 **NIH REQUIRED DOCUMENTS R01/R03/R21   
PI CHECKLIST - FORMS-I (FOR USE ON/AFTER 01/25/25)**

**URLs are denoted in underlined blue font so source instructions may be easily accessed.**

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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 | | | |
|  | 0.5” inch margins; letter sized paper | |  | No headers or footers | | |  | [No electronic signatures](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm#electronicsignatures); must flatten all PDFs with signatures | |  | No URLS except for citations in References Cited and Biosketch |
|  | **All files in PDF;**  Doc names 50 characters or less | | | |  | **No** Co-PI role used.  (If Multiple PI, list as PI) | | | |
|  | Please alert OCG Proposal Analyst if applying to a [Notice of Special Interest](https://www.niaid.nih.gov/research/notice-special-interest-nosi-sop) (in addition to FOA number). | | | | | | | | | | |
|  | Recommended file name convention: *PILastName\_DocumentTitle.pdf* | | | |  | **E-mail all docs to grantgov@colorado.edu AND Proposal Analyst** | | | | | |
| [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) | | | | | | | | | | | |
|  | **Cover Letter** (Optional) - Required if project has/is:  **•** [Late application](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) **•** [Continuous Submission](https://grants.nih.gov/policy/peer/continuous-submission.htm) **•** Video  **•** Human Fetal Tissue (HFT) **•** Sub Budgets not included for entire project period  **•** Large-scale genomic data (see budget section regarding budgeting appropriate costs)  **•** If requesting ≥$500k DC annually, request must be made to Program Officer at least 6 weeks   prior to award (some NIH Institutes require earlier deadlines)  Format:   * Addressed to Division of Receipt and Referral; Application Title; Title of FOA * See [FORMS-I Application 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 information to be provided. * Do **not** request assignment of proposal to specific NIH Institute here; address in Assignment Request Form. | | | | | | | | | | *PIName\_CoverLetter.pdf* |
| [ASSIGNMENT REQUEST FORM](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.600-phs-assignment-request-form.htm) (Optional) | | | | | | | | | | | |
|  | **Assignment Request Form** (Optional – Request form from Proposal Analyst if necessary):   * Complete and provide if you want to identify requested Institute/Center, Study Section, or Reviewers not to include. * Confirm that requested Institute listed on this form is also listed in FOA as a Participating Organization | | | | | | | | | | *PIName\_Assignment.pdf* |
| [COVER PAGE SUPPLEMENT](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.210-phs-398-cover-page-supplement-form.htm?Highlight=human%20fetal%20tissue) | | | | | | | | | | | |
|  | | Do you have Human Fetal Tissue (HFT)? **If yes – you must provide the following 2 docs:**  **Note**: For more details on HFT requirements, visit: [FORMS-I Application Guide’s HFT Section](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.210-phs-398-cover-page-supplement-form.htm?Highlight=human%20fetal%20tissue#4) | | | | | | | | | |
|  | | **HFT Compliance Assurance** (Required if applicable):   * Provide a signed letter (from PI), assuring the HFT donating organization adheres to the requirements of the informed consent process and documenting that HFT was not obtained/acquired for valuable consideration. | | | | | | | **Must be named:**  *HFTComplianceAssurance.pdf* | | |
|  | | **HFT Sample IRB Consent** (Required if applicable):   * Must be a blank sample IRB Consent Form. | | | | | | | **Must be named:**  *HFTSampleIRBConsentForm.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) | | | | | | | | | | | |

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|  | Inform Proposal Analyst of all involved on project:  [Senior/Key Personnel](https://grants.nih.gov/grants/glossary.htm#Senior/KeyPersonnel) (PI/Co-I/etc.) or any [Other Significant Contributor](https://grants.nih.gov/grants/glossary.htm#OtherSignificantContributors(OSCs))s (OSC) | *SKPSurname\_Biosketch.pdf* |

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|  | **Biosketch** (Required for PI, Co-Is, and OSCs): 5-page limit; Use [NIH Biosketch template available here](https://grants.nih.gov/grants/forms/biosketch.htm) or use  ***OCG-recommended*** [SciENcv](https://www.ncbi.nlm.nih.gov/sciencv/) to create your Biosketch, carefully following the instructions. | | | | | |
|  |  | eRA Commons ID required for all listed including OSC |  | Education/Training: List in **chronological** order. |  | C. Contributions to Science |
|  |  | A. Personal Statement *Include Personal Statement. Optional to also include:*   * Select Ongoing/Completed Research Projects from Past 3 years * Products *-* 4 products max | | | * 5 Contributions to Science max per Biosketch * 4 products max per Contributions to Science *Recommend* [*PMCIDs*](https://publicaccess.nih.gov/policy.htm)*’ inclusion for all pubs listed in bio authored/co-authored by applicant.* * Only URL allowed for full list of published work, **must** be a Federal (.gov) site. NIH’s [My Bibliography](http://www.ncbi.nlm.nih.gov/books/NBK53595/) is recommended. No other URLs allowed. | |
|  |  | B. Positions, Scientific Appointments, and Honors   * Positions and Scientific Appointments (both domestic & foreign): List in **reverse chronological** order. | | |
| *Other Support is* ***not*** *required for NIH proposal submissions and will be requested at the* [*Just-in-Time (JIT) phase*](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm)*.* [*Detailed Other Support Instructions and Format page are found here*](https://grants.nih.gov/grants/forms/othersupport.htm)*.*  ***NIH has postponed the requirements for use of the SciENcv-generated “Common Forms” for 05/25/25.*  Continue using the current Biosketch and Other Support templates for all proposal submissions.** | | | | | | |

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| [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) | | | | | | |
|  | | | **Project Summary/Abstract** (Required):   * 30 lines of text; Description of proposed work | | | *PIName\_Summary.pdf* |
|  | | | **Project Narrative** (Required):   * 3 sentences maximum; Describe relevance to public health | | | *PIName\_Narrative.pdf* |
|  | | | **Bibliography & References Cited** (Required):   * No page limit; URLs allowed * Recommend including [PMCIDs](https://publicaccess.nih.gov/include-pmcid-citations.htm)’ for all pubs listed in bio authored/co-authored by applicant and fall under [Public Access Policy](https://publicaccess.nih.gov/policy.htm) | | | *PIName\_References.pdf* |
|  | | | **Facilities & Other Resources** (Required):   * No page limit; Describe CU and all sub/performance sites and any biohazards facilities; May use [OCG Facilities template here](https://www.colorado.edu/ocg/media/92) | | | *PIName\_Facilities.pdf* |
|  | | | **Equipment** (Required):   * No page limit List major items of equipment already available for this project * If no equipment on project, provide doc stating “No Equipment” (or similar) | | | *PIName\_Equipment.pdf* |
|  | | | **Other Attachments** – Provide Other Attachments **only** if FOA requests, or if **Foreign Justification** required. | | | |
|  | | |  | [**Foreign Justification**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.220-r&r-other-project-information-form.htm#6) **\*** (Required if answered “Yes” to International Activities/Collaboration;  ***Note****: International conferences are not considered intl. collaboration.*):   * Describe special resources/characteristics of research project, including the reasons why the facilities/other aspects of the project are more appropriate than a domestic setting. | | **Must be named:**  *Foreign Justification.pdf* |
| Budget | | | | | | |
| * Use [OCG’s NIH Cost Estimation Tool](https://www.colorado.edu/ocg/media/166) for budgeting purposes. * PIs may choose whether to inflate or flat-budget salaries because NIH is reducing awards by inflated amounts. PA to confirm PI’s preference. NIH recommends using inflated costs when possible but will cut inflation from awards. * If personnel are over salary cap, use [current NIH salary cap](https://grants.nih.gov/grants/policy/salcap_summary.htm) for budgeting. 2025 cap of $225,700 for 12-month period (equates to $169,275 cap for 9-month appointment). * Contributed (unpaid) AY effort should be detailed on ESTTOOL. * If research includes HFT, **must** use R&R Detailed Budget and **cannot** use modular. * **NIH Data Management & Sharing (DMS) Policy**: DMS Costs no longer need to be specified as a separate budget line item; *only include DMS costs in appropriate budget categories.* However, DMS Justification must still be included; see DMS Justification requirements below. See [**OCG’s NIH DMSP page**](https://www.colorado.edu/ocg/NIH-DMSP) for more details on DMS requirements and allowable costs*.* | | | | | | |
| [R&R DETAILED budget](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.300-r&r-budget-form.htm) \* *(Only Use if $250,001 or MORE Direct Costs per year)* | | | | | | |
|  | | **Budget Justification**  **\*** (Required for R&R Detailed Budget)   * See [OCG Budget Justification Template](https://www.colorado.edu/ocg/media/169) for guidance on required statements; **including NIH Data Management & Sharing Policy (DMSP) requirements.** * If researcher is over the salary cap, statement must be included with base salary provided. * Contributed (unpaid) AY time detailed - Time is considered committed effort. * **Data Management and Sharing Costs** - Only budget DMS costs in appropriate budget categories. DMS-related costs must be described in Justification (see below). * **Data Management and Sharing Justification** - Must be labeled exactly “Data Management and Sharing Justification” within Other Direct Costs, up to half a page allowed. PI must provide brief summary of type & amount of scientific data to be preserved/shared and name of the repositories. **The total DMS cost estimate must be specified; must iterate in if no DMSP Costs**. PI must briefly explain personnel effort/costs associated with general cost categories: curating data and developing supporting documentation, local data management activities, preserving and sharing data through established repositories, etc. See [Justification Template](https://www.colorado.edu/ocg/media/169) for requirements.   + If there are any Genomic Data Sharing Costs included in the budget, they must be described within the DMS Justification; CU Research Computing can assist with Genomic Data Sharing Costs related to secure storage and access: [rc-help@colorado.edu](mailto:rc-help@colorado.edu). * **Human Fetal Tissue Costs** \* – Include the quantity/types/sources of the HFT, including the stage of fetal development. Information must be included even if the HFT costs have no funds requested; **Must be clearly labeled.** | | | | *PIName\_Justification.pdf* |
| [MODULAR BUDGET](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.320-phs-398-modular-budget-form.htm) \* *(Only Use if $250,000 or less Direct Costs per year)* | | | | | | |
|  | **Personnel Justification**   * Provide all personnel effort, names, roles, and effort in person-months * Contributed (unpaid) AY time detailed - Time is considered committed effort * Do not provide salary information; other rate information is not necessary | | | | | *PIName\_Personnel.pdf* |
|  | **Consortium Justification** \*   * Provide an estimate of total consortium/subaward costs (DC+IDC) for each budget period, rounded to the nearest $1,000; Do not provide salary information; other rate information is not necessary * List the individuals/orgs of sub sites and indicate if domestic/foreign site * Provide all sub personnel effort, names, roles, and effort in person-months | | | | | *PIName\_Consortium.pdf* |
|  | **Additional Narrative Justification** (Required on Modular Research Budgets)   * ***Data Management and Sharing Justification*** (required) - Must be labeled exactly “Data Management and Sharing Justification” within Other Direct Costs, up to half a page allowed. PI must provide brief summary of type & amount of scientific data to be preserved/shared and name of the repositories. **The total DMS cost estimate must be specified; must iterate in if no DMSP Costs**. PI must briefly explain personnel effort/costs associated with general cost categories: curating data and developing supporting documentation, local data management activities, preserving and sharing data through established repositories, etc. If there are any Genomic Data Sharing Costs included in the budget (including costs related to secure storage and access), they must be described within the DMS Justification; CU Research Computing can assist with costs: [rc-help@colorado.edu](mailto:rc-help@colorado.edu).   See OCG [**Additional Narrative Justification Template**](https://www.colorado.edu/ocg/media/128) for required description.   * Should explain any variation in number of modules requested annually unless FOA has DC limits that do not spread evenly across budget periods (example: R21s) * Quotes may be included here, but not required. * Should describe direct costs excluded from total direct costs (MTDC Base). | | | | | *PIName\_AddJust.pdf* |
| [PHS 398 RESEARCH PLAN](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.400-phs-398-research-plan-form.htm) | | | | | | |
|  | | | **Introduction to Application \*** (Required, if resubmission or revision)   * 1 page limit; Summarizes substantial changes to the application; only applicable for resubmission or revision, or if FOA denotes requirement * For resubmissions changing from single PI to Multiple PI, changing number/makeup of Multiple PIs, or changing from Multiple PI to single PI, the Intro to App must provide a rationale for the change. | | | *PIName\_Introduction.pdf* |
|  | | | **Specific Aims** (Required)   * 1 page limit; State concisely the goals of the proposed research and summarize the expected outcome | | | *PIName\_SpecificAims.pdf* |
|  | | | **Research Strategy** (Required)   * R03/R21: 6-page limit; R01: 12-page limit. * Sections must be labeled with following headers: **1. Significance ; 2. Innovation ; 3. Approach** * Reference DMSP and any included Resource Sharing Plan in 3. Approach as appropriate. * If Human Fetal Tissue (HFT), include HFT info in 3. Approach section under a subsection entitled “**Human Fetal Tissue Research Approach**“; details included under [“Special Instructions” section of Approach](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.400-phs-398-research-plan-form.htm?Highlight=Special%20Instructions%20for%20Applications%20Proposing%20the%20Use%20of%20Human%20Fetal%20Tissue#3). * Progress Report for Renewal and Revision Applications\* - Section only required if a renewal application; must fall within Research Strategy page limits. * For renewals changing from single PI to Multiple PI, changing number/makeup of Multiple PIs, or changing from Multiple PI to single PI, the Research Strategy must provide a rationale for the change. | | | *PIName\_ResearchStrategy. pdf* |
|  | | | **Progress Report Publication List** \* (Required for renewal applications)   * No page limit;List title and complete references to all publications resulting from project since it was last reviewed competitively. * Recommend [PMCIDs](https://publicaccess.nih.gov/include-pmcid-citations.htm)’ inclusion for all pubs listed in bio authored/co-authored by applicant and fall under [Public Access Policy](https://publicaccess.nih.gov/policy.htm). | | | *PIName\_Publications.pdf* |
|  | | | **Vertebrate Animals***\** (Required if Animal research)   * No page limit; Provide: Description of Procedures; Justifications; Minimization of Pain and Distress * Describe proposed animal activities conducted at all performance sites * Explain when/how animals are expected to be used; if plans not finalized | | | *PIName\_Vertebrate.pdf* |
|  | | | **Select Agent Research** \* (Required if [activities involve use of select agents](http://www.selectagents.gov/))   * No page limit; should identify select agents, registration status, and description of facilities to use select agents * If only use of [excluded select agents](http://www.selectagents.gov/SelectAgentsandToxinsExclusions.html), note which strains and that it has been excluded. | | | *PIName\_SelectAgent.pdf* |
|  | | | **Multiple PD/PI Leadership Plan** \* (Required only if more than 1 PI, not applicable to Co-Is)   * No page limit; should describe rationale for choosing a multiple PD/PI approach, and governance/organizational structure of leadership team * [NIH Multiple PI Leadership Plan Sample here](http://grants.nih.gov/grants/multi_pi/sample_leadership_plans.pdf). | | | *PIName\_LeadershipPlan.pdf* |
|  | | | **Consortium/Contractual Arrangements** \* (Required if there is a subcontract)   * No page limit; use [OCG Consortium template here](https://www.colorado.edu/ocg/media/31) * Describe the programmatic, fiscal, and administrative arrangements to be made between the applicant org and the consortium org/s | | | *PIName\_Contractual.pdf* |
|  | | | **Letters of Support** (Optional)   * No page limit; all letters of support in a single PDF document * [No electronic signatures](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm#electronicsignatures); print-to-PDF all letters with e-signature to flatten. * Letters should describe terms of a collaboration or consultation; must not contain data/figures/tables/graphs, preliminary data, methods, background and significance details that are expected to be found in Research Strategy | | | *PIName\_SupportLetters.pdf* |
|  | | | **Resource Sharing Plan(s)** \* (Required only if applicable)   * No page limit; required **only** when:   + FOA requires Resource Sharing Plan   + Resources/[research tools](https://sharing.nih.gov/other-sharing-policies/research-tools-policy) will be developed by NIH funds (and the associated research findings published or provided to NIH), **OR**   + Development of model organisms is anticipated. Must include a description of specific plan for sharing and distributing or state why sharing is not possible. | | | *PIName\_ResourceSharing. pdf* |
|  | | | [**Data Management and Sharing Plan**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.400-phs-398-research-plan-form.htm#11) (Required for all research proposals)   * Recommended 2 page limit * **Review the** [**CRDDS DMSP: Tools for CU Researchers**](https://cu-boulder-crdds.github.io/nih_dmsp_primer/) **primer** * **Use the** [**DMPTool**](https://dmptool.org/) **to create plan and** [**consult CRDDS**](https://www.colorado.edu/crdds/what-we-do/grant-support) **for recommendations on repository use. Refer to** [**OCG’s NIH DMSP page**](https://www.colorado.edu/ocg/NIH-DMSP) **for more info on policy.** * **DMSP Required Elements:** 1. Data Type; 2. Related Tools, Software and/or Code; 3. Standards; 4. Data Preservation, Access, and Associated Timelines; 5. Access, Distribution, or Reuse Considerations; 6. Oversight of Data Management and Sharing. [Sample plans available here](https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/writing-a-data-management-and-sharing-plan#sample-plans). * [**Please review Data Sharing Policy and any required repositories for your specific NIH Institute/Center (IC) here to confirm IC requirements**](https://sharing.nih.gov/other-sharing-policies/nih-institute-and-center-data-sharing-policies)**.** * If applying to NIAAA with human subjects please review [NIAAA Data-Sharing Policy here](https://grants.nih.gov/grants/guide/notice-files/NOT-AA-23-001.html). NIH DMSP should adhere to additional [NIAAA requirements here](https://grants.nih.gov/grants/guide/notice-files/NOT-AA-23-001.html). The NIAAA [NDA Cost Estimation Tool](https://nda.nih.gov/niaaa/forms.html) for data sharing is used for estimates. * If app includes: Genomic Data Sharing (GWAS) see [instructions for describing Genomic Summary Results in Data Management and Sharing Plans](https://sharing.nih.gov/genomic-data-sharing-policy/developing-genomic-data-sharing-plans). | | | *PIName\_DMSPlan.pdf* |
|  | | | **Authentication of Key Biological and/or Chemical Resources** \* (Required if applicable)   * No page limit but 1 page recommended * Describe methods to ensure the identity and validity of key biological and/or chemical resources | | | *PIName\_Authentication.pdf* |
|  | | | **Appendix** \* (Not typically allowed unless requested by FOA)   * FOA will specify if any special appendix instructions; carefully review [NIH Appendix Policy](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-098.html) * Allowable Appendix Items for Inclusion:   + Summary sheet encouraged but not required   + Blank data collection forms, blank survey forms and blank questionnaire forms (Do not include instruction pages)   + Simple lists of interview questions   + Blank informed consent/assent forms | | | *PIName\_DocName.pdf* |
| [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:*** | | | | | | |
|  | [**Explanation for Use of Human Specimens and/or Data Not Considered to be Human Subjects Research**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#UseOf) (Required if proposals have human specimens and/or data – Human specimens/data are **not** the same as Human Subjects Research) **\***   * Provide an explanation for any use of human specimens and/or data **not** considered to be Human Subjects research * **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.** | | | | | *PIName\_HumanSpecs.pdf* |
|  | **Human Subjects (HS) Study Record** \* (Required for all HS-research proposals)   * Proposal Analyst will provide you with HS Study Record to input responses, upload **only PDF** documents, and complete appropriate sections (detailed below); **all uploads must be in PDF** and not Word * **File Names under 50 characters in length**; Study Titles under 600 characters in length * No page limit to uploaded documents in Study Record, but there may be limitations on entered text; please see Study Record * 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 * 4 Clinical Trial Questionnaire responses: If all yes, then research is considered to be a CT * Ensure FOA matches HS requirements. * Follow Table on next page to determine which sections/documents are required for the proposal. | | | | | |
|  | **Delayed Onset Study(ies) \*** (Required if applicable)   * Include if HS research, but cannot describe the study at the time of application | | | | | |
|  |  | | | | **Delayed Onset Study Justification**   * Provide justification why HS study information is not available at the time of application * Info for a delayed onset study is not available at the time of proposal, so no full Study Record allowed | |

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| ***Required Study Record Sections based on Type of Research:*** | | | ***Human Subjects, Exemption 4*** | ***Human Subjects,  no CT*** | ***Clinical Trial (CT)*** |
|  | **Section 1 - Basic Information \*** Complete all fields | | Required | Required | Required |
|  | **Section 2 - Study Population Characteristics \*** Complete all fields | | Not  Required | Required | Required |
|  |  | [**Inclusion of Individuals Across the Lifespan**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.3.a) **\***   * Exclusion of any specific age/age range group should be justified. | Not  Required | Required | Required |
|  |  | [**Inclusion of Women and Minorities**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.4) **\***   * Describe planned distribution of subjects by sex/gender/race/ ethnicity and rationale for selection * Describe proposed outreach programs * Provide reasons for limiting any group | Not  Required | Required | Required |
|  |  | [**Recruitment and Retention Plan**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.5) **\***   * Describe how you will recruit and retain participants in your study | Not  Required | Required if study involves human participants | Required |
|  |  | [**Study Timeline**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.7) **\***   * Provide description/diagram describing study timeline | Optional | Optional | Required |
|  |  | [**Inclusion Enrollment Report**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.9) \*   * PI will need to select button to have Inclusion Enrollment Report appear within the record; complete report as needed * If app includes a study recruiting subjects at more than one site, PIs may create one IER or separate, multiple IERs to enable reporting by study or site | Not  Required | Required | Required |
|  | **Section 3 - Protection and Monitoring Plans** Complete section if required | | Required | Required | Required |
|  |  | [**Protection of Human Subjects**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.1) \*   * Include following sections:  1. Risks to Human Subjects    1. Human Subjects Involvement, Characteristics, and Design    2. Study Procedures, Materials, and Potential Risks 2. Adequacy of Protection Against Risks    1. Informed Consent and Assent    2. Protections Against Risk    3. Vulnerable Subjects *(if relevant)* 3. Potential Benefits of the Proposed Research to Research Participants and Others 4. Importance of the Knowledge to be Gained | Required | Required | Required |
|  |  | [**Single IRB Plan**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.2) (sIRB) \*   * Yes/No response must be provided * sIRB Plan **not** required at proposal; sIRB Plan required at JIT | Select N/A | Required **at JIT** only if Multi-Site Study | Required **at JIT** only if Multi-Site Study |
|  |  | [**Data and Safety Monitoring Plan**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.3)(DSMP) \*   * Provide DSMP that is commensurate with the risks of the trial, its size, and its complexity | Optional | Optional | Required |
|  |  | [**Overall Structure of the Study Team**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.5) **\***   * Brief overview of the organizational/administrative structure and function of the study team | Optional | Optional | Optional |
|  | **Section 4 - Protocol Synopsis** Do **not** complete unless required  *Question 4.6* *Is this an applicable clinical trial under FDAAA?* [*Review NIH Flowchart to determine response*](https://grants.nih.gov/clinicaltrials_fdaaa/docs/flow_chart-act_only.pdf)*.* | | Do not complete or upload | Do not  complete or upload | Required |
|  |  | [**Statistical Design and Power**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#4.3) **\***   * Specify the number of subjects planned, the expected effect size, the power, and the statistical methods | Required |
|  |  | [**FDA Regulated Intervention**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#4.5) **\***   * Provide summary describing the availability of study agents, support for acquisition/administration of study agents | Required for FDA-reg.  intervent. study |
|  |  | [**Dissemination Plan**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#4.7) **\***   * Explain briefly dissemination of NIH CT information and how policy expectations will be met | Required |
|  | **Section 5 - Other Clinical Trial-related Attachments** | | Do not complete or upload | Do not  complete or upload | As required by FOA |
|  |  | [**Other CT-related Attachments**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-i/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#5.1) \*   * Only include documents required by FOA |