**NIH F30/F31/F32 NRSA FELLOWSHIP PROPOSAL**

**SUBMISSION REVIEW CHECKLIST - FORMS-I (FOR USE ON/AFTER 05/08/25)**

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| PI Name |  | FOA |  | Due Date |  |

**\* INDICATES DOCUMENT/SECTION IS REQUIRED IF APPLICABLE; IF NOT REQUIRED/APPLICABLE, DO NOT UPLOAD**

Initiate the proposal in [ASSIST](https://public.era.nih.gov/assist) using the FOA number and the PI’s eRA Commons Username.

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| GENERAL INFORMATION | | | | | | | | | | | | | | | | | | | | | | |
|  | 11 points or larger. Recommended: black font, using Arial, Georgia, Helvetica, or Palatino Linotype | | | | | | | | |  | Smaller text in figures/graphs/diagrams/charts allowed but must be legible | | | | | | | | | | | | |
|  | All files in PDF |  | Doc names 50 characters or less | | | | | |  | | | 0.5” inch margins | | | | |  | | | No headers or footers | | |
|  | No URLS except for citations in References Cited and Biosketch | | | |  | [No electronic signatures](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm#electronicsignatures) | | | |  | [**NIH Formatting Requirements**](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) Followed | | | | | | |  | | | No Human Fetal Tissue (HFT) Research allowed | | |
|  | Parent Announcements:F30:[PA-25-425](https://grants.nih.gov/grants/guide/pa-files/PA-25-425.html) / [PA-25-426](https://grants.nih.gov/grants/guide/pa-files/PA-25-426.html) ; F31: [PA-25-422](https://grants.nih.gov/grants/guide/pa-files/PA-25-422.html) ; F32: [PA-25-423](https://grants.nih.gov/grants/guide/pa-files/PA-25-423.html) ; F33: [PA-25-424](https://grants.nih.gov/grants/guide/pa-files/PA-25-424.html) *(or institute-specific PAR number)* | | | | | | | | | | | | | |  | Recommended file name convention: *PISurname\_DocumentTitle.pdf* | | | | | | |
|  | For project start date, follow NIH Standard Due Dates unless FOA states otherwise:   * + Due: 04/08 ;  Earliest Start: 12/01   + Due: 08/08 ;  Earliest Start: 04/01   + Due: 12/08 ;  Earliest Start: 07/01 | | | **Other Budget Notes**:   * Work with OCG Proposal Analyst to develop internal Fellowship budget. When creating the budget, utilize NIH’s current stipend and budget category levels allowed. [FY24 rates available here ([**NOT-OD-24-104**](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-104.html))](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-104.html). FY25 rates expected to be released after 04/08 deadline. * NIH Fellowship Budget Template is available on the [OCG Forms page](https://colorado.edu/ocg/forms). * No detailed budget entered into ASSIST, but PA will need to enter total costs from internal budget on R&R Cover Page and enter only requested Tuition and Fees and childcare costs (if budgeted) on PHS Fellowship Supplement Form. | | | | | | | | | | | | | | | | | | |
|  | **Letters of Reference** - due by proposal deadline & are submitted in eRA Commons. [Process detailed here](https://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/reference-letters.htm). Fellow’s responsibility to request. New Letters must be submitted for Resubmission Proposals. | | | | | | |  | | eRA Commons Account Required for Fellow (PI) - please contact Proposal Analyst if you need an eRA Commons ID & ask for PI role. **ORCID ID must be linked to eRA Profile.** | | | | | | | | | | | | |
|  | **Click “Validate Application” button before submission to check for errors/warnings** | | | | | | |  | | Ensure NIH Fellowship Assurance section of PSR has been completed and acknowledged. | | | | | | | | | | | | |
| [R&R Cover Page](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.200-sf-424-(r&r)-form.htm) | | | | | | | | | | | | | | | | | | | | | | |
|  | Federal Identifier entered for resubmission/ renewal/revisions (*ex: enter MH123456 from 1R01MH123456-01 - found in eRA Commons*) | | | | | | | | | | | |  | Person to be contacted: PA | | | | |  | | | EIN: 1846000555A2 |
|  | Type of Applicant: *H: Public/State Controlled Institution* | | | | | | | | | | | | | | | | | | | | | |
|  | [Type of Application](http://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/type-of-application-submission.htm): | | | | | | [New](https://grants.nih.gov/grants/glossary.htm#NewApplicationawardgrant)  [Resubmission](https://grants.nih.gov/grants/glossary.htm#Resubmission) | | | | | | | | | | | | | | | |

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|  | Is application being submitted to other agencies? | If Yes, list other agencies |
|  | Descriptive Title of Application - *max length of 200 characters* | Click here to list title |

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|  | | Project Period | | | | | Enter Project Period | | | | | | |  | Congressional District: CO-002 | | | | | **Note**: PI info may be updated on Sr/Key Person Profile | | | | | |  | | | | Include total project costs from internal budget | | | |
|  | | Is application subject to review by E.O. 12372? No | | | | | | | | | | | | | | | | | | **Note**: No SFLLL | | | | | |  | | | | AOR info: PA | | | |
|  | | **Cover Letter** - Required   * Addressed to Division of Receipt and Referral; Application Title; Title of FOA * **Must list referees (including name, departmental affiliation, and institution)** * See [FORMS-I Guide’s Cover Page Attachment](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.200-sf-424-(r&r)-form.htm#21) for details on info to be provided. * Additionally must provide additional info if: project has video, large-scale genomic data, [late application](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html).   **Note**: Do not request assignment of proposal here; address in Assignment Request Form. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | *PISurname\_CoverLetter.pdf* | | |
| Click here to enter comments if needed. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| [Project PERFORMANCE SITES](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.230-project-performance-site-location(s)-form.htm) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | Provide CU Boulder information as the Primary Site: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | |  | | | UEI: SPVKK1RC2MZ3 | | | | | | | | | | |  | | Congressional District: CO-002 | | | | |  | | | | Department Info/PI Campus Box | | | | | |
|  | | | Include any sites where training may occur as described in Research Training Plan. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| [ASSIGNMENT REQUEST FORM](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.600-phs-assignment-request-form.htm) (Optional) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Note**: Select “Assignment Request Form” after clicking the “Add Optional Form” button on far-left side of ASSIST app | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Upload if PI wants to identify requested Institute/Center, Study Section, or Reviewers not to include; provide PI with Assignment Request Form (available in KMS) and then manually input responses into ASSIST | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| [OTHER PROJECT INFORMATION](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.220-r&r-other-project-information-form.htm) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Human Subjects (HS)? | | | | | | | |  | | IRB Pending? **Or** provide IRB approval date. | | | | | | | | | | | | | | |  | | Human Subjects: 00003492 | | | | |
|  | | | | | | | | | |  | | [Exempt](https://grants.nih.gov/sites/default/files/exemption_infographic_v7_508c-3-21-19.pdf)? If yes, enter [exemption #](https://grants.nih.gov/sites/default/files/exemption_infographic_v7_508c-3-21-19.pdf) | | | | | | | | | | | | | | | | | | | | | |
|  | | Vertebrate Animals? | | | | | | | |  | | IACUC Pending? **Or** provide IACUC approval date. | | | | | | | | | | | | | | |  | | Animal Subjects: D16-00388 | | | | |
|  | | Proprietary/Privileged Info? | | | | | | | | | | | | | |  | | Potential Impact? | | | | | | | | |  | | Historic Site? | | | | |
|  | | International Activities? **Note**: International conferences are not considered international collaboration | | | | | | | | | | | | | | | | | | | | |  | | If yes, include Foreign Justification | | | | | | | | |
|  | | **Project Summary/Abstract** - 30 lines of text; description of proposed work & the fellowship training plan and the training environment | | | | | | | | | | | | | | | | | | | | | | | | | *PISurname\_Summary.pdf* | | | | | | |
|  | | **Project Narrative** - 3 sentences maximum; describe relevance to public health | | | | | | | | | | | | | | | | | | | | | | | | | *PISurname\_Narrative.pdf* | | | | | | |
|  | | **Bibliography & References Cited** - No limit; URLs allowed; Recommend including PMCIDs’ for all pubs listed in bio authored; recommend [PMCIDs](https://publicaccess.nih.gov/policy.htm)’ inclusion for all pubs authored or co-authored by applicant. | | | | | | | | | | | | | | | | | | | | | | | | | *PILSurname\_References.pdf* | | | | | | |
|  | | **Facilities & Other Resources** - No limit; include a detailed description of the institutional facilities and resources available to the fellowship applicant | | | | | | | | | | | | | | | | | | | | | | | | | *PISurname\_Facilities.pdf* | | | | | | |
|  | | **Equipment** - No limit; if no equipment on project, upload document stating “No Equipment” (or similar) | | | | | | | | | | | | | | | | | | | | | | | | | *PISurname\_Equipment.pdf* | | | | | | |
|  | | **Other Attachments** - Do not upload anything **unless** FOA has special requirements **and/or** if international collaboration/research travel (not conference travel) is a part of the proposal. If international collaboration/research travel, include required **Foreign Justification,** provide description of how foreign training is more appropriate than in a domestic setting. | | | | | | | | | | | | | | | | | | | | | | | | | **If including Foreign Justification, required file name is:**  *Foreign Justification.pdf* | | | | | | |
| [SENIOR/Key Personnel Profile](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.240-r&r-seniorkey-person-profile-(expanded)-form.htm) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | Complete for all [Senior/Key Personnel](https://grants.nih.gov/grants/glossary.htm#Senior/KeyPersonnel) - PI (Fellow), Sponsors/Co-Sponsors, and Other Significant Contributors ([OSCs](https://grants.nih.gov/grants/glossary.htm#OtherSignificantContributors(OSCs))) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | Name | | | | | | | |  | | Organization Name | | | | | | | | | |  | Address Fields | | | | | | | | | |  | Email |
|  | Role | | | |  | | | **No Co-PD/PI** | | |  | | The fellow is identified as “PI”; for Sponsor/Co-Sponsor(s) select “Other” and enter “Sponsor” or “Co-Sponsor” into the Other Project Role Category. Identify “Other Significant Contributors” (OSCs) roles as applicable. | | | | | | | | | | | | | | | | | | | | |
|  | Degree Type and Year of Highest Degree | | | | | | | | | |  | | eRA Commons ID - Required for all listed in Sr/Key Personnel, must match biosketch. [**Fellow’s ID must be linked to ORCID in eRA Commons**](https://era.nih.gov/erahelp/Commons/default.htm#orcid.htm%3FTocPath%3D_____29) | | | | | | | | | | | | | | | | | | | | |
|  | **Biosketch** - Required for PI, Sponsors/Co-Sponsors, OSCs:   * 5-page limit; [Instructions here](https://grants.nih.gov/grants/forms/biosketch.htm) * Fellow/PI: [Template here](https://grants.nih.gov/grants/forms/biosketch-blank-fellowship-format-rev-10-2021.docx) or [use SciENcv](https://www.ncbi.nlm.nih.gov/sciencv/) * Sponsor/Co-Sponsor/OSC: [Template here](https://grants.nih.gov/grants/forms/biosketch-blank-format-rev-10-2021.docx) or [use SciENcv](https://www.ncbi.nlm.nih.gov/sciencv/) * SciENcv to be required for 05/25/25 and after deadlines * Education/Training: List in **chronological** order. | | | | | | | | | | | | | | | | | | | |  | *Sr/KeySurname\_Biosketch.pdf* | | | | | | | | | | | |
|  | C. Contributions to Science   * 5 Contributions to Science **max** per Biosketch * 4 products **max** per Contribution. *Recommend* [*PMCIDs*](https://publicaccess.nih.gov/policy.htm)*’ inclusion for all pubs listed in biosketch.* * URL allowed to full list of publish work, must be a Federal site. NIH’s [My Bibliography](http://www.ncbi.nlm.nih.gov/books/NBK53595/) is recommended. | | | | | | | | | | | |
|  |  | | | A. Personal Statement Include Personal Statement. Optional to also include:   * Select Ongoing/Completed Research Projects from Past 3 years * Products *-* 4 products max | | | | | | | | | | | | | | | | |
|  | D. Scholastic Performance   * **DO NOT INCLUDE**. No longer required and this section must not be included. * No Research Support section included. | | | | | | | | | | | |
|  |  | | | B. Positions, Scientific Appointments, and Honors   * Positions and Scientific Appointments (both domestic & foreign): List in **reverse chronological** order. | | | | | | | | | | | | | | | | |
| **Other Support not required unless specified by FOA.** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Click here to enter comments if needed. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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| [PHS Fellowship Supplemental Form](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.430-phs-fellowship-supplemental-form.htm) | | | | | | | |
|  | 1**. Introduction to Application**\* - 1-page limit; summarizes substantial additions, deletions, & changes to the application; only applicable for resubmission/revision, or if FOA requirement | | | | | | *PISurname\_Introduction.pdf* |
| **Candidate Section –** [Review detailed document instructions for this section here](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.430-phs-fellowship-supplemental-form.htm#Fellowship). | | | | | | | |
|  | 2. **Goals, Preparedness and Potential** – 3-page limit; Must include following sections: A. Overall Training Goals; B. Candidate’s Preparedness; C. Candidate’s Self-Assessment; D. Scientific Perspective | | | | | | *PISurname\_Goals.pdf* |
| **Research Training Plan –** [Review detailed document instructions for this section here](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.430-phs-fellowship-supplemental-form.htm#Research). | | | | | | | |
|  | 3. **Training Activities and Timeline** – 3-page limit; Activities should address the candidate’s goals and identified areas for development. | | | | | | *PISurname\_Training.pdf* |
|  | 4. **Research Training Project Specific Aims** – 1-page limit; state goals of proposed research & summarize expected outcome. | | | | | | *PISurname\_SpecificAims.pdf* |
|  | 5. **Research Training Project Strategy** – 6-page limit; Sections **must** have headers: 1. Scientific Foundation and Rationale; 2. Approach | | | | | | *PISurname\_ResStrategy.pdf* |
| **n/a** | 6. **Progress Report Publication List** – Not applicable for fellowships as they are not renewable; no upload. (Only for renewals) | | | | | | |
|  | 7. **Training in the Responsible Conduct of Research** – 1-page limit; The plan must address the five required components: 1. Format, 2. Subject Matter, 3. Faculty Participation, 4. Duration of Instruction, 5. Frequency of Instruction. | | | | | | *PISurname\_RCRTraining.pdf* |
| **Commitment To Candidate, Mentoring And Training Environment –** [Review doc instructions for this section here](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.430-phs-fellowship-supplemental-form.htm#Sponsor). | | | | | | | |
|  | 8. **Sponsor(s) Commitment** – 6-page limit; Sponsor + Co-Sponsor Statements must be appended together; each statement must address the following sections: A. Mentoring Approach and Candidate Mentoring Plan; B. Prior Commitment to Training and Mentoring; C. Commitment to the Candidate’s Research Training Plan; D. Research Training Environment; E. Candidate’s Potential ; include information on Clinical Trial Training (if applicable/proposed) | | | | | | *PISurname\_Commitment.pdf* |
|  | 9. **Letters of Support from Collaborators, Contributors, and Consultants** - 6 page limit (combined); all letters of support in single PDF document; [electronic signatures must be flattened](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm#electronicsignatures). Include Letters for Collaborators/Consultants/Advisors that are expected to contribute to fellow’s project & training. | | | | | | *PISurname\_SupportLetters.pdf* |
| **n/a** | 10. **Description of Candidate's Contribution to Program Goals** – Not required, **do not upload**. | | | | | | |
| **Other Research Training Plan Section –** [Review detailed document instructions for this section here](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.430-phs-fellowship-supplemental-form.htm#Other). | | | | | | | |
|  | 11. Are vertebrate animals euthanized? *If yes, is method consistent with AVMA?* *(If no to AVMA, include method and justification)* | | | | | | |
|  | 12. **Vertebrate Animals** - Required if Animal research; no page limit; Provide sections: 1. Description of Procedures, 2. Justifications (for use), 3.Minimization of Pain and Distress | | | | | | *PISurname\_Vertebrate.pdf* |
|  | 13. **Select Agent Research**\* - Required if [activities involve use of select agents](http://www.selectagents.gov/); no page limit; should identify select agents, registration status, & description of facilities to use select agents | | | | | | *PISurname\_SelectAgent.pdf* |
|  | 14. **Resource Sharing Plan(s)**\* - No page limit; Required if required by FOA, or if research includes Sharing Model Organisms or Development of Research Tools. Data Sharing Plan not required. | | | | | | *PISurname\_ResourceSharing. pdf* |
| **n/a** | 15. **Other Plan(s)** – Data Management & Sharing (DMS) Plan not required, **do not upload**. | | | | | | |
|  | 16. **Authentication of Key Biological and/or Chemical Resources**\* - No page limit, recommend 1 page; describe methods to ensure the identity & validity of key biological and/or chemical resources | | | | | | *PISurname\_Authentication.pdf* |
| **Additional Information Section –** [Review detailed document instructions for this section here](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.430-phs-fellowship-supplemental-form.htm#Addtional). | | | | | | | |
| ***Fellow-Specific Questions - Fellow Must Complete Questions 17-24 in ASSIST*** | | | | | | | |
|  | 17. Does the proposed project involve human embryonic stem cells (hESC)? *If yes, complete rest of Stem Cell section.* | | | | | | |
|  | 18. Alternate Phone Number |  | 19. Degree Sought During Proposed Award *- Degree Type & Completion Date* | | | | |
|  | 20. Field of Training for Current Proposal |  | 21. Current or Prior Kirschstein-NRSA Support? - If yes, identify prior support*.* | | | | |
|  | 22. Applications for Concurrent Support?  --- **if Yes, attach the following**: |  | Description of Concurrent Support | | | *PISurname\_ConcurrentSupport.pdf* | |
|  | 23. US Citizen? - *Fellow must be US citizen or non-citizen national of US* | | |  | 24. Change of Sponsoring Institution | | |
|  | 25. **Tuition and Fees** - Provide estimated **full/total costs of tuition and fees** by budget year for predoc fellows. NIH will award set stipend/allowance & 60% of tuition/fees requested, but full costs from budget template must be included. **No other budget details provided unless childcare; see below.** | | | | | | |
|  | 26. **Childcare Costs** - Choose “None Requested” or “Funds Requested”. If requesting funds, then list by year the amount of childcare costs requested, up to $2500/year for childcare costs provided by licensed childcare provider for children up to 13 (or 18 if disabled). | | | | | | |
| ***Senior Fellowship Applicants Only:*** | | | | | | | |
|  | 27. Present Institutional Base Salary & Stipends/Salary During First Year\* - Required **only** for senior fellowships. | | | | | | |
|  | 28. Stipends/Salary During First Year of Proposed Fellowship - Required **only** for senior fellowships. | | | | | | |
|  | 29. **Appendix** - FOA will specify if any appendix instructions; review [NIH Appendix Policy](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-098.html) | | | | | *PISurname\_DescriptiveName.pdf* | |

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| [PHS Human Subjects and Clinical Trials Information](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.500-phs-human-subjects-and-clinical-trials-information.htm) \* | | | | | | | | | | | | |
|  | Human Specimens  and/or Data?  *If yes, include:* | | | | ***Note****:* Proposals with or without Human Subjects (HS) may still have Human Specimens/Data; to determine whether PI’s research is classified as HS research or not, use [Research Involving Private Information or Biological Specimens flowchart](https://grants.nih.gov/grants/policy/hs/private-information-biospecimens-flowchart.pdf). **If flowchart indicates human subjects research, then mark “no” to Human Specimens/Data.** | | | | | | | |
|  |  | Explanation for Use of Human Specimens and/or Data not considered to be Human Subjects Research | | | | | | | | | | |
|  | Human Subjects (HS) Study Record *-* Required for all HS-research proposals; please send the HS Study Record to the PI for PI to complete and upload all necessary documents as this minimizes errors/issues, **or** have PI complete directly in ASSIST record. | | | | | | | | | | | |
|  |  | File Names under 50 characters in length | | | | | | |  | Study titles under 600 characters in length | | |
|  |  | Prior to uploading Study Record into ASSIST HS page, select the “Check Form for Errors” button | | | | | | | | | | |
| ***Notes****:* | | * **Fellows are not permitted to lead an independent Clinical Trial (CT),** [**FAQs on Clinical Trial-specific FOAs**](https://grants.nih.gov/grants/policy/faq_clinical_trial-specific_FOAs.htm).  Fellow can gain CT experience under sponsor supervision but cannot lead CT; Fellow gaining CT experience must follow below CT requirements. * PIs are encouraged to group studies that use the same HS population & same research protocols into one Study Record; if more than one study, separate Study Records will need to be uploaded * Ensure FOA matches HS requirements | | | | | | | | | | |
| ***Required Study Record Sections based on Type of Research:*** | | | | | | | | | ***Human Subjects, Exemption 4*** | | ***Human Subjects,  no Clinical Trial*** | ***Clinical Trial (CT)*** |
|  |  | Section 1 - Basic Information - Complete Entire Section (but do not provide an NCT# in Section 1, item 1.5) | | | | | | | Required | | Required | Required |
|  |  | Section 2 - Study Population Characteristics - Complete Entire Section, and upload the following documents: | | | | | | | Not Required | | Required | Required |
|  |  |  | | **Inclusion of Individuals Across the Lifespan** - No page limit | | | | | Not Required | | Required | Required |
|  |  |  | | **Inclusion of Women and Minorities** - No page limit | | | | | Not Required | | Required | Required |
|  |  |  | | **Recruitment and Retention Plan** - No page limit | | | | | Not Required | | Required if study involves human participants | Required |
|  |  |  | | **Study Timeline** - No page limit | | | | | Optional | | Optional | Required |
|  |  |  | | **Inclusion Enrollment Report** - PI will need to select button to have Inclusion Enrollment Report appear within the record for completion | | | | | Not Required | | Required | Required |
|  |  | Section 3 - Protection and Monitoring Plans - Complete Entire Section, and upload the following documents: | | | | | | | Required – only Protection doc | | Required | Required |
|  |  |  | | **Protection of Human Subjects** - No page limit | | | | | Required | | Required | Required |
|  |  |  | | **Single IRB Plan** – Do not include, will be addressed at JIT (though yes/no response should be indicated) | | | | | Select N/A | | Required **at JIT** only if Multi-Site Study | Required **at JIT** only if Multi-Site Study |
|  |  |  | | **Data and Safety Monitoring Plan** - No page limit; if CT under Sponsor, only provide:   * Names of individuals/group responsible for trial monitoring (i.e. lead investigator of trial) * If applicable, name of independent safety monitor or data safety monitoring board. | | | | | Optional | | Optional | Required |
|  |  |  | | **Overall Structure of the Study Team** - No page limit | | | | | Optional | | Optional | Optional |
|  |  | Section 4 - Protocol Synopsis - Not required for fellowships; do not provide | | | | | | | Do not complete | | Do not complete | Do not complete |
|  |  | Section 5 - Other Clinical Trial-related Attachments - Not required for fellowships; do not provide | | | | | | | Do not complete | | Do not complete | Do not complete |
|  | Delayed Onset Study(ies) - Include if HS research, but cannot describe the study at the time of application | | | | | | | | | | | |
|  |  | | Add Study Title | |  | Do not check Anticipated CT box |  | Delayed Onset Study Justification - Info for a delayed onset study is not available at the time of proposal, so no full Study Record allowed | | | | |