

Opportunity Title: FDA Surveillance of Biologics Monitored by the Sentinel/BEST Initiative

Opportunity Reference Code: FDA-CBER-2019-0034

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

Reference Code FDA-CBER-2019-0034

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.CBER@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 *Applications will be reviewed on a rolling-basis.

A research opportunity is available in the Office of Biostatistics and Epidemiology (OBE) at the Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA) located in Silver Spring, Maryland.

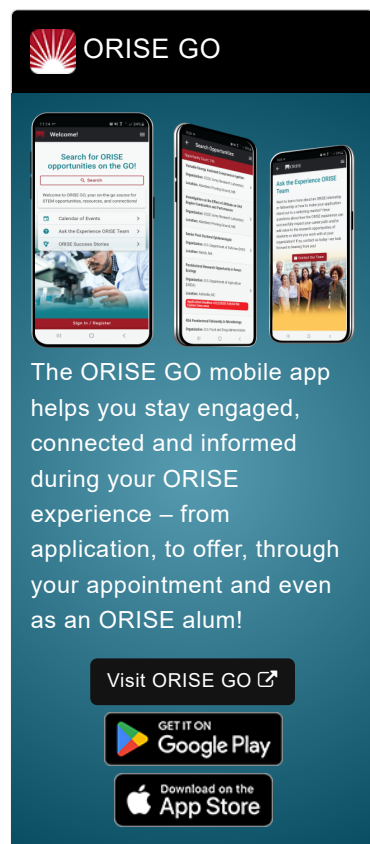
The participant will receive mentoring in the development of safety and effectiveness monitoring activities of multiple biologic products. This fellowship will focus on the design, execution, and interpretation of safety and effectiveness monitoring and assessment of biologics including vaccines, blood components, blood-derived products, tissues and advanced therapies by utilizing large health care databases. The fellowship program will include multi-disciplinary collaborations with investigators within and external to CBER and FDA including academic institutions and other government agencies. The program will provide training and mentorship in fields of pharmacoepidemiology and regulatory science among other disciplines.

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.

The Homeland Security Presidential Directive-12 (HSPD-12) mandates a background check be completed for both U.S. Citizens and foreign nationals. Foreign nationals must have resided in the U.S. for at least three (3) of the past five (5) years in order for FDA to be able to complete a background check.


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;




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- 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 doctoral degree in one of the relevant fields, or be currently pursuing the degree and will reach completion by the end of July 2019. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Experience and knowledge in epidemiologic research of infectious and non-infectious diseases
- Experience in epidemiologic and statistical methods implementation
- Strong analytical and quantitative skills
- Solid writing competency
- Advanced oral and written communications skills

- Eligibility Requirements**

 - **Citizenship:** LPR or U.S. Citizen
 - **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 7/31/2019 12:00:00 AM.
 - **Discipline(s):**
 - **Communications and Graphics Design** (1👁)
 - **Environmental and Marine Sciences** (1👁)
 - **Life Health and Medical Sciences** (45👁)
 - **Mathematics and Statistics** (10👁)