New NIH Human Subjects & Clinical Trials Information: Tips & Tricks for FORMS-E Completion

Note: These slides have been excerpted from the February 2018 NURAP at Noon presentation. For the full slide deck and more information about the event, visit the NURAP Programs & Events page.

Northwestern
New Human Subject Form

- New form is included in all applications (whether or not human subjects or clinical trials are involved)

- Required form fields vary based on a number of factors, including:
  - Whether study is delayed onset
  - Announcement-specific instructions
  - Human subject exemptions
  - Whether study involves a clinical trial
R & R Other Project Information Form

- NIH will continue to collect Human Subjects information on the R & R Other Project Information form

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**RESEARCH & RELATED Other Project Information**

1. Are Human Subjects Involved?  [ ] Yes [ ] No

1.a. If YES to Human Subjects
   Is the Project Exempt from Federal regulations?  [ ] Yes  [ ] No
   If yes, check appropriate exemption number.  [ ] 1  [ ] 2  [ ] 3  [ ] 4  [ ] 5  [ ] 6
   If no, is the IRB review Pending?  [ ] Yes  [ ] No
   IRB Approval Date: 
   Human Subject Assurance Number:
When Human Subjects = No

- When human subjects is **NO**, Applicants answer a single question, provide associated Attachment (as applicable), and are done with form unless Instructed in announcement to include other requested Information attachment.

- Information populated in this Field from R&R other project information form.

- Human specimen/data question: Answer to this question required and system enforced when Human subjects is **NO**.

- An attachment has to be Uploaded If you answer **YES**.
When Human Subjects = Yes (not delayed onset)

- Full Study records require quite a bit of data
- New data collection leads applicants through clinical trial information collection requirements
- Data collection expanded for new policies

Check FOA to determine if attachment is needed

If yes to Human Subject, add Study Title. Study title must be unique with in the application.
Delayed Onset Studies

- Delayed onset - no well defined plan for human subject involvement at time of application
  - Does NOT mean delayed start of study
  - Minimal data collection
  - Must justify why full study information cannot be provided

- Required if Delayed onset study is included.
- In addition to justification, must include information on how the study will comply with NIH single IRB if multi-site research is involved.
- Cannot add Delayed Onset study if you answer **NO** to human subjects question
Exemption 4- Research involving the collection or study of existing data or specimens if publicly available or information recorded that subjects cannot be identified.
Study Record Section 2: Study Population Characteristics

- **Conditions** - At least 1 entry is required but the PI can provide up to 20 study population characteristics. If available, use appropriate descriptors from (MeSH)

- **Inclusion** - Women, Minorities and Children all together

- **Recruitment and Retention Plan** - Describe how you will recruit and retain participants. Address both planned and proposed recruitment

- **Study Timeline** - Provide a description or diagram describing the study timeline
Inclusion Enrollment Report

Planned enrollment must be completed when answer to “using existing dataset” question is NO.
If YES then only complete cumulative enrollment.

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Study Record Section 3: Protection and Monitoring Plans

- All of Section 3 is required for all studies involving human subjects unless noted otherwise.

- Data and Safety monitoring plan is only required if you answered “Yes” to all the questions in the clinical trial questionnaire.

- If not-clinical, but has human subjects, the overall structure of the study team is optional.

- If Yes to multi-site, single IRB plan must be included.
**Study Record Section 4: Protocol Synopsis**

- **Study Design:** all questions under the study design are system enforced

- **Interventions:** up to 20 allowed

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### 4.1. Brief Summary

#### 4.2. Study Design

- **4.2.a. Narrative Study Description**

- **4.2.b. Primary Purpose**

- **4.2.c. Interventions**
  - **Intervention Type**
  - **Name**
  - **Description**

- **4.2.d. Study Phase**

- **4.2.e. Intervention Model**

- **4.2.f. Masking**
  - Yes
  - No

- **4.2.g. Allocation**
  - N/A
  - Randomized
  - Nonrandomized

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**Brief Summary:** is required for CT studies unless noted in FOA

*Limited to 5000 characters*
Outcome Measures: At least one outcome measure is required for CT studies. Up to 50 outcome measures are allowed.

Dissemination plan: one dissemination plan is sufficient. You may attach the same plan for multiple studies.
Attachments in this section are allowed for CT only. Up to 10 attachments can be uploaded, only if noted in FOA.
Tips on How to connect with your PI on New Forms

- Confirm with PI if the proposal is Clinical Trial or Not Clinical Trial
- For some research grants NIH has specific FOA for CT and for not CT
- PI’s are not familiar with new Human subjects forms
  - Send them the screen shots of the forms
  - Convert forms into PDF fillable forms
  - Set a meeting to complete these forms

Note: Please do not try to answer any question on your own.
Note: You will experience errors for copy and pasting text in some fields.