

# **NCI Instructions for Activating the Independent Phase (R00) of the Pathway to Independence Award**

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## **General Information:**

Transition from the mentored phase (K99) to the independent phase (R00) is not automatic. In order to activate the R00 phase, K99 PD(s)/PI(s) must have been offered and accepted a tenure-track, full-time assistant professor position (or equivalent) at an eligible domestic institution with the appropriate infrastructure to support the proposed research program and a history of external research funding. The job offer cannot be contingent on the transfer of the R00 award and should include strong institutional commitment from R00 institution (see “Instruction for R00 application” section).

R00 funds may not be used to offset the typical startup package or to offset the expected institutional commitment to provide salary for tenure-track (or equivalent) assistant professors who are hired without grant support, and NCI requires assurance about this in writing from the R00 institution (please see “Instructions for the R00 application” for details).

If a K99 awardee transitions to independence at NIH Intramural Research Program (IRP), the R00 phase will not be activated. In this case the K99 institution must submit a relinquishing statement to the NCI Office of Grants Administration (OGA).

It is expected that K99 awardees will complete at least 12 months of K99 support before transitioning to the R00 phase of the award.

Transition from the K99 to the R00 phase of the Pathway to Independence Award is intended to be continuous in time, i.e., there should not be a significant gap between the K99 phase and R00 phase.

If additional time is required to complete the K99 research project and to secure an acceptable independent position, K99 grantee should discuss the best approach with the assigned NCI program official, which may include a no-cost extension.

## R00 application submission process and requirements

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 NCI program officials 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.

R00 PD(s)/PI(s) are required to devote a minimum of 9 person-months/year (75% full-time professional effort) to research for the duration of the R00 award. The required 9 person-months of research effort need not be devoted exclusively to the R00-supported research. However, the proposed R00 effort should be appropriate to complete the R00 project as proposed.

Unobligated funds may not be carried over from the K99 to the R00.

R00 awards will not be issued in October and November. R00 applications received after July 1st of each year will typically be awarded in the following fiscal year (i.e., December or later).

### Instructions for the R00 application (use [PHS 398 forms](#) to assemble the application):

1. **Face page signed by the R00 phase institution Authorized Organization Representative.**
2. **Form Page 2: Summary, Relevance, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells.**
3. **Form Page 3: Research Grant Table of Contents**
4. **Form Page 4: Detailed Budget for Initial Budget Period:**
  - **Important:** Effort is the amount of **time** devoted to the project. The percent effort and percent salary requested do not need to match. Some PD(s)/PI(s) devote 75% effort to the R00 and request no salary support.
  - **Budget Justification:** Include the PD/PI level of effort on the R00 project and the 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.
  - **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 indirect costs. Indirect costs will be reimbursed at the extramural sponsoring institution's indirect cost rate. Indirect costs requested by consortium participants are included in the total cost limitation.

5. **Form Page 5: Budget for Entire Proposed Project Period**
6. **Biographical sketches (Biosketch Format Pages):** Include updated Biosketches of the R00 PD/PI, and Key Personnel (Consultants, Collaborators). Publication citations must show the [PMCID numbers](#) when applicable.
7. **New Resources Page(s):** Describe facilities and resources at the R00 institution. 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.
8. **Checklist Form Page**
9. **Final Progress Report for the K99 phase:** Describe a) the research accomplishments and b) training and professional development activities during the K99 phase. There is no template for the Final Progress Report for the K99 phase – do not include your RPPR.
10. **Final evaluation statement by the K99 phase mentor.** The primary mentor should assess the K99 PD/PI's progress and performance during the K99 phase, both in research and in terms of development into an independent investigator.
11. **Scientific separation plan:** a letter signed by both the K99-phase mentor and K99 PD/PI that describes a plan by which the K99 awardee will separate from their mentor and advance to independence. In addition, the mentor(s) should address whether the K99 PD/PI will have access to the required resources (reagents, model systems, etc. from the mentor's lab) to continue the project after transitioning to independence.
12. **Timeline to submit R01:** Include a plan and timeline for submitting an independent research grant application in a research area relevant to the mission of an NIH awarding component.
13. **Updated Specific Aims (1 page) and Research Plan (5 pages):** Describe the research project proposed for the R00 phase and identify any changes from the original research described in the K99/R00 application (do not include research that has already been completed in the K99 phase).
  - Remember to address Rigor and Transparency in the updated research plan <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-004.html>. Include a plan for the Authentication of Key Biological and/or Chemical Resources (as separate attachment).
14. **Human Subjects** (If the proposed project involves human subjects research):
  - A complete updated Human Subjects section.

- Date of the institutional review board (IRB) approval of the proposed research (if available). IRB approval is required at the time of award. **It is not required to include the IRB approval in the R00 application.**

15. **Data and Safety Monitoring Plan (DSMP)** required for clinical studies in human subjects.
16. **Vertebrate Animals** (If the proposed project involves research with live vertebrate animals):
  - An updated [Vertebrate Animals section](#).
  - Date of institutional animal care and use committee (IACUC) approval of the proposed research (if available). IACUC approval is required at the time of award. **There is no need to include the IACUC approval in the R00 application.**
17. **Updated Biohazards** (as appropriate)
18. **Updated Bibliography & References Cited section**
19. **Level of effort plan** (only required if the PD/PI will devote less than 75% effort to the R00): Documentation that the PD/PI will have a minimum of 9 person-months/year (75% full-time professional effort) devoted to research for the duration of the R00 award. Briefly describe the PD/PI's active projects (R00 project and other research projects) and address the proposed effort and funding source (NIH or non-NIH grants, start-up funding) for each research project. Provide a description of the PD/PI's level of effort spent on teaching, clinical and/or administrative duties. Teaching, clinical and/or administrative duties should be minimal during the R00 phase.
20. **A letter from the R00 Department or Division Chairperson** that describes the R00 institution's commitment to the R00 PD/PI and plans for their career development and includes the following information:
  - Describe the R00 PD/PI's academic appointment. For non-tenure-track assistant professor appointment: the R00 institution should provide a justification that the proposed appointment is the equivalent of a tenure-track assistant professor position.
  - The sponsoring institution must provide protected research time (minimum of 9 person-months: 75% of the R00 PD/PI's full time professional effort) at least for the duration of the R00 award
  - Provide assurance that the appointment is not contingent on the transfer of the R00 award to the institution.
  - The start-up package and other institutional support must be described in detail and must be comparable to that of other recently hired tenure-track assistant professors (or equivalent) in the same department that have not received R00 support.

- Assurance that R00 funds will 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.
- Detailed description of office and lab space, facilities, resources, and other support needed to conduct the proposed research.
- The R00 phase institution must describe how the R00 PD/PI's ability to apply for and secure independent research grant (NIH R01 or equivalent) support will be fostered and supported during the R00 phase of the award (e.g., senior advisory committee).
- For applications submitted on behalf of non-U.S. citizens with temporary U.S. visas: the R00 phase institution is responsible for determining and documenting in the R00 application that the PD/PI's visa will allow the PD/PI to remain in the U.S. for the duration of the R00 award.

21. **DMS plan Instructions:** <https://grants.nih.gov/grants/how-to-apply-application-guide/formsh/general/g.410-phs-398-career-development-award-supplemental-form.htm#17>

Template: <https://grants.nih.gov/sites/default/files/DMS-Plan-blank-format-page.docx>

22. **A copy of the official job offer letter** (with signed acceptance by the K99 PD/PI) for a tenure-track Assistant Professor position (or equivalent). Important: the offer cannot be contingent on the R00 and should include a strong start-up package. K99 awardees are encouraged to discuss what constitutes a strong start-up package with their mentor(s), collaborators and newly hired assistant professor colleagues.

**The R00 application (in PDF format) should be sent through the authorized organization representative of the R00 organization to the NCI Office of Grants Administration [NCIOGAPrivateReports@nih.gov](mailto:NCIOGAPrivateReports@nih.gov) and the [NCI program official](#) who is named on the Notice of Award** should be copied on the email **no later than 2 months prior to the proposed activation date**. The R00 application will be evaluated by NCI program staff for completeness and responsiveness to the program. R00 applicants who are not approved to transition will receive a written notification from NCI communicating the rationale for the disapproval. This notification typically will be sent within 60 days of receipt of the R00 application.

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**No-cost extension guidance for NCI K99/R00 awards (for details please refer to [NOT-OD-16-092](#)):**

NCI K99/R00 PD(s)/PI(s) may request a no-cost extension (NCE) through the [eRA prior approval module](#) if additional time is needed to complete the goals of the K99 phase. NCE requests will be

reviewed by NCI Grants Management and Program and decided on a case-by-case basis. All terms and conditions of the K99/R00 award (including minimum effort requirements) remain in effect when the grant is in NCE.

To request an NCE, submit the following documents no earlier than 90 days before the end of the project period and no later than the project's end date through [eRA prior approval module](#):

1. A memo requesting the NCE of the final budget period of the K99. The request should include a description of the project activities that require support during the extension (describe plans for the timely transition to an independent position) and a statement about the funds available to support the extension. This memo should be signed by the K99 PD/PI and mentor.
2. A progress report for year 02 of the K99 phase – address research accomplishments and career development activities.
3. Mentor's Report: provide a letter signed by the mentor, in PDF format, assessing the K99 PD/PI's progress and performance during the K99 phase, both in research and in terms of development into an independent investigator in the research area of the award. Include assurance on the continued commitment of the required minimum professional effort by the awardee (75% effort, 9 calendar months) to the career development award and the availability of support for the R00 PD/PI's research project during the NCE.
4. Make sure that IRB approval (for Human Subject research) and IACUC approval (for Vertebrate Animals research) are valid and up to date (as applicable).

Important: If an application for the R00 Phase with a suitable position is not submitted within the one-year period of the no-cost extension, the R00 will not be awarded. Those not continuing to seek to transition to the R00 will be permitted to extend the K99 without additional funds, allowing for an orderly phase-out of the project ([NOT-OD-16-092](#)).