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

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Center for Cancer Training

NIH NATIONAL CANCER INSTITUTE

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Use the NCI F99 Website and carefully read RFA-CA-19-002

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

Script for Slide 2

The script and slides from today's webinar will be added to the F99 website under Resources. A note about NIH-speak, for newcomers to the NIH system:

NCI is the National Cancer Institute, the oldest of the 27 institutes and centers that comprise the NIH.

FOA means Funding Opportunity Announcement. FOA is the generic "umbrella" term for all types of funding mechanisms offered by the NIH.

RFA means Request for Applications. The F99/K00 is an RFA. This means it has special terms – like having a Letter of Intent and only having one annual submission date.

NRSA refers to National Research Service Awards – these are the congressionally-mandated fellowships offered by NIH – the F30 is for MD/PhDs, the F31 is for graduate students, and the F32 is for postdocs. The F99/K00 is NOT an NRSA fellowship!

The NIH Fiscal Year (abbreviated FY) starts on October 1 and ends September 30.

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

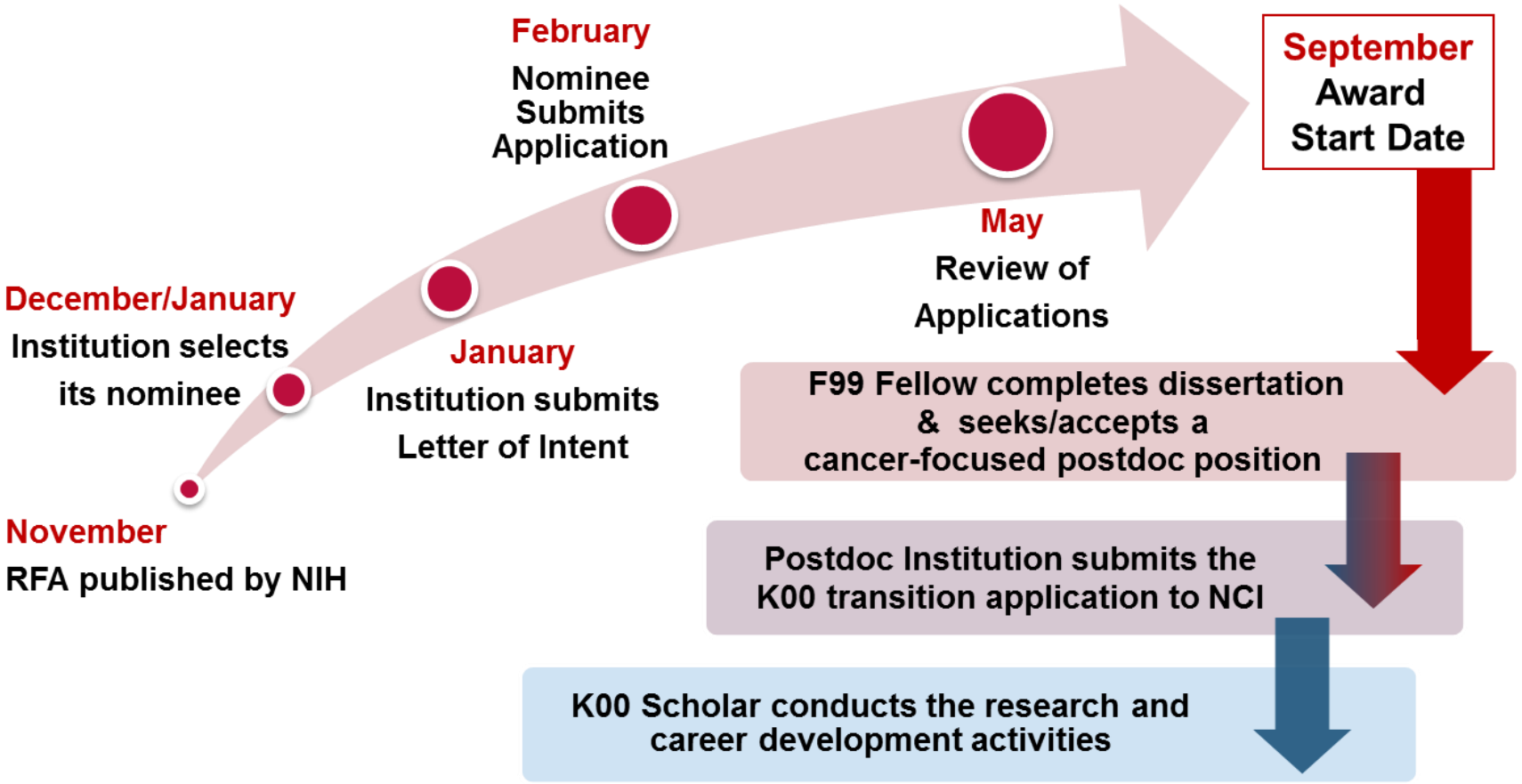
- **Transition when the dissertation research is complete**
- **Funding for the F99 phase will not be extended beyond 2 years**

Script for Slide 4

First, a bit of background information on why NCI is piloting this new funding program. Currently there is a significant imbalance between the numbers of biomedical trainees and the available tenure track positions. And there is an imbalance between the numbers of biomedical researchers and available research grants. One of the many consequences of this imbalance is that an independent research career is being viewed as a less viable career choice by some of our best graduate students.

The F99/K00 pilot program is an effort by the NCI leadership to explore innovative ideas to address this problem. NCI hopes that this dual-phase transition award will identify and encourage outstanding graduate students to commit to pursuing independent cancer research careers. More importantly we hope to show to the awardees and their peers that NCI supports a tractable career pathway for the talented and committed.

Timeline for the F99/K00



Script for Slide 6

NCI is committed to renew the F99/K00 for the next 2 years. The FY19 RFA has is similar to last year but different from other years, so it's very important to read it carefully and not rely solely on experience with a prior year's announcement. Non-compliant applications will be administratively withdrawn. If you know an awardee from prior years and plan to model your application on theirs, keep this in mind!

1. This has one receipt date per year, not like the NRSA fellowships, which have 3.
2. Each institution manages its own nomination process to select its nominee, with the lead time needed to craft a solid proposal.
3. By January 22nd, the institution's grants official, not the nominee, will submit a Letter of Intent. This helps to plan for the review and to prevent mix-ups about who the official nominee is.
4. Applications will be due February 22nd. The NCI website has a page devoted to the F99/K00 that is updated for each year's new RFA.
5. Review occurs in May and the results go to the August Council. Applications are reviewed by a special emphasis panel at NCI.
6. Awards must have a start date of September 1, 2019.

Script for Slide 6, continued

What happens next, if you receive an F99/K00 award:

1. During the F99 phase: You have 2 years to complete your dissertation research and secure a **cancer-focused** postdoc position. In year 1, you come to an NCI F99 Fellows meeting.
2. NCI will not approve transitions to the K00 phase before March 1st of the first award year.
3. Contact your Program Director ~ 4 months before you are ready to graduate and move on, for advice on preparing the K00 transition application, which will be submitted by the postdoc institution. Details are in the RFA.
4. Then you graduate with your PhD, start your new postdoc position, and conduct the research and career development activities planned for the K00 phase, which gives you up to 4 years of support.

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***

Script for Slide 9

1. Who can apply? The intended applicants PhD or other research degree students (DrPH, ScD) who are 3rd or 4th year graduate students and are within 2 years of finishing their dissertations.

2. The program year is calculated from the time of initial enrollment and not after you start your dissertation project, join a lab, or pass a candidacy exam.

3. Dual-degree, or professional doctorate/clinical degree students are not eligible. This is because their training timeline is not compatible with this new funding mechanism.

4. There is only one nominee per degree-granting institution per year. **There is one nominee for all schools/colleges/divisions in an institution, even if they have individual DUNS numbers.**

5. If you mainly work at a non-academic research center, you must apply through the institution that will confer your degree. But the research center can co-nominate you and contribute to the application.

6. International students studying in the US who are here on a visa ARE eligible for the F99/K00.

7. No resubmissions are allowed but someone may be nominated two years in a row if the person still meets the eligibility requirements.

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…**

Script for Slide 11

Are there exceptions to the eligibility rule? yes. Some examples are: Documented leaves of absence (for example, family leave but not a vacation). Or circumstances beyond your control (like a first advisor leaving the institution).

But know that if you are selected, the **institutional nomination letter** will need to document these special circumstances. Feel free to inquire in advance, before you put your name in for consideration at your institution.

Similarly, some students already have advanced degrees (MS, for example) or are truly speeding through their programs, and plan to be finished by year 4. If you can convince your selection committee that you are the best nominee, NCI will accept your application. Again, the **nomination letter** should explain the special circumstances. Remember that the 2 phases are intended to be continuous, and that the F99 funding will not be extended beyond 2 years.

Script for Slide 11, continued

The NIH does not allow two applications with substantial overlap to be under review at the same time. If a nominee submitted an F31 application for the December 8th deadline (3rd cycle), let the F99/K00 program director (me) know. It will be OK to submit but we need to carefully monitor the timing internally. We will work with you.

This award is intended for students who are near the end of their dissertation and so they really should be beyond the stage of intending to submit an F31. However, for those who still wish to submit an F31 after the F99 has been submitted, we advise you to not submit for the April 8th deadline (1st cycle), but to wait until the August 8th (2nd cycle). This gives time for the F99/K00 summary statement to be released, which will allow you to submit.

Your application will be reviewed by an NCI panel. Your application should make a strong case that your training has prepared you for a future career in cancer research and that you are sincere in your commitment.

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

Script for Slide 14

How is the award structured financially? The predoc F99 phase will give support for up to 2 years, but will not be extended. So you need to graduate by September 1, 2021 and be ready to transition to the postdoc by that date.

In the K00 postdoc phase, you are an employee with full benefits. You may postdoc at the NIH or other national laboratory, but if you do, the funds will come from a different source.

Letter of Intent

By 1/22/2019, Grants Official sends an email memo, indicating the institution's intent to submit an application to RFA-CA-19-002 to:

Michele McGuirl, Ph.D.

National Cancer Institute (NCI), Cancer Training Branch

Email: mcguirlma@mail.nih.gov

- **The memo should include:**
  - **Likely title of the application**
  - **Name, address, and telephone number of the nominee and email address!**
  - **Name of the primary sponsor/mentor**
  - **RFA number**

Script for Slide 16

The Letters of Intent (LOI) come from the university grant officer, not the applicant/nominee. They are not technically required, but they are strongly recommended. First, they let me to contact you and make you aware of webinars like this one. Second, there have been several instances where more than one person from the same university believed he/she was the nominee. When I get LOIs, I can resolve conflicts like this before someone spends a lot of time writing an application. Finally, it helps us plan for review.

- If your university has not submitted a letter of intent yet, please ask them to do so as soon as a nominee is selected. It is a simple process – the grants official emails me the requested info, which can be found in the RFA, along with the nominee's email address.

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!**

Script for Slide 18

- The F99 uses the same SF424 fellowship application package that is used for other fellowships, including the F31 NRSA pre-doctoral fellowship.
- But there are some key differences from the F31.
- A Nomination letter is required and **must** be included as part of the application. I'll add some more detail about the Nomination Letter later.
- The Specific Aims and Research Strategy Sections of the F99 do not use the typical research grant format. I'll elaborate on this in a few minutes.

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

Script for Slide 21

You must read the RFA instructions in **Section IV. Application and Submission Information** very carefully!

- There is a hierarchy to instructions for applying to the NIH: first there's the NIH application guide, which gives generic instructions. Then there are specific instructions for various types of applications (individual fellowships have their own section), and then there is the funding opportunity announcement (RFA-CA-19-002). If there is different advice offered, remember that the RFA overrules the application guide - follow the RFA.

Reference letters: Cannot re-use letters from a different/prior application. Must get new letters every time.

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.

Script for Slide 22

- , I recommend downloading the application package instructions for. Adhere to the table of page limits for fellowships, and to the RFA, and to the SF424 Forms E application guide instructions.
- Also, there are answers to FAQs found under Resources on the F99 website, and links to those for the F31 that may be helpful.

SF424 (R&R) F.200

- 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)

Script for Slide 24

- This SF424 form is often called the Cover Sheet. It is 2 pages and contains nuts and bolts information. But there are some F99-specific instructions.

- Please request the maximum time allowed (2 years for F99 and 4 years for K00). The NIH issues grants in 1-year blocks, and you don’t want to run short if you need an extra day or an extra month to finish the F99 phase. You can always finish early!

R&R Other Project Information F.220

- 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)

Script for Slide 26

- The Research and Related Other Project Information forms in this section are all about your current university and your current project, not the postdoc K00 phase.
- 1 & 2: This section starts off with Human Subjects and Vertebrate Animals. These are basic yes/no questions, but in a later section F.500 and F430, there are more parts. I'll give advice later on these topics at the end of my talk.

6. International activities: Although foreign institutions are not allowed to apply, foreign components are permitted. If you have a foreign collaborator, list them here.

- 8. Bibliography & Reference Cited Do not use *et al!* Cite using full names and the full references. DOI links are appreciated by reviewers.
- 12. Other attachments – this is where the nomination letter goes – AND NOTHING ELSE! I'll give more details on this next.

Special Instructions- Nomination Letter

- **Read the RFA instructions!!**
- **Institutional nomination letter is required as part of the application**
- **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

Script for Slides 29 and 30

Nomination Process: is handled by the institution – based on FACULTY INPUT.

The Nomination Letter should confirm eligibility, that the nominee is in the 3rd or 4th year of a PhD program in an appropriate biomedically related field.

The nominee is not required to be doing cancer research for the F99 phase, but MUST propose doing cancer-focused research for the K00 phase. It is up to the nominee to make a strong case that he/she is committed to pursuing a career as an independent cancer researcher.

If an eligibility exception was requested and granted, the nomination letter should mention the reason.

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

Script for Slides 29 and 30, continued

- The nomination letter must be no longer than 2 pages. It should be signed by the head of the graduate program and the institutional grants official. Along with the Letter of Intent, this guards against there being multiple nominees from the same place.
- If the dissertation work involves more than one institution, for example if you are doing research at a center that does not offer a formal degree, we encourage you to submit a joint nomination letter from both program heads.
- If the nominee is here on a visa, the letter should also give assurance that the candidate's visa status is up to date, that there are no known obstacles for completing the F99 phase, or for obtaining a visa at the time of the K00 transition. One example of a common obstacle for the K00 phase is a home country requirement to return after the PhD is awarded. **Do not include the visa in the application.**

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**

Script for Slide 32

- For those doing all of their research at their degree-granting university, this part is straightforward.
- For others, a second performance site should be added. The primary site should be where most of the work will be done.
- The Human Subjects and Vertebrate Animal approvals must be for each site where the work will be done.

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

Script for Slide 34

- Key Personnel: you must list yourselves and your sponsors. I'll give some advice about the biosketches on the next slide.
- Co-sponsors: reviewers look to see if their role is substantive and well-defined in the proposal. Do not include a co-sponsor just to have one, or just because they are famous! If your sponsor has limited mentoring experience, a co-sponsor who has an established track record of mentoring grad students might help your case. But only if the person meets with you regularly and is highly engaged in your training plan.

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**

Script for Slide 36

Biosketches are required for all Senior/Key Personnel and Other Significant Contributors. Be sure to use the most recent biosketch format. Fellowship applicants may include manuscripts in preparation, submitted, or in revision, but these carry less weight with reviewers. If one of these gets published and there are more than 30 days before the actual review date, you may submit an update to the SRO, Scientific Review Officer, who runs the review meeting. You may also use an update to report any positive changes in sponsor funding (new grants), since reviewers weigh this heavily when evaluating your sponsor. I do not yet know when the review will occur, but eRA Commons will post it.

Personal Statement: Briefly describe why you are well-suited for your role(s) in this project. It helps if the sponsor and other key personnel customize their PS to their roles on this application; don’t just use their research biosketch. Your yours, include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and/or your past performance in this or related fields.

Script for Slide 36, continued

If there are factors affecting your past productivity that you wish to explain, such as family care responsibilities, illness, disability, or military service, you may address them in your personal statement. Indicate if you have published or created research products under another name.

Contributions to science: Briefly describe up to five of your most significant contributions to science. While all applicants may describe up to five contributions, graduate students are encouraged to consider highlighting two or three they consider most significant. Descriptions may include a mention of research products under development, such as manuscripts that have not yet been accepted for publication.

Additional Information: Research Support and/or Scholastic Performance: Predoctoral Applicants use this section to provide information about their grades. List by institution and year all undergraduate and graduate courses, with grades. In addition, in the space following the chart, explain any grading system if other than 1-100, A, B, C, D, F, or 0-4.0. Show levels required for a passing grade.

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!)

Script for Slide 39

- Finally – the “meat” of the application! I’ll go over the parts in red in some detail. My advice is to carefully read the RFA instructions and the review criteria before writing this part. Every part of the application is important, so don’t focus solely on the research plan.
- Appendix rules are very strict. Don’t risk being returned without review for “overstuffing.”
- ATTENTION: EVERYONE MUST WRITE IN THEIR OWN WORDS AND INCLUDE ORIGINAL IDEAS – FOR ALL FELLOWSHIP APPLICATIONS!!
- NCI will not fund an f or k application that was copy/pasted from a sponsor’s prior grant even if it wasn’t not funded and even if it receives a great score. **And yes, we do check!**

Major Components in An Application: R01 vs. F

R01 Section of Application	Page Limits
Specific Aims	1
Research Strategy (Significance; Innovation; Approach)	12
Biographical Sketch	5

K (F) Section of Application	Page Limits
Specific Aims	1
Applicant section 6 p, Research Strategy 6 p	12
Training in the Responsible Conduct of Research	1
Sponsor and Co-Sponsor Statements	6
Letters of Support from Collaborators, Contributors, and Consultants	6
Description of Institutional Environment – includes a description of your degree program!	1
Biographical Sketch	5

Script for Slide 41

- Your sponsor is used to focusing on the research strategy. But training grants devote about half of their space to the applicant and the career development. Do not skimp on this! Read and follow all instructions.
- If your sponsor does not provide the information as requested in in the instructions for the sponsor statement, ask for revision – this is YOUR grant application.

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

Script for Slide 43

Fellowship Applicant Section: develop this in collaboration with sponsor but it should be written by you. This section is 6 pages long – my advice is to use it all!

This section should reinforce the Research Plan and be consistent with what your sponsor says. Some redundancy is OK. Use this attachment with its 3 sub-sections to describe personalized career goals with appropriate career stages for both phases and beyond.
Be sure to include both research & career development activities for the entire award period (both phases). Allotting 100% of your time only to research is probably not a good idea, but neither is allotting 60%.

You may wish to identify areas for growth and development and then propose activities to address these areas.

Script for Slide 43, continued

1. Doctoral Dissertation and Research Experience: Summarize all of your research experience in chronological order. include the areas studied and conclusions drawn. Place your current field and prior training within the context of your ultimate career goal.
2. Training Goals and Objectives: Describe your long term career goal, the training goals for each phase, and explain how this award will enable the attainment of these goals. Identify the skills, theories, conceptual approaches, etc. to be learned or enhanced during the award. What skills do you have, what is needed for your future independent career? **How will you identify a K00 mentor?** Discuss how the proposed research will facilitate your transition to the next career stage F99 → K00 → later on.
3. Activities Planned Under This Award: Describe the scientific and professional development activities planned for each phase and explain how the activities will facilitate the transition to each subsequent career stage. Include a timeline with scientific, professional development, and career milestones. Describe, by year, the activities (research, coursework, etc.) and estimate the percentage of time to be devoted to each activity. The activities should be individually tailored to your career and be well-integrated with your research project. Describe the skills and techniques as well as any planned, non-research activities (e.g. those relating to professional development and clinical activities). **Provide a timeline!**

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.**

Script for Slide 47

Let’s turn to the Research Training Plan. The typical nominee is far along in their defined dissertation research project but has yet not committed to a specific postdoc lab. This presents a challenge for writing a traditional Research Training Plan – NCI does not want to prolong the time to degree by having applicants propose additional new experiments for the F99 phase, and applicants are not yet in a position to write a detailed research proposal for the K00 phase.

To address this, **NCI requires that all applications must use these 2 specific aims. This is different from some Prior years!**

This is very different from other fellowships, and failure to follow the instructions can cause the NIH to reject your application.

Script for Slide 47, continued

Think of Aim 1 as setting up the dissertation's specific hypothesis and objectives that will be used to examine the hypothesis and the preliminary data, then describing the methods/approaches/techniques to be used for the remaining experiments. Add a discussion of the expected outcomes, possible problems and how they will be managed, and, when appropriate, alternative approaches that might be tried if the initial approaches do not work.

Aim 2: Should **not** be a continuation of the PhD research, unless you plan to take on a whole new aspect of the project. For example, a physicist might propose to work on the biology of the same project for her postdoc phase. Reviewers look for the training potential – **the need for additional training**. That's hard to do if you merely continue your PhD project. NCI strongly recommends that predocs move to a new mentor and institution for the postdoc phase.

Research Strategy Section (6 pages)

- ***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.**

Script for Slide 50

The Research Strategy has 2 components: Significance and Approach. Innovation is not required for fellowships. The combination of plans for the PhD and postdoc phases should prepare the applicant for a career as an independent investigator in cancer research.

There should be a logical and compelling connection between the phases and the aims, and they should support the career goal.

Aim 2: No need for K00 phase to be a continuation of the PhD research. In fact, reviewers look for evidence of training potential – the need for **more** training.

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!

Script for Slide 52

1. Use your best judgement! Reviewers will be looking to see that you can coherently explain your dissertation project, that you have a handle on the science that remains to be done, and that it is reasonable to complete the work within a 1-2 year period. Do not neglect Aim 2! I recommend at least 2 pages. Remember that the K00 phase makes up 2/3 of the funding period. So do not skimp on this part just because you don't yet have a defined postdoc project.
2. You might discuss a pressing problem in an area of cancer research, why that area piques your interest, and where you see yourself contributing. What approach will you take? Consider the kinds of skills you will need (but don't have yet) to succeed in that career.
3. Hint: if you need some coursework or other training in the F99 phase to prepare you for the K00 phase, plan for this in the "Activities planned" part of the Fellowship Applicant section.

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**

Script for Slide 54

The Sponsor statement is written by your sponsor and co-sponsors. There are 5 parts.

Research Support Available: list all current and pending research and research training support **specifically available** for this particular training experience. If the sponsor's research support will end prior to the end of the proposed training period, the sponsor should provide a contingency plan for how the fellow's research will be supported.

Previous Fellows/Trainees: Give the total number of predoctoral and postdoctoral individuals previously sponsored. Select up to five that are representative and, for those five, provide information on time spent in the lab their present employing organizations and position titles or occupations.

Training Plan, Environment, Research Facilities: Describe the research training plan that the sponsor has developed specifically for the Fellowship applicant. This should be individualized for the applicant, keeping in mind his/her strengths and any gaps and needed skills. Include items such as classes, seminars, opportunities for interaction with other groups and scientists, and professional skills development opportunities. Describe the research environment and available research facilities and equipment. Indicate the relationship of the proposed research training to the applicant's career goals.

Script for Slide 54, continued

Describe the skills and techniques that the applicant will learn. Relate these to the applicant's career goals. If a sponsor team is proposed, this plan should describe the role of each sponsor and how they will communicate and coordinate their efforts to mentor the applicant effectively. The training plan should facilitate the applicant's transition to the next stage of his/her career.

Total # of trainees to be supervised in the lab at this time. Describe how often sponsor meets with the applicant.

Applicant's Qualifications and Potential for a Research Career: Describes how the Fellowship applicant is suited for this research training opportunity based on his/her academic record and research experience level, including how the research training plan, and sponsor's own expertise will assist in producing an independent researcher.

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Letters of Support are not the same as letters of reference – they should simply state what will the person provides for the project (reagent/expertise, etc.) 6 pages total. Collaborator biosketches may be included as key personnel (recommend you so this). Again, it helps if they adjust their personal statements to their roles on the fellowship project.

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?

Script for Slide 57

1. Lack of a track record of mentoring, weak history or no current grant funding: REMEMBER these are part of the review criteria – you will likely be at a disadvantage. To mitigate weaknesses in this part, be sure the training plan is well written and detailed, and customized for you.
2. Lack of Funding: Are there other resources available to you? explain if there are back-up plans in place, should pending funding not come through.
3. Do not add a co-sponsor just to shore up the primary sponsor “on paper.” Add a co-sponsor only if the person meets a key need that your sponsor does not provide. the co-sponsor’s role should be clearly defined, the involvement should be substantive, and interactions with the applicant should be regular. Is there already an established collaboration between sponsor/co-sponsor? Do the planned activities and career goals warrant the co-sponsor’s participation?

Script for Slide 57, continued

1. No. 6 pages includes the information from All sponsors/co-sponsors combined. It may be written by the primary sponsor, by both together (“we”) or with separately written parts by each sponsor. But the information from all S and co-S must be covered within the 6 pages.
2. Reviewers look to see if the co-sponsor involvement is well-justified and integrated into the overall plan, or if it is just window dressing. Reviewers also look to see that that the sponsor’s training plan for you reinforces your career goals and activities. Be sure all of the sections support the same overall story. Disconnects between the applicant and sponsor sections generally review very badly.

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**

Script for Slide 60

This is how review works: 3 reviewers are assigned to your application. Each provides a number from 1 – 9 (1 is best) for the 5 individual review criteria and then they provide a preliminary overall impact score. This happens before the study section meets. The overall score is NOT an average of the 5 individual review criteria scores.

At the review meeting, reviewers who are in conflict of interest step out of the room when an application comes up for review. Those applications with the better (meaning lower) average preliminary overall impact scores are discussed. Reviewers may also ask for any application to be rescued and reviewed. After the discussion is over, every member of the study section in the room votes on a final impact score. Those final scores are eventually averaged and multiplied by 10 - that is the score you receive.

For fellowship and career development grants, the whole is often greater than the sum of the parts. Reviewers look to see whether each section of the application connects well to the overall goal. Use this to your advantage – one section should reinforce and not contradict what is in the other sections. Reviewers want to see that the application is well-thought out, and that the sections and other components are well-integrated and part of a greater plan.

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

Script for Slide 62

Applicant: Biosketch and Fellowship Applicant section are important, but letters of reference are very important.

Sponsor/Mentor: Biosketch and sponsor statement. Also, the plan to identify a good K00 mentor, and how you describe the type of mentor and institution you seek for the K00 phase are also important.

Research Training Plan: Reviewers want details and milestones for both phases! Use your timeline in the fellowship applicant section wisely to reinforce the research plan and integrate it with professional development activities.

Training Potential/Development Plan: mostly the applicant section, sponsor statement, and research strategy.

Institutional Environment: there is a specific section about the F99 phase, but when scoring, reviewers also evaluate the postdoc plans. Reviewers want to see your ambition here, to reach out for the best mentor in the best institution. The F99/K00 is an elite program meant to pick those who want to excel in the next phase. But you do not need to be at a high powered lab/institution for your PhD to get an award.

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**

Script for Slides 64 and 65

Finally, I want to say a couple of words about Vertebrate Animals and Human Subjects, which only cover the F99 project, not the K00 phase.

Mistakes in these sections can cause doubt in reviewers minds about the involvement of the sponsor, and this can change reviewer scores.

HUMAN SUBJECTS: There are some common mistakes that show up frequently. First, who is an investigator? Individuals who provide coded information or specimens and collaborate on other activities related to the research or training are considered to be involved in the research. This includes providers who will be co-authors. If any investigator has access to the PII (personal identifiable information), the fellowship will be considered to be Human Subject research, even if the applicant does not have access to the PII.

Samples, data from people who are dead is not HS Research. Samples from a databank or tissue bank, where the banks cannot reveal PII, are not HS Research. But if they have been collected from live people specifically for this project, it is HS Research.

Script for Slide 65, continued

E4: claiming exemption E4 means that it is HS Research! You can NOT claim E4 and say it is not HS research.

E4 is rare these days. If a collaborator who has existing specimens will provide you with a subset of samples and these are randomized and no key is created or kept, this may qualify as E4. If the collaborator retains access to a key and can identify the samples, it is HS Research, and E4 does not apply.

See the flow charts and questionnaire on the NIH HS website.

If human tissue is involved comes deidentified from a tissue bank or other source that is prohibited from releasing the PII, it is not HS research.

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