

NIH – R01 Tipsheet

****THIS DOCUMENT IS MEANT AS A TIPSHEET. PLEASE BE SURE TO READ THE SPONSOR SOLICITATION FOR ALL INFORMATION PERTAINING TO THIS SUBMISSION**

******There is no budget limit, however, if requesting more than \$500,000 in any year of the project, excluding indirect costs. Applicant must contact a scientific/research contact at LEAST 6-weeks before submitting the application. ******

Margins: ½ inch margins on all sides

Font Size: 11 points or larger

Font Type: Arial, Garamond, Georgia, Helvetica, Palatino Linotype, Times New Roman, Verdana

THERE SHOULD BE ABSOLUTELY NO HEADERS OR FOOTERS, THIS INCLUDES PAGE NUMBERING.

Project Summary

Filename should be “ProjectSummary”

Limited to 30 lines of text

Should be written in third person

Project Narrative

Filename should be “ProjectNarrative”

Limited to 2-3 sentences describing the relevance of the research to public health

Bibliography & References Cited

Filename should be “BibliographyReferencesCited”

There is no page limit. Each reference must include the names of authors, the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. When citing articles that fall under the Public Access Policy, that were authored or co-authored by the applicant and arose from NIH funding, provide the NIH manuscript submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMC is not available because the journal submits directly to PMC on behalf of the authors, indicate “PMC Journal – In Process”.

Facilities & Other Resources

Filename should be “FacilitiesOtherResources”

There is no page limit or special form but this section must be completed for submission to NIH. Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). Discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.

If there are multiple performance sites, describe the resources available at each site.

Equipment

Filename should be "Equipment"

There is no page limit or special form but this section must be completed for submission to NIH. Describe the major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities.

Biographical Sketch

Filename should be "BioSketch_LastName"

Limited to 5-pages per person

- Include biographical sketches of all senior/key personnel and Other Significant Contributors.
- Use the sample format on the [Biographical Sketch Format Page](#) to prepare this section for all (modular and other) grant applications.
- The Biographical Sketch may not exceed five pages per person. This five-page limit includes the table at the top of the first page.
- Complete the education block at the top of the format page beginning with the baccalaureate or other initial professional education, such as nursing. Include postdoctoral training, separately referencing residency and clinical fellowship training, if applicable.

eRA Commons User Name

If the individual is registered in the eRA Commons, include the Commons User Name. This data item is required for the PD/PI (including fellowship applicants), primary sponsors of fellowship applicants, and all mentors of candidates for mentored career development awards. Commons User Name is optional for other project personnel. In other federal forms this information is referred to as "Credential, e.g., agency login." For information on the eRA Commons, see <https://commons.era.nih.gov/commons/index.jsp>.

Education

Complete the education block at the top of the format page beginning with the baccalaureate or other initial professional education, such as nursing. Include postdoctoral training, separately referencing residency and clinical fellowship training, if applicable. For each entry provide:

- the name and location of the institution
- the degree received (if applicable) and the month and year of entry and completion (or expected completion)
- the field of study (for residency entries the field of study should reflect the area of residency training)

Following the education block, complete Sections A, B, C, and D as described below.

A. Personal Statement

Briefly describe why you are well-suited for your role(s) in this project. The relevant factors may include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and/or your past performance in this or related fields. Note the following additional instructions:

- For institutional research training, institutional career development, or research education grant applications, faculty who are not senior/key persons are encouraged to complete this section, but not required to do so.
- Applicants for dissertation research awards should include a description of their career goals and intended career trajectory and their interest in the specific areas of research designated in the FOA, in addition to the information outlined above.
- Candidates for Research Supplements to Promote Diversity in Health-Related Research should include a description of their general scientific achievements and/or interests, as well as specific

research objectives and career goals, in addition to the information outlined above. Indicate any current source(s) of educational funding.

- If there are factors affecting your past productivity that you wish to explain, such as family care responsibilities, illness, disability, or military service, you may address them in your personal statement.
- Indicate if you have published or created research products under another name.
- You may mention specific contributions to science that are not included in Section C. Do not present or expand on materials that should be described in other sections of this biosketch or the application.
- Figures, tables and graphics are not allowed.

You may cite up to four publications or research products that highlight your experience and qualifications for this project. Research products can include audio or video products; conference proceedings such as meeting abstracts, posters or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.

B. Positions and Honors

List in chronological order positions held since the completion of your most recent degree, concluding with your present position. High school students and undergraduates may include any previous positions. For individuals, such as fellowship applicants or career development award candidates, who are not currently located at the applicant organization, include the expected position at the applicant organization, with the expected start date.

List any relevant academic and professional achievements and honors. In particular:

- Students, postdoctorates, and junior faculty should include scholarships, traineeships, fellowships, and development awards, as applicable.
- Clinicians should include information on clinical licensure and specialty board certification, if applicable.
- Include present membership on any Federal Government public advisory committee.

C. Contributions to Science

Candidates for Research Supplements to Promote Diversity in Health-Related Research who are high school students, undergraduates, and postbaccalaureates are not required to complete this section.

Briefly describe up to five of your most significant contributions to science. While all applicants may describe up to five contributions, graduate students and postdoctorates are encouraged to consider highlighting two or three they consider most significant. Descriptions may include a mention of research products under development, such as manuscripts that have not yet been accepted for publication. Each contribution should be no longer than one half page, including citations. These contributions do not have to be related to this project. For each contribution:

- Indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work.
- **You may cite up to four papers** accepted for publication or research products that are relevant to the contribution.
 - Research products can include audio or video products; conference proceedings such as meeting abstracts, posters or other presentations; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.
 - These citations do not have to be authored by you.

You may provide a URL to a full list of your published work. This URL must be to a Federal Government website (a .gov suffix). NIH recommends using [My Bibliography](#). Providing a URL to a list of published work is not required, and reviewers are not required to look at the list. Do not include any figures.

D. Additional Information: Research Support and/or Scholastic Performance

Note the following instructions for specific types of applicants/candidates:

- High school students are not required to complete this section.
- Applicants for predoctoral and postdoctoral fellowships, dissertation research grants, and candidates for Research Supplements to Promote Diversity in Health-Related Research from the undergraduate through postdoctoral levels should use this section to provide information about their scholastic performance, following the instructions below. In situations where applicants/candidates in these categories also have research support, they should complete both parts of this section.

Research Support

For all other individuals required to complete a biosketch, list selected ongoing and completed research projects for the past three years (Federal or non-Federal support). Briefly indicate the overall goals of the projects and your responsibilities. **Do not include number of person months or direct costs.**

Do not confuse “Research Support” with “Other Support.” Though they sound similar, these parts of the application are very different.

- As part of the biosketch section of the application, “Research Support” highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual’s qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team.
- In contrast, “Other Support” information is required for all applications that are selected to receive grant awards. NIH staff will request complete and up-to-date “other support” information from you after peer review.

Specific Aims

Filename should be “SpecificAims”

Limited to 1-page

Research Strategy

Filename should be “ResearchStrategy”

Limited to 12-pages

1. Significance

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

2. Innovation

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

3. Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Unless addressed separately in Item 15 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- Explain how relevant biological variables, such as sex, are factored into 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.
- If your study(s) involves human subjects, the sections on the Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion on inclusion and justify the proposed proportions of individuals (such as males and females) in the sample, but it must also be addressed here in the Approach section.
- Please refer to [NOT-OD-15-102](#) for further consideration of NIH expectations about sex as a biological variable.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in [Item 5](#), below.
- If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.

If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.

As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.

Preliminary Studies for New Applications:

For new applications, include information on Preliminary Studies. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application. Except for Exploratory/Developmental Grants (R21/R33), Small Research Grants (R03), and Academic Research Enhancement Award (AREA) Grants (R15), preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data.

Human Subjects

If human subjects, these are the files needed for submission:

Protection of Human Subjects, filename "ProtectionHumanSubjects"

Data Safety Monitoring Plan, filename "DataSafetyPlan"

Inclusion of Women and Minorities, filename "InclusionWomenMinorities"

Inclusion of Children, filename "InclusionChildren"

Vertebrate Animals

Filename should be "VertebrateAnimals"

Select Agent Research

Filename should be "SelectAgentResearch"

Multiple PD/PI Leadership Plan

Filename should be “MultiPILeadershipPlan”

Consortium/Contractual Arrangements

Filename should be “ConsortiumArrangement”

Letters of Support

Filename should be “LettersSupport”

Resource Sharing Plan(s)

Filename should be “ResourceSharingPlan”

Investigators conducting biomedical research frequently develop unique research resources. NIH considers the sharing of such unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, when these resources are developed with NIH funds and the associated research findings have been published or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. At the same time NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with federal funding pursuant to the Bayh Dole Act. See the [NIH Grants Policy Statement](#), and the Office of Extramural Research, Division of Extramural Inventions & Technology Resources (DEITR), Intellectual Property Policy page: <http://inventions.nih.gov>.

The adequacy of resource sharing plans is considered by reviewers when a competing application is evaluated. Reviewers are asked to describe their assessment of the sharing plan(s) in an administrative note, and will not normally include their assessment in the overall impact/priority score. Program staff are responsible for overseeing resource sharing policies and for assessing the appropriateness and adequacy of any proposed resource sharing plans.

1.5.1 Data Sharing Policy

All investigator-initiated applications with direct costs of \$500,000 or greater (exclusive of consortium F&A) in any single year are expected to address data-sharing in their application. Applicants are encouraged to discuss data-sharing plans with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application as described at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>.

Applicants are reminded that agreement to accept assignment of applications \$500,000 or greater must be obtained at least six weeks in advance of the anticipated submission date. Instructions related to the data-sharing policy as it is applied to applications and proposals responding to a specific Request for Application (RFA) or Request for Proposals (RFP) will be described in the specific solicitation. In some cases, other Funding Opportunity Announcements (FOAs) may request data-sharing plans for applications that are less than \$500,000 direct costs in any single year.

NIH recognizes that in some cases data-sharing may be complicated or limited by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the HIPAA Privacy Rule. The rights and privacy of individuals who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data-sharing is limited, applicants should explain such limitations in their data-sharing plans.

For SBIR grantees only, under the Small Business Act, SBIR grantees may withhold their data for 4 years after the end of the award. The Small Business Act provides authority for NIH to protect

from disclosure and nongovernmental use all SBIR data developed from work performed under an SBIR funding agreement for a period of 4 years after the closeout of either a Phase I or Phase II grant unless NIH obtains permission from the awardee to disclose these data. The data rights protection period lapses only upon expiration of the protection period applicable to the SBIR award, or by agreement between the small business concern and NIH.

For more information on data-sharing, please see: http://grants.nih.gov/grants/policy/data_sharing/ and the [NIH Final Policy on Sharing Research Data](#).

1.5.2 Sharing Model Organism Policy

All applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, or state appropriate reasons why such sharing is restricted or not possible. Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

This expectation is for **all** applications where the development of model organisms is anticipated, regardless of funding amount.

For additional information on this policy, see the NIH Model Organism for Biomedical Research Web site at: <http://www.nih.gov/science/models/> and NIH Guide Notices OD-04-042: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>, and OD-04-066: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-066.html>.

1.5.3 NIH Genomic Data Sharing (GDS) Policy

All applications, regardless of the funding amount requested, proposing to generate large-scale human or non-human genomic data (e.g., genome-wide association studies (GWAS), single nucleotide polymorphism (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data) are expected to provide a genomic data sharing plan. Investigator and institution responsibilities for data submission and access are governed by the NIH (GDS Policy, NIH Guide [NOT-OD-14-124](#)). Supplemental Information to the Genomic Data Sharing Policy provides examples of genomic research projects that are subject to the policy. Investigators proposing to generate large-scale human genomic data from samples, clinical specimens or cell lines collected after January 25, 2015, are expected to have consent for the use and sharing of genomic and phenotypic data for future research purposes and to be shared broadly, even if the specimens or cell lines are de-identified. Applicants may request exceptions to the NIH consent expectations for compelling scientific reasons in the funding application. For additional information see the GDS website at <http://gds.nih.gov/>.

In addition to the information detailed above, grantees are required to submit an Institutional Certification as part of the Just in Time process (see [Part III 1.7 Just-in-Time Policy](#)).

Authentication of Key Biological and/or Chemical Resources

Limited to 1-page

Filename should be "AuthenticationKeyBiologicalChemResources"

If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. No more than one page is suggested.

- Key biological and/or chemical resources may or may not be generated with NIH funds and: 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. These include, but are not limited to, 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 biologicals or chemicals.
- See NIH's page on [Rigor and Reproducibility](#) for more information.

Reviewers will assess the information provided in this Section. Any reviewer questions associated with key biological and/or chemical resource authentication will need to be addressed prior to award.

Applications identified as non-compliant with this limitation will be withdrawn from the review process (see [NOT-OD-15-095](#) and [NOT-OD-16-011](#)).