The Early K99: A Funding Mechanism Designed for the Career Paths of Data and Cancer Control Scientists (RFA-CA-20-014 and RFA-CA-20-015)

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K08: Non-tenured clinician-scientists seeking mentored research experience
K22: Late-stage postdocs (2-8 yrs experience), awarded when independent
K99/R00: Postdocs (up to 4 yrs experience) open to US visa holders
more than 80% of K99/R00 applicants in 3-4 years of postdoc
Early K99/R00 – Rationale for a New Transition Award for Early-Stage Postdocs

- A significant number of outstanding early-stage postdocs, mostly from data, population and behavioral sciences, get tenure-track positions after 1-2 years of postdoctoral training.
- Usually they are not competitive for available K awards, which typically target those with 4-8 years of research experience (i.e., parent K99/R00, K08, K22) and a substantial publication record.
- They are, therefore, disadvantaged compared with peers who had K transition awards:
  - No protected time from teaching
  - No assurance of a competitive startup package
  - Takes longer on average to get first R01 (~6 yrs) than parent K99/R00 awardees (~3 yrs)
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Early K99/R00: 0-2 yrs experience, open to US visa holders
Early K99/R00 – a Pilot Program in its 2nd Year

Statistics for the first year of the early K99/R00 program

- In 2019 NCI received 53 early K99/R00 applications
  - 45% - Data Science
  - 32% - Cancer Control Science
  - 23% - Other Sciences

- Submitted by 37 organizations
  - 3 organizations – 3 apps/org
  - 10 organizations – 2 apps/org
  - 24 organizations – 1 app/org

- NCI expects to make up to 16 awards in FY 2020
Early K99/R00 RFAs have been re-issued

**Objective:** facilitate a timely transition of outstanding postdocs to independence

RFA-CA-20-014 (Independent Clinical trial Not Allowed)
RFA-CA-20-015 (Independent Clinical Trial Required)

**The Early K99/R00 Timeline**

- **November**
  - RFA published by NIH

- **December/January**
  - Institution selects its nominees

- **January**
  - Institution submits Letters of Intent

- **February**
  - Nominee submits application

- **May/June**
  - Review of applications

- **December/January**
  - Award Start Date
Early K99/R00 – Eligibility

- Postdocs with less than 2 years of postdoctoral research experience (as of February 26, 2020) who do not require an extended period of mentored postdoctoral training to achieve independence, especially those in data science or cancer control. Proposed research must be cancer focused.

- Clock begins when all requirements for the degree were met, not when degree was officially awarded.

- Postgraduate clinical training not counted against the 2-year cap.

- Candidate must be nominated by an institution. An Institution may nominate up to 3 candidates, one each in data science, cancer control science, and other sciences.

- U.S. citizenship or permanent residency not required - Individuals on visas are eligible to apply

- No resubmissions allowed but may apply again next year if still eligible and re-nominated
Institutions limited to Three Applications per Due Date

**EACH application MUST be in a different scientific area, as defined here:**

(A) **Data Science:** an interdisciplinary field of inquiry in which quantitative and analytical approaches, processes, and systems are both developed and used to extract knowledge and insights from increasingly large and/or complex sets of data. This includes cancer-focused data integration and visualization, systems biology, artificial intelligence, machine learning, informatics, genomics, precision oncology, and developing analytics for epidemiological or biostatistical studies.

(B) **Cancer Control Science:** basic and applied research in the behavioral, social, and population sciences to create or enhance interventions that, independently or in combination with biomedical approaches, reduce cancer risk, incidence, morbidity, and mortality, and improve quality of life. This includes research in epidemiology, behavioral sciences, health services, surveillance, cancer survivorship, and healthcare policy.

(C) **Other Sciences:** all scientific fields supported by the NCI that are not included in (A) or (B). Applicants proposing research in (C) "Other Sciences" may apply if it is reasonable to expect them to transition to independence with an abbreviated period of mentored research training beyond their original doctoral degrees.
The Early K99-specific Types of Letters Needed

**BEFORE APPLYING:** LETTER OF INTENT requested by January 26, 2020
- Email to sradaev@mail.nih.gov from institutional grants official

**IN THE APPLICATION:** INSTITUTIONAL NOMINATION LETTER – 2 page limit
- Required part of the Early K99 application
Special Instructions - Letter of Intent

By January 26, 2020, Grants Official sends an email memo indicating the institution’s intent to submit an application(s) to RFA-CA-20-014 and/or RFA-CA-20-015 to:

Sergey Radaev, Ph.D.
NCI, CTB
email: sradaev@mail.nih.gov

The memo should include:

• RFA number and title
• Title of the application
• Name, address, and telephone number of the nominee
• Name of other key personnel
• Participating institution(s)
• Scientific area: (A) Data Science; (B) Cancer Control Science, or (C) Other Sciences
Special Instructions - Nomination Letter

- Institutional nomination letter is required
- Must be written and signed by the head of the candidate’s department or program
- Submitted under “Other Attachments”. No Other Attachments are allowed
- The letter is limited to 2 pages
- The letter must include the following information:
  - **Must identify one of the three scientific areas:** (A) Data Science, (B) Cancer Control Science or (C) Other Sciences
  - Must affirm that the candidate is the institution’s **sole nominee in the specified scientific area for the specified application due date**
  - Should describe the institutional commitment to supporting the candidate's search for a tenure-track or equivalent position
  - Should describe the main factors that identify the nominee as likely to obtain a tenure-track or equivalent research position at an early career stage
Early K99/R00 – Key Features (identical to the parent K99/R00)

- Two-stage award: **K99 phase** – up to 2 years of mentored training (1 year minimum);
  **R00 phase** – up to 3 years of support as an independent scientist

- K99 to R00 transition is not automatic - tenure-track position (or equivalent) must be offered and accepted

- The award provides:
  - **K99 phase**: Salary up to $100,000/year + fringe benefits; R&D funds up to $30K/year
  - **R00 phase**: up to $249,000/year in total costs
Early K99/R00 – Distinct Features

- Publications from postdoctoral training are **not** required
- Preliminary data are **not** required. Reviewers evaluate creativity and potential of research to launch and sustain a career rather than extensive preliminary data
- Applications reviewed by an “early K99” Special Emphasis Panel – they don’t compete with “regular K99” (parent K99) applications
- One receipt per year, no resubmissions allowed
- This is *a pilot program* – up to 16 awards/year.
- This pilot program is expected to continue for the next 3 years
Application Sections and Tips for Writing the Early K99 Application
# Major Components of K99/R00 Application

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<td>Candidate Information and Goals for Career Development and Research Strategy</td>
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<td>Training in the Responsible Conduct of Research</td>
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<td>Plans and Statements of Mentors and Co-Mentor(s)</td>
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<td>Description of Institutional Environment</td>
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Example of K99/R00 outline, sections highlighted yellow - 12 pages combined

- Candidate’s Background (1/2 – 1 pages)
- Career Goals and Objectives (1/2 – 1 pages)
- Candidate’s Plan for Career Development/Training Activities (2 pages)
- Specific Aims (1 page)
- Research Strategy (8-9 pages)
- Training in the Responsible Conduct of Research (1 page)
- Plans and Statements of Mentor and Co-mentor(s) (6 pages)
- Letters of Support from Collaborators, Contributors, and Consultants (6 pages)
- Description of Institutional Environment (1 page)
- Institutional Commitment to Candidate’s Research Career Development (1 page)
- Biographical sketch (5 pages)
Review criteria: **Candidate**
*(what reviewers are looking for)*

- Potential to become an independent investigator
- Research productivity, awards
- Strong letters of support
- Prior training

Application section(s)
*(where reviewers are looking for it)*

- Biosketch
- Candidate’s Background
- Letters of Support
- Letters of Reference
Review criteria: CDP

(what reviewers are looking for)

- Justified?
- Relevant to the proposed research/career path?
- Timeline with milestones of activities, transition to independence
- Advisory committee

Application section(s)

(where reviewers are looking for it)

- Career Goals and Objectives
- Candidate’s Plan for Career Development/Training Activities
- Plans and Statements of Mentor and Co-mentor(s)
**Review criteria: Research Plan**

(what reviewers are looking for)

- Strong rationale
- Innovative, hypothesis-driven mechanistic research
- Pitfalls and alternative solutions
- Clear outline K99 vs. R00
- Could it form a strong basis for an independent career?

**Application section(s)**

(where reviewers are looking for it)

- Specific Aims
- Research Strategy
Review criteria: Mentor(s)

(what reviewers are looking for)
- Expertise
- Mentoring track record
- Funding
- Clear statement that the project is portable with the candidate
- Clear outline of their involvement in the project and career development

Application section(s)

(where reviewers are looking for it)
- Plans and Statements of Mentor and Co-mentor(s)
- Letters of Support from Collaborator(s), Consultant(s), etc.
Review criteria: Environment

(what reviewers are looking for)

- Min. 75% effort assurance
- Clearly stated support for the candidate and mentor(s)
- Availability of resources and training

Application section(s)

(where reviewers are looking for it)

- Description of Institutional Environment
- Institutional Commitment to Candidate’s Research Career Development
- Facilities and Other Resources
Tips for the Mentor and Candidate Sections

- **The primary mentor:** strong track record of funding and mentoring similar young investigators

- **The mentoring team:** encompass all the areas of expertise needed for you to achieve your research and career development goals

- **Plans for career development:**
  - Your plans and mentor’s plans should be in sync and personalized
  - **Mentor should clearly state that the project is yours when you move to independence**
  - Coursework, seminars, workshops, conferences, meeting with mentors
  - Describe roles of mentors, collaborators in training and research
  - State whose ideas are in the application
  - Describe future plans for publications and grant applications
  - Show relationship between the specific aims and other activities
Tips for Writing the Early K99 Research Strategy

- Develop a research plan feasible for one person to carry out in 5 years.
- Aims should span both K99 and R00 phases. Identify which aims will be done in the K99 phase vs. R00 phase.
- Preliminary data not required – may be based on literature to show feasibility.
- Address Significance, Innovation, and Approach, including Rigor & Reproducibility.
- Reviewers typically like hypothesis-driven innovative research.
- Good foundation to establish independence – can lead to R01.
General Tips

- Read the Funding Opportunity Announcement
- Follow the instructions in the Application Guide
  - Include everything that is requested and nothing that is not
- Apply before the due date and take advantage of the 2-day application viewing window
- If you have any questions before submitting your K99/R00 application contact:

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  NCI/CCT/CTB
  sradaev@mail.nih.gov