RAS Checklist: NIH Pathway to Independence Award (Parent K99/R00)

- ☐ Read the solicitation
- ☐ In all cases the SF 424 and instructions in the PA takes precedence over these guidelines.
  - See How to Apply – Application Guide.
- ☐ Eligible Individuals to apply: Candidates must have a clinical or research doctorate **and no more than 4 years** of postdoctoral research training at the time of the application. See PA for further detail.
- ☐ **Special Note:** Because of the differences in individual Institute and Center program requirements for this FOA, applicants are strongly encouraged to consult the Table of IC-Specific Information, Requirements and Staff Contacts, to make sure that their application is responsive to the requirements of one of the participating NIH ICs. See also Frequently Asked Questions.
- ☐ NIH will only accept six new, renewal, resubmission, or revision applications from an individual Principal Investigator/Program Director or Multiple Principal Investigator for all council rounds in a calendar year. This policy applies to all activity codes except T activity codes and R13 Conference Grant Applications. It also does not apply to non-competing continuations, administrative supplements or change in institution applications. Please see NOT-OD-25-132 for details.

KC Specifics

- ☐ Candidate should be named PI on the Investigator Tab.
- ☐ Any Mentor or Co-Mentor(s) should be listed on the Key Person Tab.
- ☐ All mentors, co-mentors or key personnel need to certify in KC. If the Key Person certifying does not have an MIT Kerberos ID, an MIT Guest Account MUST be obtained in order for them to certify. Please allow three days from the time of request to the time of adding the individual to a proposal. This will provide sufficient time for the account to be created and fed to Kuali Coeus.

- ☐ The fellow needs PI status approval.
- ☐ The institute accepts the F&A rate of 8%, UR approval is not needed,
- ☐ It is helpful for the DLCI to attach the cover letter and Data Management Sharing Plan (attached in field 17) to KC since they do not print out as part of the application.
- ☐ DLCI should also attach the PHS Assignment form as an attachment in KC if that is being submitted (optional form in application package).

Suggestions

- ☐ **Delivery Info tab**: Submission Account ID: Suggest the Workspace or Assist number is in this field.
- ☐ **Sponsor & Program Information Tab**: Opportunity ID: Suggest the FOA is added to this field

Note, because proposals are not submitted via KC, it is very helpful to have the DLCI include this information.

[1] PHS Career Development Award Supplemental Form

Introduction

1. Introduction to Application - for Resubmissions only - **1 Page**
   NIH policy allows a thirty-seven month window for resubmissions (A1 applications) following the submission of a New, Renewal, or Revision application (A0 application).

Candidate Section

2. Candidate Information and Goals for Career Development
   Note, this now combines the candidate background, Career Goals, and Career development and training. This attachment + research strategy (attachment 4) cannot exceed a combined 12 pages.

Research Plan Section

3. Specific Aims (1 page limit)
4. Research strategy (*attachments 2 and 4 combined are limited to 12 pages*).
5. Progress Report Publication List (Leave blank)
6. Training in the Responsible Conduct of Research – (**1 page limit**). *Note, plan should incorporate the five instructional components outlined in the NIH Policy on Instruction in the Responsible Conduct of Research: format, subject matter, faculty participation, duration, and frequency*.

Other Candidate Information Section

7. Candidates Plan to Provide Mentoring attachment – not required for a K99 application.

Mentor, Co-Mentor, Consultant, Collaborators Section

8. Plans and Statements of Mentors and Co-Mentors– limited to 6 pages.
9. Letter of Support from Collaborators – include in **ONE PDF attachment of 6 pages or less**

Environment and Institutional Commitment to Candidate Section

10. Institutional Environment– (**1 page limit**)
11. Institutional Commitment to the Candidate's Research Career Development – On Institutional letterhead, **dated and signed** by person who can commit the Institute to the plan described. Letter should agree to allow candidate to devote the required time to research. If the candidate is not a U.S. Citizen or permanent resident, include information about the candidate's visa status, an assurance that the candidate's visa provides sufficient time to complete the K99 phase of the award at a U.S. institution, and assurance that there are no known obstacles (e.g. home country requirement) to the candidate obtaining a visa at the time of the R00 transition. **1 page limit**

Other Research Plan Sections

12. Vertebrate Animals - include if answered YES on R&R Other Project Information.
13. Select Agents – include if required by the science
14. Consortium/Contractual Arrangements:
    If part of project, explain programmatic, fiscal and administrative arrangements to be made between lead and subawardees. For MIT internal procedures, submit required documents (see below)
15. Resource Sharing Plan (optional).
16. DMSP **should not** be included in the application per NOT-OD-26-120.

17. Authentication of key biological and/or chemical resources
    New: Required if project involved key biological and/or chemical resources. Suggested one page max.

Appendix

18. Appendix – note NIH limits in SF424 on numbers and types of publications that can be included

Citizenship

Provide information requested. Note: It is the responsibility of the sponsoring institution to determine and retain documentation indicating that the individual candidate's visa will allow him/her to reside in the proposed research.

[2] PHS 398 Cover Page Supplement

- ☐ *Boxes 1 and 2 completed if answered YES to humans or animals on the Other Project Information Form.*
- ☐ *Boxes 3 and 4 should be answered appropriately.*

[3] Performance Site

- ☐ List MIT and any other sites where science will be performed

[4] RR Budget

- ☐ Detailed (itemized) budget is required for the K99 phase. An itemized budget is not required for the R00 phase, a total requested for each period is acceptable. At the time of transition, a detailed budget is required.
- ☐ Candidate must commit at least 75% (9 person months) effort for the K99 phase to the project, and at least 75% effort in research to the R00 phase.

K99 Phase:

- ☐ Enter salary + fringe and Materials & Supply costs.
- ☐ Ensure effort is included in person months.
- ☐ Salary cap and M&S allowance can vary from NIH institute; check web site to verify allowable budget.
- ☐ Indirect is 8% for this phase.
- ☐ Salary for mentors, and secretarial and administrative assistance, etc., is not allowed.

R00 Phase:

- ☐ Cap for total cost is $249,000/year (direct + indirect costs).
- ☐ Section A: Provide an entry for the PD/PI, including appropriate level of effort but $0 for Requested Salary and $0 for Fringe Benefits. In Section F: "other Direct Costs" add a line item titled 'R00 Independent Phase' and provide the total request for that period (up to $249,000)
- ☐ At the time of transition to R00 phase, a detailed budget w/direct and F&A will be submitted to NIH.

[5] R & R Senior/Key Persons

- ☐ PD/PI (in this case the applicant/Postdoc), Mentor and Co-Mentors **MUST** provide eRA Commons User ID, others do not. Enter the eRA Commons username for the

PD/PI (Fellowship candidate). **The eRA Commons Personal Profile associated with the username entered in the Credential field must include an ORCID ID. This is something the key person adds in their eRA Commons profile – RAS can not confirm if this has been updated.**

- ☐ Ensure the Position/Title & Organization Name are complete, otherwise will error.
- ☐ List Mentor and Co-mentors. OSCs and Consultants are listed after other Senior/Key persons if they meet the definition of key personnel.
- ☐ Biosketches required for ALL persons listed in this Senior/Key Persons module. Should use SciENcv to generate the biosketch.

Note: For primary mentor and all co-mentors provide a separate attachment with "Current and Pending" information following the SciENcv format, which will produce a digitally certified PDF(s) for use in application submission. Do not flatten this PDF attachment.

"Current & Pending Support" for the Candidate will be requested at Just-in-Time.

NIH Forms Directory

[6] R & R: Other Project Information

Yes or No questions items 1-6 on form, answer accordingly:

1. Human Subjects Assurance No. 00004881
2. Animal Assurance No. D16-00078
3. Proprietary information – see SF424 Guide for instructions
4. Environmental Impact
5. Designated site
6. International Collaboration – ensure on compliance tab + VPR has approved the proposal.

Attachments (must have an attachment in each field):

7. Project Summary "Abstract" – 1 page max, description of research proposed for the mentored (K99) and independent (R00) phase. *In addition to summarizing the research project to be conducted under the career development award, describe the candidate's career development plan and career goals and the environment in which the career development 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.
10. Facilities/Resources – Provide in the Attachment a detailed description of the institutional facilities and resources available to the candidate. The information provided is of major importance in establishing the feasibility of the goals of the career development plan
11. Equipment – list equipment available to the program to demonstrate capability of research site.
12. Other Attachments - usually blank .

RR SF 424 V2-0 (Face page)

Important elements to the SF424

Box 1. Type of application – make sure either 'application' or 'change/corrected' is checked.
Box 4c. Used for 'change/corrected' ONLY, the GRANTxxxxxx should be entered.
Box 8. Ensure correct application type is reflected.

Box 11. Title: ensure no special characters, only letters, digits & underscore. Limit the title characters to 200, including spaces between words and punctuation.

Cover Letter File

THIS IS REQUIRED for K99/R00 proposal – should be addressed to the Division of Receipt and Referral.

Include**:**

a. Application Title
b. NIH's Funding Opportunity
c. **REQUIRED**: The list of referees (including name, departmental affiliation, and institution)
d. If submitting a change/corrected after the due date, explain the reasoning.

Optional Form – PHS Assignment Request Form

This form is optional and may be omitted from your application submission if you do not wish to make any specific assignment or review requests. There is no requirement that all fields in the form are completed; you have the flexibility to enter a single request or provide extensive information using this form.

Common Errors

If PI/PD needs their eRA commons ID linked into the MIT system, they need to email NIH-Help@mit.edu

File Name: Save all files with descriptive file names of **50 characters or less**. Do not use the ampersand (&) character in the file name. Use one space (not two or more) between words or characters. Just like letters, a space counts as one character.

NIH **REQUIRES** all text attachments to be submitted as **PDF (Portable Document Format)** files

Information on Human Subject Attachment

Information on Human Subjects

As of January 25, 2018 NIH updated their forms, and definition of clinical trial. Studies with human subjects may be categorized as clinical trials; and MIT may apply, where in the past they were not. PIs should contact COUHES for guidance if they are unsure if their project should be classified as a clinical trial.

PHS Human Subjects and Clinical Trials Information

Introduced new form for consolidated human subjects, inclusion enrollment report, and clinical trial information.

Includes attachment to comply with NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research. See the NIH Guide Notice on Notice of Extension of Effective Date for more information.

Added exemption numbers 7 and 8 to question 1.3; however, these exemptions will not be used at this time.