NCI Predoc to Postdoc Transition Award (F99/K00)  
RFA-CA-19-002

*meeting begins at 1 pm*

*please mute your microphone*

Michele McGuirl, Ph.D.
mcguirlma@mail.nih.gov
Center for Cancer Training

January 24, 2019
Use the NCI F99 Website and carefully read RFA-CA-19-002

[Link to cancer.gov/cct]

Resources

- Program Announcement
- Transition Info/Forms
- Informational Webinar held 11/05/2018 (slides with transcript)
- Nominee Webinar held 1/24/2019 (slides with transcript)
- Answers to frequently asked questions
Purpose of the NCI F99/K00

An independent research career is being viewed as a less viable career choice

- F99/K00 Goal: Identify and encourage outstanding graduate students to pursue cancer research careers as independent investigators

- Dual-phase Funding:
  - 1-2 years of support for completing PhD dissertation (F99)
  - Up to 4 years of support for postdoctoral training (K00)

  The two phases are intended to be continuous in time

- Transition when the dissertation research is complete
- Funding for the F99 phase will not be extended beyond 2 years
Timeline for the F99/K00

- **November**: RFA published by NIH
- **December/January**: Institution selects its nominee
- **January**: Institution submits Letter of Intent
- **February**: Nominee submits Application
- **May**: Review of Applications
- **September**: Award Start Date
  - F99 Fellow completes dissertation & seeks/accepts a cancer-focused postdoc position
  - Postdoc Institution submits the K00 transition application to NCI
  - K00 Scholar conducts the research and career development activities
Eligibility

Applicant must be nominated by a PhD-granting institution

- Students earning PhD or other doctoral research degree
  - 3rd or 4th year PhD students finishing up dissertation research
- One nominee per domestic, PhD-granting institution per year
  - identified by a single DUNS number or by multiple DUNS numbers for schools/colleges/divisions within the institution
- US citizens and international students
- Unsuccessful applicants may submit if eligible and re-nominated
- Current F31 awardees and applicants* are eligible

* Check with Program Director
Frequently Asked Questions about Eligibility

- I am in my 5th year but...
- I am in my 2nd year but...
- I have an F31 under review – is that OK?
- I want to submit an F31 after the F99/K00 - is that OK?
- My dissertation research is in (______) but I want to pursue cancer research for my postdoc...
Funding

1-2 years of support for completing PhD dissertation (F99)
- Stipend, Tuition, and Training Related Expenses similar to F31
- Funds to attend an F99 Fellows meeting

Up to 4 years of support for postdoc training (K00) at a US institution
- Higher salary than F32
  - ($50,000 with $3,300 annual increase + fringe benefits)
- Up to $4500 for Tuition, plus $3000 for Research Expenses
- 8% Indirect Costs allowed for the Institution
- Funds to attend a K00 Scholars meeting
Special Instructions for F99/K00 application

*Use the Forms E fellowship package with the following modifications:*

- Institutional nomination letter is required
- Fellowship Applicant Section has modified instructions
- **Specific Aims and Research Strategy** follow a non-traditional format
- Review Criteria are different from the F31!
General Guidance

- Read the RFA including review criteria
- Read Section F.130 of Application Guide
- Start NOW on Letters of Reference (F.130)
  - Provide directions to your referees – they submit through eRA Commons. See NIH Reference Letter website
  - Tell your referees to enter FOA Number as CA-19-002 (not RFA-CA-19-002)
  - 3 minimum, 5 maximum (NOT in Letters of Support or Other Attachments)
  - Referees should not be directly involved in the application - not sponsor or co-sponsor
  - Check the status often – late letters are not accepted
    - If the 3 required letters are missing, application will not be reviewed
Download Application Package or Apply Online

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA officials regarding availability.

3. Use Grants.gov Workspace to prepare and submit your application and eRA Commons to track your application.

   VIEW GRANT OPPORTUNITY

   RFA-CA-19-002
   The NCI Predoctoral to Postdoctoral Fellow Transition Award (F99/K00)
   Department of Health and Human Services
   National Institutes of Health
<table>
<thead>
<tr>
<th>Select Forms to Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mandatory</strong></td>
</tr>
<tr>
<td>SF424 (R &amp; R)</td>
</tr>
<tr>
<td>Research And Related Other Project Information</td>
</tr>
<tr>
<td>Project/Performance Site Location(s)</td>
</tr>
<tr>
<td>Research and Related Senior/Key Person Profile (Expanded)</td>
</tr>
<tr>
<td>PHS Fellowship Supplemental Form</td>
</tr>
<tr>
<td>PHS Human Subjects and Clinical Trials Information</td>
</tr>
<tr>
<td><strong>Optional</strong></td>
</tr>
<tr>
<td>□ PHS Assignment Request Form</td>
</tr>
</tbody>
</table>
8. Type of Application: **NEW** (even if you applied last year)

12. Start Date: the start of the F99 phase - Use September 1, 2019

12. Ending Date: the end of the K00 phase – Use August 31, 2025

15. **Estimated** Project Funding: covers both phases
   - Use the Budget section of RFA-CA-19-002 & your current institution’s fringe benefits costs

21. Cover Letter
   - Cite RFA-CA-19-002 and include list of your referees (reference letter writers)
1. Human Subjects: More on this later (F.500)!

2. Vertebrate Animals: More on this later (F.430)!

6. International activities
   - Although foreign institutions are not allowed to apply, foreign components are permitted

8. Bibliography & Reference Cited
   - Do not use *et al*!

12. Other Attachments
    - Nomination Letter (RFA-CA-19-002)
Special Instructions - Nomination Letter

- Read the RFA instructions!!
- **Institutional nomination letter** is required
- The nominee is to be selected based on faculty evaluation of an applicant’s potential and desire to become a successful independent cancer researcher.

Nomination Letter must include:
- a description of the nomination process
  - how are eligible students are informed/solicited?
  - how is faculty evaluation/selection conducted?
Nomination Letter (2 pages)

- Signed by the head of the graduate program and the institutional grants official
  - If research involves another institution, submit a joint nomination letter with signatures from both institutions
- Names the nominee and the primary sponsor
- Describes the nominee and the nomination process
- Confirms the eligibility of the nominee
  - 3rd or 4th year of a PhD program and expected to finish within 2 years
- If applicable, describes any exception to eligibility
- If applicable, describes the visa status
Project/Performance Site Location(s)  F.230

- Degree-granting institution must submit application
- If research is not done on the degree-granting campus, add a second site
  - Degree-granting institution may be the primary or secondary performance site
- If work involves Human Subjects or Vertebrate Animals, be sure the site where the work will be done has the proper assurances
Senior/Key Personnel F.240

Applicant /Nominee: your role is PD/PI

Sponsor: role is “Other ( Specify)” then

- Enter “Sponsor” or “Co- Sponsor” in the Other Project Role Category field

Others (Collaborators, Contributors)

- Include here if they contribute in a substantive, meaningful way to the project (not just handing you a reagent)
- May not write letters of reference for you!
- Include biosketches of collaborators
Biosketches

- Nominees use the Predoctoral Fellowship Applicant BioSketch
- It is OK for fellows to list manuscripts in preparation, submitted, or in revision
- Provide a link to your MyNCBI list of publications/products
- Personal statement:
  - Explains suitability for role on this fellowship project
  - May cite up to 4 relevant publications or research products
- Contributions to Science (up to 5):
  - Fellowship applicants may want to highlight 2-3 contributions
  - Each no longer than ½ page, each including up to 4 citations
- For Nominees: Research Support → Your Scholastic Performance
PHS Fellowship Supplemental Form F.430

- Fellowship Applicant Section
- Research Training Plan Section
- Sponsor(s), Collaborator(s), and Consultant(s) Section
- Institutional Environment and Commitment to Training Section
- Other Research Training Plan Section
- Additional Information Section
- Budget Section
- Appendix *(do not use!)*
Fellowship Applicant Section

- Applicant’s Background and Goals for Fellowship Training
  - Doctoral Dissertation and Research Experience
  - Training Goals and Objectives
  - Activities Planned Under This Award
- Reinforced by the Research Training Plan & the Sponsor Section
- Describe personalized career goals with appropriate career stages for both phases and beyond
- Include research & career development activities for the entire award period (both phases)
  - Identify areas for growth and development
  - Propose activities to address these areas
Research Training Plan Section

- 3. Specific Aims*
- 4. Research Strategy*
- 5. Respective Contributions
- 6. Selection of Sponsor and Institution
- 8. Training in the Responsible Conduct of Research

Follow the normal guidance for 5, 6, and 8. I’ll go over Specific Aims and Research Strategy next.
Specific Aims (1 page)

All applications *MUST* have these two Specific Aims:

**Aim 1:** The Dissertation Research Project – progress thus far

**Aim 2:** The Postdoctoral Research Direction

Research Experiences in Clinical Trials

*If the applicant is proposing to gain experience in a clinical trial as part of his or her research training*, describe the relationship of the proposed research project to the clinical trial.
Aim 1 – Significance: Overview of the dissertation research, the scientific question being addressed and its potential impact on the research field.

Aim 1 – Approach: Background, goal, rationale and hypotheses of the graduate research project(s).

Aim 2 – Significance: Describe a specific scientific question or observation for the K00 phase work. Place in context with applicant’s research interests and advancing this research field.

Aim 2 – Approach: A general description of how the research will be conducted, including approaches and methodologies, anticipated results, challenges that might arise and how to address them.
Frequently Asked Questions about the Research Training Plan

- How many pages do I write for each Aim?
- How do I write my introductory paragraphs for the Specific Aims?
- I know someone who could be my postdoc mentor. Should I get a Letter of Support from that person?
- And the question I WISH people asked...

Should the application title, project summary, and project narrative reflect BOTH my dissertation project and my postdoc plans?

YES!
Sponsor(s), Collaborator(s), and Consultant(s) Section

- Sponsor and Co-Sponsor Statements
  - Research Support Available – for your dissertation project
  - Previous Fellows/Trainees
  - Training Plan, Environment, Research Facilities
  - Total Number of Fellows/Trainees to be Supervised
  - Applicant’s Qualifications and Potential for a Research Career – as an independent investigator

- Letters of Support from Collaborators, Contributors, Consultants
Frequently Asked Questions about the Sponsor Statement

- My sponsor is an Assistant Professor and doesn’t yet have (funding/mentoring experience). How do we handle this?
- Is having a co-sponsor recommended?
- Do my sponsor and co-sponsor get 6 pages each?
- What do Reviewers look for?
F99/K00 Review Criteria and Scoring

- Overall Impact:
  - Likelihood for fellowship to enhance applicant’s potential for, and commitment to, an independent scientific research career

- 5 Scored Review Criteria:
  - Applicant
  - Sponsor/Mentor
  - Research Training Program
  - Training Potential/Development Plan
  - Institutional Environment
F99/K00 Review Criteria Differ from F31

- **Applicant:** Emphasizes Letters of Reference
- **Sponsor/Mentors:** Evaluates the plan for identifying a K00 mentor
- **Research Training Program:** Evaluates the research plans for both phases and the research milestones for transitioning to K00
- **Training Potential/Development Plan:** Evaluates plans to monitor the progress in research & career development for both phases and the professional skills milestones for transitioning to K00
- **Institutional Environment:** Evaluates the plan to identify a K00 institution and mentor and its fit with the K00 research direction
Vertebrate Animals

- As applicable to the F99-phase research
- Follow current NIH Guidelines and include a Vertebrate Animal Section in the application
  - Instructions have recently changed (now only 4 points)
    - if reviewers raise concerns, this holds up the award
  - Xenografts: identify the source of human tissue
    - Might qualify it as Human Subjects Research
- IACUC approval needed before an award can be made, but not for submitting the application
Human Subjects Research

- As applicable to the F99-phase research

- Common mistakes involve the E4 exemption status, and human specimens, cell lines or data.

  - *It is important to note that for HS, an investigator is defined as anyone involved in conducting the research*

- If your work uses human materials but does not qualify as HS, you must explain this (now a required question).

- If reviewers raise concerns, this holds up the award

- IRB approval is needed before an award can be made, but not to submit an application