

Opportunity Title: FDA Summer Biostatistical Research Fellowship

Opportunity Reference Code: FDA-CDER-2020-0002

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

Reference Code FDA-CDER-2020-0002

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 5/15/2020 3:00:00 PM Eastern Time Zone

Description *Applications will be reviewed on a rolling-basis. The preferred/preferential application deadline for this program is March 13, 2020. However, if additional opportunities remain beyond this date, applications will continue to be accepted through May 15, 2020.

The Office of Biostatistics (OB) in the Center for Drug Evaluation and Research (CDER) at the US Food and Drug Administration (FDA) is recognized for excellence in the application and communication of statistical science in drug regulation and development. We play a central role in promoting innovative, science-based quantitative decision making throughout the drug development life cycle. We provide statistical leadership, expertise and advice to foster the expeditious development of safe and effective drugs and therapeutic biologics for the American people.

We anticipate having multiple training opportunities available for advanced graduate students in Statistics or Biostatistics from May 26, 2020 through August 28, 2020, to engage in research projects on topics relevant to OB scientific needs. Participants will gain hands-on experience with regulatory research projects under the guidance of an expert OB mentor, utilizing real or simulated data, in a stimulating, collaborative, and supportive environment. Some past research project areas have included: modeling and simulation, missing data, non-inferiority trials, multiple endpoints, adaptive designs, Bayesian design and analysis methods, meta-analyses, benefit-risk analyses, subgroup analyses, biosimilars, and data-mining. Participants have been involved in contributing to development of statistical methods, software tools, and new drug application databases for the analyses of pre-clinical as well as pre- and post-market clinical 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 appointment is for three months, beginning May 26, 2020 through August 28, 2020. 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



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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 a master's or doctoral degree in one of the relevant fields, or have received a master's degree. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Strong problem-solving and computational skills
- Creativity and innovation
- Self-management skills
- Proficiency with Microsoft Office
- Programming experience with SAS and/or R

Eligibility • **Degree:** Master's Degree or Doctoral Degree.

Requirements • **Discipline(s):**

- **Life Health and Medical Sciences** ([1](#) )
- **Mathematics and Statistics** ([10](#) )

Affirmation I am currently pursuing a master's or doctoral degree, or have received a master's degree within the past five years.