Agency	National Institutes of Health (NIH)
Program	Research Project Grant Program (R01)
Project period	≤ 5 years
Budget	Total direct costs: Modular budgets, ≤ $250,000/year; Detailed budgets, ≤ $500,000/year *Preapproval must be obtained from the NIH for budgets that exceed $500K in direct costs/year.*
Due date(s)	NIH standard due dates New: Feb 5, June 5, Oct 5 Resubmission: Mar 5, July 5, Nov 5

Formatting

Font: Arial/Helvetica in black color with a size of 11 points or larger.

Margins: At least ½ inch on all sides.

No information should appear in the margins. For example, don't make headers or footers with the PI's name, or with page numbers.

Spacing: Single-spaced.

Figures: Within the figure/chart itself, you may use Arial/Helvetica font in a smaller type size; however, it must be easily legible and black in color. For the figure legend, use the same font size as the main text.

File format: Convert to PDF before uploading. Use a file name of 50 characters or less. Do NOT use any special characters (&, -, *, %, /, #) OR SPACES in file names. To separate words, use an underscore ("My_Attached_File.pdf").

Application Documents

- **Cover Letter** (optional)

  The cover letter should contain any of the following information, as applicable:

  - Application title.
  - Title of the FOA (PA or RFA).
  - For late applications, information about the timing and nature of the delay

- For changed/corrected applications submitted after the due date, explain the reason for late submission of the changed/corrected applications. If you already submitted a cover letter with a previous submission and are now submitting a late change/corrected application, you must include all previous cover letter text in the revised cover letter.
- For supplemental video files, a statement that you intend to submit a video.
- Explanation for subaward budget components that are not active for all budget periods of the proposed grant.
- A statement that you have attached all required agency approval documentation for the type of application submitted (e.g. agency approval for applications that request ≥ $500,000). It is recommended that you include in your cover letter the official communication from an NIH official.
- A statement indicating that the proposed studies will generate large-scale genomic data that will be shared according to the NIH Genomic Data Sharing Policy (see NIH Guide Notices on the Implementation of the NIH Genomic Data Sharing Policy and Reminder about the Implementation of the Genomic Data Sharing Policy).

- **PHS Assignment Request Form** (replaces the cover letter)

  This information is entered directly into the SF424 application. Provide this information to the THI Office of Sponsored Projects (OSP):

  - Funding opportunity number (e.g. PA-16-160) and funding opportunity title (e.g. NIH Research Project Grant (Parent R01))
  - Up to 3 suggested NIH institutes/centers (e.g. NHLBI) (You may also exclude up to 3 NIH Institutes/centers)
  - Up to 3 suggested study sections (You may also exclude up to 3 study sections)
  - (Optional) A list of individuals who should not review your application and the reason why (usually a conflict of interest)
  - Up to 5 scientific areas of expertise needed to review your application (e.g. cardiovascular physiology, stem cell biology)

- **Project Summary**

  An abstract. No more than 30 lines of text.

- **Project Narrative**

  A concise lay summary. 2-3 sentences only. Think big picture/human health.

- **Multiple PD/PI Leadership Plan** (if applicable)

  For projects designating multiple PDs/PIs, a leadership plan must be included. The rationale for choosing a multiple PD/PI approach should be described. The governance and organization of the leadership team and the research project should be described, including communication plans, the process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PDs/PIs and for other collaborators.

  If budget allocation is planned, the distribution of resources to specific components of the project or the individual PDs/PIs should be delineated in the leadership plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Grant Award.

- **Consortium/Contractual Arrangements** (for subawards)

  Describe the arrangement, stating the roles/responsibilities of the people and organizations involved. Explain the plan for adequate communication.

- **Facilities & Other Resources**

  A separate Facilities & Other Resources document is required for each subaward institution.

- **Major Equipment**

  A separate Major Equipment document is required for each subaward institution.

- **Budget Justification:**

  A 'modular budget' is allowed if the direct costs do not exceed $250K per year. A 'detailed budget' is required if the direct costs are greater than $250K per year.

  A modular budget justification should include

  - **Personnel Justification**

    List *Senior/Key Personnel* (the PI and those essential to the project), *Other Significant Contributors* (individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort, e.g. unpaid collaborators, unpaid consultants), and *Other Personnel* (e.g. students, postdocs, technicians). State their title, % effort in person months, and role in the project.

    The *Senior/Key Personnel* comprise all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project (regardless of whether salary is requested). Consultants should

be included if they meet this definition. List individuals that meet the definition of senior/key regardless of what organization they work for.

- **Consortium Justification** (for subawards)

  Include the total costs (direct costs plus F&A costs), rounded to the nearest $1,000, for each consortium/subcontract. List all subcontract personnel, their % effort in person months, and their role in the project. Indicate if a consortium component is foreign.

- **Additional Narrative Justification** (if applicable)

  Include explanations for variations in the number of modules requested annually. 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.

A detailed budget justification should include

- **Senior/Key Personnel**
- **Other Personnel**
- **Equipment (Items ≥ $5,000)**
- **Travel**
- **Materials and Supplies**
- **Animal Costs (e.g. vivarium per diems)**
- **Publication Fees**
- **Consultant Services**
- **ADP/Computer Services**—research-specific computer services, not office computer, notebook, or general institutional IT support
- **Subawards/Consortium/Contractual Costs**
- **Equipment or Facility Rental/User Fees**
- **Alterations and Renovations**
- **Service Fees (core facilities or companies)**
- **Research Patient Care Costs**
- **Graduate Student Tuition**
- and other stuff worth itemizing

- **Biosketches** for all Senior/Key Personnel and Other Significant Contributors listed in the Personnel Justification and all Senior/Key Personnel listed in the Consortium Justification (4 pages max per biosketch)

  Must use new biosketch template which includes A) Personal Statement, B) Positions and Honors (listed in chronological order), C) Contributions to Science (briefly describe up to 5), and D) Research Support (list both ongoing and completed research projects for the past 3 years). *Do not* state % effort or direct

costs. Include PubMed Central ID (PMCID) numbers (if available) on all references. Include a link to your NCBI MyBibliography webpage. An eRA Commons username is required for the PI and any postdoctoral fellows.

- **Protection of Human Subjects** (if applicable)
- **Vertebrate Animals** (if applicable)

  Include these 4 sections:

  1. Description of Procedures

  Concisely describe all procedures involving live vertebrate animals (Don't explain anything done after euthanasia). Identify the species, strains, ages, sex, and total number of animals by species. If dogs or cats are involved, indicate the source of the animals.

  2. Justifications

  Describe why the species is appropriate for the proposed research. Explain why the research goals cannot be accomplished by using an alternative model (e.g. computational, human, invertebrate, *in vitro* model).

  3. Minimization of Pain and Distress

  Describe the measures that will be taken to minimize discomfort, distress, pain, and injury. These include analgesia, anesthesia, sedation, palliative care, and humane endpoints.

  4. Method of Euthanasia

  For most applications, state that the animals will be euthanatized in a manner consistent with the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If a method is not consistent with AVMA guidelines, describe the method, provide a scientific justification, and indicate steps that will be taken to minimize pain and distress.

- **Select Agent Research** (if applicable)
- **Resource Sharing Plan**
  - *Data Sharing Plan* (only necessary if direct costs are ≥ $500K in any one year). Describe your plan for sharing final research data (not summary statistics or tables; rather, the data on which the summary statistics or tables are based), or state why data sharing is not possible.
  - *Sharing Model Organisms*. If the project involves developing a model organism, include a plan to share and distribute that resource or explain why sharing is restricted or not possible.

- *Genomic Data Sharing*. Describe your plan for sharing large-scale genomic data or an explanation for why sharing is not possible.

- **Authentication of Key Biological and/or Chemical Resources**

  Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources.

  Key biological and/or chemical resources are those that
  1) may differ from laboratory to laboratory or over time;
  2) may have qualities and/or qualifications that could influence the research data; and
  3) are integral to the proposed research.
  (e.g. cell lines, specialty chemicals, antibodies, and other biologics)

  Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common reagents or chemicals.

- **Letters of Support** (if applicable)

  New/early investigators—letters to demonstrate independence and institutional support
  Letters of commitment from collaborators, consultants, and co-investigators

- **Introduction to Resubmission** or **Introduction to Revision** (1 page)

  Note, a "resubmission" is common. A "revision" is essentially an amended proposal that significantly expands the scope of the project that is already funded.

- **Research Plan:**

  - **Specific Aims** (1 page)

    Suggested format:

    Paragraph 1. Introduce the problem. What is known and unknown? What is the critical need?

    Paragraph 2. Rationale, preliminary data, overall hypothesis, and objective(s). If you feel it will help, state why you and your lab are particularly qualified to do this.

    Specific Aims. List 2-4 specific aims (3 is common). Give each aim a title that is the objective of the aim. Briefly summarize the rationale, objective, and experimental approach for each aim. If relevant, include a sub-hypothesis.

Summary. In 2-3 sentences, state the expected outcome, why the project is innovative, and why the project is significant.

- **Research Strategy** (12 pages)

  Subsections:

  A. Significance

  Rigor and Transparency guidance: Describe the scientific premise for the proposed project, including the strengths and weaknesses of published research, or preliminary data crucial to the support of your application.

  B. Innovation

  C. Approach

  a. Preliminary Studies

  b. Research Design and Methods

  Rigor and Transparency guidance: Describe the experimental design and methods in sufficient detail to convey how you will obtain robust and unbiased results. Indicate what statistical tests will be used and the number of biological replicates to be performed.

  Sex as a Biological Variable guidance: Explain how relevant biological variables, such as sex, are factored into your research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex.

  c. Timeline (optional)

  d. Summary/Concluding Remarks (optional)

  Important notices:
  Implementing Rigor and Transparency (NOT-OD-16-011)
  Consideration of Sex as a Biological Variable (NOT-OD-15-102)

- **Progress Report Publication List** (if renewal)

- **References Cited**

  No specific format is required. Include the names of all authors (don't use "et al"). Include PMCID numbers (if available) when citing applicable papers that you author or that arise from your NIH-funded research. Here are instructions to add PMCID numbers to all your EndNote references.

Items for the Office of Sponsored Projects (OSP)

1 month in advance of deadline:

- Title of the proposal
- Number and title of the funding opportunity announcement (FOA)
- A list of all key personnel (name, title, institution, role in the project, % effort)
- Contact information for subaward recipients (consortium members)
- A **Statement of Work (SOW)** for each subaward institution

  Briefly describe the work to be conducted by the subrecipient, define the deliverables (if applicable), and outline the time frame in which they are to be delivered. Provide enough detail that someone could read it and determine whether the other lab lived up to its commitment. If the PI deems it necessary, the SOW can also define all personnel and their responsibilities. It should be accurate and concise as to what, when, and (if appropriate) how your organization will accomplish the work to be performed. The SOW usually includes a timeline in the form of a chart.
- A budget (spreadsheet) and **Budget (Consortium) Justification** (Word document) for each subaward
- The subaward institution must provide
  - An institutional letter of intent to establish a consortium
  - A detailed budget
  - A detailed Budget Justification

2 weeks in advance of deadline:

- DRAFT Budget
- DRAFT **Budget Justification**
  - Use our Excel budget spreadsheet. See 'Detailed Budget' under 'Budget Justification' for a list of costs that should be estimated.
  - Detailed costs for itemized budgets (> $250K direct costs/year). Note: preapproval must be obtained from the NIH for budgets that exceed $500K in direct costs/year.
  - Personnel Justification only for modular budgets (≤ $250K direct costs/year)

Consultants, Collaborators, and Co-investigators

A **consultant** provides advice or services. List consultants as key personnel only if they contribute substantively and measurably to the scientific development or execution of a project. Typically, consultants do not receive a salary from your grant, but in some cases, they may receive a fee.

For paid consultants, don't indicate % effort in the personnel justification; instead, indicate their commitment in hours/week and cost/hour. List fees for paid consultants in the 'Consultant Services' section of the detailed budget. Their letter of support should complement the budget justification by stating their hourly commitment and cost per hour.

A **collaborator** is a scientist whose distinct expertise complements your own. Collaborators always play an active role in the research and are typically listed as key personnel. They may or may not receive salary from the grant.

A **co-investigator** shares your area of expertise and therefore contributes in guiding the scientific direction of the overall project.

Collaborators or co-investigators at other institutions can have their salary paid through a consortium agreement (subaward).

Subawards

Subawards allow another organization to perform some activities for your grant under your supervision. They enable collaborations between you—the grantee—and the subawardee. You must still include the details of the work in your application because the initial peer review committee needs to evaluate it (unlike a purchase contract). A subaward requires a financial agreement between THI and the other organization.

THI (not the subawardee) is accountable to the NIH for the performance of the research project, spending of grant funds by all parties, fulfilling reporting requirements, negotiating assurances for animal and human subjects, and meeting other obligations for the grant.

4/17/2018