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

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

Reference Code FDA-CDRH-2025-Summer

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. Your application will be considered incomplete and will not be reviewed until one recommendation is submitted.

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

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

Application Deadline 6/30/2025 11:59:59 PM Eastern Time Zone

Description ***Although the application deadline is June 30th, mentors will start reviewing submitted applications before the deadline.**

FDA Office and Location: Summer research opportunities are available at the U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH) located in Silver Spring, Maryland.

Research Project: The Oak Ridge Institute for Science and Education (ORISE) Research Participation Programs at the U.S. Food and Drug Administration are educational and training programs designed to provide students and recent graduates, opportunities to participate in project-specific research and developmental activities at the Center for Devices and Radiological Health (CDRH).

The mission of CDRH is to protect and promote the public health. CDRH assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. CDRH provides consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. CDRH facilitates medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

Participants will have an opportunity to gain a hands-on research experience on a variety of regulatory research projects related to CDRH'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; evaluation of acoustic noise levels in neonate, tools for regulating 21st-century microbubble products for pharmaceutical delivery, biological sex differences in the safety of vagus nerve stimulation, bioprinting materials performance assessment, microelectrode array recordings from induces pluripotent stem cell-derived neurons, machine learning in image reconstruction, and optical performance characterization of mixed reality devices.

Learning Objectives: The learning objectives will be related to the specific assigned project and could include learning the scientific method and its application, experimental design and execution, in vitro culture techniques, different sensing and monitoring techniques, performing statistical analyses, benchmark testing, advanced techniques for analyzing data, interpreting results, and drawing scientifically sound conclusions.

Anticipated Appointment Start Date: Anticipated start day is on or around May 12, 2025 but can be negotiated with the mentor to commence on any Monday throughout the summer in order to best align with school schedules.

To avoid conflict of interest, participants cannot be placed in the same CDRH program office where a relative is employed.

Appointment Length: The appointment will be 2-3 months.

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

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. The appointment is part-time or full-time at FDA in the Silver Spring, Maryland area. 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.

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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) at least 18 years of age and recent graduates who have graduated within the past 60 months of the start date. Demonstrated excellence in science-related courses is preferred.

Eligibility Requirements

- **Degree:** 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** (12 👁)
  - **Communications and Graphics Design** (2 👁)
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Earth and Geosciences** (21 👁)
  - **Engineering** (27 👁)
  - **Environmental and Marine Sciences** (14 👁)
  - **Life Health and Medical Sciences** (48 👁)
  - **Mathematics and Statistics** (11 👁)
  - **Physics** (16 👁)
  - **Science & Engineering-related** (1 👁)
  - **Social and Behavioral Sciences** (29 👁)
- **Age:** Must be 18 years of age

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.