

# Navigating the Changes to the NIH Application Instructions

*EFFECTIVE JANUARY 25, 2010*

# Why the Change?

## To Enhance NIH Peer Review

- ▶ Align the structure and content of the forms with review criteria
  - To focus the applicants and reviewers on the same elements
  - To help ensure a more efficient and transparent review process
- ▶ Identify and encourage new and early stage investigators
  - New Investigator checkbox removed from PHS 398 Face Page (paper) and PHS 398 Cover Page Supplement (electronic)
- ▶ Streamline time to award
- ▶ Fund the best science, by the best scientists, with the least amount of administrative burden

# Overview of the Changes

- ▶ Research Plan
- ▶ Biographical Sketch
- ▶ Facilities and Other Resources

# Research Plan **Shorter** Page Limits

## Current Page Limit

## New Page Limit

<25 (e.g R21, R03)

6

25 (e.g. R01)

12

*New page limits are applicable to ALL New, Renewal, Resubmission, and Revision applications, unless otherwise stated in the Funding Opportunity Announcement (FOA).*

# New Structured Research Plan

1. Intro to Application (Resubmission/Revision only)
2. Specific Aims – 1 page limit
3. Research Strategy – R21=6 pages, R01=12 pages
  - a. Significance
  - b. Innovation
  - c. Approach
    - ▶ Prelim Studies for new applications
    - ▶ Progress Report for renewal/revisions

# New Research Strategy Section

Structure of research narrative changed to match new review criteria

<b>Current Application</b>	<b>New Application</b>
Background and Significance	<b>Research Strategy</b> a. Significance b. Innovation c. Approach <ul style="list-style-type: none"><li>• Preliminary Studies for New Applications</li><li>• Progress Report for Renewal/Revision</li></ul>
Research Design and Methods	
Preliminary Studies/Progress Report	

# New Research Strategy Preparation

- ▶ A **single PDF attachment** for the Research Strategy (previously 3 separate files) increases applicant control over the look and feel of the application.
  - Simplified preparation for the applicant
  - Easier reading for reviewers
  - Electronic validation of page limits for Research Strategy in one file

# New Order of Research Plan Section

## 2. Research Plan Attachments:

Please attach applicable sections of the research plan, below.

- |                                     |                      |   |  |  |
|-------------------------------------|----------------------|---|--|--|
| 1. Introduction to Application      | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| (for RESUBMISSION or REVISION only) |                      |   |  |  |
| 2. Specific Aims                    | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 3. *Research Strategy               | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 4. Inclusion Enrollment Report      | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 5. Progress Report Publication List | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |

### Human Subjects Sections

- |                                      |                      |   |  |  |
|--------------------------------------|----------------------|---|--|--|
| 6. Protection of Human Subjects      | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 7. Inclusion of Women and Minorities | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 8. Targeted/Planned Enrollment Table | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 9. Inclusion of Children             | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |

### Other Research Plan Sections

- |   |                      |   |  |  |
|---|----------------------|---|--|--|
| 10. Vertebrate Animals                  | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 11. Select Agent Research               | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 12. Multiple PD/PI Leadership Plan      | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 13. Consortium/Contractual Arrangements | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 14. Letters of Support                  | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 15. Resource Sharing Plan(s)            | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |

- |              |  |   |   |
|--------------|--|---|---|
| 16. Appendix | <input type="button" value="Add Attachments"/> | <input type="button" value="Remove Attachments"/> | <input type="button" value="View Attachments"/> |
|--------------|--|---|---|



# Research Strategy - Significance

- ▶ Explain importance of problem or critical barrier to progress in field.
- ▶ Explain how project will improve scientific knowledge, technical capability, clinical practice in one or more broad fields.
- ▶ Describe how concepts, methods, etc. that drive this field will be changed if aims achieved.

# Research Strategy - Innovation

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

# Research Strategy - Approach

- ▶ Describe overall strategy, methodologies, and analyses proposed in specific aims.
- ▶ Discuss potential problems, alternative strategies, and benchmarks for success.
- ▶ If in early stages, describe strategy to establish feasibility, management of high risk aspects.
- ▶ Point out any hazardous procedures, materials.
- ▶ For new applications, include **Preliminary Studies** as part of Approach.
- ▶ For renewal/revision applications, provide a **Progress Report** as part of Approach.

# Facilities & Other Resources Section

- ▶ **Scientific Environment** – Describe how the scientific environment will contribute to the probability of success of the project, and unique features of the environment.
  - Discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject population or will employ useful collaborative arrangement.

# Facilities & Other Resources Section

- ▶ **Early Stage Investigators (ESIs)** – will require the institutional investment in the success of the investigator.
  - e.g. classes, travel, training, collegial support, administrative support, and financial support.
- ▶ **Definition of Early Stage Investigator (ESI):** Within 10 years of completing their terminal research degree or within ten years of completing their medical residency.

# Facilities & Other Resources Section

- ▶ **Biohazards or Other Potentially Dangerous Substances** – describe any special facilities used for working with these substances.

# Biographical Sketch Changes

- ▶ Section A - A new **Personal Statement** will be incorporated.
  - This will change the parts formerly called A, B, and C, to Parts B, C, and D.
  - Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g. PD/PI, collaborator, mentor, etc.) in the project that is the subject of the application.

*Therefore, Biosketch may have to be revised for EVERY proposal submission depending on your role on the project.*

# Biographical Sketch Changes

- ▶ Section B (formerly Section A)
  - Positions and Honors
- ▶ Section C (formerly Section B)
  - Publications (suggest limiting to 15 selected peer-reviewed pubs).
    - ▶ Choose 15 based on recency, importance to field, and/or relevance to proposed research.
    - ▶ Be sure to include the **PMCID #** where applicable!
- ▶ Section D (formerly Section C)
  - Research Support Ongoing and Completed – No change to instructions.



# New Page Limitations

*unless the FAO specifies otherwise*

SECTION OF APPLICATION Also refer to the relevant section of the application instructions and the FOA.	PAGE LIMITS *
<a href="#">Introduction to Resubmission Application</a> (3 pages for R25 on PHS398 Research Plan and 3 pages for K12, T and D Training Grants on PHS398 Training Program Plan)	1 page
<a href="#">Introduction to Revision Application</a>	1 page
<a href="#">Specific Aims</a>	1 page
<a href="#">Research Strategy (Item 5.5.3 of Research Plan)</a> For Activity Codes R03, R13, R21, R36, SC2, SC3	6 pages
<a href="#">Research Strategy (Item 5.5.3 of Research Plan)</a> For Activity Codes R01, R10, R15, R18, R21/R33, R24, R33, R34, DP3, G08, G11, G13, SC1, X01	12 pages
<a href="#">Research Strategy (Item 5.5.3 of Research Plan)</a> For all other Activity Codes, including S Activity Codes	Follow FOA instructions
<a href="#">Research Education Program Plan</a> For R25 Research Education Grant Applications	25 pages
<a href="#">Biosketch (per person)</a> (2 pages for DP1 and DP2 Activity Codes)	4 pages
<a href="#">Career Development Award (K) Application</a> Upload to PHS 398 Career Development Award Supplemental Form: Combined Candidate Information (Items 3-5: Candidate's Background, Career Goals and Objectives, Career Development/Training Activities During Award Period, and Training on the Responsible Conduct of Research) and Research Strategy (Item 11)	12 pages
<a href="#">Institutional Research Training and Career Development Applicants, Including Ruth L. Kirschstein NRSA Application</a> Research Training Program Plan: Combined Sections 8.7.2.2 – 8.7.2.5 (Background, Program Plan, Recruitment and Retention Plan to Enhance Diversity, and Plan for Instruction in the Responsible Conduct of Research)	25 pages

# Important Links

- ▶ NIH Notice, [NOT-OD-149](#), regarding the restructured application forms and instructions.
- ▶ NIH website for [Enhancing Peer Review](#).
- ▶ [NIH FAQs](#) on application enhancements, peer review, scoring, new investigators/ESIs, etc.
- ▶ New NIH [Forms & Applications](#).
- ▶ New [NIH Biosketch SAMPLE](#), with an example of the Personal Statement.
- ▶ NIH [New and Early Stage Investigator Policies](#).
- ▶ DOM info on [NIH Public Access Policy](#).

# Steps for Success

- ▶ Read the new instructions thoroughly and carefully to ensure successful preparation and submission.
- ▶ Submit **EARLY** for the February and March deadline to allow enough time to make any required corrections prior to proposal submission.

# DOM DRA 3-Day Policy

- ▶ **Reminder:** All Grants.gov/Cayuse proposals are required to be submitted to the Department of Medicine's Departmental Research Associate (DOM DRA) at **least 3 business days PRIOR to the federal agency deadline.**