A to Z Of Research (R) Grants

Presented by
Audrey Streeter, CPC- Grant Manger for NCCC
Heather Arnold, Assistant Director, Office of Sponsored Projects
May 19, 2015
Planning your application

1. Familiarize yourself with
   - The Funding Opportunity Announcement
     - Parent: unsolicited investigator initiated R01 applications and other common grant mechanisms. ([http://grants.nih.gov/grants/guide/parent_announcements.htm](http://grants.nih.gov/grants/guide/parent_announcements.htm))
     - Requests for applications (RFA) and Program Announcements (PA): identifies special research opportunities
   - The NIH SF 424 Application guide for electronic applications and all the requirements. ([http://grants.nih.gov/grants/funding/424/index.htm](http://grants.nih.gov/grants/funding/424/index.htm))
   - The NIH Forms and Applications ([http://grants.nih.gov/grants/forms.htm](http://grants.nih.gov/grants/forms.htm))
Planning your application- continued

2. Know the Systems
   - Grants.Gov (http://www.grants.gov/)
   - NIH eRA commons (https://commons.era.nih.gov)
   - RAPPORT (http://www.dartmouth.edu/~osp/resources/rapgrants.html)

3. Notify
   - Your Grant Manager
   - Office of Sponsored Projects
NIH DEADLINES

- NIH has 3 cycle due dates in which applications are submitted for all Activity Codes.

- PLEASE NOTE: RFAs and some PARs (Program Announcements with special receipt, referral and/or review consideration) have special receipt dates indicated in the FOA.

- Some applications must be postmarked by a specific date, while other applications must be *received* by the specified date. The [Standard Due Dates for Competing Applications](http://grants.nih.gov/grants/funding/submissionschedule.htm) should be referenced for the latest requirements.

- Standard NIH due dates can be found at ([http://grants.nih.gov/grants/funding/submissionschedule.htm](http://grants.nih.gov/grants/funding/submissionschedule.htm))
<table>
<thead>
<tr>
<th>Activity Codes</th>
<th>Program Description</th>
<th>Application Instructions</th>
<th>Cycle I Due Date</th>
<th>Cycle II Due Date</th>
<th>Cycle III Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01 - new</td>
<td>Research Grant</td>
<td>SF424(R&amp;R)</td>
<td>February 5</td>
<td>June 5</td>
<td>October 5</td>
</tr>
<tr>
<td>R01- renewal, resubmission, revision</td>
<td>Research Grant</td>
<td>SF424(R&amp;R)</td>
<td>March 5</td>
<td>July 5</td>
<td>November 5</td>
</tr>
<tr>
<td>R03, R21- new</td>
<td>Other Research Grants</td>
<td>SF424(R&amp;R)</td>
<td>February 16</td>
<td>June 16</td>
<td>October 16</td>
</tr>
<tr>
<td>R03, R21- renewal, resubmission, revision</td>
<td>Other Research Grants</td>
<td>SF424(R&amp;R)</td>
<td>March 16</td>
<td>July 16</td>
<td>November 16</td>
</tr>
</tbody>
</table>
Internal Deadlines

- **7 business days** prior to the sponsor deadline
  - the PI should have a final budget, budget justification and abstract to submit to OSP for the first review.

- **2 business days** prior to the sponsor deadline
  - the PI should have the final proposal ready to submit to OSP for final review and submission.

**PLEASE NOTE**: If you are not going to make the 2 day deadline, it is requested of OSP that you contact them to make them aware. Check with you grant manager on whom you should contact.
SF 424 (R&R) Form: Cover Letter

- Applicants are encouraged to include a cover letter with the application.
- The cover letter will not be shared with peer reviewers.
- The letter should contain the following:
  - Application Title
  - Funding Opportunity (PA or RFA) title of the NIH initiative
  - Request of assignment to a particular awarding component(s) or scientific review group.
  - List of individuals who should not review your application and why.
- No page limit
Other Project Information Form: *Project Summary/Abstract*

- The purpose of the project summary/abstract is to describe every major aspect of the proposed project.

- It should contain a statement of objectives and methods to be used.

- The project summary must be no longer than 30 lines of text and follow the required font and margin specifications.
Other Project Information Form: Project Narrative

- Describe the relevance of this research to public health using no more than two or three sentences.

- Provide the project narrative in accordance with the announcement and/or agency specific instructions.

- Follow the required font and margin specifications.
Unless otherwise noted in the FOA, this section is required for submissions to NIH and other PHS Agencies.

Include ONLY Bibliographic citations.

Select only those references pertinent, relevant and current to the proposed research.

Provide the NIH Manuscript reference # or the Pub Med Central ID # (PMCID) for each article.

Indicate “PMC Journal- In Process”.
Other Project Information Form: Facilities and Other Resources

- This information is used to assess the ability of the organizational resources available to achieve the effort proposed.

- Identify the facilities to be used. This would include, Laboratory, Animal, Computer, Office, Clinical and other.

- If appropriate, specify the capacities, pertinent capabilities, relative proximity and extent of availability to the project.

- Define only those resources that are directly pertinent to the proposed work.

- Follow the required font and margin specifications.
Other Project Information Form: 

**Equipment**

- In this section, List the major items of equipment already available for this project and, if appropriate indicate the location and pertinent capabilities.

- Follow the required font and margin specifications.
PHS 398 Research Plan Form: Introduction to Application

- This section is required for Resubmissions or Revisions ONLY.

- Make sure your introduction does the following:
  - Summarizes the substantial additions, deletions, and changes to the application.
  - Responds to the issues and criticisms raised in the Summary Statement.

- Include any new preliminary data you have, and strengthen the application where possible—even in areas your reviewers did not question.

- 1 Page Limitation. Follow the required font and margin specifications.
PHS 398 Research Plan Form: Specific Aims

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 use on the research fields involved.

The Specific Aims should cover:
- Broad, long term goals
- The specific objectives and hypothesis to be tested
- Summarize expected outcomes
- Describe impact in the research field

1 PAGE limit. Follow the required font and margin specifications.
The Research Plan is organized in three sections:

- Significance
- Innovation
- Approach

Follow the table of page limits for the maximum length of the research plan. Typical R01 format allows 12 pages for this section. [http://grants.nih.gov/grants/forms_page_limits.htm](http://grants.nih.gov/grants/forms_page_limits.htm)

Follow the required font and margin specifications.
Explain the importance of the problem or describe the critical barriers 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.

Define how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the aims of this project are accomplished.

Approximately should take 1-2 pages.

Follow the required font and margin specifications.
Research Strategy/Plan- INNOVATION

- Explain how the application challenges and seeks to change the current research or clinical practice paradigms.
- Describe any novel theoretical concepts, methodologies, approaches, instrumentation or interventions to be used.
- Explain any refinements, improvements, or new application of the above.
- Approximately this should take ½ to 1 page.
- Follow the required font and margin specifications.
Research Strategy/Plan- **APPROACH**

- Describe the overall strategy, methodology and analyses to be used to accomplish the specific aims.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- Number the sections in this part of the applications to correspond to the numbers of the Specific Aims.
- Approximately 9-10 pages for this section.
- Follow the required font and margin specifications.
This is required for RENEWAL APPLICATIONS ONLY.

List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively.

No page limit. Follow the required font and margin specifications.
Human Subjects Sections: Protection of Human Subjects

- Provide a complete description of the proposed involvement of human subjects as it relates to the work outlined in your research plan section.

- If an exemption has been designated on the face page, enough detail still must be provided to all determination of the appropriateness of the exemption.

Protection of Human Subjects con’t

- 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 risk (45CFR 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 the requirements of NIH policy on reporting race and ethnicity data for subjects in clinical research.

- No page limits, however be concise.
Human Subjects Sections: 
*Inclusion of Women and Minorities*

- Address plans for inclusion on the basis of sex/gender, race, and ethnicity as well as complete the Planned Enrollment Report.

- Describe the subject selection criteria and rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design.

- Provide a compelling rationale for proposed sample specifically addressing exclusion of any sex/gender, racial, or ethnic group that comprises the population under study.

- Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members as subjects.

Human Subjects Sections: 
Inclusion of Children

- Provide either a description of the plans to include children, including the particular age ranges to be included, or, if children (or a subset) will be excluded from the proposed research, present an acceptable justification for the exclusion.
Application Sections:

*Planned Enrollment and Cumulative enrollment reports*

- The Planned Enrollment Report is used if your application requires the inclusion of Women and Minorities.
- A justification is required if there is limited representation of children, women and minorities.
- The Cumulative Inclusion Enrollment Report is used to report the sex/gender, race, and ethnicity of the actual participants that have been enrolled.
- If an applicant is proposing a new study using an existing dataset/resource where the participants have already been enrolled, us the Cumulative Inclusion Enrollment Report.
Other Research Plan Sections: *Vertebrate Animals*

- There are 5 points which must be addressed in this section
  - 1) Identify the species, strains, ages, sex and number of animals to be used.
  - 2) Justify the use of animals, the choice of species and the numbers to be used.
  - 3) Provide information on the veterinary care of the animals involved.
  - 4) Describe the procedures for ensuring comfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of the research.
  - 5) Describe any method of euthanasia to be used and the reasons for it’s selection.

- No page limits. Follow the required *font and margin specifications*. 

Other Research Plan Sections:  
**Select Agent Research**

- The select agent requirements do not apply when identification of strain(s) of select agents and toxins have been excluded.
- List of these agents can be found at [http://www.selectagents.gov/](http://www.selectagents.gov/)
- Contact OSP or your Grant Manager if you need additional information.
- If you are responding to a specific funding opportunity announcement (e.g., PA or RFA), address any requirements specified by the FOA.
Other Research Plan Sections: Multi-PD/PI Leadership Plan

- A leadership plan must be included.
- All such PI’s must be assigned the PD/PI role on the senior/key personnel profile form.
- A rationale for choosing multiple PD/PI approach should be described.
- The organizational structure of the leadership team and research project should be described.
- Description of communication plans, decision making, scientific direction and procedures for resolving conflict.
- No page limit. Follow the required font and margin specifications.
Other Research Plan Sections: 
**Consortium/Contractual Arrangements**

- Describe the programmatic, fiscal and administrative arrangements to be made between the applicant organization and the consortium organization(s).

- No page limit. Follow the required **font and margin specifications.**
Other Research Plan Sections: **Letters of Support**

- Provide letters necessary to establish the support of consortium participants
- Letter of collaborators such as Senior/Key Personnel and Other Significant Contributors
- For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per year anticipated.
- Letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service.
- No page limitations.
Other Research Plan Sections:

**Resource Sharing Plan**

- **Data Sharing Plan**: Investigators seeking $500,000 or more in direct cost for any year are expected to include a brief 1 paragraph description on how final research data will be shared, or explain why data sharing is not possible.

- **Sharing Model Organisms**: 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 organisms or state why such sharing is restricted or not possible.

- **Genome Wide Association Studies (GWAS)**: Applicants seeking funding for a genome-wide association are expected to provide a plan for submission of GWAS data to NIH Data repository, or an appropriate explanation as to why submission is not possible.

- See OSP website for a template to get you started [http://www.dartmouth.edu/~osp/resources/data_management_planning/](http://www.dartmouth.edu/~osp/resources/data_management_planning/)

- No page limit. Follow the required font and margin specifications.
Application Sections: Appendix

- New, Resubmissions and revision applications may include the following materials in the appendix (note: some FOA’s do not permit publications)
- Applicants may submit up to 3 of the following types of publications
  - Manuscripts and/or abstracts accepted for publication, but not yet published.
  - Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available.
  - Patents directly related to the project.
- A maximum of 10 PDF attachments is allowed in the appendix. Follow the required font and margin specifications.
Application Sections: 

**Budget**

- 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.

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

- **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 and administrative (F&A) costs are not factored into the direct cost limit. The modular budget is applicable only to applications for R01, R03, R15, R21 and R34.

- 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.
Application Sections: **Budget - Continued**

- **R&R Detailed Budget** - The R&R budget form includes three separate data entry screens.

- 1) Section A&B - This is where you detail out senior key personnel and all other personnel.

- 2) Section C, D and E - This is where you detail out equipment costs, travel and if applicable-participant trainee support costs.

- 3) Section F, G and H - indicate here other direct costs, which would include supplies, publication costs, consultants, Sub awards/consortium/contractual costs, and indirect cost rate. This is also where you would load the budget justification under year 1.
Application Sections: *Budget Justification*

- Use the Budget Justification to provide additional information requested in each budget category you completed.
- Use this section to list roles, associated months, salary and fringe benefits for all Key Personnel and in addition to all personnel indicated in Section B- Other Personnel.
- You must justify (where applicable) equipment, travel, participant-trainee support and other direct cost categories.
- Include a justification for any significant increases or decreases from the initial budget year.
- Indicate salary increases from year to year as well as any increases to fringe.
- Should note the current F&A Rate and the agreement date.
- No page limits. Follow the required font and margin specifications.
Overall Considerations

- Observe application guidelines strictly.
- Start early in writing your grants, as it may take many revisions.
- Make sure all acronyms are spelled out when used initially.
- Observe the type size and page limitations strictly; do not use a small font.
- Include only those graphs, tables, etc., that are unpublished and essential to the narrative.
- Be consistent with terms, references and form writing style.
- Make sure all citations are complete. When citing articles that fall under the Public Access Policy, provide the NIH Manuscript submission reference number OR the PubMed Central ID # (PMCID).
- Have an outside reader review the application for clarity and consistency.
- Be sure that your application is received by all internal and external deadlines.