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

3/31/2020 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 New Drugs/Immediate Office, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

This project in the Office of New Drugs/Immediate Office will research and develop novel, user-friendly software solutions to facilitate the review of toxicology study data by FDA CDER pharmacology/toxicology reviewers. The methods developed may potentially be incorporated into existing software tools or a new platform may be developed to deploy and maintain these custom SEND data analysis/visualization tools. The project will enhance the ability of FDA/CDER reviewers to leverage electronic SEND datasets to improve both the thoroughness and efficiency of their review process.

Under the guidance of a mentor the participant will be trained on the following topics:

- The fundamentals of how FDA/CDER reviewers interpret toxicology study results
- The SEND data standard and how it maps onto toxicology study design and results
- Development of R scripts to analyze and visualize toxicology study results encoded in SEND datasets
- Deployment of R Shiny-based web applications to aid in the analysis and visualization of toxicology study data

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 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 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.

Preferred skills:

- Strong organizational, analytical, interpersonal, and research skills in biology, pharmacology, toxicology, or a related field of biomedical science
- Familiarity with R, Python, MATLAB, Perl, JavaScript, Java, or a similar programming language to analyze and visualize scientific data; and
  R to develop interactive data visualization applications via the Shiny package

**Eligibility Requirements**

- **Degree:** Master’s Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - Computer Sciences (5)
  - Life Health and Medical Sciences (4)
  - Mathematics and Statistics (1)