## **Application Instructions for R00 Transition Applications**

## **Submission Instructions**

- Due Date: The application for the extramural independent scientist R00 phase of the award should be submitted **no later than 2 months prior to the proposed activation date of the R00 award** by the R00 phase recipient organization. To avoid potential problems in activation of the R00, K99 awardees are strongly encouraged to contact their program official as soon as plans to assume an independent position develop, and no later than 6 months prior to the termination of the K99 phase of the award to discuss plans for transition to, and the application for, the R00 phase.
- File format: Use <a href="PHS398 Form Pages">PHS398 Form Pages</a> and combine into a single .pdf file. See below for required application components.
- Submission method: an authorized signing official for the R00 organization must submit the
  application via email to the Grants Management Specialist and Program Official listed on your
  K99 Notice of Award.

## **Required R00 Application Components**

- 1. Face page (PHS 398, Form Page 1) signed by the R00 phase Authorized Organization Representative.
- 2. Updated Project Summary page (PHS 398, Form Page 2). A new project description page or abstract updated to reflect current plans for the R00 phase.
- 3. Budget pages: detailed budget page (PHS 398, Form Page 4) required for the first year of the R00 award, and categorical budget (PHS 398, Form Page 5) for the entire project period. The budget may include salary to support your research effort on the R00 award. However, the portion of your base salary provided by the hiring institution must be consistent with that provided routinely to newly appointed, independent faculty members.
  - Allowable Costs: The total cost for the independent phase (R00) may not exceed \$249,000 per year. This amount includes salary, fringe benefits, research costs, and applicable facilities & administrative (F&A or indirect) costs. F&A costs will be reimbursed at the R00 institution's current F&A rate. F&A costs requested by consortium participants are included in the total cost limitation.
- 4. Budget Justification (<u>use Continuation Page</u>): include your level of effort on the R00 project and any portion of the required 75% research effort to be supported by institutional funds. Also include an explanation for supplies, equipment purchased, and other research-related expenses.
- 5. Biographical sketches (<u>see Biosketch Format Page and instructions</u>): Include updated biosketch of Candidate, and biosketches for any Key Personnel. Publication citations must show the PMCID numbers when applicable.
- 6. New Resources Page(s) (<u>PHS 398, Resources Format Page</u>): Also include a detailed explanation of existing equipment purchased during the K99 phase that will transition to the R00 institution.

Describe any special facilities used for working with biohazards or other potentially dangerous substances. Note: Information about Select Agents must be described in the Research Plan.

- 7. New Checklist (PHS 398, Checklist Format Page).
- 8. K99 Final Progress report (PHS 398 Continuation Format Page): Describe the research accomplishments and training and career development during the K99 award. All training and career development goals should be completed. Please describe how the training and career development goals/objectives were met during the K99 award including proposed coursework and training in responsible conduct of research, or if all the goals/objectives were not accomplished, how you plan to meet them during the R00 award.
- 9. Final evaluation statement by the K99 phase mentor.
- 10. Updated research plan (PHS 398 <u>Continuation Format Page</u>, 5 pages or less). Identify any changes from the original research project described in your K99/R00 application, i.e., update specific aims.
- 11. Human Subjects: If the research will use human subjects, provide:
- A complete updated <u>Human Subjects section</u>, including an "Inclusion Enrollment Report".
- Current IRB approval or expected approval date. Award is not made until final IRB approval is granted.
- Data and Safety Monitoring Plan (DSMP, see <u>Human Subjects section</u> 4.1.5) for clinical studies in human subjects that involve more than minimal risk. The DSMP needs to be approved by the IRB.
- 12. Vertebrate Animals: If the research will use vertebrate animals, provide:
- A complete updated Vertebrate Animals section (Worksheet for the VAS).
- Current IACUC approval or expected approval date. Award is not made until final IACUC approval is granted.
- 13. If applicable please include a <u>Sharing Model Organisms</u> Plan and a <u>Genomic Data Sharing Plan</u> (GDS).
- 14. Current Other Support page for the R00 candidate.
- 15. The R00 organization must provide a document on institutional letterhead that describes its commitment to the candidate and the PI's career development and research, independent of the receipt of the R00 award. It is essential to document the institution's commitment to the retention, development, and advancement of the candidate during the period of the award. The institutional commitment letter must include the following:
- The letter must state that the candidate has been offered and accepted a tenure-track, full-time assistant professor position (or equivalent) with 75% protected research time that is not contingent on receiving the R00 award. The letter of commitment should briefly describe the

nature of the appointment (duration, time until tenure review), and list features of start-up package, space, and other support provided to ensure the candidate can conduct the proposed R00 research and will be fostered to apply for and secure independent research grant (R01) support during the R00 phase. This must be comparable to what is offered to any other faculty hire without the potential of R00 funding. Note that R00 funds may not be used to offset the typical startup package or to offset the usual institutional commitment to provide salary for tenure-track (or equivalent) assistant professors who are hired without grant support. This agreement should satisfy the criteria described in the Career Development Award Section of the SF424(R&R) Application Guide.

- The letter should document the institution's agreement to provide adequate time, support, equipment, facilities, and resources to the candidate for research and career development activities, and must include:
- Agreement to release the candidate from other duties and activities so that the candidate can
  devote the required percentage of time for development of a research career, as specified by the
  K99-R00 funding opportunity.
- Describe actions that will be taken to ensure that the candidate can devote the required time to
  research career development (e.g., reduction of the candidate's teaching load, committee and
  administrative assignments, and clinical or other professional activities for the current academic
  year). If the candidate's clinical or teaching responsibilities will be reduced, describe how this will
  be accommodated (e.g., hiring additional staff, reassigning staff, etc.)
- Describe the candidate 's academic appointment, bearing in mind that the appointment must be
  full-time, and that the appointment (including all rights and privileges pertaining to full faculty
  status if in an academic setting) and the continuation of salary should not be contingent upon
  the receipt of this award.
- Describe what the candidate 's institutional responsibilities will be if an award is made.
- Describe how the institution will provide the candidate with appropriate office and laboratory space, equipment, and other resources (including access to clinical and/or other research populations) to carry out the proposed Research Plan.
- Describe how the institution will be supportive of any proposed mentor(s), other staff, and/or collaborations with other faculty consistent with the R00 research plan.
- The institutional commitment letter must be dated and signed by the person who is authorized to commit the institution to the agreements and assurances listed above. In most cases, this will be the dean or the chairman of the department.

## Requirements for the K99 Recipient Organization

- Final FFR: the K99 organization must submit a Final FFR for the K99 phase no later than 120 days after the end date of the K99 phase.
- If the K99 is terminating early (K99 period is less than 2 full years), NLM typically uses the unobligated balance from the K99 to offset the next year of the R00. Refer to your Notice of Award for information about the disposition of unobligated balances.