Before you begin:

- **READ THE PA/RFA/FOA SOLICITATION AND MAKE SURE YOU CHOSE THE RIGHT FUNDING OPPORTUNITY.** In May 2020 NIH updated the parent awards. Pay attention to the “Application and Submission Information” section.

- Individual NIH PA/RFA/FOAs take precedence over NIH SF424 general guidelines; the NIH SF424 Application Guide takes precedence over this document. All documents should be reviewed before submission.

- Proposals MUST be submitted via Grants.Gov on or before *5:00pm Local Time* on Deadline Date. Cayuse is GSU’s system-to-system grant submission service that is used to submit NIH applications to grants.gov. Please note that correction of errors or addressing warnings after 5 PM on the application due date will be either rejected or considered a late application. See below for examples of reasons why and why not late applications may be considered. There is a **two-week window of consideration** after the application due date, during which time NIH might consider accepting a late application. NIH will not consider accepting late applications for RFAs that must be reviewed on a compressed timeline and that have declared, in the Application Due Date field, “No late applications will be accepted for this Funding Opportunity Announcement”. If an NIH “standard deadline” date falls on a weekend or **Federal** holiday, the deadline is extended to the following business day. For RFAs with specific deadline dates the deadline is fixed and does NOT change for any reason.

- Continuous Submission is alternative submission policy that is available for grant applications where one or more of the designated PD/PIs serve as an appointed member of an NIH chartered standing study section, NIH Board of Scientific Counselors, NIH Advisory Board or Council, or an NIH Program Advisory Committee. This policy allows applications to be submitted on a continuous basis. Please see the end of this document under Helpful Websites for additional information.

**Examples of Reasons Why Late Applications Might Be Accepted**

- Death of an immediate family member of the PD/PI (or MPI).
- Sudden acute severe illness of the PD/PI (MPI) or immediate family member.
• Temporary or ad hoc service by a PD/PI on an NIH advisory group during the two months preceding or the two months following the application due date. Examples of qualifying service include participation in an NIH study section/special emphasis panel, NIH Board of Scientific Counselors, Program Advisory Committee, or an NIH Advisory Board/Council. Qualifying service does not include participation in NIH activities other than those involved in extramural/intramural peer review or NIH Advisory Council/Board service.

• Delays due to weather, natural disasters, or other emergency situations, not to exceed the time the applicant organization is closed.

• For PD/PIs who are eligible for continuous submission (https://grants.nih.gov/grants/peer/continuous_submission.htm), the late application policy applies to activities not covered under the continuous submission policy (i.e., other than R01, R21, and R34 funding opportunities that use standard due dates).

Examples of Reasons Why Late Applications Will Not Be Accepted

• Heavy teaching or administrative responsibilities, relocation of a laboratory, ongoing or non-severe health problems, personal events, participation in review activities for other Federal agencies or private organizations, attendance at scientific meetings, or a very busy schedule.

• Review service for participants other than a PD/PI or MPI, acute health issues or death in the family of a participant other than a PD/PI or MPI.

• Problems with computer systems at the applicant organization, problems with a system-to-system grant submission service, or failure to complete or renew required registrations in advance of the application due date.

• Failure to follow instructions in the Application Guide or funding opportunity announcement.

• Correction of errors or addressing warnings after 5 PM local (applicant organization) time on the application due date. Applicants are encouraged to submit in advance of the due date to allow time to correct errors and/or address warnings identified in the NIH validation process.

Sections of the Application:

(1) SF424 R&R (Cover Page) – self-explanatory, but please note:

Box 1. Ensure correct box is checked: “Application” or “change/corrected”

Box 2. The “Date Submitted” field will auto-populate upon application submission.

Box 3. Skip the “Date Received by State” and “State Application Identifier” fields

Box 4a. Box MUST be completed with the NIH grant serial number if a Resubmission or Renewal, e.g., format: CA123456

Box 4.b. Agency Routing Identifier: if required by FOA. However, applications in response to a NIH Notice of Special Interest (NOSI) MUST input the notice number (e.g., NOT-IC-FY-XXX) into this field to assign and track applications and awards for the described initiative.

Box 4.c. The “Previous Grants.gov Tracking ID” field is required if OSPA needs to submit a Changed/Corrected Application. Leave blank.

Box 5. Applicant Information should ALWAYS be that of GSURF (not GSU).
Box 6. TIN/EIN = 58-1845423

Box 8. Type of application: Please ensure to select: M: Nonprofit with 501C3 IRS Status (Other than Institution of Higher Education)

Box 10. This box is grayed out for proposal submissions

Box 11. Title: limit 200 characters including spaces. Please note for “revision” applications must have the same title as the currently funded award. For “resubmission” or “renewal” applications, you should have the same title as the previous unfunded proposal or previous cycle award, respectively. However, if the specific aims of the project have significantly changed, choose a new title.

Box 12. Ensure start dates are correct. NIH start dates correspond to award cycles: Cycle I (due dates between January 25 - May 7) earliest start dates are the proceeding September or December; Cycle II (due dates between May 25 - September 7) earliest start date is the proceeding April; Cycle III (due dates between September 25 - January 7) earliest start date is the proceeding July.

Box 13. GSU Congressional District = G A - 0 0 5

Box 16. The program is NOT covered by E.O. 12372

Box 17. Should be AGREE

Box 21. Cover letter is attached here. If there is a PHS assignment, please include it on the cover letter and ensure the PHS assignment request form is completed on the application.

**Cover letter** – usually optional and used for NIH internal purposes only. A cover is required if your application meets the following criteria:

- For late applications, must justify reason per NIH late submission policy
- Changed/corrected applications submitted after the due date; include all previous cover letter text
- Explanation of any subaward budget components that are not active for all budget periods of the proposed grant
- Statement that you have attached any required agency approval documentation or official communication from NIH approval for applications that request $500,000 or more, approval for Conference Grant or Cooperative Agreement (R13 or U13).
- When intending to submit a video as part of the application,
- If the proposed studies will generate large-scale human or non-human genomic data as detailed in the NIH Genomic Data Sharing Policy
- If the proposed studies involve human fetal tissue obtained from elective abortions (HFT), regardless of whether Human Subjects are involved and/or there are costs associated with the HFT.

(2) **Project/Performance Site Information(s)**

- List GSU plus any other sites where science will be performed.
- If the application has subcontracts, each site should be listed.
- Need to use a 9-digit zip code for all US sites, if site outside USA use 00-000.

(3) **R&R Other Project Information**

(1) Human Subjects-Assurance No. FWA00004881.
(2) If YES and EXEMPT: the exemption number must be included.
(3) If YES and IRB review is necessary: ensure all necessary attachments are included on the study record attachment ‘PHS Human Subjects and Clinical Trials Information’ (see more information below).
(4) Animal Assurance No. D16-00527 (A3914-01)

Note: For NEW applications, the IACUC review should always be ‘pending’. If applicant answers “NO” to “PENDING” then an approval date must be entered. If not, the package will error.’

(5) Proprietary information – see SF424 Guide for instructions. If ‘YES’ text must be marked.
(6) Environmental Impact – yes or no
(7) Research at a historical place – yes or no
(8) International Collaboration – if YES, a foreign justification MUST be included in field 12. (See SF424 guidance).
(9) Project Summary /Abstract – 30 lines max; summary of the proposed activity
(10) Narrative - short 2-3 sentences for lay audience explaining “relevance to Public health”. Three sentences are the max.
(11) Bibliography and References – NIH has relaxed their guidance for references, please see SF424 guidance if unsure of format. We strongly discourage the use of URLs or hyperlinks. Please see Helpful Websites at the end of this document for additional guidance.
(12) Facilities/Resources – Identify the facilities available to the program to demonstrate capability of research site to complete the proposal, include all performance sites.
(13) Equipment – list equipment already available to the program to demonstrate capability of research site, include all performance sites
(14) Other Attachments - If required by PA/RFP/FOA solicitation

(4) Research & Related Senior/Key Persons
- Ensure the all fields are completed (address, e-mail, phone number and use a 9-digit zip code).
- List OSCs and Consultants after other Senior/Key persons. Please note that GSU employees are restricted from serving as consultants.
- Biosketches required for ALL persons listed in this Senior/Key Person Profile page.

Note: 5 pages max. for each bio and includes (see NIH guides for required format and content):
   A. Personal Statement – Brief description of experience and qualifications for the role in project
   B. Positions and Honors- chronological list of previous positions, concluding with current position.
   C. Contributions to Science – describe up to 5 of their most significant contributions to science. Up to four papers accepted for publication or research products that are relevant to the contribution may be cited. Optional: provide a URL to a full list of published work. This URL must be to a Federal Government website (a .gov suffix)
   D. Research Support – list ongoing then completed support relevant to the proposal. (Completed within the last three years).

Unless the PA/RFA/FOA requires, do not provide “Current & Pending Support” at proposal time

(5) PHS 398 Cover Page Supplement
   Section is self-explanatory.

(6) PHS 398 Research Plan

Research Plan Attachments:
1. Introduction – ONLY for application type = resubmission or revision. 1 page limit.
2. Specific Aims – 1 page limit.
3. Research Strategy – Limited to 12 pages for an R01; 6 pages for an R21
   a. Significance
   b. Innovation
   c. Approach

Note: new proposals should include preliminary studies; Renewal/Revisions should include progress report.
4. Progress Report Publication List - for renewal submissions only

Other Research Plan Sections

5. Vertebrate Animals if “YES” - this section should address the following:
   • 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 numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed provide the source of the animals.
   • 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).
   • Minimization of Pain and Distress: Describe the interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints to minimize discomfort, distress, pain, and injury.
     For additional information, see http://grants.nih.gov/grants/olaw/VASchecklist.pdf.
6. Select Agents: See SF424 for instructions; complete if project uses hazardous biological agents or toxins.
7. Multiple PI Plan: A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts.
8. Consortium/Contractual Arrangements:
   a. this section should describe arrangement with the subawardees.
9. Letters of Support - If a consultant letter is included, ensure it states the rate and hours expected to dedicate to project.
10. Resource Sharing Plan - Data Sharing required for proposals greater than $500,000 TDC per year and some PA/RFA/FOAs. Model Organisms Plan required wherever they might be developed.
11. Authentication of Key Biological and/or Chemical Resources: Attach if applicable to the proposed science
12. Appendix – it is UNUSUAL if anything is attached in this section. Only if instructed in FOA.

(7) Budget

Two options exist:
- PHS 398 Modular Budget – when requesting $250,000 Direct Cost or less/year
- R&R Categorical Budget – when requesting $250,001 or more Direct Cost/year

**PHS 398 Modular Budget:**

Funds are requested in $25,000 increments (or modules) up to $250,000 direct cost/year. Could have up to three attachments for the budget justification:
1. Personnel Justification (mandatory) – list all personnel including name, person months devoted to project and role.

2. Consortium Justification – state dollars of subaward rounded to nearest thousand for each year, state domestic or foreign entity, list personnel including name, effort, and role.

3. Additional Narrative Justification – usually only to explain different numbers of modules per year. Can be used to explain anything unusual in the budget. If you have a quote(s), you may include it here. Also, this section should describe any direct costs that were 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 rate.

Note: The Additional Narrative Justification is not needed in applications to FOAs with direct cost limits that do not spread evenly across budget periods (e.g., R21 FOAs that allow $275,000 in direct costs over two years).

R&R Categorical Budget:

Detailed Budget module used for budgets of greater than $250,000 TDC per year.

- Personnel should include their role and effort. To be considered key personnel, effort must be on the budget form + justification. (Other significant contributors do not have effort and therefore are not included in the budget section).
- The salaries of administrative and clerical personnel should normally be treated as F&A costs. Inclusion of such costs may be appropriate only if all the following conditions are met:
  1. Administrative or clerical services are integral to a project or activity.
  2. Individuals involved can be specifically identified with the project or activity.
  3. Such costs are explicitly included in the budget or have prior written approval of the Federal awarding agency; and
  4. The costs are not also recovered as indirect costs.

Requests for direct charging or Secretarial/Clerical Personnel (i.e., administrative, and clerical staff) must be appropriately justified in the Budget Justification.

- All budget categories should be justified.
- If there is a consortium agreement, the subaward budget needs to be completed and uploaded (See R&R 424 instruction for additional details).

Notes:

- If personnel have effort without salary, that is cost sharing.
- Be aware of the NIH salary cap in effect.
- In general, modular budgets are used only for R01, R03, R15, R21, and R34 applications.
- Unless the PA/RFA/FOA requests – do NOT use Budget Section E – Participant/Trainee Support Costs.
- Foreign subawardee F&A is limited to 8%
- Graduate Students: the total compensation that will currently be funded for graduate students is the zero-level post doc level (stipend + tuition) – you can ask for above this level, but it may be reduced.

In accordance with the Notice: NOT-OD-02-017 entitled, "GRADUATE STUDENT COMPENSATION" published on December 10, 2001, in the NIH Guide for Grants and Contracts, total direct costs (salary, fringe benefits and tuition remission) for graduate students are provided at the NIH maximum allowable amount (zero level of the Ruth L.
Information on Human Subjects:

As of January 25, 2018, NIH updated their forms, and definition of clinical trial. With the new definition, some GSU applications may be classified as a clinical trial. PIs should contact IRB for guidance if they are unsure if their project should be classified as a clinical trial. Not all human research is considered a clinical trial, but the definition is broader than in the past.

Human Subjects Scenarios

A. Human Subjects Research - not a clinical trial
   1. Complete sections 1 – 3.2 on form. (Note, section 1.5 will be blank)
   2. Sections 3.3-3.5 are optional; but most likely left blank
   3. Do not complete sections 4 or 5

B. Human Subjects Research – clinical trial
   1. Within the Human Subjects noted on the compliance tab, the box for clinical trial should be checked
   2. Complete sections 1-4 (note, section 1.5 will be blank)

C. Exempt Human Subject Research:
   1. complete all of section 1 and section 3.1 which is a justification of the exemption. (Note, section 1.5 will be blank)
   2. Note, IRB should also approve the exemption.

D. Delayed Onset Human Subject study
   1. Delayed onset justification is attached (not the study record as noted on scenarios A, B, and C).

Human Specimens: an application may say NO to human subjects but does include human specimens.

Notes:
• Since you can name more than one Study Record attached, one may exempt, and one may be clinical trial – make sure the correct FOA is chosen.
• If the PI has answered YES to all the questions in section 1.4 of the Study Record – this is a clinical trial – make sure the correct FOA is chosen, and the all the correct fields are complete.
Helpful Web sites:

SF424 Instructions: https://grants.nih.gov/grants/how-to-apply-application-guide.html#inst


Parent FOAs: https://grants.nih.gov/grants/guide/parent_announcements.htm

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Additional Information for Subcontracts:

The following two paragraph statement can be provided in a document signed (electronic is OK) by the Subawardee RAS Representative in lieu of a signed PHS398. XXX’s must be filled in with the Subawardee Institution name.

“In signing below and offering to participate in this research program, XXX certifies that: neither it nor their principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from receiving funds from any federal department or agency and are not delinquent on any federal debt; it is in compliance with the Drug Free Workplace Act of 1988; it is in compliance with U.S. Code, Section 1352, restrictions on the use of federal funds for the purpose of lobbying; it is in compliance with 42 CFR part 50 (Objectively in Research) regarding financial conflict-of-interest; it has filed annually with the Office of Scientific Integrity a PHS form 6349 governing Misconduct in Science; it has filed with DHHS compliance offices certification forms governing Civil Rights (441), Handicapped Individuals (641), Sex Discrimination (639-A), and Age Discrimination (680); it is in compliance with PHS policy governing Program Income; it has established policies in compliance with 45 CFR Part 46, Subpart A (protection of human subjects); the Animal Welfare Act (PL-89-544 as amended) and the Health Research Exchange Act of 1985 (Public Law 99-158); and that it is in compliance with NIH guidelines regarding human pluripotent stem cell research, transplantation of fetal tissue, recombinant DNA and human gene transfer research, and inclusion of women, children & minorities in research.

The appropriate programmatic and administrative personnel of each institution involved in this grant application are aware of the National Institutes of Health consortium grants policies and procedures for research administration and are prepared to establish the necessary inter-institutional agreement(s) consistent with the policy.