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| **Internal Institutional Documents** | **Date:** |
| **All items are due to OSP three business days before the Sponsor’s deadline** |  |
| IAS Form |  |
| FCOI Training |  |
| FCOI Disclosure Form |  |

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| **Items for Grant Application** | **Date:** |
| [**Formatting Requirements**](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm)* Save documents as PDF files
* File names: 50 characters or less including spaces; no ‘&’; 1 space between words
* Recommended Fonts: Arial, Helvetica, Palatino Linotype, Georgia; black; 11 pts or larger
* Page size: 8.5 x 11
* Margins: at least half-inch
* Header/Footer: not allowed; clear of any information; including no page numbers
* URLS: none except for citations in Biosketches and Publication Lists
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| [**SF424 R&R**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.200-sf-424-%28r%26r%29-form.htm?Highlight=cover%20letter)* Form: Complete items 1-19
* [Cover Letter](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.200-sf-424-%28r%26r%29-form.htm?Highlight=cover%20letter#21):
* Required for Changed/Corrected Application submitted after the deadline and/or if video to be sent and/or large-scale genomic data to be collected. Otherwise not required, but strongly encouraged
* Include application title, funding opportunity title, disciplines if multidisciplinary, explanation of subaward budget components not active for all periods
* See [Instructions FORMS-G](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.200-sf-424-%28r%26r%29-form.htm?Highlight=%20video%20large%20scale%20genomic%20data#21) for other details to include for video, large-scale genomic data, and/or required NIH approvals
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| [**SF424 R&R Project/Performance Site Location(s)**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.230-project-performance-site-location%28s%29-form.htm)* Form: Needed information Organization Name, DUNS Number, Street1, City, County, State, Country, ZIP/Postal Code, and Project/Performance Site Congressional District
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| [**SF424 R&R Other Project Information**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.220-r%26r-other-project-information-form.htm)* Questions: Answer questions on the use of human subjects, vertebrate animals, and environmental impact
* Project Summary:
* No more than 30 lines of text, understandable to a scientifically/technically literate lay reader
* Concise description of project objectives and methodologies suitable for dissemination to the public
* Include broad, long-term objectives and specific aims, making reference to the mission of NIH
* Note: Will be public domain
* Project Narrative:
* Describe the relevance of this research to public health in, at most, three sentences
* Use plain language
* Bibliography & References Cited:
* No page restriction
* Do not require a specific citation format
* Most style guides include format guidance for citations and all formats are acceptable
* The use of "et al." in place of listing all authors of a publication is allowable
* URLS are allowable
* Remember to comply with the [public access policy](https://publicaccess.nih.gov/) by [including](http://publicaccess.nih.gov/include-pmcid-citations.htm) the PMC reference number (PMCID) when citing [applicable papers](http://publicaccess.nih.gov/determine-applicability.htm) that you author or that arise from your NIH-funded research
* Should include any references cited in R.400 - PHS 398 Research Plan Form and in the R.500 - PHS Human Subjects and Clinical Trials Information Form
* Facilities and Other Resources:
* No page restriction
* Identify resources available to the program to demonstrate capability of research site to complete the proposal (include all performance sites)
* Equipment:
* No page restriction
* List major items of equipment already available and, if appropriate, identify location & pertinent capabilities
* If no equipment on project, provide document stating “No Equipment” (or similar)
* Other Attachments
* [Foreign Justification](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.220-r%26r-other-project-information-form.htm#6) (Required if answered “Yes” to International Activities/Collaboration; ***Note***: International conferences are not considered international collaboration.)
* Must be named: Foreign Justification.pdf
* Describe special resources or characteristics of the research project, including the reasons why the facilities or other aspects of the proposed project are more appropriate than a domestic setting
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| [**SF424(R&R) Senior/Key Person Profile**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.240-r%26r-seniorkey-person-profile-%28expanded%29-form.htm)* Required for [senior/key personnel](https://grants.nih.gov/grants/glossary.htm#SeniorKeyPersonnel) and [Other Significant Contributors](https://grants.nih.gov/grants/glossary.htm#OtherSignificantContributorsOSCs)
* Form: Enter data in this “Profile – Project Director/Principal Investigator” section for the Project Director/Principal Investigator (PD/PI) and enter data in this "Profile - Senior/Key Person" section to provide information on a senior/key person (other than the PD/PI listed above), if applicable.
* Biosketch:
* Up to 5 pages in length
* Use [NIH template](https://grants.nih.gov/grants/forms/biosketch.htm) or [SciENcv](https://www.ncbi.nlm.nih.gov/sciencv/)
* May provide a URL to a full list of your published work and it must be a Federal site. NIH’s [My Bibliography](http://www.ncbi.nlm.nih.gov/books/NBK53595/) is recommended
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| [**Budget**](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm)* Are not limited but need to reflect the actual needs of the proposed project
* Can be limited in a specific FOA, so it is important that applicants note any budgetary limits indicated in Part 2. Section 2. Award Budget of the FOA
* NIH's [Modular Budget Policy](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_13/13.2_applicability.htm) applies to R01 applications submitted by domestic institutions
* Are awarded for 1 - 5 budget periods, each normally 12 months in duration
* Can be renewed by competing for an additional project period
* For requests of more than $500,000 in direct costs in any year, the PD/PI must contact the NIH IC program staff at least six weeks before submission to obtain an agreement that the IC will accept the application
* Include cover letter with application, identifying staff member and IC who agreed to accept application
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| [**RR Budget**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.300-r%26r-budget-form.htm)* RR Budget Form (direct costs of $250,001 or more per year)
* The “Budget Justification" attachment is required
* Attach only one file
* Provide the additional information requested in each budget category and any other information the applicant wishes to submit to support the budget request
* The following budget categories must be justified, where applicable: equipment, travel, participant/trainee support, and other direct cost categories
* Include a justification for any significant increases or decreases from the initial budget period
* Justify budgets with more than a standard escalation from the initial to the future year(s) of support
* Explain any exclusions applied to the F&A base calculation
* If you have a quote(s), you may include it here
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| [**Modular Budget**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.320-phs-398-modular-budget-form.htm)* Modular budget Form (direct costs of $250,000 or less per year)
* Personnel budget justification
* Should include the name, role, and number of person-months devoted to this project for every person on the project
* Do not include salary information in the justification
* Consortium if applicable
* Include total costs (direct + F&A) rounded to the nearest $1,000 for each and identify any foreign consortiums
* Should include the name, role, and number of person-months devoted to this project for every person on the project
* Do not include salary information in the justification
* Additional (usually used to explain different number of modules per year) if applicable
* Include explanations for any variations in the number of modules requested annually
* Quotes may be included here, but not required
* Describe any direct costs excluded from the total direct costs (such as equipment, tuition remission) and any work being conducted off-site, especially if it involves a foreign study site or an off-site F&A rated
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| [**R&R Subaward Budget Attachment(s)**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.310-r%26r-subaward-budget-attachment%28s%29-form.htm)* The R&R Subaward Budget Attachment(s) Form is required if you have a subaward/consortium and are using the R&R Budget Form.
* Do not use this form if you are using the PHS Modular Budget Form or if you do not have a subaward/consortium
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| [**PHS 398 Research Plan**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.400-phs-398-research-plan-form.htm)* Introduction (Resubmission or Revision only):
* Maximum of 1 page
* Specific Aims:
* Maximum of 1 page
* Concisely state goals and specific objectives of the proposed research and summarize expected outcomes, including the impact the results will exert on the research and health fields
* Research Strategy:
* Single PDF document
* Maximum 12 pages
* Sections – Must be labeled in this order and with each header: 1.Significance; 2. Innovation; 3. Approach
* Approach includes information on Preliminary Studies for New Applications and Progress Report for Renewal/Revision Applications
* Progress Report Publication List (Renewal applications only):
* No page restriction
* List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the 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)
* Vertebrate Animals (if Vertebrate Animals is Yes):
* No page restriction
* Description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used
* Justifications for the use of animals versus alternative models and for the appropriateness of the species proposed
* Interventions to minimize discomfort, distress, pain and injury
* Justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals
* Select Agent Research (if applicable):
* No page restriction
* Identify [select agent(s)](https://www.selectagents.gov/) to be used
* Provide the registration status of all entities where select agent will be used
* Provide a description of facilities where select agent will be used
* If only use of [excluded select agents](http://www.selectagents.gov/SelectAgentsandToxinsExclusions.html), note which strains and that it has been excluded
* Multiple PD/PI Leadership Plan (if more than one PD/PI is specified):
* No page restriction
* Only required if multiple PIs Rationale for multiple PI approach should be described, as well as organizational structure of the leadership team and research project, including communication plans, processes for making decisions on scientific direction, and procedures for resolving conflict budget information
* Consortium/Contractual Arrangements (if applicable):
* No page restriction
* Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s)
* If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee. Signed by authorized representative
* Letters of Support (if applicable):
* Single PDF document
* No page restriction
* Font and margin requirements do not apply to letters of support
* [No electronic signatures](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm#electronicsignatures)
* Attach a file with all letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application
* For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per budget period anticipated. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service
* Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project
* [Resource Sharing Plan](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.400-phs-398-research-plan-form.htm#10):
* No page restriction
* Data Sharing Plan
* Required if DC of $500k or more in any budget year, if required by FOA, or if required below; otherwise highly encouraged
* Provide a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible
* If applying to NIAAA with Human Subjects, must include NIAAA Data Archive Sharing Plan - [NIAAADA DSP template](https://nda.nih.gov/niaaa/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/application.html)”) for data sharing is available for this purpose
* If applying to NIMH with Human Subjects, must include Resource Sharing Plan
* Sharing Model Organisms (if applicable)
* Genomic Data Sharing Plan (if applicable)
* [Authentication of Key Biological/Chemical Resources](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.400-phs-398-research-plan-form.htm#11) (if applicable):
* No page restriction, but 1 Page Recommended
* Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies
* Appendix:
* It is unusual if anything is attached in this section. Only if instructed in FOA
* Review [NIH Appendix Policy](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-098.html)
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| [**PHS Human Subjects and Clinical Trials Information**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm)* Questions: Answer questions on the use of human subjects, vertebrate animals, and environmental impact
* If you answered “Yes” to the question “Are Human Subjects Involved?” on the R&R Other Project Information Form, you must include at least one human subjects study record using the Study Record: PHS Human Subjects and Clinical Trials Information Form or Delayed Onset Study record
* Study Record: PHS Human Subjects and Clinical Trials Information
* Delayed Onset Study
* Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start)
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| [**PHS 398 Cover Page Supplement**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.210-phs-398-cover-page-supplement-form.htm)* Complete Vertebrate Animals Section and Program Income Section, and Human Embryonic Stem Cells Section
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| [**PHS Assignment Request Form**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.600-phs-assignment-request-form.htm) **(optional)*** Do **not** include this information in Cover Letter
* Optional-Award Component Assignment Request: up to three NIH Institutes/Centers can be requested using their abbreviations (PI can also choose 3 “do not assign”). First choice should be #1.
* Optional- Study Section Assignment Request: up to three study sections or special emphasis panels (use short abbreviations) can be requested (PI can also choose 3 “do not assign”). First choice should be #1
* Optional-List of individuals who should not review and why
* Optional-Expertise needed to review your application
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