

A Review of Recent Changes to NIH Forms & Instructions

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Today's Topics

- Important Dates
- Changes common to all applications
- Changes specific to the SF424 Forms (electronic submissions)
- Changes Specific to the PHS 398 forms (paper submissions)
- Reminder of PHS 2590 changes
- Available Resources

Important Dates

- Effective January 25, 2010 all grant applications must use the new forms and instructions
- The *grant deadline* determines which forms should be used
- Deadlines prior to 1/25/10 – old forms
- Deadlines on or after 1/25/10 – new forms

Changes Common to All Applications (paper or electronic)

- Shortened Page Limits
- Restructured Research Plan
- Bios tailored to each application
- Resources tailored to each application

New Page Limits

- Introduction – 1 page
 - 3 pages for certain mechanisms (see FOA for details)
- Specific Aims – 1 page
- Research Strategy
 - For R03, R21, R36, SC2, SC3, F awards – 6 pages
 - For R01, R10, R15, R21/R33, R24, R33, R34, DP3, G08, G11, G13, SC1, X01, single project U01 – 12 pages
 - For R25 – 25 pages
 - For P grants - for each project and core of multi-component applications – 6 or 12 pages
 - For individual K awards – 12 pages
 - For institutional K awards and institutional training awards – 25 pages
 - Everything else – follow FOA instructions

See http://enhancing-peer-review.nih.gov/page_limits.html for further details

Restructured Research Plan

■ Specific Aims

- Should also include the impact of the results of the proposed research on the research field

■ Research Strategy

- Significance
- Innovation
- Approach
 - Preliminary Studies for New Applications
 - For new applications, include information on Preliminary Studies as part of the Approach section.
 - Progress Report for Renewal and Revision Applications
 - For renewal/revision applications, provide a Progress Report as part of the Approach section.

Significance

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed 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.

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.

Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. 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.
- Point 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 11, below.

Biosketch

- New format:

- A. Personal Statement
- B. Positions & Honors
- C. Selected Peer-reviewed Publications
- D. Research Support

- Sample available at:

<http://grants1.nih.gov/grants/funding/phs398/biosketchsample.pdf>

Biosketch

■ Personal Statement

- Should describe why the individual's experience and qualifications make him/her particularly well-suited for their role (e.g., PD/PI, mentor) in the project

■ Positions & Honors

- As before

■ Publications

- NIH *encourages* applicants to limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Publications may be selected on the basis of recency, importance to the field, and/or relevance to the proposed research.

■ Research Support

- As before - list both selected ongoing and completed (during the last three years) research projects

Resources

- Include the following information:
 - As before, identify the facilities and resources available
 - How does the scientific environment contribute to the probability of success (e.g., institutional support, physical resources, and intellectual rapport)?
 - How will the proposed studies benefit from unique features of the scientific environment or subject populations? Will the proposed studies employ useful collaborative arrangements?

Resources for ESI

■ Early Stage Investigators

- Additional requirements for ESI applicants
- describe institutional investment in the success of the investigator:
 - resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESI's project
 - availability of organized peer groups; logistical support such as administrative management and oversight and best practices training;
 - financial support such as protected time for research with salary support.

Changes to the SF424

- Grant Application Face Page
 - The Competition ID field will read “**Adobe Forms B**”
- SF424 Cover Component (Face Page)
 - New 4b – agency-assigned routing # (ignore for now)
 - Item 13 – now only requires congressional district of applicant (previously applicant and project)
 - Item 18 – new section (use only if indicated)
 - Other items – complete as before

Changes to the SF424

■ Project/Performance Site

- New checkbox (I am submitting an application as an individual ... etc)
– do NOT check
- The Congressional District is required for all performance sites
- Format for congressional district info
 - For one district use NY-028
 - For all districts in a given state use NY-all
 - For the whole US use US-all
 - Outside the US use 00-0000

Changes to the SF424

■ Other Project Info

- New question under Human subjects section
 - Is the research exempt from Federal Regulations? Yes or No answer required if human subjects are involved
- New question 5 (Response **REQUIRED**)
 - Is the research performance site designated a historic place?
- Updated Resources section (refer back to changes common to all applications)
- All other sections as before

Changes to the SF424

- Senior/Key Personnel
 - Revamped bio (refer back to changes common to all applications)
 - New fields for degree type and degree year (*optional*; NOT mandatory)
 - Everything else as before
- Cover Page Supplement
 - New Investigator box is gone
 - Eligibility determined by data in NIH Commons

Changes to the SF424

■ Research Plan Component

- Slots for Introduction, Specific Aims, Research Strategy
 - Introduction – 1 page
 - Specific Aims – 1 page
 - Research Strategy – dependent on mechanism
- Refer back to changes common to all applications for details on the content of the Research Strategy section

Changes to the PHS398

- New forms are dated June 2009 (PHS 398 rev 06/09)
- Face Page – no new investigator check box
- Table of contents – revised
- Bios – refer to changes common to all applications
- Resources – refer to changes common to all applications
- Research Plan – refer to changes common to all applications
- Personal Data form – no more

Other Notable Items

- Reminder: all post-docs need an eRA Commons user name
- Institutional Training Grants will transition to electronic submission effective 1/25/2010
- Revised Table 12A (part of the institutional training application)
 - now requires data on the % of students who attain a doctoral degree and the average time to receive the doctoral degree

Reminder: Changes to the PHS 2590

- Current forms are dated PHS 2590 (rev. 06/09)
- Use is mandatory after October 1, 2009
- New All Personnel Report
 - PD/PI(s) should be listed on the form
 - regardless of the source of compensation all personnel who participated in the project for at least one person month should be listed
- New Biosketch Format
 - only required as part of the progress report for **new** senior/key personnel since the previous submission (uses new format and includes personal statement).

NIH Resources

- Forms and instructions for the electronic SF 424 (R&R) applications are available at <http://grants.nih.gov/grants/funding/424/index.htm>
- Forms and instructions for paper-based PHS 398 applications are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html>

More NIH Resources

- NIH Enhancing Peer Review site (<http://enhancing-peer-review.nih.gov/index.html>)
- Enhancing Peer Review Listserv at <https://list.nih.gov/archives/enhancingpeerreview.html>
- A sample biosketch is available at <http://grants.nih.gov/grants/funding/2590/biosketchsample.pdf>
- Summary of changes http://enhancing-peer-review.nih.gov/docs/application_changes.pdf

ORPA Resources

- Recent orpa-1s
- The ORPA Guide to *Assembling the SF424*
(revisions in progress)
- Your ORPA RA

Happy Holidays!