**NIH R01//R03/R21 PROPOSALSUBMISSION REVIEW CHECKLIST - FORMS-F**

*Office of Grants and Contracts Administration*

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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.

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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*** *Co-PI role used. (If Multiple PI, list as PI)* |[ ]  *No URLS except for citations in Research Strategy and Biosketch*  |[ ]  [*No electronic signatures*](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm#electronicsignatures) |
|[ ]  ***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-f/general/g.200-sf-424-%28r%26r%29-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) [ ]  [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: AK-001 | ***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:  |
| [ ]  | Cover Letter\* - *Required if: project has video, Human Fetal Tissue (HFT), large-scale genomic data, sub budgets missing budget period,* [*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.*  |
| Click here to enter comments if needed.  |
| [Project PERFORMANCE SITES](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.230-project-performance-site-location%28s%29-form.htm) |
| [ ]  | Provide UAF information as the Primary Site: |
|  | [ ]  | DUNS: 615245164 | [ ]  | Congressional District: AK-001 | [ ]  |  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-f/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 and then manually input responses into ASSIST* |
| Click here to enter comments if needed. |
| [COVER PAGE SUPPLEMENT](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.210-phs-398-cover-page-supplement-form.htm?Highlight=human%20fetal%20tissue) |
|[ ]  Vertebrate animals euthanized? |[ ]  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-F Application Guide’s HFT Section*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/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-f/general/g.220-r%26r-other-project-information-form.htm) |
|[ ]  Human Subjects (HS)? |[ ]  IRB Pending? **Or** provide IRB approval date. |[ ]  Human Subjects: 00001041 |
|  |[ ]  [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: D16-00482 |
|[ ]  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-f/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#SeniorKeyPersonnel) (PI/Co-I/etc.) and [Other Significant Contributor](https://grants.nih.gov/grants/glossary.htm#OtherSignificantContributorsOSCs)s (OSC)*Senior/Key Personnel must have measurable effort. OSCs contribute to project but commit no measurable effort FAQ here:* [*https://grants.nih.gov/faqs#/senior-key-personnel.htm*](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 PI; recommended for all Co-Is;*  |
| [ ]  | Biosketch/es – 5-page limit; required for PI, Co-Is, and OSCs; *Recommended* *Biosketch template expires 02/28/2023* | [ ]  | eRA Commons ID matches |
|  | [ ]  | A. Personal Statement*Optional to include products -* 4 products max  | [ ]  | B. Positions and Honors*Chronological Order Recommended* |
|  | [ ]  | C. Contributions to Science  | [ ]  | D. Research Support - *Not Other Support; should include overall goals of the project.*  |
|  |  | [ ]  | 5 Contributions to Science max per Biosketch |  | [ ]  | Ongoing Research Support  |
|  |  | [ ]  | 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.* |  | [ ]  | Research Support within Past 3 Years |
|  |  | [ ]  | 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.  |  | [ ]  | *Do not include person months or direct costs.*  |
| ***Note****: Current & Pending 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)*.* |
| Click here to enter comments if needed. |

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| budget \* |
| * *As of 10/2018, 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 PI is over salary cap, use* [*current NIH salary cap*](https://grants.nih.gov/grants/policy/salcap_summary.htm) *for budgeting. 2020 cap of $197,300 for 12-month period (equates to $147,975 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*
 |
| Click here to enter comments.  |

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| [R&R DETAILED budget](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/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)* |
| [ ]  | Human Fetal Tissue Costs\* *- If HFT research, the HFT line item* ***must*** *be titled exactly as “****Human Fetal Tissue Costs****”. 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: Office of Naval Research (ONR) |
| [ ]  | 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)* |
|  | [ ]  | *If GRAs on project: Additional Justification for Grad Students compensated above Zero-Level Postdoc (refer to Justification template)* |
|  | [ ]  | *If Materials & Supplies are over $1,000, itemize and provide details on individual categories* |
|  | [ ]  | 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* | [ ]  | Subaward Budget Justification\* *- Attached to sub R&R* |
|  [MODULAR BUDGET](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/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: Office of Naval Research (ONR) |
| [ ]  | Personnel Justification |
|  | [ ]  | *Provide all personnel effort, names, roles, and effort in person-months* | [ ]  | *Do not provide salary information; other rate information is not necessary* |
|  | [ ]  | *Contributed (unpaid) AY time detailed - Time is considered committed effort* |  |  |
| [ ]  | 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\* |
|  | [ ]  | *Should explain any variation in number of modules requested annually –* ***Note****: Not required for FOAs with DC limits that do not spread evenly across budget periods (example: R21s)*  |
|  | [ ]  | *Quotes may be included here, but not required* |
| [PHS 398 RESEARCH PLAN](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/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 |
|  |[ ]  *If Human Fetal Tissue (HFT), include HFT info in* 3. Approach *section under a subsection entitled “***Human Fetal Tissue Research Approach***“; details included on* [*pages G-145 – G-146 of the FORMS-F Application Guide*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general-forms-f.pdf) |
|  |[ ]  *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* |
|[ ]  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,*  |
|[ ]  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* |
|[ ]  Consortium/Contractual Arrangements\* - *Required if there is a subcontract; no page limit; 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;* [*no electronic signatures*](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm#electronicsignatures)*, 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)\* - *Required if DC of $500k or more in any budget year, if required by FOA, or if required below; no page limit; highly encouraged* |
|  |[ ]  *If applying to NIAAA with Human Subjects, must include NIAAA Data Archive Sharing Plan -* [*NIAAADA DSP template*](https://nda.nih.gov/niaaa/pre-award/application.html) *encouraged; Costs associated with submitting data to the NIAAADA should be included in grant applications. A cost estimation tool (“*[*NDA Cost Estimation Tool*](https://nda.nih.gov/niaaa/pre-award/application.html)*”) for data sharing is available for this purpose.* |
|  |[ ]  *If applying to NIMH with Human Subjects, must include Resource Sharing Plan* |
|  |[ ]  *If app includes: Sharing Model Organisms or Genomic Data Sharing (GWAS), include Resource Sharing Plan* |
|[ ]  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-f/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) |
|  |[ ]  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* |
|  |[ ]  *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****:* | * *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 within the record for completion* | Not Required | Required | Required |
|  |[ ]  Section 3 - Protection and Monitoring Plans | 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* | Optional | Optional | Required |
|  |  |[ ]  Overall Structure of the Study Team *- No page limit* | Optional | Optional | Required |
|  |[ ]  Section 4 - Protocol Synopsis | Do not complete | Do not complete | Required |
|  |  |[ ]  Statistical Design and Power *- No page limit* | Do not include | Do not include | Required |
|  |  |[ ]  FDA Regulated Intervention *- No page limit* | Do not include | Do not include | Required for FDA-reg. inter. study  |
|  |  |[ ]  Dissemination Plan *- No page limit* | Do not include | Do not include | Required |
|  |[ ]  Section 5 - Other Clinical Trial-related Attachments | Do not complete | Do not complete | As Required by FOA |
|  |  |[ ]  Other CT-related Attachments  | Do not include | Do not include | As Required by FOA |
|[ ]  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. |