

# NIH 424 Cheat Sheet

## **\*\*Notable Changes\*\***

**Biosketch:** 4 Page limit on combined sections, no headers/footers.

- A. **Personal statement - Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor) in the project.**
- B. Positions and Honors.
- C. **Peer-reviewed publications or manuscripts in press - NIH encourages applicants to limit the list to no more than 15. For publicly available citations after April 8, 2008, URLs or PMC submission identification numbers must accompany the list of publications. Insert line for pubs after 4/8/08.**
- D. Research Support.

**Literature Cited:** Only pubs that applicant PI(s) (co)authored or funded require PMCID.

### **Research Plan:**

#### **Specific Aims (limit 1 page)**

State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. 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.

#### **Research Strategy (limit 6 or 12 pages)**

**Research Strategy - 3 sections; Significance, Innovation & Approach with a 6 or 12 page limit depending on the opportunity type.**

##### (a) 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.

##### (b) 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 intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

##### (c) Approach ([discuss preliminary studies here](#))

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. 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 out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.

**Please note: submissions after January 1, 2009 there will only be one resubmission.**

## New FOA Numbers

Type	Title	FOA #	New Submission Date	Renewal/ Resubmission
<b>R01</b>	Research Project Grant ( <b>Parent R01</b> )	PA-10-067	2/5, 6/5, 10/5	3/5, 7/5, 11/5
<b>R03</b>	Small Research Grant Program ( <b>Parent R03</b> )	PA-10-064	2/16, 6/16, 10/16	3/16, 7/16, 11/16
<b>R13/U13</b>	Support for Conferences & Scientific Meetings ( <b>Parent R13/ U13</b> )	PA-10-071	4/12, 8/12, 12/12	4/12, 8/12, 12/12
<b>R15</b>	Academic Research Enhancement Award (Parent R15)	PA-10-070	2/25, 6/25, 10/25	2/25, 6/25, 10/25
<b>R21</b>	Exploratory/Developmental Research Grant Program ( <b>Parent</b>	PA-10-069	2/16, 6/16, 10/16	3/16, 7/16, 11/16

Section of Application with Page Limits	Page Limits *
<b>Introduction to Resubmission Application:</b> For all Activity Codes, EXCEPT <a href="#">I</a> , <a href="#">K12</a>	1 page
<b>Introduction to Resubmission Application:</b> For institutional ( <a href="#">I</a> ), Institutional CDA ( <a href="#">K12</a> )	3 pages
<b>Specific Aims:</b> all Activity Codes that use an app form with the Specific Aims section	1 page
<b>Research Strategy:</b> <a href="#">R03</a> , <a href="#">R13/U13</a> , <a href="#">R21</a> , <a href="#">Fellowships (F)</a> ,	6 pages
<b>Research Strategy:</b> <a href="#">R01</a> , single project <a href="#">U01</a> , <a href="#">R10</a> , <a href="#">U18</a> , <a href="#">R21/R33</a> , <a href="#">R34</a> , <a href="#">U34</a>	12 pages
<b>Research Strategy:</b> For each project & core of multi-component apps, such as ( <a href="#">P</a> )	6 or 12 pages*
<b>Combined:</b> <b>Research Strategy</b> & first four items of Candidate Information for <a href="#">Individual CDA(K)</a> Apps	12 pages
<b>Items 2-5 of Research Training Program Plan:</b> For Institutional Career Development and Research Training Applications, including <a href="#">K12</a> , <a href="#">I</a>	25 pages
<b>Biographical Sketch:</b> For all Activity Codes except DP1 and DP2	4 pages

\*FOA instructions always supersede these instructions.

## Tips and Tricks for the new “funky” Adobe Forms B Brought to you by the NIH OER’s Office of Electronic Research Administration

### *SF424 (R&R) cover form*

- A new “Agency Routing Identifier” field follows the “Federal Identifier” field in item #4. NIH has not yet defined how this field will be used. For now, the important thing to remember is that the new field in no way affects the use of the long-standing Federal Identifier field.
- Grants.gov is enforcing nine-digit postal codes for all US addresses on federal-wide forms. The form will identify a formatting issue if you forget the “plus four” part of the zip code and you can correct it. Be careful, though—if that zip code field was used to forward populate to other editable areas of the form, your correction won’t carry forward (yes, that is experience talking.) The US Postal Service has a [Zip Code Lookup](#) tool you might find handy. Note: Our PHS forms will still accept five or nine-digit zip codes.
- The “Congressional District of Project” field is now located on the Project/Performance Site Locations form.
- The “Areas Affected by Project” field (formally item #12) is gone. We were getting responses like “the world” anyway—although it may be true, it isn’t terribly helpful from a reporting perspective.
- There is a new “SFLLL or other Explanatory Documentation” attachment in section 18. We have removed our “Assurances/Certifications Explanation” attachment from the PHS 398 Checklist form and will use the new attachment instead.
- In the Estimated Project Funding section there is a new line item for “Total Non-Federal Funds.” You should just enter “\$0” unless the specific announcement indicates cost sharing is a requirement.

### *PHS 398 Research Plan & PHS 398 Career Development Award Supplemental Form*

- The “Background and Significance,” “Preliminary/Studies/Progress Report” and “Research Design and Methods” attachments have been combined into a single “Research Strategy” attachment. In ADOBE-FORMS-A applications, the three separate attachments and the Specific Aims have to be within a certain page limit. In ADOBE-FORMS-B applications, the Specific Aims is a separate, one-page attachment and the combined Research Strategy is also validated for page length, typically 6 or 12 pages (see [Table of Page Limits](#)). This approach eliminates any doubt as to whether the application is within the appropriate length, since we no longer need to account for white space introduced when separating the research plan into the various pieces.

### *R&R Senior Key Person Profile (Expanded) form*

- You’ll notice new “Degree Type” and “Degree Year” fields for each Sr/Key entry. These federal-wide form fields have allowed us to remove our own degree fields from our agency-specific PHS 398 Cover Page Supplement form. Information supplied in the new fields will show on the application image, but NIH will use the degree information contained in the PD/PI’s eRA Commons profile as the official data source for degree information post-submission. Please make sure all PD/PIs update their Personal Profiles.
- The NIH instructions for the Biographical Sketch attachment include a new Personal Statement requirement and guidelines for selecting the publications to include. The eRA system limits the biographical sketch attachment to 4 pages, but it will not catch issues with content. Be sure to follow the new instructions carefully to avoid issues post-submission.
- The drop-down list of values for the Project Role field now includes “Post-doctoral Scholar” and “Co-Investigator.” The “PD/PI” role still must be used for all principal investigators on a multiple-principal-investigator application. The new “Co-Investigator” role, however, recognizes that many institutions use the “Co-Investigator” role internally and including it in the drop down accommodates that special institution use.
- You will be able to scroll through Sr/Key entries. This is a big improvement from having to use the “Next” button and waiting for each entry to come up to get to the middle of the list of entries.
- If you’ve ever started a Sr/Key entry, selected the “Role” for the individual and later decided that the entry wasn’t needed, then you are probably painfully aware of the form bug that forces users to supply data in the Sr/Key entry or start fresh with a new form package. There still isn’t an “empty” Role selection that returns an entry to its beginning state, but there is a more acceptable work-around than starting over. Work-around: Complete the required fields for the entry and click the “Next Person” button. This will activate the “Delete Entry” button. Scroll back to entry and delete it.
- You may notice a note at the bottom of the updated form - “To ensure proper performance of this form, after adding 20 additional Senior/Key Persons, please save your application, close the Adobe Reader, and reopen it.” Peter, our most experienced eSubmission tester, lost an entire application after entering all 40 Sr/Key entries for a test. He

asked me to let you all know that the Grants.gov note should be taken seriously; periodic saves may take a little extra time, but they save the time and heartache of starting over.

#### *Project Performance Site Location(s) form*

- The use of this form was expanded across all Grants.gov form families. In order to accommodate Agencies that award grants to individuals, you'll see a Checkbox at the top for Individual applicants. All NIH opportunities are geared towards Organizations. DO NOT CHECK THE BOX or you'll get one of those dreaded eRA validations.
- The new form will allow you to provide information for the primary site and up to 29 additional sites (old form only allowed 7 additional sites). Applicants have the ability to provide additional sites in an attachment once all 30 site entries with structured data are used.

Note: We currently have a bug in our application image assembly code that prevents the Additional Performance Site attachment from displaying in the eRA Commons application image. We do receive the file from Grants.gov and the vast majority of NIH applications fit within the 30 available sites, so this bug was not deemed a "show-stopper" for our form transition and is scheduled to be fixed in late February.

#### *R&R Other Project Information form*

- While testing for our transition, we discovered that the latest production version of this form no longer allowed for the collection of the Human Subject Assurance Number under common NIH scenarios. Unfortunately, it was not discovered in time for Grants.gov to provide a fix that we could accommodate in our ADOBE-FORMS-B form packages. Consequently, for the foreseeable future we will need to deal with inconsistent form behavior between the Human Subject and Vertebrate Animal sections of the form.
  - Human Subject section – If Human subjects are involved and you answer "Yes" to the "is the IRB review Pending" question, then the form does not allow you to enter the Human Subject Assurance Number information. Since NIH still must collect this information, we have modified our eRA Commons Just-In-Time (JIT) functionality to allow applicants to select the appropriate Human Subject Assurance Number from those listed in the eRA Commons Institution Profile. Reminder: Don't submit JIT information unless requested to do so by NIH.
  - Vertebrate Animal section – If Vertebrate Animals are used and you answer "Yes" to the "Is the IACUC review Pending" question, you must provide either your Animal Welfare Assurance Number or the text 'None' if you don't have one. Failure to provide this information will result in an eRA Validation error (same requirement and validation we used with ADOBE-FORMS-A).
- I've noticed some funky form behavior with the environment impact question (item #4). When you answer "Yes", the Explanation field (#4b) does not always become active. If you run into this issue, try to save, close, reopen the form and return to the question—this has worked for me every time.
- The following question (item #5) has been added to the form, "Is the research performance site designated, or eligible to be designated, as a historic place?"

#### *PHS 398 Cover Page Supplement form*

- The New Investigator field has been removed. The eRA system determines New Investigator eligibility based on the grant history associated with the PD/PI's eRA Commons account. Similarly, the system calculates Early Stage Investigator status from the data in the Degrees/Residency section of the PD/PI's eRA Commons Personal Profile. It is imperative that PD/PIs periodically review/update the data associated with their eRA Commons account. PD/PIs should check their List of Applications in eRA Commons Status to confirm all their prior grants are displayed. To view/update degree and other profile information, PD/PIs should click through the different sections of the Commons Personal Profile. The [eRA Commons Help Desk](#) can assist, if needed.
- The link in the Human Embryonic Stem Cells section of the form has been updated to: <http://stemcells.nih.gov/research/registry/>. From this page you can access the NIH Human Embryonic Stem Cell Registry. Applicants should enter the 4-character NIH Registration Number (e.g., 0001) for the cell line from the list of approved lines. From the same page, you can access the list of cells lines pending approval. These lines cannot be referenced on an electronic application until approved and assigned an NIH Registration Number.

#### *PHS 398 Checklist form*

- A new Disclosure Permission Statement has been added to the form, though your response will not affect any peer review or funding decisions. I've had a few inquiries regarding how the information would be used if permission is given. Per our policy office, we do not systematically compile information on applications that do not result in an award. An organization interested in possible collaborations or investment would need to contact NIH and express

interest with relation to a particular area of research or other defined parameter. NIH would then query its system for unsuccessful applications meeting the defined parameters. If the applicant organization has checked “Yes” to the Disclosure Permission Statement, NIH could then disclose the title of the project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization.