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Opportunity Title: FDA Program, Policy and Operational Analysis Fellowship
Opportunity Reference Code: FDA-CDER-2019-0423

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

Reference Code FDA-CDER-2019-0423

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@orau.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 Strategic Programs/Office of Program & Strategic Analysis, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

This project in The Office of Strategic Programs (OSP) /Office of Program & Strategic Analysis (OPSA) will support and analyze a broad range of proposed and current CDER programs and policies by conducting quantitative and qualitative analyses to address operational needs. OPSA assesses the impact and efficiency of CDER initiatives and programs, designs and implements new programs, advances structured benefit-risk assessment in regulatory decision making and evaluates key business processes using an evidence-based approaches that assess the value of each step and leads to sustained practical solutions for complex problems. OPSA's work informs and influences organizational strategy and decision-making by senior management and serves as key input into decision-making around the related program, policy or operational issue.

Under the guidance of a mentor the participant will be trained on: conducting background research related to a policy or data need identified by the mentor, participating in the development of research methodology and project plan through contributing to relevant research, compiling and analyzing relevant qualitative and quantitative data, and synthesizing and presenting findings. This training is critical to our public health mission and will prepare the participant for a successful career transition into regulatory science research.

***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 insurance is required for participation in this program. The appointment can be full-time or part-time (20 hours per week), at the participant's discretion, 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 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 bachelor's, master's or doctoral degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Strong analytical skills are strongly desired.

Eligibility Requirements

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (16 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)
  - **Mathematics and Statistics** (10 👁)
  - **Social and Behavioral Sciences** (1 👁)