Opportunity Title: FDA-OSEL Research Fellowship in Pediatric Artificial Intelligence Device Evaluation
Opportunity Reference Code: FDA-CDRH-2024-0013

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

Reference Code FDA-CDRH-2024-0013

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

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

FDA Office and Location: A research opportunity is available in the Office of Science and Engineering Laboratories (OSEL), within the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) located in White Oak, Maryland, **with the potential to be remote.**

Research Project: The selected fellow will participate in a research project funded by an intramural FDA Critical Path Award. The fellow will collaborate closely with a multidisciplinary research group (engineers, physicists, mathematicians, clinicians, and statisticians) on developing regulatory science methods and tools to support regulatory evaluation of artificial intelligence (AI)-based computer aided detection and triage devices in pediatric and other under-represented groups. The research will involve analysis of patient computed tomography (CT) data and modeling of human anatomy and pathology as well as deep learning algorithm design and validation leveraging virtual imaging trials. The selectee will be appointed as an ORISE Fellow at the DIDSR/OSEL/CDRH/FDA laboratories. Extensive opportunities for training and teaching in the metro DC area.

Learning Objectives: This research will facilitate learning about the assessment of image-based artificial intelligence (AI) devices used in radiology as well as objective and task-based assessments of image quality. The participant will also learn about the design and simulation of x-ray imaging systems including CT and its impact on image quality and AI device performance. The participant will also learn about the key anatomy, pathology, and imaging practices relevant to both adult and pediatric to neuroimaging. This will culminate in the development of virtual imaging trials to evaluate AI devices used in neuroimaging and their performance differences in adult and pediatric patients. The research effort will be summarized in conference and journal publications for which the ORISE

fellow will get authorship recognition.

Anticipated Appointment Start Date: May 2024. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for two years, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is full time.

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 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 a master's or doctoral degree in the one of the relevant fields (computer science, physics, electrical engineering, biomedical engineering, medicine, or applied mathematics).

Preferred skills:

Preferred candidates should have demonstrated academic or professional experience with some of the following:

- Medical image reconstruction or analysis in CT, PET/SPECT, or MRI.
- Developing and analyzing machine learning and deep learning methods,
- Computational modeling of patient anatomies and simulation of x-ray imaging systems
- Statistical and objective image quality assessment
- Programming with Python and deep learning frameworks (TensorFlow, PyTorch, etc.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree.
- **Academic Level(s):** Graduate Students, Postdoctoral, or Post-Master's.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17)
  - **Engineering** (27)
  - **Life Health and Medical Sciences** (51)
  - **Mathematics and Statistics** (11)
  - **Other Non-Science & Engineering** (1)
  - **Physics** (16)

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.)

I have read the FDA Ethics Requirements.