Opportunity Title: FDA Clinical Research Fellowship
Opportunity Reference Code: FDA-CDER-2026-0023

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

Reference Code FDA-CDER-2026-0023

How to Apply ***Connect with ORISE...on the GO!*** Download the new ORISE GO mobile app in the Apple App Store 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 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 within the Division of Applied Regulatory Science (DARS), Office of Clinical Pharmacology (OC), Office of Translational Science (OTS), Center for Drug Evaluation and Research (CDER), at the 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. This work covers more than just medicines.

Research Project: DARS is uniquely positioned within CDER to conduct integrated clinical research covering clinical pharmacology, experimental medicine, and post-market analyses. Through this research project, the participant will collaborate with mentors to investigate critical questions spanning three interconnected research areas: translational safety biomarkers and clinical trial methodologies, emerging substances of public health concern and pharmacological interactions, and safety evaluation of widely used over the counter (OTC) and generic drugs. Specific aspects of the current project are related to effects of THC and alcohol alone or in combination on driving impairment and perception. Through this hands-on research experience, the participant will help advance regulatory science by developing innovative methodologies and generating real-world evidence that enhances FDA's ability to protect and promote public health. Results from this research would directly inform discussions with other regulatory agencies on how co-use should be evaluated for impairment.

Learning Objectives: The fellowship will provide structured learning opportunities in clinical pharmacology, pharmacokinetics, regulatory science methodology, and translational research design. The participant will develop competencies in good clinical practice (GCP) standards,

clinical trial ethics, protocol development, pharmacokinetic data analysis, and research writing and dissemination. Under the guidance of a mentor, the participant will learn about reviews of the literature, designing clinical studies and analysis plans, as well as learn to perform analyses on clinical data available to the FDA. In addition, the participant will be given the opportunity to write and publish scientific manuscripts and present findings internally and externally. Training will encompass both didactic components and hands-on clinical trial design involvement. The participant will have opportunities to participate in interdisciplinary team meetings, scientific seminars, and collaborative discussions with clinical investigators across CDER. The participant will also contribute to clinical pharmacology studies and post-market surveillance research that provides the scientific evidence base for drug approvals, labeling updates, and safety communications.

Mentor: The mentor for this opportunity is Pablo Salcedo (pablo.salcedo@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 and Lawful Permanent Residents (LPR) only.

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 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

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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 a doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Knowledge in clinical pharmacology, clinical study design, clinical study analysis, literature review, and epidemiology is preferred.

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (2 👁)
  - **Life Health and Medical Sciences** (51 👁)

Affirmation 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.)