Opportunity Title: FDA Biostatistical Research Fellowship
Opportunity Reference Code: FDA-CDER-2020-0583

Organization	U.S. Food and Drug Administration (FDA)
Reference Code	FDA-CDER-2020-0583
How to Apply	***Connect with ORISE...on the GO!*** Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

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	3/31/2021 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 Translational Sciences/Office of Biostatistics (OB), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) located in Silver Spring, Maryland.

The FDA's Comprehensive In Vitro Proarrhythmia Assay (CiPA) initiative represents a new paradigm to improve the specificity of proarrhythmic risk assessment of new drugs. There has been great progress in this area including in-silico models, human-induced pluripotent stem cell-derived cardiomyocytes (hiPSC-CMs), and different animal proarrhythmia models. However, there is still a lack of quantitative approaches to link the many observations in these biological models to the high, medium, and low risk categories of drugs in humans.

Under the guidance of a mentor, the participant will research statistical methodologies in quantifying model predictive ability and validating the fitted statistical models. In addition, the participant will become familiar with CiPA.

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 seven months, 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 part-time (20 hours per week) 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;
- 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 doctoral degree in statistics or biostatistics.

Preferred skills:

- Familiarity with Microsoft Office and programming languages such as SAS and/or R

Eligibility Requirements
- **Degree:** Currently pursuing a Doctoral Degree.
- **Discipline(s):**
  - **Mathematics and Statistics** (2 👁)