

# Frequently Asked Questions (FAQs) about the INCLUDE F99/K00

Use the following FAQ answers to complete an application for the INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE) Project F99/K00 Notice of Funding Opportunity (NOFO).

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## Who is eligible?

### *Career Stage/Degree Program*

At the **time of application**, you must be:

- A graduate student with 1.5 to 2.5 years left in a biomedical, behavioral, or clinical research doctoral degree program (1 to 2 years left at time of award); Typically, this would include applicants in their 3rd or 4th year
- Enrolled at a domestic (U.S.) institution
- On track to graduate within 2.5 years (2 years, at time of award); the F99 phase will not be extended, nor will the K00 phase be postponed, except under rare and unforeseen circumstances

At the **time of award**, you must be:

- A U.S. citizen or permanent resident
- At the dissertation stage, meaning you have passed any and all requirements, as set by your institution, for advancement to the Ph.D. candidacy stage

Please note: If you complete the Ph.D. degree requirements or begin a postdoctoral position before an award is made, neither the F99 nor the K00 award will be made.

Students enrolled in the following programs are NOT eligible for this NOFO:

- 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 completion of the research degree

### ***Research Area***

This NOFO supports all areas of research that are focused on Down syndrome (DS), and that meet programmatic objectives for the INCLUDE Project. The INCLUDE Project wants to expand the community of investigators conducting research related to DS by encouraging trainees early in their research careers to develop research projects related to co-occurring conditions associated with DS.

- No area of research is given preference.
- Both the F99 and K00 phases must fall within a priority area of the INCLUDE Project.
- All applications will be reviewed together in the same study section, meaning applicants do not need to indicate a study section or direct their application to a specific institute.
- If unsure, contact the Scientific Contacts listed in the NOFO.

### **Is there a diversity requirement?**

This NOFO also intends to enhance the diversity of the DS research workforce by supporting a defined pathway across career stages for outstanding graduate students from diverse backgrounds, including those from groups underrepresented

in biomedical and behavioral sciences. NIH encourages institutions to diversify their student and faculty populations to enhance the participation of individuals from groups that are underrepresented in the biomedical, clinical, behavioral, and social sciences (See [NOT-OD-20-031: Notice of NIH's Interest in Diversity](#)).

## **Are foreign components allowed?**

Although foreign institutions are not eligible for this NOFO, Foreign components are allowable.

## **What is the relationship of the F99 to the F31 Ruth L. Kirschstein National Research Service Award (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 two overlapping applications to be “pending review” at the same time. “Pending review” covers the time from when an application has been submitted until the release of its Summary Statement. You may not submit an F99 application and an F31 application for due dates in the same review cycle.
- 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.

## **Who is my sponsor, and what is their role?**

- Your primary F99 sponsor needs to demonstrate the availability of research resources, funding, 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. Co-sponsors are recommended if your primary mentor is junior and/or has not graduated many Ph.D. students.

## How does the F99 transition to the K00 phase?

- F99 awardees may not transition to the K00 phase until after their first year of F99 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 DS -focused, mentored postdoctoral research position.
- Applicants are encouraged to apply for postdoctoral positions at institutions different from where they conducted their doctoral research. Applicants who intend to stay at the predoctoral phase institution for the postdoctoral phase should consider how they will separate scientifically from their Ph.D. sponsor.
- The transition from the predoctoral phase to the postdoctoral phase is intended to be continuous in time and, except in unusual circumstances, the INCLUDE Project 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 DS -focused research, submit a K00 application, and secure approval of the K00 application.
- 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 must contact the INCLUDE Program Official as soon as a plan to assume a postdoctoral position develops but **at least 9 months prior to the end of the F99 phase of the award** to allow adequate time for approval of the sponsor and the project and for development of a complete application. This timeframe will also ensure the transition to the K00 phase takes place without interruption in funding.

## What guidance is available for preparing a F99/K00 application?

Use the Fellowship (F31-specific) section of the SF424 (R&R) application package for guidance, except where the instructions in the NOFO (i.e., the NOFO tells 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:

- **Fellowship Applicant Section:** Follow the instructions in the NOFO. This section should address both phases of the F99/K00.
- **Biographical Sketch for applicant and sponsor(s):** Follow the instructions in the NOFO, paying special attention to the personal statement and scholastic performance.
- **Specific Aims:** Follow the instructions in the NOFO.
- **Research Strategy:** Follow the instructions in the NOFO. Applicants should individually address the Significance and Approach for each Specific Aim.
- **Training Plan, Environment, Research Facilities:** Follow the instructions in the NOFO. This section should not just be a list of activities, but a fully individualized plan for the applicant.
- **Institutional Environment and Commitment to Training Section:** Follow the instructions in the NOFO. There are several required elements for this section.

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

- **Item 12, Start Date:** Refers to the start of the F99 phase
- **Item 12, End Date:** Refers to the end of the K00 phase
- **Item 15, Estimated Project Funding:** An estimate that covers both phases; see the NOFO

### ***F.220 - R&R Other Project Information***

- **Item 7, Project Summary/Abstract:** Address both phases
- **Item 8, Project Narrative:** Address both phases

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

- Applicants must use the Predoctoral Biosketch form. Applicants must include the start date (month and year) of all education/training experiences.
- In the "Personal Statement" section, applicants should follow the instructions labeled "applicants for dissertation research awards" and include a description of their career goals, their intended career trajectory, and their interest in the specific areas of research supported by the INCLUDE Project. When relevant, applicants are encouraged to account for factors that affected past productivity.
- Under the section "Scholastic Performance," applicants should list undergraduate courses, but should not include undergraduate grades. Graduate courses and grades must be included.
- 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.
- In the "Personal Statement" section, the sponsor and any co-sponsors should include a statement describing their mentoring and training philosophy, including commitment to diversity and inclusion in their training environments.

### ***F.430 - PHS Fellowship Supplemental Form***

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

- **Item 8. Training in the Responsible Conduct of Research:** Required; limited to 1 page. Remember to address each of the 5 required components.
- **Item 9. Sponsor and Co-Sponsor Statements:** The 6-page limit is the total for the sponsoring team (not 6 pages per sponsor)

- **Vertebrate Animals:** Include if applicable to the F99-phase research. Follow [current NIH Guidelines](#) and include a Vertebrate Animal Section in the application.
  - Institutional Animal Care and Use Committee (IACUC) approval is needed before an award can be made, but not before the application is submitted.
- **Item 15. Resource Sharing Plan:** This is a REQUIRED element for all NIH Fellowship applications. Include a plan that covers the F99 phase and addresses the following:
  - NIH policy that the results and accomplishments of the activities it funds should be made available to the public
  - The special guidance for research involving special topics such as model organisms
- **Item 24. Authentication of Key Biological and/or Chemical Resources:** If applicable to the F99 phase, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. A maximum of one page is suggested.
- **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 the NOFO, to estimate the total budget.
  - If an award is made, the 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.
  - F99 applicants may request \$2,500 per budget period for costs of childcare provided by a licensed childcare provider. See full instructions in [NOT-OD-21-074](#)

### ***F.500 - Human Subjects and Clinical Trials Information***

You, your sponsor, and your grants manager should read the instructions for this section carefully.

- Include this section if applicable to the F99-phase research only, not the K00 phase.
- Institutional Review Board (IRB) approval is needed before an award can be made, but not before an application can be submitted.
- Follow [current NIH guidelines](#), read the FAQs, and then include the Human Subjects section in your application, if appropriate.
- Common mistakes involve the E4 exemption status and [human specimens, cell lines, or data](#). Visit the NIH Office for Human Research Protections (OHRP) website for guidance.
  - If specimens were not collected specifically for your project and nobody involved with the research\* has 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 viewed as being 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.