

Opportunity Title: FDA Drug Abuse Epidemiology Fellowship

Opportunity Reference Code: FDA-CDER-2019-0427

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

Reference Code FDA-CDER-2019-0427

How to 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. 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.CDER@oraui.org. Please include the reference code for this opportunity in your email.

Application Deadline 12/31/2019 3:00:00 PM Eastern Time Zone

Description A research opportunity is available in the Office of Surveillance and Epidemiology/Office of Pharmacovigilance and Epidemiology, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

This project in The Office of Surveillance and Epidemiology/Office of Pharmacovigilance and Epidemiology will address the need for additional resources to develop surveillance protocols and leverage available data sources for identifying concerning rises in rates of abuse, misuse, and overdose of FDA-regulated products over time. This project will facilitate evidence-based regulatory decision making to address the opioid crisis and any new signals of abuse of other FDA-regulated products. In addition, FDA needs to train epidemiologists in methods for assessing risks of drug abuse and in using unique data sources for assessing risks of drug abuse to facilitate future advances in drug abuse epidemiology.

Under the guidance of a mentor the participant will receive training in:

- Contributing to the development of a surveillance protocol to identify risks of misuse, abuse, and overdose related to FDA-regulated products utilizing available data resources such as poison control calls, death certificate literal text, emergency department visits, and treatment center surveys
- Conducting analysis for surveillance of selected FDA-regulated drugs for outcomes of misuse, abuse, and overdose using the developed surveillance protocol as a proof of concept.

The participant will also attend trainings on data sources capable of identifying abuse and related outcomes. This training will prepare the participant for a successful career transition into regulatory science research - training he/she cannot obtain elsewhere.


***Although the application deadline is December 31, applications will be reviewed on a rolling-basis.**


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




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insurance is required for participation in this program. The appointment is full-time 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.

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 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 one of the relevant fields. Degree must have been received within five years of the appointment start date.

Previous training in drug abuse epidemiology is preferred.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
 - **Life Health and Medical Sciences** ([3](#))
 - **Mathematics and Statistics** ([1](#))