Opportunity Title: FDA Biomedical/Electrical/Mechanical Engineer Research Fellowship
Opportunity Reference Code: FDA-CDRH-2023-14

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

Reference Code FDA-CDRH-2023-14

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 12/31/2023 3:00:00 PM Eastern Time Zone

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

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 Silver Spring, Maryland.

The candidate will join a research team studying regulatory science questions to advance new patient monitoring and physiological closed-loop controlled medical devices. The candidate will collaborate closely with other team members on a project to study and determine best practices in the design, evaluation, and use of patient specific models (e.g., physiological models of the respiratory system) for medical device testing. Candidates will be involved with and learn about developing computational modeling and simulation methods for testing physiological closed-loop controlled medical devices, writing and maintaining software documentation, developing scientific manuscripts, and contributing to future research study design.

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 initial appointment is for one year, but may be renewed 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. The appointment is full-time on-site for laboratory research 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.

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Completion of a successful background investigation by the Office of Personnel Management (OPM) 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 have received a master's or doctoral degree in one of the relevant fields (e.g. Biomedical Engineering, Electrical Engineering, Mechanical Engineering), or be currently pursuing one of the degrees with completion before the appointment start date. Degree must have been received within the past five years.

Preferred skills/experience:

- A strong interest in biomedical research career
- Strong technical background and experience in signal processing, system identification, control system design and analysis, estimation theory in physiology, computational modeling and simulations of physiological and/or medical device systems
- Experience in one or more of the following:
  - Designing, evaluating, and implementing simulations of computational physiologic systems models
  - Computational analysis of physiologic signals (e.g., respiratory variables)
- Excellent programming skills in high level languages (e.g., Matlab / Python) and software for system modeling, simulation, and testing (e.g., Simulink / LabView)
- Background or research experience in cardiorespiratory physiology
- Strong communication and writing skill

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 12/31/2023 11:59:00 PM.
- **Discipline(s):**

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- **Computer, Information, and Data Sciences** (1 👁)
- **Engineering** (7 👁)
- **Life Health and Medical Sciences** (6 👁)
- **Mathematics and Statistics** (2 👁)

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.