National Institutes of Health (NIH) – HSCTI Form Checklist

Please review program specific solicitation for compliance and completeness. **Guidelines in the solicitation may *supplement* or *deviate* from guidelines below.**

FORMATTING GUIDELINES	
Document formatting	✔ PDF attachments only ✔ No headers or footers ✔ Headings within the text of attachments are encouraged ✔ Complete NIH formatting guidance is here: Format Attachments
Font type/size	✔ Arial, Georgia, Helvetica, Palatino Linotype are recommended ✔ Size 11 or larger (smaller font may be used for figures, charts, graphs)
Line spacing/Type Density	✔ No more than 6 lines of type within a vertical space of 1 inch ✔ No more than 15 characters per linear inch (including spaces) ✔ Only single column formatting; Multi-column format is discouraged
Page size	✔ 8.5 x 11
Margins	✔ At least 0.5" all sides
URLs	✔ Most sections do not allow for inclusion of URLs unless specified in the FOA

GRAMS 424 Human Subjects & Clinical Trial Information (HSCTI) Form

☐ **PHS Human Subjects and Clinical Trials Information**

The designation of your FOA will determine how to use the SF424 Guide, G.500 instructions and how to complete this form. **Complete the Human Subjects section of the Research & related Other Project Information form prior to completing this form in your 424 application.**

- ✔ **Use of Human Specimens and/or Data? –** Answer question. If "Yes", upload an explanation for any use of human specimens and/or data not considered to be human subjects research.
- ✔ **Are Human Subjects Involved? If you answered "Yes" proceed in completing the form as required and attach required documents.** Refer to SF424 Guide, G.500 when completing.
- ✔ **Other Requested Information -** Limited to what is described in your FOA/solicitation
- ✔ **Study Record(s) Form -** Add a Study Record for each proposed study involving human subjects in the proposal and/or each delayed onset study in the proposal, if applicable. For delayed onset studies, see instructions in the SF424 Guide for Delayed Onset Studies
  - **Section 1 - Basic Information**
    - **1.1 Study Title -** maximum 600 words
    - **1.2 Is this Study Exempt from Federal Regulations?** - Answer question
    - **1.3 Exemption Number** - if 1.2 is "Yes", select exemption number
      NOTE: If you selected only Exemption 4 and not other exemptions, some sections of the HSCTI form will not be required. Please review carefully.
    - **1.4 Clinical Trials Questionnaire** - Answer Clinical Trial Questions, responses determine whether sections 4 & 5 will be required or applicable. See SF424 Guide, G.500, Section 1.4 for special instructions for Career Development & Fellowship applications

Form Section	If you answered "yes" to all the questions	If you answered "no" to any of the questions
Section 2 - Study Population Characteristics	Required	Required
Section 3 - Protection and Monitoring Plans	Required	Required
Section 4 - Protocol Synopsis	Required	Do not complete
Section 5 - Other Clinical Trial-related Attachments	Check FOA	Do not complete

    - **1.5 ClinicalTrials.gov Identifier** - Enter ClinicalTrials.gov identifier if clinical trial has already been entered into ClinicalTrials.gov.

- **Section 2 - Study Population Characteristics** – See SF424 Guide, G.500, Section 2 for detailed information on below items. **NOTE: This section is not required if the study meets the following requirements: If you selected only Exemption 4 and no other Exemptions in "1.3 Exemption Number"**
  - **2.1 Conditions or Focus of Study** – At least 1 entry is required, up to 20 entries allowed. Each entry limited to 255 characters.
  - **2.2 Eligibility Criteria** - limited to 15,000 characters, but typically needs only 500 characters
  - **2.3 Age Limits** - select numerical values for min. and max. ages.
  - **2.3a Inclusion of Individuals Across the Lifespan** – attach PDF file addressing items in SF424 Guide
  - **2.4 Inclusion of Women and Minorities** – attach PDF file addressing items in SF424 Guide
  - **2.5 Recruitment and Retention Plan** – attached PDF file, if applicable
  - **2.6 Recruitment Status** - make selection, if applicable
  - **2.7 Study Timeline** – upload document, if applicable
  - **2.8 Enrollment of First Participant** - enter data, if applicable
  - **2.9 Inclusion Enrollment Report** – enter data
- **Section 3- Protection and Monitoring Plans**
  - **3.1 Protection of Human Subjects** - see SF424 Guide, G.500, Section 3.1 for detailed requirements and special instructions for studies claiming exemptions.
  - **3.2 Multi-Site study using the same protocol** - answer, if "Yes", attach a Single IRB Plan and see SF424 Guide, G.500, Section 3.2 for detailed requirements and special instructions for Career, Training, and Fellowship applications.
  - **3.3 Data and Safety Monitoring Plan - NOTE: only required if you selected *"Yes"* to all questions in "1.4 *Clinical Trial Questionnaire",*** see SF424 Guide, G.500, Section 3.3 for detailed requirements and special instructions for Career and Fellowship applications.
  - **3.4 Data and Safety Monitoring Board** - answer question if *"Yes"* to all questions in "1.4 *Clinical Trial Questionnaire".*
  - **3.5 Overall Structure of the Study Team -** optional attachment - refer to specific FOA instructions and see SF424 Guide, G.500, Section 3.5 for content guidance.
- **Section 4. Protocol Synopsis - NOTE: This section is required only when: *If you selected "Yes"* to all questions in "1.4 *Clinical Trial Questionnaire"* Important: Inputting information in this section when 1.4 includes any "no" responses will cause proposal submission errors.**
  - **4.1 Study Design**
    - **4.1.a. Detailed Description** - limited to 32,000 characters, see SF424 Guide, G.500, Section 4.1 for content guidance.
    - **4.1.b. Primary Purpose** - make selection
    - **4.1.c. Interventions** - add up to 20 interventions
    - **4.1.d. Study Phase** - select phase and whether study is Phase III Clinical Trial, see NIH-defined Phase III clinical trial for information.
    - **4.1.e. Intervention Model** - select model
    - **4.1.f. Masking** - select Yes/No and the types of masking, see masking for more information.
    - **4.1.g. Allocation** - make selection
  - **4.2 Outcome Measures** - add up to 50 outcome measures. Enter Name, Type, Time Frame, & a Brief Description for each outcome measure.
  - **4.3 Statistical Design and Power** - see SF424 Guide, G.500, Section 4.3 for content guidance.
  - **4.4 Subject Participant Duration** - 255 character limit
  - **4.5 FDA-regulated intervention** - select Yes/NO
    - **4.5.a. Description of IP and IND/IDE status** - if *"Yes"* to *"4.5 FDA-regulated intervention"*, upload required PDF File. Typical length is 3,000 characters; see SF424 Guide, G.500, Section 4.5 for content guidance.
  - **4.6 Is this an applicable clinical trial under FDAAA? -** Answer question
  - **4.7 Dissemination Plan** - One Dissemination Plan per application is sufficient, but a file for each study must be uploaded with a unique file name. You may either attach the same Dissemination

Plan to different studies or attach a file that refers to the Dissemination Plan in another study within your application. For example, you may attach a file that says "See Dissemination Plan in the 'My Unique Study Name' study." See SF424 Guide, G.500, Section 4.7 for content guidance.

- **Section 5 - Other Clinical Trial-related Attachments**
  - **5.1 Other Clinical Trial-related Attachments - NOTE: required only required if "Yes" to all questions in "1.4 Clinical Trial Questionnaire" AND only if your FOA specifies that an attachment(s) is required or permitted; otherwise, do not include any Other Clinical Trial-related attachments.**