Opportunity Title: FDA Fellowship on Identifying Sex Disparities in Opioid Drug Safety Signals in FAERS
Opportunity Reference Code: FDA-OWH-2023-07

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

Reference Code FDA-OWH-2023-07

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.

Application Deadline 7/31/2023 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available with the Office of the Commissioner (OC) Office of Women's Health (OWH), U.S. Food and Drug Administration (FDA). The project will be located at the Division of Bioinformatics and Biostatistics (DBB) within the National Center for Toxicological Research (NCTR), Food and Drug Administration (FDA) located in Little Rock, Arkansas.

The use of opioid drugs for pain treatment is widespread in the United States, with women being significantly impacted by its use. Opioid-related overdose deaths in women have increased tenfold from 1999 to 2020, while the rate in men increased by eightfold. Therefore, understanding how women respond to opioid drugs, especially with regard to adverse events, is crucial for the development of opioid drugs that have a low potential for adverse events. This project aims to investigate the sex differences in opioid-related adverse events using real-world data sources, including social media and the FDA Adverse Event Reporting System (FAERS) using different statistical methods.

Anticipated Appointment Start Date: June 19, 2023; start date is flexible.

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 Little Rock, Arkansas, 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 or be currently pursuing a doctoral degree in one of the relevant fields (e.g. bioinformatics, computational biology, mathematics, statistics, public health, chemical engineering, toxicology, systems biology/pharmacology, biophysics) with an emphasis on modeling and scientific computing. Degree must have been received within the past five years. A history of peer-reviewed publications is referred.

Preferred skills include:

- A strong background in Python, R programming languages
- Machine Learning
- Computational modeling
- Scientific computing
- Text mining

Must meet security requirements including a minimum of 3 out of the past 5 years with residency status in the US.

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Engineering** (27 👁)
  - **Life Health and Medical Sciences** (48 👁)

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- **Mathematics and Statistics** (11 👁)

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.