**NIH PROPOSAL R01/R03/R21 SUBMISSION**

 **REVIEW CHECKLIST - FORMS-H (FOR USE ON/AFTER 10/05/23)**

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

**\* INDICATES DOCUMENT/SECTION IS REQUIRED IF APPLICABLE; IF NOT, 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.
URLs are denoted with **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*  |
|[ ]  ***All files in PDF*** |[ ]  *Doc names 50 characters or less* |[ ]  *0.5” inch margins; letter-sized paper* |[ ]  *No headers or footers* |
|[ ]  ***No*** *Co-PI role used. (If Multiple PI, list as PI)* |[ ]  *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)*; must flatten all PDFs with signatures* |
|[ ]  ***Click “Validate Application” button before submission to check for errors/warnings*** |
| Click here to enter comments if needed.  |
| [R&R Cover Page](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.200-sf-424-%28r%26r%29-form.htm?Highlight=cover%20letter) |
|[ ]  Federal Identifier entered for resubmission/ renewal/revisions (*ex: enter MH123456 from 1R01MH123456-01 - found in eRA Commons*) |[ ]  Person to be contacted: PA |[ ]  EIN: 1846000555A2  |
|[ ]  Agency Routing Number *(for* [***NOSIs***](https://www.niaid.nih.gov/research/notice-special-interest-nosi-sop) *if applicable)* |[ ]  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) [ ]  [Renewal](https://grants.nih.gov/grants/glossary.htm#RenewalApplication)[ ]  Select Revision if [Competing Revision](http://grants.nih.gov/grants/competing-revisions.htm) or [Non-competing Supplement](http://grants.nih.gov/grants/administrative-supplements.htm) |

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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* |[ ]  Estimated Project Funding matches budget sheet |
|[ ]  Is application subject to review by E.O. 12372? No | ***Note****: No SFLLL* | [ ]  | AOR info: PA |
| [ ]  | Cover Letter\* - *Required if: project has video, Human Fetal Tissue (HFT), large-scale genomic data, sub budgets missing budget period,* [*continuous submission*](https://grants.nih.gov/policy/peer/continuous-submission.htm)*, or* [*late application*](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html)*. Must be addressed to Division of Receipt and Referral & include Application Title, and Title of FOA.* ***Note****: Do not request assignment of proposal here; address in Assignment Request Form.* |
| Click here to enter comments if needed.  |
| [Project PERFORMANCE SITES](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.230-project-performance-site-location%28s%29-form.htm) |
| [ ]  | Provide CU Boulder information as the Primary Site: |
|  | [ ]  | UEI: SPVKK1RC2MZ3 | [ ]  | Congressional District: CO-002 | [ ]  |  Department Info/PI Campus Box |
|[ ]  Provide information on subaward sites including DUNS and Congressional District.  |
| Subaward details and/or comments may be entered here if needed.  |
| [ASSIGNMENT REQUEST FORM](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/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****Confirm that requested Institute listed on this form is also listed in FOA as a Participating Organization*** |
| Click here to enter comments if needed. |
| [COVER PAGE SUPPLEMENT](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.210-phs-398-cover-page-supplement-form.htm?Highlight=human%20fetal%20tissue) |
|[ ]  Vertebrate animals euthanized? (Answer if “Yes” to Animals on Other Project Information) |[ ]  Method consistent with AVMA? |
|[ ]  Program Income?  |[ ]  Human Embryonic Stem Cells? *If yes, complete remainder of section.* |
|[ ]  Human Fetal Tissue (HFT)? *If yes – include the following 2 docs:*  |[ ]  HFT Compliance Assurance: *HFTComplianceAssurance.pdf* |[ ]  HFT Sample IRB Consent:*HFTSampleIRBConsentForm.pdf* |
| ***Note****: For more details on HFT requirements, visit:* [*FORMS-H Application Guide’s HFT Section*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.210-phs-398-cover-page-supplement-form.htm?Highlight=human%20fetal%20tissue#4) |
|[ ]  Inventions and Patents?\* - *Renewals only* |[ ]  Change of PI/Change of Institutions?\* - *If applicable* |
| Click here to enter comments if needed. |
| [OTHER PROJECT INFORMATION](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.220-r%26r-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* |[ ]  Project Narrative - *3 sentences maximum; describe relevance to public health* |
|[ ]  Bibliography & References Cited - *No limit; URLs allowed; recommend* [*PMCIDs*](https://publicaccess.nih.gov/policy.htm)*’ inclusion for all pubs authored or co-authored by applicant.*  |[ ]  Facilities & Other Resources - *No limit; describe CU and all sub/performance sites; describe any special biohazards facilities* |
|[ ]  Equipment - *No limit; if no equipment on project, upload document stating “No Equipment” (or similar)* |
| [ ]  | Other Attachments – *Attach file* ***only*** *if FOA requests; if Foreign Justification is needed due to international collaboration or international research travel (not including conferences)*  |
| Click here to enter comments if needed. |
| [SENIOR/Key Personnel Profile](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.240-r%26r-seniorkey-person-profile-%28expanded%29-form.htm) |

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| [ ]  | Complete for all [Senior/Key Personnel](https://grants.nih.gov/grants/glossary.htm#Senior/KeyPersonnel) (PI/Co-I/etc.) and [Other Significant Contributor](https://grants.nih.gov/grants/glossary.htm#OtherSignificantContributors(OSCs))s (OSCs) Senior/Key Persons must have measurable effort. OSCs contribute to project but commit no measurable effort. [FAQ here](https://grants.nih.gov/faqs#/senior-key-personnel.htm). |

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| [ ]   | Name | [ ]  | Organization Name | [ ]  | Address Fields | [ ]  | Email |
| [ ]  | Role  | *No Co-PD/PI, Use Co-Investigator only; if Multiple PIs, choose “PI” role for all additional PIs.*  |
| [ ]  | Degree Type and Year of Highest Degree | [ ]  | eRA Commons ID - *Required for every person listed in Senior/Key Personnel Profile* |
| [ ]  | Biosketch/es – 5-page limit; required for PI, Co-Is, and OSCs; [Templates and detailed guidance found here](https://grants.nih.gov/grants/forms/biosketch.htm). *Recommended* *use of* [*SciENcv*](https://www.ncbi.nlm.nih.gov/sciencv/) *by PI to create Biosketch. Current Biosketch template expires 02/28/2024.*  |
|  | [ ]  | eRA Commons ID matches Biosketch | [ ]  | 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 to full list of publish work, must be a Federal .gov site. NIH’s [My Bibliography](http://www.ncbi.nlm.nih.gov/books/NBK53595/) is recommended.
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|  | [ ]  | B. Positions, Scientific Appointments, and Honors* Positions and Scientific Appointments (both domestic & foreign): List in **reverse chronological** order.
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| ***Note****: Other Support is* ***not*** *required for NIH proposal submissions and will be requested at the* [*JIT phase*](https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.5.1_just-in-time_procedures.htm)*.*[*Detailed Other Support Instructions found here*](https://grants.nih.gov/grants/forms/othersupport.htm)*; please note that there have been major changes per NIH* [*NOT-OD-21-073*](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-073.html)*.* |
| Click here to enter comments if needed. |

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| budget \* |
| * *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.*
* *If personnel is over salary cap, use* [*current NIH salary cap*](https://grants.nih.gov/grants/policy/salcap_summary.htm) *for budgeting. 2024 cap of $221,900 for 12-month period (equates to $166,425 cap for 9-month appointment).*
* *Contributed (unpaid) AY effort should be detailed on ESTTOOL*
* *If research is HFT,* ***must use R&R Detailed Budget and cannot use modular***.
* *Select “R&R Budget” or “Modular Budget” after clicking the “Add Optional Form” button on far-left side of ASSIST*
* ***NIH Data Management & Sharing (DMS) Policy****: For proposals submitted on/after 10/05/23, 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.*
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| Click here to enter comments. |

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| [R&R DETAILED budget](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.300-r%26r-budget-form.htm) \* *(Only Use if $250,001 or MORE Direct Costs per year)* |
| [ ]  | Budget Periods: *Consecutive Dates, Match Cover Page* | [ ]  | Budget Total: *Matches Cover page* |
| [ ]  | *PI is listed as PD/PI every budget year* | [ ]  | *Person Months listed for all personnel (including unpaid effort)* |
| [ ]  | Data Management and Sharing Costs - *No longer a required separate budget line item for proposals due on/after 10/05; only include DMS costs in appropriate budget categories. DMS-related costs must be described in* [*Justification*](https://www.colorado.edu/ocg/node/226/attachment)*. See* [***NIH ESTTOOL template***](https://www.colorado.edu/ocg/node/2177/attachment) *and the* [***OCG’s NIH DMSP page***](https://www.colorado.edu/ocg/NIH-DMSP) *for more details on requirements and allowable costs .*  |
| [ ]  | Human Fetal Tissue Costs\* *- If HFT research, the HFT line item* ***must*** *be titled exactly as “****Human Fetal Tissue Costs****” and included in F8-F17. The line item must only be used for HFT costs and cannot include/be combined with any “Other” costs. If there are no HFT costs but your proposal has HFT, you must still include as a line item but with “0” costs specified.* |
| [ ]  | Cognizant Agency: Mr. Patrick J. Cogley, HHS, 816-426-3200 |
| [ ]  | Budget Justification |
|  | [ ]  | *Contributed (unpaid) AY time detailed - Time is considered committed effort* |
|  | [ ]  | *If Personnel have institutional base salary (IBS) over* [*current NIH salary cap*](https://grants.nih.gov/grants/policy/salcap_summary.htm)*, include statement that person is over cap and provide current IBS (refer to Justification template)* |
|  | [ ]  | Additional Justification for Grad Students compensated above Zero-Level Postdoc: *Include if GRAs on project and refer to* [*Justification Template*](https://www.colorado.edu/ocg/node/226/attachment). |
|  | [ ]  | *If Materials & Supplies are over $1,000, itemize and provide details on individual categories* |
|  | [ ]  | Data Management and Sharing Justification - *Must be clearly labeled as “Data Management and Sharing Justification” within Other Direct Costs section. See* [*Justification Template*](https://www.colorado.edu/ocg/node/226/attachment) *for requirements. PI must provide a 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 here.*** *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* [*Budget Justification Template*](https://www.colorado.edu/ocg/node/226/attachment) *for requirements; must iterate in if no DMSP Costs.*  |
|  | [ ]  | 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*** |
|  | [ ]  | Justification of Budget Fluctuation *- if any significant increases/decreases in budget from Year 1*  |
| **Provide R&R Budget for each Subaward Site:** | Click here to enter comments. |
| [ ]  | Subaward R&R Budget\* *Download from ASSIST to send to sub; upload final version to ASSIST. Confirm UEI & Cognizant Agency listed. Ensure DMS Justification is included in Sub Justification.*  | [ ]  | Subaward Budget Justification\* *- Attached to sub R&R* |
|  [MODULAR BUDGET](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.320-phs-398-modular-budget-form.htm) \* *(Only Use if $250,000 or less Direct Costs per year)* |
| [ ]  | Budget Periods: *Consecutive Dates, Match Cover Page* | [ ]  | Budget Total: *Matches Cover page* |
| [ ]  | *Sub’s DC is part of requested Module DC* | [ ]  | *Sub IDC listed under “Consortium Indirect”* |
| [ ]  | Cognizant Agency: Mr. Patrick J. Cogley, HHS, 816-426-3200 | [ ]  | F&A Rate Agreement Date |
| [ ]  | 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 not necessary* |
| [ ]  | Consortium Justification\* |
|  | [ ]  | *Provide an estimate of total consortium/subaward costs (DC+IDC) for each budget period, rounded to the nearest $1,000* | [ ]  | *Provide all sub personnel effort, names, roles, and effort in person-months* |
|  | [ ]  | *List the individuals/orgs of sub sites and indicate if domestic/foreign site* | [ ]  | *Do not provide salary information; other rate information is not necessary* |
| [ ]  | Additional Narrative Justification |
|  | [ ]  | ***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. See OCG* [***Additional Narrative Justification Template***](https://www.colorado.edu/ocg/node/2207/attachment) *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* | [ ]  | *List any IDC-excludable costs*  |
| [PHS 398 RESEARCH PLAN](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.400-phs-398-research-plan-form.htm) |
|[ ]  Introduction to Application\* - *1 page limit; summarizes substantial additions, deletions, and changes to the application; only applicable for resubmission or revision, or if FOA denotes requirement* |
|[ ]  Specific Aims - *1 page limit;* *state concisely the goals of the proposed research and summarize the expected outcome*  |
|[ ]  Research Strategy - *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-h/general/g.400-phs-398-research-plan-form.htm?Highlight=Special%20Instructions%20for%20Applications%20Proposing%20the%20Use%20of%20Human%20Fetal%20Tissue#3)*.* |
|  |[ ]  *As applicable, also include preliminary studies for new applications and progress report for renewal and revision applications as part of the Research Strategy, keeping within the three sections listed above* |
|  |[ ]  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.* |
|[ ]  Progress Report Publication List\* - *Required for renewal applications; no page limit; recommend* [*PMCIDs*](https://publicaccess.nih.gov/policy.htm)*’ inclusion for all pubs listed in bio authored/co-authored by applicant* |
|[ ]  Vertebrate Animals\* - *Required if Animal research; no page limit; provide Description of Procedures, Justifications (for use of animal), Minimization of Pain and Distress* |
|[ ]  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* |
|[ ]  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.* [*NIH Multiple PI Leadership Plan Sample here*](http://grants.nih.gov/grants/multi_pi/sample_leadership_plans.pdf)*.* |
|[ ]  Consortium/Contractual Arrangements\* - *Required if there is a subcontract; no page limit;* [*OCG template here*](https://www.colorado.edu/ocg/node/1250/attachment)*; explains the programmatic, fiscal, and administrative arrangements to be made between the applicant org and the consortium org/s* |
|[ ]  Letters of Support - *All letters of support in a single PDF document; no page limit; must print-to-PDF all letters with e-signatures), 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* |
|[ ]  Resource Sharing Plan(s)\* - *No page limit; include* ***only*** *when 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*** *when development of model organisms is anticipated (must include a description of specific plan for sharing and distributing or state why sharing is not possible).* |
|[ ]  Other Plan(s): Data Management and Sharing Plan - *2 pages max recommended; DMSP required for all research proposals.* ***PIs should 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 specific 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-23-002.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) |
|[ ]  Authentication of Key Biological and/or Chemical Resources\* - *No page limit but 1 page recommended; describe methods to ensure the identity and validity of key biological and/or chemical resources* |
|[ ]  Appendix – *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) |
|  | Click here to enter comments if needed. |

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| [PHS Human Subjects and Clinical Trials Information](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/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 - *Include only if the human specimens/data are* ***not*** *Human Subjects research. Human specimens/data are not the same as Human Subjects (HS) 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* |
|  |[ ]  *File Names under 50 characters in length* |[ ]  *All HS Docs are PDF* |[ ]  *Study titles under 600 characters in length* |
| ***Notes****:* | * *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*
 |
| ***Required Study Record Sections based on Type of Research:***  | ***Human Subjects, Exemption 4*** | ***Human Subjects, no Clinical Trial*** | ***Clinical Trial*** |
|[ ]  **Section 1 - Basic Information** | Required | Required | Required |
|[ ]  **Section 2 - Study Population Characteristics** | 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 in record for editing* | Not Required | Required | Required |
|[ ]  **Section 3 - Protection and Monitoring Plans** | Required - only Protect. of HS doc | Required | Required |
|  |[ ]  Protection of Human Subjects *- No page limit; Sections include:* 1. Risks to Human Subjects  2. Adequacy of Protection Against Risks 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 *– 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* | Optional | Optional | Required |
|  |[ ]  Overall Structure of the Study Team *- No page limit* | Optional | Optional | Optional |
|[ ]  **Section 4 - Protocol Synopsis** | Do not complete | Do not complete | Required |
|  |[ ]  Statistical Design and Power *- No page limit* |  |  | Required |
|  |[ ]  FDA Regulated Intervention *- No page limit* |  |  | Required for FDA-reg. intervent. study |
|  |[ ]  Dissemination Plan *- No page limit* |  |  | Required |
|[x]   | **Section 5 - Other Clinical Trial-related Attachments** | Do not complete | Do not complete | As Required by FOA |
|  |[ ]   | Other CT-related Attachments  |  |  |  |
|[ ]  Delayed Onset Study(ies) - *Include if HS research, but cannot describe the study at the time of application;*  |
|  |[ ]  *Add Study Title* |[ ]  *Indicate if Clinical Trial anticipated* |[ ]  Delayed Onset Study Justification - *Info for a delayed onset study is not available at the time of proposal, so no full Study Record allowed* |
|  | Click here to enter comments if needed. |