General Advice
In addition to these F99/K00-specific topics, you may wish to review FAQs for the F31 Ruth L. Kirschstein National Research Service Award (NRSA) for help in preparing the application (remember to select the appropriate F31 filters).

Eligibility

Career Stage
At the time of application, you must be:

- A graduate student in your 3rd or 4th year of a biomedical, behavioral, or clinical research doctoral degree program. This is calculated from the time of enrollment at the institution.
- Enrolled at a domestic (US) institution.
- Foreign students are eligible.
- On track to graduate within 2 years. The F99 phase will not be extended, nor will the K00 phase be postponed, except under rare and unforeseen circumstances.
- Exceptions:
  - If a 2nd year student is expected to graduate within 2 years, an exception may be requested. Applicants may check with the Program Official prior to the selection of the nominee. If granted, the exception should be explained in the Nomination Letter.
  - If a 5th year student took a documented and extended Leave of Absence, an exception may be requested. Applicants may check with the Program Official prior to the selection of the nominee. If granted, the exception should be explained in the Nomination Letter.
- Be at the dissertation stage at the time of application. This means you have passed any and all requirements, as set by your institution, for advancement to the Ph.D. candidacy stage.
- If you complete the PhD degree requirements or begin a postdoctoral position before an award is made, neither the F99 nor the K00 award will be made.

Degree Program
You must be enrolled in a Ph.D. program or other research doctoral program (e.g., DrPH, ScD). Students enrolled in the following programs are NOT eligible for this pilot program:

- Dual-degree programs, even if the degrees are completed in separate phases.
- Professional doctorate or clinical practice degree programs.
- Any degree programs that require an extended internship following the research degree.

Research Area
NCI supports all areas of cancer research.

- No area of research is given preference.
- The K00 phase MUST be cancer-focused.
- The F99 dissertation research must be in a biomedical, behavioral, or clinical research area that prepares you for a future career in cancer research.

Citizenship
There is no citizenship requirement; you may be a US citizen or permanent resident, or hold a valid U.S. visa.

- The Nomination Letter for an applicant holding a U.S. Visa must provide assurance that the candidate’s visa provides sufficient time to complete the F99 phase of the award at a U.S. institution, and that there are no known obstacles (e.g., home country requirement) to the
candidate obtaining a visa at the time of the K00 transition.

Nomination Process
You must be nominated by your institution.

- Only one nomination is allowed per institution per year; your institution determines the nomination process.
- An eligible institution includes all schools/colleges/divisions within the institution, whether they are identified by a single DUNS number or by multiple DUNS numbers.
- It is expected that institutions will select their nominees by (1) soliciting applications from eligible students and (2) using faculty input and review as the key determinant when evaluating a potential nominee’s ability and desire for a career as an independent cancer researcher.
- The nomination process must be described in detail in the nomination letter.
- Resubmissions and renewals are not allowed.
- An institution may choose to nominate the same person two years in a row, if the nominee is still eligible.

Diversity
Although the F99/K00 does not have a diversity-specific complementary program, the NIH always encourages submissions from these individuals.

Foreign Components
Although foreign institutions are not eligible, foreign components are allowed.

Timing
F99/K00 awards are made at the end of the NIH fiscal year and it is not possible to delay an award until the next fiscal year.

- An applicant risks losing the F99 award if all requirements for funding are not met in a timely manner.
- This includes termination of another fellowship and providing all other information requested by the NCI.

Relationship to the F31 Ruth L. Kirschstein NRSA and other Fellowships
F31 applicants and current awardees are eligible for the F99.

- Only one fellowship award may be active at any given time. F31 awardees will need to terminate the F31 prior to accepting the F99/K00.
- The NIH does not allow 2 overlapping applications to be “under review” at the same time. “Under Review” covers the time an application has been submitted until the release of its Summary Statement.
- For F99 nominees who submitted an F31 before the F99 due date:
  - If you submitted the F31 in December, the F31 may still be “under review” at the time the F99 is to be submitted in February. This potential problem can be addressed by contacting the Program Official in advance.
- For F99 nominees who plan to submit an F31 after the F99 due date:
  - You may not submit for the April 8th due date that immediately follows the F99/K00 submission, since the F99 Summary Statements will not be released until July. Instead, you must wait until the August 8th due date to submit the F31.
- The F99/K00 is not an NRSA fellowship. Having prior NRSA support does not impact the years of support that may be requested for the F99/K00. Similarly, having an F99/K00 award does not impact any eligibility for future NRSA support.
- Neither the F99 phase nor the K00 phase may be held concurrently with another federally sponsored fellowship or similar Federal award that provides a stipend or salary, or otherwise duplicates the provisions of this award.
Sponsor

- Your primary F99 sponsor is not strictly required to have peer-reviewed, cancer-related research grant at the time of application or award. However, the sponsor needs to demonstrate the availability of research resources, scientific and technical expertise, and mentorship experience to effectively mentor you. This is part of the review criteria.
- The roles of any co-sponsors should be clearly described in the application.

The Transition to the K phase

- F99 awardees may not transition to the K00 phase until March 1st of their first year of funding.
- The F99/K00 award is intended to facilitate successful transition to the postdoctoral career stage. Consequently, a requirement for the K00 phase award is successful completion of the doctoral dissertation degree and subsequent transition to a cancer-focused, mentored postdoctoral research position.
- Applicants are strongly encouraged to apply for postdoctoral positions at departments and institutions different from where they conducted their doctoral research.
- The transition from the predoctoral phase to the postdoctoral phase is intended to be continuous in time and, except in unusual circumstances, NCI will not extend the F99 phase or delay the start of the K00 phase.
- To begin the K00 phase of the grant, individuals must have been offered and accepted a postdoctoral appointment to carry out cancer-focused research.
- When the K00 phase of the award begins, the F99 phase of the award ends.
- A transition application is required for the K00 phase. Prospective applicants are strongly encouraged to contact the NCI Program Official as soon as a plan to assume a postdoctoral position develops, and not later than 4 months prior to the end of the F99 phase of the award.

Guidance for Preparing the F99/K00 Application

General Advice

Use the Fellowship (F31-specific) section of SF424 (R&R) application package for guidance, except where the instructions in the FOA, the Funding Opportunity Announcement, (RFA-CA-19-002) tell you to do something else.

This guidance is listed in the order it appears in the Fellowship Instructions of the Application Guide. Please pay special attention to the following sections that deviate significantly from the F31 application:

- **Letter of Intent** – requested by January 22, 2019. follow the specific instructions in the FOA
- **Nomination Letter** – required, follow the specific instructions in the FOA
- **Fellowship Applicant Section** - follow the specific instructions in the FOA
- **Specific Aims** – follow the specific instructions in the FOA
- **Research Strategy Section** – follow the specific instructions in the FOA

F.200 - SF 424 (R&R) Form

- **Item 12, Start Date** - refers to the start of the F99 phase. The start date must be September 1, 2019.
- **Item 12, End Date** - refers to the end of the K00 phase. NCI advises applicants to request 6 total years, even if they plan to transition to the K00 in year 1.
• **Item 15, Estimated Project Funding** - This is an estimate that covers both phases. See below for more information.

F.220 - R&R Other Project Information

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

• **Item 7, Project Summary/Abstract** – Address both phases.

• **Item 8, Project Narrative** – Address both phases.

• **Item 12, Other Attachments** - This is the place to upload the **Nomination Letter**.
  - The institutional nomination letter must include a description of the nomination process, including how eligible students are informed/solicited and how faculty evaluation/selection is conducted. The nominee is to be selected based on faculty evaluation of an applicant’s potential and desire to become a successful independent cancer researcher.
  - If the applicant is not a U.S. Citizen or permanent resident, the sponsoring institution must include information about the candidate's visa status, an assurance that the candidate’s visa provides sufficient time to complete the F99 phase of the award at a U.S. institution, and assurance that there are no known obstacles (e.g. home country requirement) to the candidate obtaining a visa at the time of the K00 transition.

F.240 - R&R Senior/Key Person Profile (Expanded) Form

• Applicants are to use the Predoctoral Biosketch form. See the Application Instructions and the F31 FAQs.

• Manuscripts that are submitted or in preparation may be listed on the F99 applicant's biosketch, but not on the biosketch of a Sponsor, Co-sponsor, or any other significant contributors.

F.430 - PHS Fellowship Supplemental Form

You MUST follow the FOA-specific instructions for all sections.

• **Item 8. Training in the Responsible Conduct of Research** - required; limited to 1 page. Don’t forget to address each the 5 required components:
  - the format (face to face and online components)
  - the topics covered (describe the course content)
  - faculty participation (who participates in teaching the course)
  - the duration (the NIH requires 8 hours of face-to-face time)
  - the frequency (the NIH requires this to be repeated every 4 years and when you advance to a new career stage, i.e., the K00 phase)

• **Item 9. Sponsor and Co-Sponsor Statements**
  - The 6-page limit is the total for the sponsoring team (not 6 pages per sponsor)

• **Item 11. Institutional Environment and Commitment to Training Section** - follow the instructions given for F31 applications.

• **Vertebrate Animals** – include if applicable to the F99-phase research. Follow current NIH Guidelines and include a Vertebrate Animal Section in the application.

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

• **Item 15. Resource Sharing Plan** – include a plan that covers the F99 phase and addresses:
  - This is a REQUIRED element for all NIH Fellowship applications
  - NIH policy that the results and accomplishments of the activities that it funds should be made available to the public.
  - The special guidance for research involving special topics such as Model Organisms.
  - Although Data Sharing and Genomic Data Sharing policies are not applicable to the F99 fellowship, reviewers often comment on whether fellowship applicants are aware of NIH policy. If you are doing work in these areas, NCI suggests that you add a brief description
to show you are aware of the policies. If applicable, indicate that F99-generated data will be
deposited as part of your sponsor’s funded research Genomic Data Sharing Policy.

- **Item 24. Authentication of Key Biological and/or Chemical Resources** Do not include.
- **Item 25. Budget Section** - use the F99 institution’s current graduate student and postdoc
  policies to estimate the costs for both phases, in conjunction with the Budget section of RFA-CA-
  19-002, to estimate the total budget.
  - If an award is made, the NCI Grants Management Specialist will verify the tuition and fees
   for the F99 phase.
  - At the time of transition to the K00 phase, awardees will be asked to submit a new budget
   as part of the transition application.

**F.500 Human Subjects and Clinical Trials Information**
This part of the form is new so you, your sponsor, and your grants manager should read
the instructions carefully.

- Include if applicable to the F99-phase research only, not the K00 phase.
- IRB approval is needed before an award can be made, but not to submit the
  application.
- Follow current NIH guidelines, read the FAQs, and then include the Human
  Subjects section in your application.
- Common mistakes involve the E4 exemption status and human specimens, cell lines or
data. See the NIH OHRP website for guidance.
  - If specimens were not collected specifically for your project and nobody
    involved with the research** has no access to the personally identifiable
    information, it is probably NOT HUMAN SUBJECTS research.
- **If you answered “No”** to the question “Are Human Subjects Involved” but are using human
  specimens and/or data, you must provide a justification for your claim that no human
  subjects are involved.

**An “investigator,” as it pertains to research involving human subjects, is defined as anyone involved in conducting the research.** Individuals who provide coded information or specimens and collaborate on other activities related to the research are considered to be involved in the research, and are therefore also considered to be investigators. Providers of data or samples who will be co-authors are also considered investigators. **If any “investigator” has access to personally identifiable information, the work is categorized as Human Subjects Research.**