Opportunity Title: FDA Research Opportunity - Pediatric and Perinatal Devices
Opportunity Reference Code: FDA-CDRH-2026-0020

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

Reference Code FDA-CDRH-2026-0020

How to Apply ***To submit your application, scroll to the bottom of this opportunity and click APPLY.***

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

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!

Application Deadline 9/30/2027 3:00:00 PM Eastern Time Zone

Description ***Applications will be reviewed on a rolling-basis.**

FDA Office and Location: 15 research opportunities are available immediately with the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), located in Silver Spring, Maryland.

Oak Ridge Institute for Science and Education (ORISE) Research Participation Programs at the U.S. Food and Drug Administration are educational training programs designed to provide students and recent graduates, opportunities to participate in project-specific research and developmental at the Center for Devices and Radiological Health (CDRH). The mission of CDRH is to protect and promote 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, caregivers, and providers with understandable and accessible science-based information about products. 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.

Research Project: The Pediatric and Perinatal Devices Program within the FDA's Center for Devices and Radiological Health (CDRH) conducts regulatory science research aimed at advancing the development and evaluation of medical devices for pediatric and perinatal populations. This research initiative focuses on developing and validating specialized tools to assess device performance in conditions unique to pediatric and perinatal

care. Such tools include non-clinical testing methods, curated datasets, physical phantoms, and computational models. By addressing gaps in existing evaluation approaches, the program seeks to improve regulatory decision-making and facilitate the timely availability of appropriately designed medical devices for these vulnerable populations.

Learning Objectives: Under the guidance of a mentor, you will:

- Learn to conduct regulatory science research within the FDA's Center for Devices and Radiological Health (CDRH), focused on pediatric and perinatal medical devices.
- Gain experience developing and validating specialized evaluation tools to assess device performance in pediatric and perinatal care settings.
- Develop skills in designing non-clinical testing methods, including the creation and use of curated datasets, physical phantoms, and computational models.
- Learn to identify and address gaps in current device evaluation approaches specific to pediatric and perinatal populations.
- Contribute to improving regulatory decision-making by generating evidence that supports the safe and effective use of medical devices in vulnerable populations.
- Strengthen understanding of the regulatory framework guiding the development and evaluation of pediatric and perinatal medical devices.

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

Anticipated Appointment Start Date: 2026/2027. 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

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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 The qualified candidate should be currently pursuing or have received an associate's, bachelor's, master's, or doctoral degree in the one of the relevant fields.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Associate's Degree, Bachelor's Degree, Master's Degree, or Doctoral Degree.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Communications and Graphics Design** (2 👁)
  - **Computer, Information, and Data Sciences** (17 👁)

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- **Earth and Geosciences** (21 👁)
- **Engineering** (29 👁)
- **Environmental and Marine Sciences** (14 👁)
- **Life Health and Medical Sciences** (51 👁)
- **Mathematics and Statistics** (11 👁)
- **Physics** (16 👁)
- **Science & Engineering-related** (2 👁)
- **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.