 2 different widely used algorithms for digitally detecting tumors. A will be used in half of the patients; B will be used in the other half.
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The study involves the recruitment of research participants suspected to have disease X. It is designed to compare the ability of 2 different widely used algorithms for digitally detecting tumors. A will be used in half of the patients; B will be used in the other half.

1. **Does the study involve human participants?** Yes, the study involves human participants.

2. **Are the participants prospectively assigned to an intervention?** No, not in this context. The study is not intended to assess how the choice of detection algorithm modifies a health related biomedical or behavioral outcome.

**X This study is not a clinical trial.**
Case Studies for determining whether a study is a clinical trial

The study involves the recruitment of research participants suspected to have disease X. It is designed to compare the ability of 2 different widely used algorithms for digitally detecting tumors and inform the management of clinical outcomes. A will be used in half of the patients; B will be used in the other half.
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2. **Are the participants prospectively assigned to an intervention?** Yes, the participants are prospectively assigned to receive an intervention, one of two diagnostic devices.
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3. **Is the study designed to evaluate the effect of the intervention on the participants?** Yes, the study is designed to evaluate the ability of the algorithms to diagnose disease X, and in that way to inform diagnosis and clinical management.
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2. **Are the participants prospectively assigned to an intervention?** Yes, the participants are prospectively assigned to receive an intervention, one of two diagnostic devices.

3. **Is the study designed to evaluate the effect of the intervention on the participants?** Yes, the study is designed to evaluate the ability of the two commercially available devices to diagnose disease X, and in that way to inform diagnosis and clinical management.

4. **Is the effect being evaluated a health-related biomedical or behavioral outcome?** Yes, the effect being evaluated, the extent to which providing specific information to physicians informs the treatment of patients, is a health-related outcome.

+ This study is a clinical trial.
Case Studies for determining whether a study is a clinical trial

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Case Studies for determining whether a study is a clinical trial


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1. **Does the study involve human participants?** Yes, the visitors to the library are human participants.

2. **Are the participants prospectively assigned to an intervention?** No, not in this context. The study is not designed to determine whether the two announcements modify a health-related behavioral or biomedical outcome.

**X This study is not a clinical trial.**
The study involves randomizing individuals to different processes for informed consent. It is designed to assess the effectiveness of interactive and multimedia components in enhancing participants’ understanding of the study’s purpose and procedures.
Case Studies for determining whether a study is a clinical trial

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2. **Are the participants prospectively assigned to an intervention?** Yes, the participants are prospectively assigned to an intervention, different consent processes.

3. **Is the study designed to evaluate the effect of the intervention on the participants?** Yes, the study is designed to evaluate the effect of different informed consent processes on understanding the study.

4. **Is the effect being evaluated a health-related biomedical or behavioral outcome?** Yes, enhanced comprehension of information is a health-related behavioral outcome.

+ This study is a clinical trial
Follow-up Actions

✓ Read the Funding Opportunity Announcements and the instructions very carefully
✓ Start the application process early
✓ Understand how these new policies will affect your application and award

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Pick up a copy of the links to more information