Grant Bootcamp:
Session 4: “How to deal with PHS SF 424 Forms E”

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Office of Grants and Contracts
The SF424 application package is imported into BearGrants (“BG”) for ease of access and data entry. Most of the information is pre-populated into the form based on information entered in the Funding Proposal (“FP”) smartform pages.
# SF424 Forms E
Most Common Application Package Forms

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<th>SF424 (R&amp;R)</th>
<th>Budget Forms:</th>
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<tr>
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<td>PHS Modular Budget</td>
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<td><strong>R&amp;R Other Project Information</strong></td>
<td>R&amp;R Budget</td>
</tr>
<tr>
<td>Project/Performance Site Location(s)</td>
<td>R&amp;R Subaward Budget</td>
</tr>
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<td>R&amp;R Senior/Key Person Profile</td>
<td>PHS 398 Training Budget</td>
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<td>SBIR/STTR Information</td>
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<td><strong>PHS Human Subjects and Clinical Trials Information</strong></td>
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<td>PHS Assignment Request Form</td>
<td>Construction Budget</td>
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<tr>
<th>Research Plan and Equivalent Forms</th>
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<tr>
<td>PHS 398 Research Plan</td>
</tr>
<tr>
<td>PHS 398 Career Development Award Supplemental Form</td>
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<td>PHS 398 Research Training Program Plan</td>
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<td>PHS Fellowship Supplemental Form</td>
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Questionnaire – Research Involving Human Subjects:

Question One
Please check which best describes your research:

- For the purpose of this study, at some point there will be an intervention or interaction with subjects for the collection of specimens or biological material or data (including health or clinical data, surveys, focus groups or observation of behavior).
- This study will involve only the use of secondary analysis of biological material/tissue/specimens or data not collected specifically for this study.
- This study will involve materials/specimens or data from deceased individuals only.
- My study does not fit any of these categories

Question Two
Will this study involve any of the following (select all that apply):

- An intervention, such as the administration of a medication, collection of biological data (such as a blood collection, MR imaging, EER or EKG) cognitive behavioral therapy, a clinical trial, or manipulating a subject’s environment to record the reaction. Or an interaction with subjects, such as playing a computer game.
- Collection of biological specimens from subjects, such as blood or tissue, specifically for the study.
- The study of acceptable educational practices in a normal educational setting.
- Collection of data via surveys, interviews, questionnaires, focus groups, or observation of public behavior (but no collection of biological specimens).

If your study involves a clinical trial you must include a Data and Safety Monitoring Plan (DSMP) commensurate with the risk of your study.

If your study involves an NIH-defined Phase III or multisite clinical trial your DSMP must include a Data and Safety Monitoring Board.
• The (new) PHS Human Subjects and Clinical Trials Information Form is required on all applications proposing work involving human subjects.
• Used to collect information on human subjects research, clinical research, and/or clinical trials.
• When Human Subjects = Yes on Research & Related Other Project Information form applications must include one of the following on the new PHS Human Subjects and Clinical Trials Information Form:
  
  q 1 or more full study records, OR
  q 1 or more delayed onset study records, OR
  q A combination of full and delayed onset study records

Required form fields vary based on a number of factors, including:
  q Announcement-specific instructions
  q Is study delayed onset?
  q Are there any Human subject exemptions?
  q Does study include a clinical trial?
Using the PHS Human Subjects and Clinical Trials Information form:

Follow instructions on the PHS Human Subjects and Clinical Trials Information form that are specific to your answer to the "Are Human Subjects Involved?" question on the G.220 - R&R Other Project Information Form. The PHS Human Subjects and Clinical Trials Information form allows you to add study record(s) and/or delayed onset study(ies), as applicable.

Within each Study Record: PHS Human Subjects and Clinical Trials Information, you will add detailed information at the study level. Add a separate study record for each protocol involving human subjects proposed in your application. Do not duplicate studies within your application. Each study within the application should be unique and should have a unique study title. Each study record is divided into numbered sections:

- Section 1 - Basic Information
- Section 2 - Study Population Characteristics (includes Inclusion Enrollment Report)
- Section 3 - Protection and Monitoring Plans
- Section 4 - Protocol Synopsis
- Section 5 - Other Clinical Trial-related Attachments

**Note:** The PHS Human Subjects and Clinical Trials Information form will capture detailed information at the study level. Although you are encouraged to refer to information in the PHS Human Subjects and Clinical Trials Information form in your discussion of the Research Strategy, do not duplicate information between the Research Strategy attachment and the PHS Human Subjects and Clinical Trials Information form.

The PHS Human Subjects and Clinical Trials Information form is dynamic and may eliminate sections that are not relevant to your application. The dynamic form behavior may not be enabled on all submission methods.
Basic Information

Study Record: PHS Human Subjects and Clinical Trials 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
   - Answer required and system enforced.

1.3. Exemption Number
   - [ ] 1  [ ] 2  [ ] 3  [ ] 4  [ ] 5  [ ] 6  [ ] 7  [ ] 8
   - If Study Exempt is Yes, must provide exemption number. Exemptions 7 and 8 are not currently used.

1.4. * Clinical Trial Questionnaire
   - Answers to questionnaire required and system enforced.
   - 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

Optional. Provide NCT# for this study, if available. Newly proposed studies do not need to be entered in ClinicalTrials.gov at time of application. If building on an existing study, enter NCT# for ancillary study (if available), not the parent study.
Study Population

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.
- Age limits are required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

2.3. Age Limits
- Minimum Age
- Maximum Age

2.4. Inclusion of Women, Minorities, and Children
- Required and system enforced unless study is exemption 4.

2.5. Recruitment and Retention Plan
- Required and system enforced unless study is exemption 4.

2.6. Recruitment Status
- Required and system enforced unless study is exemption 4.

2.7. Study Timeline
- Required and system enforced unless study is exemption 4.

2.8. Enrollment of First Subject
- Inclusion Enrollment Report(s)
  - Date: MM/DD/YYYY
  - Anticipated
  - Actual

Inclusion Enrollment Reports required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

* 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. Answering Yes to all four Clinical Trial Questionnaire questions will not flag the study as a clinical trial. These studies must include HS information, but will receive a system error if information is included in study fields in sections 4 or 5 of form.
Section 3 - Protection and Monitoring Plans

### 3.1. Protection of Human Subjects
- **Required and system enforced.**

### 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, and career development applications OR if study is exempt from federal regulations (i.e., Question 1.2a is Yes).

If yes, describe the single IRB plan:
- **Required and system enforced if Yes. Can attach same plan (unique filenames) in multiple studies.**

### 3.3. Data and Safety Monitoring Plan
- **Required and system enforced for CT study. Optional for HS study.**

### 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.**
### Protocol / Synopsis

<table>
<thead>
<tr>
<th>Section 4 - Protocol Synopsis</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1. Brief Summary</td>
<td>Up to 5000 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.</td>
</tr>
<tr>
<td>4.2. Study Design</td>
<td>All Study Design fields (4.2.a thru 4.2.g) are required and system enforced for CT studies unless otherwise noted in opportunity.</td>
</tr>
<tr>
<td>4.2.a. Narrative Study Description</td>
<td>Up to 32,000 characters.</td>
</tr>
<tr>
<td>4.2.b. Primary Purpose</td>
<td>Dropdown list: Treatment; Prevention; Diagnostics; Supportive Care; Screening; Health Services Research; Basic Science; Device Feasibility; and Other.</td>
</tr>
<tr>
<td>4.2.c. Interventions</td>
<td><strong>Up to 20 interventions allowed.</strong></td>
</tr>
</tbody>
</table>

#### Intervention Type

<table>
<thead>
<tr>
<th>Name</th>
<th>Up to 200 characters.</th>
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<tbody>
<tr>
<td>Description</td>
<td>Up to 1,000 characters.</td>
</tr>
</tbody>
</table>

#### Study Phase

<table>
<thead>
<tr>
<th>Dropdown list: Early Phase 1 (or Phase 0); Phase 1; Phase 1/2; Phase 2; Phase 2/3; Phase 3; Phase 4; and Other</th>
<th>Is this an NIH-defined Phase III clinical trial?</th>
</tr>
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<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

#### Intervention Model

<table>
<thead>
<tr>
<th>Dropdown list: Single Group; Parallel; Cross-Over; Factorial; Sequential; and Other.</th>
</tr>
</thead>
</table>

#### Masking

<table>
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<tr>
<th>Yes</th>
<th>No</th>
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</thead>
</table>
### Protocol / Synopsis Cont’d

#### 4.2. Allocation
- Dropdown list: N/A; Randomized; and 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.
- **Name**: Up to 255 characters.
- **Type**: Dropdown list: Primary; Secondary; and Other
- **Time Frame**: Up to 255 characters.
- **Brief Description**: Up to 999 characters.

#### 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 (unique filenames) in multiple studies.
Include an attachment **only if the solicitation specifies that an attachment(s) is required or permitted**; otherwise, do not include any Other Clinical Trial-related attachments.

If you answered “No” to any question in the “Clinical Trial Questionnaire:” **Do not provide** information in this section or your proposal will be rejected.
Highlights

Start Early! - Allow time to:

Check with PO / confirm requirements
Complete all required components
Include all required attachments
Review & clear validations
System processing
Highlights

Validation Errors:
• Must be corrected for application to proceed
• Must be corrected BEFORE application deadline
• Corrected submission override previous submission(s)

Warnings do not stop application progress;
(corrected based on your circumstances as appropriate)

NOTE: Reviewers do not see applicant warnings, nor can they tell how many submission attempts were needed to complete the submission process
<table>
<thead>
<tr>
<th>Form Section</th>
<th>If you answered &quot;yes&quot; to all the questions in the Clinical Trial Questionnaire</th>
<th>If you answered &quot;no&quot; to any of the questions in the Clinical Trial Questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 2 - Study Population Characteristics</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Section 3 - Protection and Monitoring Plans</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Section 4 - Protocol Synopsis</td>
<td>Required</td>
<td>Do not complete</td>
</tr>
<tr>
<td>Section 5 - Other Clinical Trial-related Attachments</td>
<td>Required if specified in the RFP</td>
<td>Do not complete</td>
</tr>
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Links / Resources

G.500 - PHS HSR & Clinical Trials Information
Human Subjects Questionnaire
YouTube HSR Walkthrough
HSR Exemptions FAQs
HSR Infographic
HSR Forms E Scenarios
Annotated Forms E
Annotated Forms E (Multi-Project)
NIH Pre-Award Process
Delayed Onset or Delayed Start