Opportunity Title: FDA Nonclinical Data and Drug Safety Regulatory Research Fellowship
Opportunity Reference Code: FDA-CDER-2026-0133

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

Reference Code FDA-CDER-2026-0133

How to Apply ***Connect with ORISE...on the GO!*** Download the new ORISE GO mobile app in the Apple or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

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 8/28/2026 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 Translational Sciences (OTS) Office of Clinical Pharmacology (OCP) Division of Applied Regulatory Science (DARS) at the Center for Drug Evaluation and Research (CDER) of the U.S. Food and Drug Administration (FDA) located in Silver Spring, MD.

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. This effort covers more than just medicines.

Research Project: This research project will examine the use of nonclinical in vitro studies to evaluate drug safety and support regulatory decision-making. Research involves using state-of-the-art automated patch clamp electrophysiology to assess mechanisms of drug effects on cardiac and neuronal ion channels critical for safety evaluation. Additionally, the research will include advanced statistical modeling for data analysis and developing comprehensive databases to systematically evaluate the current landscape of in vitro data utilization in drug development.

This research will contribute to the development of innovative translational strategies to facilitate leveraging in vitro data and cutting-edge scientific information to yield regulatory solutions that directly impact human health and drug development efficiency. Results will advance FDA's regulatory science mission and public health objectives while promoting the 3Rs principles (replacement, reduction, and refinement) of animal use during drug development.

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Learning Objectives: Under the guidance of a mentor, you will have Opportunities for engagement and collaboration with internal FDA scientists and regulators, external academic researchers, and industry stakeholders. During the appointment, you will gain comprehensive knowledge of FDA regulatory policies and regulations regarding the evaluation of safety and efficacy of new drugs, along with hands-on experience in regulatory science methodologies. The appointment will also allow opportunities to present research results at internal and external scientific conferences and participate in writing high-impact scientific manuscripts will be available.

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

Anticipated Appointment Start Date: 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, 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

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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 be currently pursuing or have received a doctoral degree in one of the relevant fields.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Doctoral Degree.
- **Discipline(s):**
  - **Engineering** (29)
  - **Life Health and Medical Sciences** (51)

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.