NIH NRSA Fellowship – Proposal Preparation Checklist

Before you begin:

- **READ THE FOA** which can be found at [http://grants.nih.gov/training/F_files_nrsa.htm](http://grants.nih.gov/training/F_files_nrsa.htm)
- **Refer to the SF424 Guidelines** which can be found at [http://grants.nih.gov/grants/funding/424/index.htm](http://grants.nih.gov/grants/funding/424/index.htm)
- Proposals MUST be submitted via Grants.Gov on or before 5:00pm Local Time on Deadline Date. If an NIH “standard deadline” date falls on a weekend or *Federal* holiday, the deadline is extended to the following business day.
- The individual Fellowship applicant for whom support is being requested is designated as the PD/PI on the application and must be registered in eRA Commons as PI. The mentor, also needs a valid eRA Commons ID listed with the role of “mentor.” Please contact NIH-help@mit.edu if an eRA Commons ID or new role are needed.
- Current form set: FORMS F

**Kuali Coeus (known as KC) specifics:**
- Candidate should be the named PI in the proposal. At award stage an account is established with the Mentor as the PI and the candidate referenced in the title. (note, the fellow does not need PI status).

**Sections of the Application:**
The Grants.gov forms should be reviewed prior to submission. For S2S submissions, they can be accessed on the S2S Opportunity Search screen under the Forms tab.

**RR SF424 – please note:**

Box 1. Ensure correct box is checked: “Application” *Note: change/corrected applications are only used if the original proposal submitted errored before reaching NIH and needs to be resubmitted.*
Box 4a. Box is completed with the NIH grant number if a Resubmission i.e., CA123456
Box 6. TIN/EIN = 1042103594A1
Box 8. Type of application: ensure correct box is check *(either NEW or RESUBMISSION)*
Box 10. Ensure solicitation information is completed.
Box 11. Title: No special characters should be used. Limit 200 characters including spaces and punctuation.
Box 12. Ensure start dates are correct. Note: Enter the proposed start date of the project. The start date is an estimate, and is typically at least nine months after application submission
Box 13. MIT Congressional District = MA-007
Box 16. The program is NOT covered by E.O. 12372
Box 17. Should be AGREE

Box 21. **Cover letter** – Required for fellowship applications. The cover letter must contain the list of referees (including name, department affiliation, and institution). It should not contain information regarding assignment of the application. Please see the new Assignment Request Form (optional) for submitting this information. [http://kc.mit.edu/quick-reference-cards](http://kc.mit.edu/quick-reference-cards) Attached Forms: User-Attached Optional S2S Forms

**R&R Other Project Information**

1. Human Subjects – if Yes, then include Assurance No. 00004881
   a. If YES and EXEMPT: the exemption number must be included.
   b. If YES and IRB review needed: ensure all necessary attachments are included on the study record attachment ‘PHS Human Subjects and Clinical Trials Information’ (see more information below).

2. Animal Assurance No. D16-00078. Animal subjects should always be listed as “Pending” at proposal

Revised: July 2020
Note: if applicant answers “NO” to “PENDING” for animal or human approval then an approval date must be entered. If not, the package will error.

If animal involvement is anticipated within the period of award but plans are indefinite, check “Yes” and provide an explanation and anticipated timing in the Vertebrate Animal attachment to the Research Plan. In all cases, an approved protocol is required prior to any work with animal subjects.

3. Proprietary information – expected to be NO. If yes, see SF424 Guide. Text must be marked.
4. Environmental Questions – expected to be NO
5. Historic Place – expected to be NO
6. International Collaboration – YES if the performance of any significant scientific element or segment of the project will be performed outside of the United States. If you have checked "Yes" to Question 6, you must include a "Foreign Justification" attachment in Field 12, Other Attachments.
7. Project Summary/Abstract – 30 lines max; summary of the research, fellowship training plan, and environment. In addition the research project to be conducted under the fellowship award, describe the fellowship training plan and the environment in which the research training will take place. The entire “Project Summary/Abstract” attachment is limited to 30 lines of text.
8. Narrative - short 2-3 sentences for lay audience explaining “relevance to Public Health”
9. Bibliography and References cited – list all authors – “et al” not allowed; PMCID numbers if available.
10. Facilities/Resources – Identify the facilities available to the program to demonstrate capability of research site to complete the proposal, include all performance sites
   Provide in the Attachment a detailed description of the institutional facilities and resources available to the Fellowship applicant. The information provided is of major importance in establishing the feasibility of the goals of the fellowship training plan.
11. Equipment – list equipment available to the program to demonstrate capability of research site.
12. Other Attachments - If required by PA/RFP solicitation (but are discouraged)
   Need attachment If you answered “Yes” to question 6 (see SF424 for guidance).
   If this is an (F31) Pre-doctoral Fellowships (F31) to Promote Diversity, a Certification Letter is required.
   The Certification Letter (titled Diversity_Eligibility_Ltr) from the institution is certifying eligibility of the Fellowship applicant for the program. The letter should avoid revealing sensitive personal information, such as the candidate’s specific racial/ethnic background or type of disability. The Certification Letter must be on institutional letterhead and scanned so that an institutional official signature is visible.

Performance Site Information(s)
   – List MIT plus any other sites where science will be performed.

R&R Key Persons
   – The Fellow is listed with the PD/PI role and MUST provide eRA Commons User ID in the “Credential” box.
   **In eRA Commons, the fellow must have an ORCID number; [https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-109.html](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-109.html); if this is not in eRA Commons, the application will error. RAS can not confirm if the fellow has included this in their eRA Profile (we do not have access), so it is good practice to remind the DLC this is required.
   – Ensure the * sections are completed (address, including 9 digit zip code, e-mail, phone number).
   – List Mentor (s), OSCs and Consultants. Note: Project role is ‘Other’, then ‘Sponsor” for the faculty mentor, they also MUST have an eRA commons ID.
   – Biosketches required for ALL persons listed in this Senior/Key Person Profile page.
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- Predoctoral applicants (F31) should include all courses in the Scholastic Performance section.

- Postdoctoral applicants (F32) should include all scientific and/or professional courses in the Scholastic Performance section.

*See the website for further guidance as needed*
http://grants.nih.gov/grants/forms/biosketch.htm

*Unless the PA/RFA requires, do not provide “Current & Pending Support” at proposal time*

**PHS 398 Fellowship Supplement**

1. Introduction:
   - Use ONLY for Resubmission
   - Limited to ONE PAGE unless specified otherwise in FOA.

2. Applicant’s Background and Goals Section – **limit 6 pages.**
   a. Doctoral Dissertation and Research Experience
   b. Training Goals and Objectives:
   c. Activities Planned Under this Award:

3. Specific Aims – Limited to one page

4. Research Strategy – **Limited to 6 pages.**
   a. Significance
   b. Innovation (*do not use unless specified in the FOA*)
   c. Approach
   d. **Note:** do not duplicate information collected in the PHS Human Subjects and Clinical Trials Information form.

5. Respective Contributions – **Limited to 1 page**
   *Describe the collaborative process between you and your sponsor/co-sponsor in the development, review, and editing of this research training plan. Discuss the respective roles in accomplishing the proposed research.*

6. Selection of Sponsor and Institution – **Limited to 1 page.**
   a. **Describe the rationale/justification for the selection of the sponsor and institution**

7. Progress Report (leave blank)

8. Training in the Responsible Conduct of Research – **limited to 1 page.**
   - **Must address the 5 required instructional components:**
     1. Format
     2. Subject Matter
     3. Faculty Participation
     4. Duration of Instruction
     5. Frequency of Instruction

9. Sponsor and Co-Sponsor Statements – **limited to 6 pages.**
   A. Research Support Available
   B. Sponsor’s/Co-Sponsor’s Previous Fellows/Trainees
   C. Training Plan, Environment, Research Facilities
   D. Number of Fellows/Trainees to be Supervised During the Fellowship
   E. Applicant’s Qualifications and Potential for a Research Career

10. Letters of Support - **limited to 6 pages**
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OPTIONAL: Attachments may be provided (if applicable) by collaborators, consultants, advisors, etc.

11. Description of Institutional Environment and Commitment to Training – **limit 2 pages.** Document a strong, well-established research program related to the candidate's area of interest. Describe opportunities for intellectual interactions with other individuals in training and other investigators, including courses offered, journal clubs, seminars, and presentations. Indicate the facilities and other resources that will be made available for both career enhancement and the research proposed in this application.

**Additional Educational Information (required for F30 and F31 applications):**
- Describe the institution’s dual-degree (F30) or graduate (F31) program in which the applicant is enrolled, e.g. the structure of the program, required milestones and their usual timing (number of courses, any teaching commitments, qualifying exams, etc.) and the average time to degree over the past 10 years. Describe the progress/status of the applicant in relation to the program’s timeline, and the frequency and method by which the program formally monitors and evaluates a student’s progress.
- This information is typically provided by the director of the graduate program or the department chair. Include the name of the individual providing this information at the end of the description.
- Note that a listing of the applicant’s courses and grades must be included in the Fellowship Applicant Biographical Sketch, and NOT in this attachment.

12. **Description of Candidate’s Contribution to Program Goals – 2 page limit**
- Applicants to diversity-related FOAs (e.g., diversity-related F31): The “Description of Candidate’s Contribution to Program Goals” attachment is required.
- All other Fellowship applicants: Skip the “Description of Candidate’s Contribution to Program Goals” attachment, as it is not required.

The sponsoring institution must provide a document on institutional letterhead that explains how the candidate’s participation will further the goals of the fellowship program to promote diversity in health-related research. Letter must be dates and signed by Institutional Official (i.e., dean or chairperson of department).

**Other Research Training Plan (complete as needed):**
- Vertebrate Animals - required if answered “YES” to the question ‘are vertebrate animals involved?’
  - a. Description of procedures
  - b. Justifications
  - c. Minimization of Pain and Distress
    - must additional identify all project performance sites and explain when and how animals are anticipated to be used if plans have not been finalized.
- Select Agent Research – if Yes, include attachment addressing the following 3 points:
  - a. identify select agents to be used
  - b. Provide the registration status of all entities* where select agent(s) will be used.
  - c. Provide a description of all facilities where the select agent(s) will be used.
- Resource Sharing Plan – complete as applicable
- Authentication of Key Biological and/or Chemical Resources - If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. A maximum of one page is suggested.

**Additional Information Section: (complete as needed)**
- Field of Training: drop down list, not 4-digit codes.
- Citizenship – Provide information requested. **Note:** It is the responsibility of the sponsoring institution to
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determine and retain documentation indicating that the individual candidate’s visa will allow him/her to reside in the proposed research.

In KC – this info will be populated directly from HR data, but if no HR data available, aggregator can input appropriate Visa Type into KC using one of the following codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Form Field(s) Populated</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>U.S. Citizen or Non-Citizen National</td>
</tr>
<tr>
<td>N</td>
<td>Non-U.S. Citizen, With a Permanent U.S. Resident Visa</td>
</tr>
<tr>
<td>A</td>
<td>Non-U.S. Citizen, With a Temporary U.S. Visa <strong>Not valid for F-Series except Fogerty</strong></td>
</tr>
<tr>
<td>B</td>
<td>Non-U.S. Citizen, both “With a Temporary U.S. Visa” and “Has applied for permanent resident status and expect to hold a permanent resident visa by the earliest possible start date of the award”</td>
</tr>
</tbody>
</table>

**Budget**
– Add tuition and fees or check box funds not requested.
– Final stipend and institutional allowance will be determined at the time of award.

**Notes:**
Should an ASSIGNMENT REQUEST FORM be included?

**Helpful Web sites:**
Solicitations/FOA:

**Application Guidance:**

**NOTE:** A common error is that the fellow is not affiliated with MIT in eRA Commons (as noted on page 1 of this checklist). Check the status in eRA Commons to ensure the fellow has PI status at MIT and the mentor is there too with role of sponsor!
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PHS Human Subjects and Clinical Trials Information

If the application answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, at least one human subjects study record using the Study Record: PHS Human Subjects and Clinical Trials Information form or a Delayed Onset Study record must be included in the application.

In KC:
- In the compliance tab – human subjects should be pending.
- If you click on HUMANS SUBJECTS on the compliance tab, the study record should be uploaded here.
- Note, HUMAN SUBJECTS may appear more than once on this tab, if so, each time there should be a different study record attached (an application may have more than one study record/protocol associated with the study). If there is more than one study record, each attached form needs a unique name.
- What is completed on the study record is dependent on the type of study:

Human Subjects Scenarios

A. Human Subjects Research - not a clinical trial
   1. Complete sections 1 – 3.2 on form. (note, section 1.5 will be blank)
   2. Sections 3.3-3.5 are optional; but most likely left blank
   3. Do not complete sections 4 or 5

B. Human Subjects Research – clinical trial
   1. In KC, within the Human Subjects noted on the compliance tab, the box for clinical trial should be checked.
   2. Complete sections 1-4 (note, section 1.5 will be blank)

C. Exempt Human Subject Research:
   1. Complete all of section 1 and section 3.1 which is a justification of the exemption. (note, section 1.5 will be blank)
   2. Note, COUHES should also approve the exemption.

D. Delayed Onset Human Subject study
   1. In KC, within the Human Subjects noted on the compliance tab, the ‘delayed onset’ box should be checked.
   2. Delayed onset justification is attached (not the study record as noted on scenarios A,B and C).

Human Specimens: an application may say NO to human subjects, but does include human specimens. In this case, you will see, on the Attachment Tab of KC, an upload/explanation for human specimen.

Notes:
- Since you can name more than one Study Record attached, one may exempt and one may be clinical trial – make sure the correct FOA is chosen.
- If the PI has answered YES to all of the questions in section 1.4 of the Study Record – this is a clinical trial – make sure the correct FOA is chosen and the all the correct fields are completed.

The RA-Help team developed a few quick card for guidance: https://kc.mit.edu/quick-reference-cards
See: Populating the PHS Human Subjects and Clinical Trial Information (HSCT) form in KC Proposals
User-Attached Mandatory S2S Forms
User-Attached Optional S2S Forms