NIH “Forms E” Changes for Human Subject and/or Clinical Trial Applications

Attached are the Forms E application pages with the most significant changes (pages 11-16). Many of the new fields require a short answer, rather than an attached document. This information will be needed from the PI in order to complete the application. Helpful information about the field is included in the blue boxes. Forms E is used for applications submitted with due dates on or after January 25, 2018.

Page 11:
Additional questions if “No” is answered to involvement of human subjects. Additional attachment required if using human specimens and/or data.

If “Yes” to human subjects, additional attachment(s) may be required for delayed onset studies including human subject study records. Here is the first place that Clinical Trial is checked and correct FOA must be used. Moving forward FOAs will distinguish between CT accepted, excluded, or optional.

Page 12:
This page is included in applications that accept clinical trials. Notice in section 1.4 that you answer all four of the questions to determine if this is a clinical trial. A NIH decision tree can be found at https://grants.nih.gov/ct-decision/index.htm and this should be determined early in your decision process to submit an application.

Section 2 covers Study Population Characteristics. New questions and attachments for inclusion and recruitment are covered here.

Note the F and K application notes about clinical trials at the bottom of the page.

Page 13:
This is the new Inclusion Enrollment Report for Planned Enrollment and only rows and columns applicable can be filled (does not include unknown). Foreign locations are listed by country.

Page 14:
This is the new Inclusion Enrollment Report for Cumulative (Actual) Enrollment and only rows and columns applicable can be used (includes unknown).

Pages 15-16:
Section 3 Protection and Monitoring Plans. New questions about multi-site, single IRB protocols and appointments of DSMB boards.

Section 4 Protocol Synopsis for Clinical Trials only. These fields are mainly short description and drop-down lists that will be needed to complete the CT application. Please familiarize yourself with these requirements if you are planning to submit a CT application.
Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved?  
☐ Yes  ☐ No

Is the Project Exempt from Federal regulations?  
☐ Yes  ☐ No

Exemption number:  
1  2  3  4  5  6  7  8

If No to Human Subjects

Does the proposed research involve human specimens and/or data?  
☐ Yes  ☐ No

If Yes, provide an explanation of why the application does not involve human subjects research.

Add Attachment  Delete Attachment  View Attachment

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

If Yes to Human Subjects

Add a record for each proposed Human Subject Study by selecting 'Add New Study' or 'Add New Delayed Onset Study' as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

Other Requested Information

Check Application Guide and opportunity instructions to determine if attachment is needed.

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1

Delayed Onset Study(ies)

Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.

Multiple delayed onset studies can be grouped in a single record.

Study Title  Anticipated Clinical Trial?  Justification

Required and system enforced for each delayed onset study. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

If Anticipated Clinical Trial box is checked, FOA must allow clinical trials. When multiple studies are included in the same delayed onset record, select Yes if it is anticipated that any study will be a clinical trial.

Required and system enforced for each delayed onset study. In addition to justification, must include information regarding how the study will comply with the NIH single Institutional Review Board (sIRB) policy prior to initiating any multi-site study, as well as, a plan for the dissemination of NIH-funded clinical trial information.
Section 1 - Basic Information

1.1. * Study Title (each study title must be unique)  
Required and system enforced. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

1.2. * Is this Study Exempt from Federal Regulations?  
☐ Yes ☐ No

1.3. Exemption Number

1.4. * Clinical Trial Questionnaire  
If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.
1.4.a. Does the study involve human participants?  
☐ Yes ☐ No
1.4.b. Are the participants prospectively assigned to an intervention?  
☐ Yes ☐ No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?  
☐ Yes ☐ No
1.4.d. Is the effect that will be evaluated a health-related, biomedical, or behavioral outcome?  
☐ Yes ☐ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study  
Required and system enforced unless study is exemption 4. Up to 20 conditions at 255 characters each.

2.2. Eligibility Criteria  
Required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

2.3. Age Limits

2.4. Inclusion of Women, Minorities, and Children

2.5. Recruitment and Retention Plan

2.6. Recruitment Status

2.7. Study Timeline

2.8. Enrollment of First Subject

Inclusion Enrollment Report(s)

* Fellowship (F) and Career Development (K) applications to FOAs that do not allow clinical trials cannot propose independent clinical trial studies led by applicant PD/PI. However, proposing studies under the leadership of a sponsor/mentor that allows for clinical trials research experience is encouraged. Such studies must include HS information, but will receive a system error if information is included in CT study fields in sections 4 or 5 of form.
Inclusion Enrollment Report

1. * Using an Existing Dataset or Resource
   - Yes
   - No
   Answer required and system enforced.

2. * Enrollment Location Type
   - Domestic
   - Foreign
   Answer required and system enforced. Do not mix domestic and foreign enrollment data on the same inclusion enrollment report.

3. Enrollment Country(ies)
   Multi-select from list of countries:

4. Enrollment Location(s)

5. Comments
   Up to 500 characters.

Planned
Planned enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is No. System enforcement relaxed if Comment is provided.

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Updated: July 17, 2017
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Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects

Required and system enforced.

Add Attachment Delete Attachment View Attachment

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

☐ Yes ☐ No ☐ N/A

Answer required and system enforced. "N/A" is only a valid option for fellowship, career development and D43 applications or if exemption 4.

If yes, describe the single IRB plan

Required and system enforced if Yes.

Add Attachment Delete Attachment View Attachment

3.3. Data and Safety Monitoring Plan

Required and system enforced for CT study. Optional for HS study.

Add Attachment Delete Attachment View Attachment

3.4. Will a Data and Safety Monitoring Board be appointed for this study?

☐ Yes ☐ No

Answer required and system enforced for CT study unless otherwise noted in opportunity. Optional for HS study.

3.5. Overall Structure of the Study Team

Optional.

Add Attachment Delete Attachment View Attachment

Section 4 - Protocol Synopsis

You are not allowed to complete fields in Section 4 (i.e., will receive system error) if FOA does not allow clinical trials and/or you answered No to one of the Clinical Trial Questionnaire questions in Section 1.

4.1. Brief Summary

Up to 5000 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

4.2. Study Design

All Study Design fields (4.2.a thru 4.2.g) are required and system enforced for CT studies unless otherwise noted in opportunity.

4.2.a. Narrative Study Description

Up to 32,000 characters.

4.2.b. Primary Purpose

Dropdown list

4.2.c. Interventions

Up to 20 Interventions allowed.

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<td>Description</td>
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4.2.d. Study Phase

Dropdown list

Is this an NIH-defined Phase III clinical trial? ☐ Yes ☐ No

4.2.e. Intervention Model

Dropdown list

4.2.f. Masking

☐ Yes ☐ No

Participant Care Provider Investigator Outcomes Assessor

If Masking is Yes, you must select at least 1 of the Participant/Care Provider/Investigator/Outcomes Assessor check boxes.

Updated: July 17, 2017
4.2.g. Allocation

Dropdown list

Not randomized
Randomized
Non-randomized

4.3. Outcome Measures

At least one Outcome Measure required and system enforced for CT studies unless otherwise noted in opportunity. Up to 50 Outcome Measures allowed.

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<tr>
<td>Brief Description</td>
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</table>

4.4. Statistical Design and Power

Required and system enforced for CT study unless otherwise noted in opportunity.

4.5. Subject Participation Duration

Up to 255 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

4.6. Will the study use an FDA-regulated intervention?  

☐ Yes  ☐ No  

Answer required and system enforced for CT study unless otherwise noted in opportunity.

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

Required and system enforced if Yes.

4.7. Dissemination Plan

Required and system enforced for CT study. Generally one Dissemination Plan per application is sufficient. Can attach same plan in multiple studies.

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments

Form supports up to 10 attachments. Attachments only allowed for CT studies. Only include attachments requested in opportunity.