Opportunity Title: FDA CDER Summer 2025 Research Participation Program
Opportunity Reference Code: FDA-CDER-2025-0000

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

Reference Code FDA-CDER-2025-0000

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 4/18/2025 3:00:00 PM Eastern Time Zone

Description ***Although the application deadline is April 18th, 3p ET however mentors will start reviewing submitted applications before the deadline.**

FDA Center and Location: Summer research opportunities are available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER). On-site participation engagement in the summer opportunity is encouraged at the FDA facilities in the Silver Spring, Maryland or St. Louis, Missouri area in alignment with the Mentor's on-site reporting schedule. *Off-site and alternate locations may be approved at the mentor's discretion.*

Research Project: 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 FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. CDER's mission is to protect and promote health by helping to ensure that these human drugs are safe and effective for their intended use, that they meet established quality standards, and that they are available to patients who need them.

Learning Objectives: Participants will have an opportunity to gain hands-on research experience on a variety of regulatory research projects related to CDER's mission. The program is designed for participants to engage with an expert mentor or mentors during the summer to examine a question of interest related to those projects within the placement office. Past projects have been related to: drug metabolism, bio-statistical questions, in-vitro models for drug toxicology, safety and efficacy, benefit-risk assessments, etc.

Appointment Length: The appointment is for 2-3 months.

Level of Participation: Both full-time and part-time appointments are typically available.

Anticipated Start Date: Anticipated start day is on or around May 1, 2025, but can be negotiated with the mentor to commence on any Monday throughout the summer in order to best align with school and/or vacation schedules.

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To avoid conflict of interest, participants cannot be placed in the same CDER program office where a relative works.

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 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

These opportunities are open to currently enrolled university students (all levels) and recent graduates (post-baccalaureate, post-master's, or postdoctoral) who have graduated within the past 60 months of the start date. Demonstrated excellence in science-related courses is preferred.

Eligibility Requirements

- **Degree:** High School Diploma/GED, Associate's Degree, Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (7 👁)
  - **Communications and Graphics Design** (2 👁)
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Engineering** (12 👁)
  - **Environmental and Marine Sciences** (3 👁)
  - **Life Health and Medical Sciences** (46 👁)
  - **Mathematics and Statistics** (10 👁)

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- **Other Non-Science & Engineering** (2 👁)
- **Physics** (3 👁)
- **Science & Engineering-related** (1 👁)
- **Social and Behavioral Sciences** (10 👁)

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.)

I have read the FDA Ethics Requirements.