

Opportunity Title: Research Participation Opportunities at the FDA Center for

Devices and Radiological Health (CDRH)

Opportunity Reference Code: FDA-CDRH-2023-General

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

Reference Code FDA-CDRH-2023-General

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!

This is an open announcement to collect applications for future research opportunities. A complete

- 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.CDRH@orau.org. Please include the reference code for this opportunity in your email.

Description The Oak Ridge Institute for Science and Education (ORISE) Research Participation Programs at the U.S. Food and Drug Administration (FDA) 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 FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. 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 overseen by CDRH. 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.

> This is an open announcement to collect applicants for future research opportunities. The opportunities include full-time, part-time, and summer appointments at CDRH located in Silver Spring, Maryland.

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. Appointments can vary from a few months to one year, but may be renewed for up to five years upon recommendation of FDA, contingent on the availability of funds. 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.

See https://orise.orau.gov/fda/default.html or https://www.fda.gov/ for more information.

Completion of a successful background investigation by the Office of Personnel Management is



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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 Applicants must be enrolled as an undergraduate, graduate, or doctoral student at an accredited U.S. college or university pursuing a degree in a STEM discipline or have received an undergraduate, graduate, or doctoral degree within five years of the start date of the appointment.

> Generally, participants are not required to hold U.S. citizenship; however, a few CDRH divisions may appoint only U.S. citizens due to the sensitive nature of the research performed.

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 (11 👁)
 - Communications and Graphics Design (1...)
 - Computer, Information, and Data Sciences (11 ⑤)
 - Engineering (19 •)
 - Life Health and Medical Sciences (24 ♥)
 - Mathematics and Statistics (10.
 - Physics (<u>16</u> ●)
 - Science & Engineering-related (1)

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.)

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