General Grant Proposal Checklist – NIH

Additional requirements may apply to a given Funding Opportunity Announcement (FOA). Prospective applicants should always refer to the FOA to confirm all required application components, page limits, and policies regarding appendix materials, etc. This document is intended as a guide only.

Key Components	Page Limits	Notes/Guidance
Letter of Intent (LOI) (if applicable)	No page limit	LOIs are not always mandatory, but it is a best practice to submit a LOI when it is included in a Funding Opportunity Announcement (FOA). The LOI puts your project on the Program Officer's radar. For funding opportunities reviewed by Special Emphasis Panels (SEP), the submitted LOIs give the Scientific Review Officer (SRO) information that helps him/her anticipate the level of interest in the FOA and the specific expertise that must be recruited for a particular review panel.
Cover Letter (Title and FOA # must match the application)	No page limit	Cover letters are not shared with peer reviewers. Letters should contain the following information, as it applies to the application: ○ Project title ○ Funding Opportunity Announcement (FOA) title/# ○ Request of assignment to a particular Scientific Review Group, if applicable to the FOA ○ List of individuals who should not review your application and why ○ Disciplines involved in the project, if multidisciplinary ○ Explanation of any subaward budget components that are not active for all period of the proposed grant. ○ Statement that you have attached any required agency approval documentation for the type of application submitted If submitting a changed/corrected application, a cover letter is required explaining the reason for the changed/corrected application. The NIH grant system does not retain previously submitted cover letters; therefore all information from the previously submitted cover letter must be included along with additional information.
Project Summary/Abstract	Max. 30 lines of text	This section summarizes the proposed activity suitable for dissemination to the public. The summary should not include any proprietary/confidential information. It should state the application's broad objectives and specific aims.
Project Narrative	Max. 2-3 sentences	Describe the relevance of the research project to public health.
Bibliography & References	No page limit	Provide a bibliography of any references cited in the Project Narrative. For renewals, list the titles and complete references to all publications and manuscripts accepted for publication, patents, and other printed materials the resulted from the project since the last review.
Facilities & Other Resources	No page limit	This section is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (e.g., laboratory, animal, computer, office, clinical and other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources directly applicable to the proposed work.
Equipment	No page limit	List major items of the clinical area available for this project and, if appropriate identify location of person capabilities. List items and dollar amount for each item exceeding $5,000 in acquisition cost an expected service life of more than 1 year. Allowable items are limited to research equipment apparatus.

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Specific Aims	1 page	The aims contain three key things about your proposal: why you want to do the work, what you want to do, and how you want to do it. The specific aims page should state concisely the goals of the proposed research and summarize the expected outcomes, including the impact that the results of the proposed research will exert on the research field(s) involved. This section should also correspond with the specific objectives of the proposed research.
Research Strategy (refer to page 6 for more details)	6 or 12 pages, depending upon the FOA	Revisions to the application guide instructions have taken place as of Nov. 25,2015 to include the following additional guidance for the Significance and Approach sections of the Research Strategy, in addition to the existing instructions. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html **Significance** 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. **Approach** Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. 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. Refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable.
Multiple PI Leadership Plan		The role of Co-PI is not currently used by the NIH and other PHS agencies. For applications utilizing multiple PIs, all individuals must be assigned to the PI role, even those at organizations other than the applicant organization (e.g. subaward and consortium sites). The individual designated as the contact PI must be affiliated in the eRA Commons with the applicant organization. Each PI on the project must be assigned the PI role in eRA Commons or they will not have full access to the application. Applications that propose a multiple PI approach require a project leadership plan. For more information, visit: http://grants.nih.gov/grants/multi_PI/
Consortium/Contractual Arrangements	No page limit	Separate budgets are required for subaward and consortium organizations that will perform a substantive portion of the project. In addition to budget information, additional documentation may be required by your institution for sub award and consortium organizations, including but not limited to letters of intent and financial conflict of interest (FCOI).
Letters of Support	No page limit	If permitted within the application, letters of support should include a statement of institutional commitment (e.g. protected time to conduct the research, cost share, facilities and resources). Other important letters of support include letters from collaborators and consultants stating their commitment to the project and their specific contribution to the scope of work.

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Resource Sharing Plan	No page limit	When resources have been developed with NIH funds and the associated research findings published or provided to NIH, they must be made readily available for research purposes to qualified individuals within the scientific community - or an explanation must be provided as to why such sharing is restricted or not possible. All NIH applications must include a Resource Sharing Plan, which can include any (or all) of the following components: ○ Data Sharing Plan ○ Sharing Model Organisms ○ Genome Wide Association Studies
Biosketches**	5-page limit for each bio-sketch	Biosketches should be included for all senior/key personnel. Note: each bio includes a Personal Statement – Brief description of experience and qualifications for the role in project. A. Positions and Honors- chronological list of previous positions, concluding with current position. B. Contributions to Science - describe up to 5 of their most significant contributions to science. In addition to the descriptions of specific contributions and documentation, researchers will be allowed to include a link to a full list of their published work as found in a publicly available digital database such as MyBibliography or SciENcv. - See more at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-032.html C. Research Support - list ongoing then completed support relevant to the proposal. (Completed within the last three years).
Budget and Budget Justification	No page limit	Budgets must be prepared using the R&R budget form. Some NIH funding mechanisms utilize the modular budget format while others utilize the detailed budget format. For NIH guidance on developing modular and detailed budgets, refer to: http://grants.nih.gov/grants/developing_budget.htm If a project includes a subaward or consortium arrangement, a separate budget and budget justification must be included in the application.
Human Subjects Section		The following four sections are required for human subject research, if applicable: ○ Protection of human subjects ○ Inclusion of women and minorities ○ Targeted/planned enrollment ○ Inclusion of children
Vertebrate Animal Section		Care and use of vertebrate animals http://grants.nih.gov/grants/olaw/VASfactsheet_v12.pdf Applicant responsibilities - Each of the five points [as indicated in the worksheet] must be addressed in the VAS of NIH grant applications. Failure to address the five points may result in the application being designated as incomplete and will be grounds for the PHS to defer the application from the peer review round. Alternatively, the application's impact/priority score may be negatively affected.

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Authentication of Key Biological and/or Chemical Resources Attachment	New required attachment	Grant applications for the activity codes covered by the policy must include a new PDF attachment related to the authentication of key biological and/or chemical resources. **Authentication of Key Biological and/or Chemical Resources** Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. 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. 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. Information in this section must focus only on authentication and/or validation of key resources to be used in the study; all other methods and preliminary data must be included within the page limits of the research strategy. Applications identified as non-compliant with this limitation will be withdrawn from the review process (see NOT-OD-15-095). Applications submitted for *due dates between January 25, 2016 and May 24, 2016* will use the FORMS-C forms and application guide. The general application guide will be updated by November 25, 2015 with instructions for this new attachment and guidance to upload your PDF document (titled "Authentication of Key Resources Plan") in the "Other Attachments" section of the "Other Project Information" form. Applications submitted for *due dates on or after May 25, 2016*, will use updated FORMS-D forms. The PHS 398 Research Plan form will include a new "Authentication of Key Biological and/or Chemical Resources" attachment field. FORMS-D application forms and instructions will be available for all active Funding Opportunity Announcements at least 60 days prior to due dates that fall on or after May 25, 2016.
Select Agent Research		This section is required is activities proposed in the application involve the use of hazardous biological agents and toxins that have been identified by the DHHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products.
Introduction* (for re-submissions and renewals only)	Max. 1 page	Only allowed for re-submissions and renewals. For a resubmission application, the Introduction must summarize the substantial additions, deletions, and changes to the application. The Introduction must also include a response to the issues and criticisms raised in the Summary Statement. ***See note regarding NIH's A02 Policy (Notice #NOT-OD-14-074)**

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Inclusion Enrollment Report (for renewals and revisions only)		If the renewal or revision involves clinical research, the grantee must report on the moment of research subjects and their distribution by ethnicity/race and sex/gender.

* **On April 22, 2014, the NIH and AHQR released a new policy (Notice # NOT-OD-14-074) governing application submission.** The policy states that following an unsuccessful resubmission (A1), an applicant may submit the same idea as a new (A01 application) without making substantial changes to the science. All other application (re) submission policies apply. An application submitted as a new A01 is not permitted an Introduction or response to criticisms identified in the Summary Statement. In turn, the NIH and AHQR will not compare the new A01 to any previously reviewed application. All other submission and resubmission policies apply. For a complete discussion of this NIH/AHQR policy, refer to the public notice: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html

** **According to NIH notice #NOT-OD-15-032, a new 5-page biosketch format is mandatory for all research, training, and career development grants with due dates on or after May 25, 2015.**