

INFORMATION ON APPLICATIONS

LISTING OF CHANGES TO APPLICATIONS

Notice NOT-OD-16-081 at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-081.html>

ENHANCING REPRODUCIBILITY IN RESEARCH THROUGH RIGOR AND TRANSPARENCY INITIATIVE

You should see these NIH Peer Reviewer Guidance documents pertaining to this initiative.

https://grants.nih.gov/grants/peer/guidelines_general/Reviewer_Guidance_on_Rigor_and_Transparency.pdf

“Sex as a Biological Variable” (**SABV**)

https://grants.nih.gov/grants/peer/guidelines_general/SABV_Decision_Tree_for_Reviewers.pdf

APPENDIX MATERIAL LIMITATIONS (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-129.html>)

Notice NOT-OD-16-129 indicates elimination of most appendix materials.

VERTEBRATE ANIMALS SECTION (VAS) (https://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm)

In the **four**-point VAS, provide:

- 1. Description of Procedures.** Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex*, and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals. ***TIP:** As part of the consideration of sex as a biological variable, the use of single-sex animal models should be justified in the Research Strategy.
- 2. Justifications.** Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro). **NOTE:** justification for the number of animals has been eliminated from the VAS and should now be addressed in the Research Strategy.
- 3. Minimization of Pain and Distress.** Describe the interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints to minimize discomfort, distress, pain, and injury.
- 4. Method of Euthanasia (In the cover page supplement),** Answer the question, "Is the method consistent with AVMA guidelines?", If "No", then describe the method and provide a scientific justification.

INCLUSION OF WOMEN

As part of the consideration of sex as a biological variable, the use of single-sex or gender models should be well justified in the Research Strategy and Inclusion of Women and Minorities Section.

INCLUSION OF CHILDREN (<https://grants.nih.gov/grants/funding/children/children.htm>)

For the purposes of inclusion, the age of a child will be defined as individuals under eighteen (18) years old.

GENOMIC DATA SHARING (GDS) PLAN APPLIES TO MORE THAN JUST “GENOMICS”

GDS website: <https://gds.nih.gov/>

The GDS-resource sharing policy applies to large-scale sequence data including (but not limited to) genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data, irrespective of funding level and funding mechanism. See what is covered at https://gds.nih.gov/PDF/Supplemental_Info_GDS_Policy.pdf.

ASSIGNMENT REQUEST FORM (ARF)

Note: The information in the ARF is used by NIH staff only, and reviewers are not allowed to see it.

ARF website: <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general/g.600-phs-assignment-request-form.htm>

On the ARF, provide the:

1. Funding Opportunity Announcement Number (FOA)
2. FOA title
 - List of Parent Program Announcements (PA):
https://grants.nih.gov/grants/guide/parent_announcements.htm
 - PA-16-160 NIH Research Project Grant (Parent R01)
 - PA-16-161 Exploratory-Developmental Research Grant Program (Parent R21)
 - PA-16-162 NIH Small Research Grant Program (Parent R03)
3. FOA Search page: <https://grants.nih.gov/grants/guide/index.html>
3. 1st, 2nd, 3rd preferred assignments to an institute/center as well as “don’t assign to”
4. 1st, 2nd, 3rd preferred study section as well as “don’t assign to”
(Use the 2- to 4-character acronym like VIRA and not hyphenated (VIR-A) or written out (Virology A). If intended for a special emphasis panel, indicate the Integrated Review Group by acronym.
 - List of CSR Study Sections: <https://public.csr.nih.gov/StudySections/Standing/Pages/default.aspx>
 - List of CSR Integrated Review Groups (IRG):
<https://public.csr.nih.gov/StudySections/IntegratedReviewGroups/Pages/default.aspx>
 - List of CSR SBIR-STTR Panels:
<https://public.csr.nih.gov/StudySections/SmallBusinessTechnologyTransfer/Pages/default.aspx>
5. Requests & brief reasons why a person should not review your application
6. Areas of expertise needed for thorough review

The screenshot shows the PHS Assignment Request Form (ARF) interface. It includes a header with 'View Bulletin Statement', 'PHS Assignment Request Form', and 'OMB Number: 0302-0046 Expiration Date: 10/31/2020'. The form has several sections: 'Funding Opportunity Number' and 'Funding Opportunity Title' with input fields; 'Assigning Component Assignment Request (optional)' with a table for assigning components; 'Study Section Assignment Request (optional)' with a table for assigning study sections; and 'List individuals who should not review your application and why (optional)'. There are also checkboxes for 'Assign to Awarding Component', 'Do Not Assign to Awarding Component', 'Assign to Study Section', and 'Do Not Assign to Study Section'.

APPLICATION COVER LETTER

Note: The information in the cover letter is used by NIH staff only, and reviewers are not allowed to see it.

Use the Cover Letter Attachment field (item #21) at the bottom of the SF424 (R&R) form within your application.

Provide an Application Cover Letter to:

Explain Late Submission of an application: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html>

State Continuous Submission eligibility: https://grants.nih.gov/grants/peer/continuous_submission.htm

State that Videos will be submitted as Post-Submission Application Materials

https://grants.nih.gov/grants/funding/post_submission_faq.htm

State that a Genomic Data Sharing (GDS) Plan is provided in the “Resource Sharing Plan”

GDS website: <https://gds.nih.gov>

Examples of what’s covered https://gds.nih.gov/PDF/Supplemental_Info_GDS_Policy.pdf

State agency approval for budgets \geq \$500K, conference grants, co-operative agreements

Provide information on sub-award budgets not active for all periods

ARF information should not be included in the cover letter

===== Sample Cover Letter =====

NIH Center for Scientific Review
6701 Rockledge Dr.
Bethesda, MD 20892

Dear Division of Receipt and Referral,

Application title: Development of NS1 Inhibitors to Block Influenza Virus Infection

Reason for Late Submission: I served as a member on the WXYZ study section which met Month Day Year at the Washington Hotel. The SRO is First Last Name, Ph.D. (email, phone).

Eligibility for Continuous Submission: I am currently eligible for continuous submission as a standing member of the WXYZ study section for the term of (Date) to (Date). The WXYZ SRO is First Last Name, Ph.D. (email, phone).

Videos: I intend to submit videos embedded within an Acrobat PDF document under the post-submission application materials policy.

Genomic Data Collection: As part of our analyses of mechanism of resistance, we propose deep sequencing drug-resistant variants of viruses that develop from *in vivo* and *in vitro* infections and expect to collect sequence data from more than 100 isolates. A genomic data sharing plan will be provided.

Sincerely,
Name of Principal Investigator
Institution
Address
City, State Zip code
Email address
Phone number

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USE THE UPDATED BIOSKETCH FORMAT

Instructions: <https://grants.nih.gov/grants/forms/biosketch.htm>

LIMITED USE OF INTERNET WEB SITE ADDRESSES (URLs)

Except for the Biosketch or where specifically instructed, Internet Web site addresses, including embedded URLs, may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites, and they are advised not to click on them.

FONT GUIDELINES: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-009.html>

Recommended fonts: Arial, Garamond, Georgia, Helvetica, Palatino Linotype, Times New Roman, Verdana (Others are acceptable if they meet the requirements listed)

Text Color: must be black (color text in figures, graphs, diagrams, charts, tables, footnotes and headings is acceptable as long as it is legible)

Font size: must be 11 points or larger (smaller text in figures, graphs, diagrams and charts is acceptable as long as it is legible when the page is viewed at 100%)

Type density: must be no more than 15 characters per linear inch (including characters and spaces)

Line spacing: must be no more than six lines per vertical inch

TIPS: Text with embedded URLs may still appear as blue underlined text after conversion to PDF.

Not all colors are legible to some persons.

POST-SUBMISSION APPLICATION MATERIALS (PSAM)**

- FAQs page: https://grants.nih.gov/grants/funding/post_submission_faq.htm.
- Other than news of an article accepted for publication or recent promotion or video files declared in the cover letter, the only post-submission materials that the NIH will accept are those resulting from unforeseen administrative issues, an option to be used when an unexpected event such as the departure of a participant, natural disaster, etc. has occurred, and not to correct oversights/errors discovered after submission of the application.
- The deadline for receipt of post-submission application materials by the appropriate Scientific Review Officer is thirty days before the meeting date.
- Materials are required to have direct concurrence of the Signing Officer/Authorized Organizational Representative (SO/AOR) and Project Director/Principal Investigator (PD/PI), and conform to NIH policy.
- **The usual process is for the contact PD/PI to email to the SO/AOR a request to include the PSAM into the grant folder and attach the PSAM to the message. The SO/AOR then forwards that email with the SO/AOR's concurring request to the SRO with the PSAM attached and PD/PI's request in the email trail/thread.**
- E-mail submission of materials as a PDF attachment named by the applicant (Last, First name) and application number is encouraged.
- The list of acceptable post-submission materials in the policy includes:
 - News of an article accepted for publication (a copy of the article should *not* be sent)
 - News of promotion or positive tenure decision
 - Video files declared in the cover letter (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-141.html>)
 - Revised budget page(s) (e.g., change in budget request due to new funding or institutional acquisition of equipment)
 - Biographical sketches (e.g., change in senior/key personnel due to the hiring, replacement, or loss of an investigator) (Missing biosketches due to error of omission are not acceptable)
 - Letters of support or collaboration resulting from a change in senior/key personnel due to the hiring, replacement, or loss of an investigator (Missing letters due to error of omission are not acceptable)
 - Adjustments resulting from natural disasters (e.g., loss of an animal colony)
 - Adjustments resulting from change of institution (e.g., PD/PI moves to another university)

**It is important to note that reviewers are not required to read post-submission applications materials. Accepted materials are incorporated into the official file