New NIH Forms-E and the Clinical Trial Identifier on FOAs

SMART Meeting
Sonia Barragan, Associate Director
Research Management Group
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New NIH Forms-E Grant Application Forms

• Forms-E: Use for NIH application deadlines on or after Jan 25, 2018.

• Forms-D: Use for application deadlines prior to Jan 25, 2018.

• Question: If my proposal has an NIH due date of January 25, 2018 but I plan to complete my proposal by Dec 18, 2017, before winter break, what forms package will be required?

  – The required forms package is determined by the application deadline and not by the application submission date. Forms-E will be required because the sponsor’s deadline is on or after Jan 25, 2018.
What New In Forms-E?

• Text has been edited to add clarity.

• Fields have been renumbered.

• The human subjects section and following attachments
  • Protection of Human Subjects
  • Data Safety Monitoring Plan
  • Inclusion of Women and Minorities
  • Inclusion of Children

has moved to a new section called the

**Human Subjects and Clinical Trials Information Form.**

⭐ Watch 9 min You Tube video: [PHS Human Subjects and Clinical Trial Information Form Walk-through](#)
Decision Tree for NIH Clinical Trial Definition

1. Does the study involve human participants research?
   - YES: Proceed to step 2.
   - NO: The study is NOT a clinical trial.

2. Are participants prospectively assigned to an intervention?
   - YES: Proceed to step 3.
   - NO: The study is NOT a clinical trial.

3. Is the study designed to evaluate the effect of the intervention on the participants?
   - YES: Proceed to step 4.
   - NO: The study is NOT a clinical trial.

4. Is the effect being evaluated a health-related biomedical or behavioral outcome?
   - YES: This study is a clinical trial.
   - NO: The study is NOT a clinical trial.
Application Instructions Available:


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<tr>
<th>Application Form Instructions</th>
<th>Description</th>
<th>SF424 (R&amp;R) - Version D</th>
<th>SF424 (R&amp;R) - Version E</th>
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<tr>
<td><strong>Application Instructions</strong></td>
<td></td>
<td>Use for due dates on and before January 24, 2018</td>
<td>Use for due dates on and after January 25, 2018</td>
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<tr>
<td>General Instructions</td>
<td>Comprehensive guidance for research, training, fellowship, career development, multi-project, and small business applications</td>
<td>HTML / PDF</td>
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<td><strong>Filtered Application Instructions</strong></td>
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Funding Opportunity Announcements (FOA)

How will NIH differentiate FOAs that support clinical trials from those that do not?

- Look at the title of the FOA. Imbedded in the title you will find:
  - Clinical Trial Optional
    - or -
  - Clinical Trial Not Allowed
Examples of FOAs

• **PA-17-487** New Onset Depressive Symptoms in Acute Illness (R21 Clinical Trial Not Allowed)

• **RFA-DK-17-016** Lymphatics in Health and Disease in the Digestive System (R01- Clinical Trials Not Allowed)

• **RFA-AG-18-013** Continuation of the AMP-AD Target Discovery and Preclinical Validation Consortium (U01 Clinical Trial Optional)

• **PA-17-492** Addressing Chronic Wound Trajectories Through Social Genomics Research (R01- Clinical Trial Optional)
How to prepare for these changes?

- If the project involves human subjects research, use decision tree to determine whether study meets the NIH definition of a clinical trial.

- These case studies may be helpful in determining whether CT = Yes.

- If CT = Yes, make sure the FOA to which the PI is responding supports clinical trials.

- If CT=Yes, make sure researchers on the study complete GCP training before the award arrives.
  - CITI - Group 7 for medical research or
  - CITI - Group 2 for non-medical researchers.