Opportunity Title: FDA Developmental Safety Fellowship
Opportunity Reference Code: FDA-CDER-2026-0006

Organization U.S. Food and Drug Administration (FDA)

Reference Code FDA-CDER-2026-0006

How to Apply ***To submit your application, scroll to the bottom of this opportunity and click APPLY.***

A complete application consists of:

- An application
- Transcripts – Click here for detailed information about acceptable transcripts
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- One educational or professional recommendation

All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.CDER@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 4/30/2026 3:00:00 PM Eastern Time Zone

Description ***Applications will be reviewed on a rolling-basis.**

FDA Office and Location: A research opportunity is available in the Office of Clinical Pharmacology (OCP), Office of Translational Sciences (OTS) at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), located in Silver Spring, Maryland.

The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. These efforts cover more than just medicines.

Research Project: Pediatric developmental safety studies in drug development have been restricted to juvenile animal studies for the past 20 years. The FDA program to reduce, refine and replace animal studies has stimulated an important discussion about both increasing the effectiveness of pediatric developmental safety studies and utilizing non-animal resources through new approach methodologies (NAMs). This project will involve review of the 750 secondary pharmacology targets submitted to the FDA by industry during their IND phase, and assessment of those targets for association with pediatric development so that a database of potential pediatric developmental secondary pharmacology targets can be developed.

Under the guidance of the mentor(s), the selected fellow will: - in addition to the project, the fellow will participate a variety of educational activities, such weekly journal club meetings and project meetings, to better understand pediatric drug development and clinical pharmacology

concepts. The fellow will be able to observe, but not participate in, the regulatory review process.

Learning Objectives: Under the guidance of the mentor(s),you will develop the following skills during the fellowship; (1) data collection and analysis, (2) clinical pharmacology and statistical tools used for data analysis; (3) modeling and simulation related to quantitative systems pharmacology in the quantitative analysis of secondary targets, (4) develop a qualification and validation system for the secondary targets related to developmental safety; (5) presentation and organizational skills through weekly journal club meetings and project meetings; (6) gain a better understanding of pediatric drug development and clinical pharmacology concepts; and (7) you will be able to observe, but not participate in, the regulatory review process. All of these skills are critical to be an effective reviewer and for understanding drug safety which is a critical part of FDA's public health mission.

Mentor: The mentor for this opportunity is Gilbert Burckart (Gilbert.Burckart@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor(s).

Anticipated Appointment Start Date: June 2026. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for one year but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is full time.

Participant Stipend: The participant will receive a monthly stipend commensurate with educational level and experience.

Citizenship Requirements: This opportunity is available to U.S. citizens, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the Guidelines for Non-U.S. Citizens Details page of the program website for information about the valid immigration statuses that are acceptable for program participation.

This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals,

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including non-US Citizens, who have resided in the US for a total of three of the past five years.

FDA Ethics Requirements

If an ORISE Fellow, to include their spouse and minor children, reports what is identified as a Significantly Regulated Organization (SRO) or prohibited investment fund financial interest in any amount, or a relationship with an SRO, except for spousal employment with an SRO, and the individual will not voluntarily divest the financial interest or terminate the relationship, then the individual is not placed at FDA. For additional requirements, see FDA Ethics for Nonemployee Scientists.

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications The qualified candidate should have received or be currently pursuing a doctoral degree in one of the related fields. Degree must have been received within the past five years, or is anticipated to be completed by June 30, 2027.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 6/30/2027 11:59:00 PM.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (2 👁)
  - **Life Health and Medical Sciences** (14 👁)

Affirmation I am a U.S. citizen, or I have lived in the United States for at least 36 out of the past 60 months. (36 months do not have to be consecutive.)
and
I have read the FDA Ethics Requirements.