QUICK GUIDE FOR GRANT APPLICATIONS

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INTRODUCTION

The guide is organized according to the major sections of the SF 424 (or PHS398) Grant Application Instructions. Each section is described, and a checklist is provided detailing what that section should cover. In addition, suggestions are included to enhance an application's success. The checklists are not exhaustive, but rather are designed to jog the application writer's memory and ensure completeness. This document in no way obviates the need for an inexperienced applicant to seek further advice from experienced colleagues or from appropriate NCI program personnel.

PLANNING YOUR APPLICATION

Several key issues should be considered before, during, and after your application is written.

1. Before you begin writing your grant application, familiarize yourself with the new NIH SF 424 Application Guide for electronic applications and all the requirements and certifications. See NIH Forms and Applications for other types of required forms and applications, including the PHS 398 application for multi-component applications.
2. The submission of electronic applications to NIH involves the interaction between two systems: Grants.gov (http://grants.gov) and the NIH eRA Commons (https://commons.era.nih.gov/commons/). Individual investigators do not need to register with the Grants.gov system; however, you must be a registered Commons user to submit an application or be included as a Senior/Key Person. For more information, see Electronic Submission.
3. All applications must be submitted in response to a Funding Opportunity Announcement (FOA). The NIH has developed Parent FOAs (http://grants1.nih.gov/grants/guide/parent_announcements.htm#more) for use by applicants who wish to submit unsolicited investigator initiated R01 applications and other common grant mechanisms. In addition, NIH publishes FOAs for specific Request for Applications (RFA) and Program Announcements (PA) that identify special research opportunities. Responding to such an FOA ensures that the correct application package is used and enables NIH to receive the application from Grants.gov. FOAs can be found at Grants.gov/FIND for all government agencies and in the NIH Guide for Grants and Contracts. If you are submitting to a specific RFA or PA, read the announcement in detail to be sure your application will be responsive to the announcement.
4. The deadlines for NIH grant applications depend on the grant mechanism. See schedule of standard due dates on: http://grants.nih.gov/grants/funding/submissionschedule.htm. For new R01 applications, February 5, June 5, and October 5 are the due dates. March 5, July

5, and November 5 are the due dates for R01 renewals, resubmissions and revisions. **Please note**: The deadlines for investigator-initiated applications in response to specific FOAs, such as RFAs and Program Announcements with special receipt (PAR), may differ. Always check the FOA for the receipt date.

5. The review and selection process for applications takes 8 to 10 months. Submit your very best application because reviewers expect you to have taken the time needed to think it through before submitting. For new investigators, there is an opportunity for resubmission of your application in the next review round when there are only minor concerns.
6. If at all possible, find someone in your institution that can assist you in understanding and completing the application. Ask your colleagues for copies of successful NIH grant applications to get a more concrete idea of what each section should include. Incomplete applications are returned without review.
7. Establish deadlines for the preparation of the grant application, particularly when collaborating investigators are involved. Be aware of institutional deadlines that could delay your application. Allow time for equipment failures, personnel shortages, etc.
8. Publish the papers; you can only cite published or accepted for publication papers. With the new page limitations, preliminary data should be published.
9. Become familiar with the NIH peer review criteria; reviewers will use them to rate your application.
10. Reread your application. Have someone else read it. Proofread it again.
11. If several people have major contributions to the research project, consider the option for multiple Principal Investigators (PIs). A Leadership Plan is required and New Investigator policies do not apply unless all PIs are considered New Investigators.
12. If possible, have objective experts (e.g., successful grantees, an institutional panel) review your application. Friends or close associates are rarely as critical as the reviewers on an NIH study section.
13. Do not feel inhibited about requesting technical assistance from the funding agency or your institution. Talk to the program representative (http://www.cancer.gov/researchandfunding/contacts) who will manage the grant for advice on scientific and technical issues, grant mechanisms, and information on special initiatives. Your institutional grants office can also be of assistance. Talk to them and find out how they can help you.
14. Investigate any special research priorities of funding agencies. Search the NIH Guide for Grants and Contracts for current FOAs and ascertain from the program representative whether your project falls within the scope of an existing RFA or PA or an area of special emphasis.
15. When submitting a revised application (resubmission), answer all reviewer concerns mentioned in the earlier Summary Statement. Substantial scientific changes must be described in the Introduction and marked in the text by bracketing, indenting, or change of typography. Only one resubmission is allowed so prepare carefully.
16. Regardless of how you feel, don't insult the reviewers. If you differ in your opinion try to courteously convince the reviewers of your point -of views. In addition to responding to specific reviewer concerns, review all other aspects of the application to determine whether updating or improvement is called for or

possible. Just because it was not criticized before is no guarantee it will not be criticized in the review of the resubmission.

PROJECT SUMMARY/ABSTRACT

Project Summary: The purpose of the Project Summary/Abstract is to describe succinctly every major aspect of the proposed project. It should contain a statement of objectives and methods to be employed. Members of the Study Section who are not primary reviewers may rely heavily on the abstract to understand your application. Consider the significance and innovation of the research proposed when preparing the Project Summary.

The Project Summary must be no longer than 30 lines of text, and follow the required font and margin specifications.

The second component of the Project Summary is **relevance** of this research to **public** health. Use plain language that can be understood by a general, lay audience. The Project Summary should not contain proprietary confidential information.

The abstract should include:

- a brief background of the project;
- specific aims, objectives, or hypotheses;
- the significance of the proposed research and relevance to public health;
- the unique features and innovation of the project;
- the methodology (action steps) to be used;
- expected results; and
- description of how your results will affect other research areas.

Suggestions

- Be complete, but brief.
- Use all the space allotted.
- Avoid describing past accomplishments and the use of the first person.
- Write the abstract last so that it reflects the entire application.
- Remember that the abstract will be used for purposes other than the review, such as to provide a brief description of the grant in annual reports, presentations, and dissemination to the public.

RESEARCH PLAN (Overview)

Purpose: NIH has restructured the applications by aligning the structure and content with review criteria. This alignment will help ensure that both reviewer and applicant expectations coincide for a more efficient and transparent application process. The

Research Strategy/Plan is now organized into three sections: Significance, Innovation, and Approach. The assessment of this research plan will largely determine whether or not the application is favorably recommended for funding.

For an application with multiple Specific Aims, the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or address Significance, Innovation and Approach for all of the Specific Aims collectively.

Recommended Length: See Table of Page Limits (http://enhancing-peer-review.nih.gov/page_limits.html) for the maximum length of the research plan. For the example below, the R01 format will be used with a maximum of 12 pages.

Content: The Research Strategy should answer the following questions:

- What do you intend to do?
- Why is this worth doing or the significance of the research? How is it innovative?
- What has already been done in general, and what have other researchers done in this field? Use appropriate references. What will this new work add to the field of knowledge?
- What have you (and your collaborators) done to establish the feasibility of what you are proposing to do?
- How will the research be accomplished? Who? What? When? Where? Why?

Suggestions

1. Make sure that all sections are internally consistent and that they dovetail with each other. Use a numbering system, and make sections easy to find. Lead the reviewers through your research plan. One person should revise and edit the final draft.
2. Show knowledge of recent literature and explain how the proposed research will further what is already known.
3. Emphasize how some combination of a novel hypothesis, important preliminary data, a new experimental system and/or a new experimental approach will enable important progress to be made.
4. Establish credibility of the proposed principal investigator and the collaborating researchers.

RESEARCH PLAN PART 1: Specific Aims

Purpose: The purpose of the specific aims is to describe concisely and realistically the goals of the proposed research and summarize the expected outcome(s), including the impact of the proposed research will exert on the research fields involved.

Recommended Length: The recommended length of the specific aims is one page.

Content: The specific aims should cover:

- broad, long-term goals;
- the specific objectives and hypotheses to be tested;
- summarize expected outcomes; and
- describe impact on the research field.

Suggestions:

1. Generally, the Specific Aims section should begin with a brief narrative describing the long-term goals or objectives of the research project and the hypothesis to be tested. This is followed by a numbered list of the Aims.
2. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.
3. Make sure your specific objectives or hypothesis are clearly stated, are testable, and adequately supported by citations and preliminary data. Be sure to explain how the results to be obtained will be used to test the hypothesis.
4. *Be as brief and specific as possible*. For clarity, each aim should consist of only one sentence. Use a brief paragraph under each aim if detail is needed. Most successful applications have 2-4 specific aims.
5. Don't be overly ambitious. A small, focused project is generally better received than a diffuse, multifaceted project.
6. Be certain that all aims are related. Have someone read them for clarity and cohesiveness.
7. Focus on aims where you have good supporting preliminary data and scientific expertise.
8. Include a brief statement of the overall impact of the research studies.
9. This is the most important page of the entire application since it may be the only section the unassigned reviewers read to understand approach, impact, and innovation.

RESEARCH PLAN PART 2: Significance

Purpose: The Significance section should explain the importance of the problem or describe the critical barrier to progress in the field that is being addressed. Explain how the proposed research project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

Recommended Length: Approximately 1-2 pages

Content: The Significance section replaces the previous Background and Significance section. It should cover:

- the state of existing knowledge, including literature citations and highlights of relevant data;
- rationale of the proposed research;
- explain gaps that the project is intended to fill; and
- potential contribution of this research to the scientific field(s) and public health.

Suggestions

1. Make a compelling case for your proposed research project. Why is the topic important? Why are the specific research questions important? How are the researchers qualified to address these?
2. Establish significance through a careful review of published data in the field, including your own. Avoid outdated research. Use citations not only as support for specific statements but also to establish familiarity with all of the relevant publications and points of view. Your application may well be reviewed by someone working in your field. If their contributions and point of view are not mentioned, they are not likely to review your application sympathetically.
3. Highlight success of your related grants and awareness of potential barriers and alternative approaches.
4. Highlight why research findings are important beyond the confines of a specific project i.e., how can the results be applied to further research in this field or related areas.
5. Clearly state public health implications.
6. Show that the objectives are attainable within the stated time frame. Include a time frame for each specific aim.
7. Stress any innovations in experimental methods (e.g., new strategies, research methods used, interventions proposed).

RESEARCH PLAN PART 3: Innovation

Purpose: 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.

Recommended Length: The recommended length of the innovation section is 1/2-1 page.

Content: The innovation section should include the following:

- Explain why concepts and methods are novel to the research field.
- Focus on innovation in study design and outcomes.

▪ Summarize novel findings to be presented as preliminary data in the Approach section.

Suggestions

1. Describe how the application differs from current research or clinical practice paradigms.
2. Provide a careful review of the current literature to support the innovative methodologies, approaches, or concepts of your research.
3. Demonstrate familiarity with novel methodologies by citing your publications or your collaborator's publications.
4. Summarize novel findings to be presented as preliminary data in the Approach section.

RESEARCH PLAN PART 4: Approach

Purpose: The purpose of the approach section is to describe how the research will be carried out. This section is crucial to how favorably an application is reviewed.

Recommended Length: The maximum recommended length of the approach section is 9-10 pages.

Content: The research design and methods section should include the following:

- PI's preliminary studies, data, and experience relevant to the application and the experimental design;
- the overview of the experimental design;
- a description of methods and analyses to be used to accomplish the specific aims of the project;
- a discussion of potential difficulties and limitations and how these will be overcome or mitigated;
- expected results, and alternative approaches that will be used if unexpected results are found;
- a projected sequence or timetable (work plan);
- 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;
- a detailed discussion of the way in which the results will be collected, analyzed, and interpreted;
- a description of any new methodology used and why it represents an improvement over the existing ones;

Suggestions

Number the sections in this part of the application to correspond to the numbers of the Specific Aims.

1. Preliminary data, or a progress report, may be included before the Specific Aims sections. Alternatively, integrate preliminary data with the methods description for each Specific Aim. Preliminary data can be an essential part of a research grant application and helps establish the likelihood of success of the proposed project.
2. Avoid excessive experimental detail by referring to publications that describe the methods to be employed. Publications cited should be by the applicants, if at all possible. Citing someone else's publication establishes that you know what method to use, but citing your own (or that of a collaborator) establishes that the applicant personnel are experienced with the necessary techniques.
3. If relevant, explain why one approach or method will be used in preference to others. This establishes that the alternatives were not simply overlooked. Give not only the "how" but the "why."
4. If employing a complex technology for the first time, take extra care to demonstrate familiarity with the experimental details and potential pitfalls. Add a co-investigator or consultant experienced with the technology, if necessary.
5. Explain how the research data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
6. Develop alternative strategies for potential problems.
7. Document proposed collaborations and offers of materials or reagents of restricted availability with letters from the individuals involved.
8. Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised (i.e., use of Select Agents).

BUDGET AND JUSTIFICATION

Purpose: The purpose of the budget and justification is to present and justify all expenses required to achieve project aims and objectives. For multi-institutional applications, there must be a separate budget for each subcontractor or consortium member.

Recommended Length: Special forms are provided for the budget and justification. Read the instructions carefully. If there is a co-investigator at another institution, for whom funds are requested, be sure to include his/her budget.

Modular Budget Guidelines. Modular budgets are applicable to certain research grant applications requesting $250,000 or less per year for direct costs. Note, consortium/contractual facilities and administrative (F&A) costs are not factored into the direct cost limit. Consortium F&A costs may be requested in addition to the $250,000 limit. Modular budgets are simplified; therefore, detailed categorical information is not to be submitted with the application.

Content: The budget and justification should cover personnel, consultants, equipment, supplies, travel, and other expenses (e.g., animal maintenance).

Suggestions:

2. Be realistic. Both "padding" and deliberately under budgeting reflect naiveté, which will be recognized by reviewers.
3. Provide brief descriptions of duties for all positions listed in the budget, with the number of person months requested each year and any anticipated fluctuations. Special skills or accomplishments of a designated person may be included if not discussed elsewhere. For guidance on current salary limitations, contact your office of sponsored programs.
4. If possible, try to identify specific individuals for each position requested. "To be named" personnel are very often deleted by reviewers.
5. For modular budgets, a detailed budget is not required for supplies, equipment, and travel costs.
6. For non-modular budgets, justify all equipment purchases. The proposed acquisition of major pieces of equipment is likely to be scrutinized very carefully. Details are important, especially for non-project specific equipment e.g., FAX machine and computers.
7. For non-modular budgets, break out supply costs into major categories (reagents, disposables, etc.) and travel. Provide special justification for any unusual expenses requested.
8. Explain any year-to-year fluctuations in the budget, including the level of effort of personnel, especially if they can not be attributed to routine salary increases. Changes should parallel the research plan and project aims.
9. Check indirect costs. Some institutions have on-campus and off-campus rates.
10. Be complete but concise. There are no page limits in this section.
11. Provide adequate justification for the need to use outside consultants, if applicable.
12. The budget must be approved by the grantee institution business office before they can sign the application.
13. If applicable, provide documentation of institutional rates for animal maintenance and acquisition. Exceptionally large numbers of animals will need detailed justification.
14. Prorate service contracts to percentage of time equipment if used for the project.

ASSURANCES

Purpose: The purpose of the assurances section is to ensure that the applicant organization will comply with all relevant Federal laws and guidelines.

Recommended Length: A special form must be completed for the assurances section. See page B of the PHS 398 application or section18 of the SF424 (R&R) form.

Content: The assurances cover:

Human Subjects Research; Research on Transplantation of Human Fetal Tissue; Research Using Human Embryonic Stem Cells; Women and Minority Inclusion Policy; Inclusion of Children Policy; Vertebrate Animals; Debarments and Suspension; Drug Free Workplace; Lobbying; Non-Delinquency of Federal Debt; Research Misconduct; Civil Rights; Handicapped Individuals; Sex Discrimination; Age Discrimination; Recombinant DNA, including Human Gene Transfer Research; Financial Conflict of Interest; Smoke-Free Workplace; Prohibited Research; Select Agent Research; Principal Investigator Assurance

Suggestions

1. Be familiar with assurances, certifications and requirements for complying with these regulations.
2. Begin to obtain assurances early, since they tend to require the cooperation of different institutions.
3. Check your institution's grants management office for additional requirements. Different institutions follow different procedures and timelines.

HUMAN SUBJECTS

Purpose: The purpose of this section describing the involvement of human subjects is to ensure the protection of the rights and welfare of people who participate in research projects.

Recommended Length: There is no specified length, but be succinct.

Content: See Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan in the SF 424 or PHS 398 application to determine whether this section is required or your human subjects research is exempt.

Provide a complete description of the proposed involvement of human subjects as it relates to the work outlined in the Research Plan section. If an exemption has been designated on the face page, enough detail still must be provided to allow the determination of the appropriateness of the exemption. You must provide sufficient information for reviewers to determine that the proposed research meets:

1. the requirements of the DHHS regulations to protect human subjects from research risks (45 CFR Part 46);
2. NIH and NCI policy requirements for Data and Safety Monitoring for Clinical Trials, if applicable;
3. the ClinicalTrials.gov requirements, if applicable;
4. the requirements of NIH policies on inclusion of women, minorities, and children; and
5. the requirements of NIH policy on reporting race and ethnicity data for subjects in clinical research.

If the application involves the Inclusion of Women and Minorities, complete the Targeted/Planned Enrollment Table. A justification is required if there is limited representation of children, women, and minorities. Peer review and NIH program staff will consider this justification in their evaluation of your application. Failure to address this issue will impose a bar on funding until all the concerns raised by the IRG have been resolved.

VERTEBRATE ANIMALS

Purpose: The purpose of this section describing the use of vertebrate animals is to ensure the humane treatment of live animals involved in the proposed research.

Recommended Length: There is no specified length, but be succinct.

Content: Provide a complete description of the proposed use of vertebrate animals as it relates to the work outlined in the Research Plan section. There are five points which must be addressed in this section. A full description of these points can be found in the PHS 398 or SF 424 application package. Be thorough in addressing these five areas. Failure to address any of these areas will delay any award until these issues have been resolved.

RESOURCES AND ENVIRONMENT

Purpose: The purpose of the resources and environment section is to describe the resources, facilities, and support available to the researcher.

Recommended Length: There is no specified length, but be succinct.

Suggestions

1. Make sure the resources and environment section addresses all requirements of the proposed research plan.
2. Justify any reliance on resources external to the research.
3. Make sure all subcontractors and consortium members have the capability to perform the tasks assigned to them.
4. Make certain your resources and budget requests are consistent.
5. Make sure appropriate letters of collaboration are included.

OVERALL CONSIDERATIONS

1. Observe application guidelines strictly.
2. Use basic English and avoid jargon.
3. Make sure all acronyms are spelled out when used initially.
4. Observe the type size and page limitations strictly; do not use a small font.

5. Include only those graphs, tables, etc., that are unpublished and essential to the narrative.
6. Make sure all citations are complete: title, authors, book or journal, volume number, inclusive pages, year of publication. When citing articles that fall under the Public Access Policy, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference.
7. Include a section on Resource Sharing Plans, including sharing model organisms or genome wide association studies, if appropriate.
8. Have an outside reader review the application for clarity and consistency.
9. Proofread carefully by reading aloud. Do not rely on computer "spell check" to point out mistakes.
10. Be consistent with terms, references, and form writing style.

Be sure that your application is received by the appropriate deadline.