

NIDDK R00 Transition Application Process and Format

As indicated in the K99/R00 program announcement, transition from the mentored phase (K99) to the independent scientist phase (R00) is NOT automatic. **You are strongly encouraged to consult with your NIDDK Program Director well in advance of preparing an R00 transition application.** Transition to the independent phase is subject to NIDDK's review of the research training/career development accomplishments during the K99 award, documentation of a bona fide tenure track position and suitable institutional commitment of resources, and the evaluation of the research plan that will be carried out at the sponsoring institution to which the K99 grantee has been recruited. Transition from the mentored phase to the independent phase is intended to be continuous in time. In order to transition to the R00 phase, the K99 grantee needs to (1) find a suitable position as a tenure-track, full-time assistant professor (or equivalent) at an academic institution, and once that is accomplished, (2) provide NIDDK with the required documentation to initiate the R00 phase of the award. When preparing the R00 application, K99 awardees should use the following instructions, and contact NIDDK staff if there are any questions:

The following documents (items a, b, c) must be submitted to NIDDK so that we may review the request to initiate the R00 phase of an award:

a) A copy of the official offer letter for a faculty position from the Chairperson or Dean of the institution where the K99 grantee has been recruited, addressing the following issues:

Status as a bona fide tenure-track (or equivalent), full-time Assistant Professor. The appointment must NOT be contingent on the transfer (or continuation) of the R00 award to the sponsoring institution.

Percent of effort: Documentation that there will be a minimum of 75% (9 calendar months) effort devoted to the R00 research project during the entire period of the award, and a description of the percent of effort spent on teaching, clinical and/or administrative duties.

Institutional Commitment: The institution's plans for providing start-up funding, technical personnel, research resources and facilities, and paying the PI's salary. The start-up package must be similar to that which is typically offered to new faculty members at that institution.

Laboratory and Office Space: Describe the laboratory and office space that will be provided to conduct the proposed research.

Clinical Space: For patient-oriented research projects, describe the clinical space that will be accessible for conducting the proposed research. Include details of other research support services (e.g. core facilities, research coordinators, statistical support, nurse coordinators, etc.). For clinical projects performed within an institutional General Clinical Research Center (GCRC) or Clinical and Translational Science Award (CTSA), submit a letter from the GCRC or CTSA Director indicating support of the R00 research project.

b) A new NIH Grant application from the proposed R00 grantee institution:

Face page with the appropriate institutional signatures.

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.

Budget Justification (including the percent of effort on the R00 project).

Environment and resources.

Updated Biographical Sketch.

Progress report and mentor's letter, describing the research accomplishments and career development during the K99 phase of the award.

Updated research plan. Identify any changes from the original research project described in the K99/R00 application. If the research project will change substantially, please discuss this with NIDDK staff immediately. **Please be aware that R00 research projects that change substantially and no longer fit**

within the mission of the NIDDK are at risk of either being delayed or not being approved to transition to the R00 phase.

New Vertebrate Animal and/or Human Subjects sections.

Plans and time-line for submitting an independent research grant application (e.g. R01) in a research area relevant to the mission of the NIDDK.

PHS398 Checklist Form Page

c) The following items, with a Cover Letter countersigned by the appropriate institutional business official:

Other Support: Show salary and fringe benefits (or none) from all other Federal or non-Federal grants. (may use PHS 398 Other Support Format Page)

Salary and Fringe Benefits from the Institution for the R00 award: From the business office, please state the current institutional base salary and the institution's fringe benefit rate. (Salary support from your R00 award may be requested.)

Should a K99 grantee wish to activate the R00 phase of the award at the same department or institution as the mentored research (K99) phase, a **1) justification addressing the decision to remain at the same institution and 2) plans for transition to independence away from the K99 mentor's group must be provided.**

Protocol certification for Human Subjects & Animals: If the research project involves human subjects and/or animals, send an updated certification for protocols at the institution.

Copy of a sharing plan for any new model organisms that you propose to generate: All NIH applications and proposals that will produce new, genetically modified variants of model organisms and related resources are expected to include a sharing plan or to state why such sharing is restricted or not possible. Examples of Plans for Sharing of Model Organisms and Related Resources are available at:

http://grants.nih.gov/grants/policy/model_organism/index.htm

Data and Safety Monitoring Plan for any clinical studies involving human research subjects.

The following information is needed from the K99 grantee institution for those R00 grants transferring to a new institution: Official Statement Relinquishing Interests and Rights to a PHS Grant (Form PHS 3734); Final Invention Statement and Certification (Form HHS 568) and a final Financial Status Report (within 90 days of terminating the K99 grant). Forms are available at:

<http://grants.nih.gov/grants/forms.htm>