

Opportunity Title: FDA Public Health and Regulatory Research Fellowship

Opportunity Reference Code: FDA-OPHSA-2022-0001

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

Reference Code FDA-OPHSA-2022-0001

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 maximum one-page cover letter highlighting candidate's interests in the fellowship and relevant experiences
- Two writing samples – technical, research, and/or policy oriented
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- Two educational or professional recommendations

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 8/31/2022 3:00:00 PM Eastern Time Zone

Description *Applications will be reviewed on a rolling-basis.

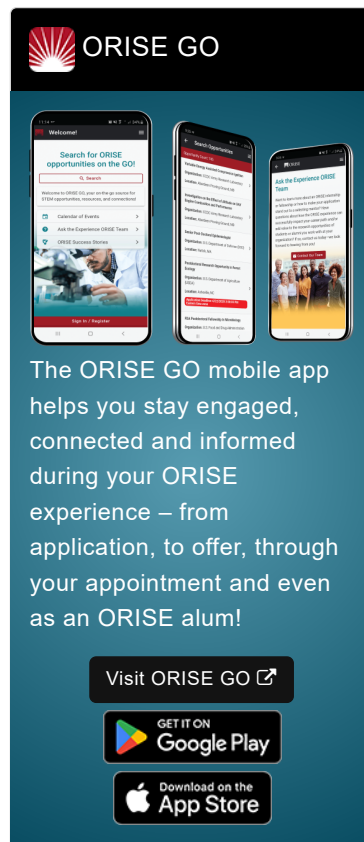
Location: A research opportunity is available at the U.S. Food and Drug Administration (FDA), Public Health Strategy and Analysis Staff (PHSA). This opportunity is located on FDA's main campus in Silver Spring, MD, but will be virtual while pandemic-related restrictions are in place. After the restrictions are lifted, the fellow will be expected to complete their fellowship in-person from FDA campus.

Research Project: PHSA conducts evidence-to-policy work via quantitative and qualitative research on emerging and priority public health issues such as health equity, drug availability and competition, and transparency. Under the guidance of a mentor, the fellow will assist on research projects to provide evidence to inform FDA's public health policy priorities. The fellow will be assigned to quantitative and qualitative research projects related to FDA's domestic and/or global regulatory research in the generic drug space. In addition to the mentor, the fellow will collaborate with subject matter experts across the FDA to accomplish project goals.

Potential projects include (but are not limited to) research and analysis of:

- Generic drug approvals and market competition
- FDA's foreign inspections of generic drug manufacturers
- The quality of drug marketing applications submitted to the FDA.

While at the FDA, the fellow will have additional learning opportunities such as attending workshops, professional conferences, high-level policy meetings with the director, staff, and FDA senior leadership as well as the opportunity to learn from other PHSA research, and to explore other parts of FDA.



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Anticipated Start Date: **October 1, 2022.** All start dates are flexible and vary depending on numerous factors.

Deadlines: The tentative deadline for applications is August 31, 2022. However, the applications for this fellowship will be reviewed on a rolling-basis, and selections may be made at any time during the review process and before the application closing deadline. Thus, early submission is strongly encouraged.

Appointment length: The fellowships are time-limited for 12-months. Extensions are not guaranteed and may only be considered depending on funding availability.

Level of Participation: The appointment is full-time.

Participant Stipend: A competitive stipend, based on FDA criteria for candidate's education level (~\$74,000 per year), is provided. In addition to the stipend, a supplement for health insurance is provided. The fellow will be eligible to obtain insurance coverage through the [ORISE health insurance plan](#), or may obtain coverage under another insurance plan from another carrier

FDA Clearance: Any fellowship offer is contingent on successful completion of FDA's required security clearance (fingerprints and background check) and satisfactory assessment for conflicts of interest. 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 of the past five years for FDA to be able to complete a background check.

Questions: Please submit any inquiries to OPHSAFellows@fda.hhs.gov.

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.

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Qualifications The qualified candidate must have received or is currently pursuing (expected within a year) a doctorate-level epidemiology, economics, or public health related degree from an accredited institution: Such as PhD, MD, PharmD, or other similar disciplines.. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Experience in quantitative research (data collection, secondary data analysis, mathematical modeling, etc.) is highly desired
- Demonstrated ability to work independently

Point of Contact [Sherry](#)

- Eligibility Requirements**
- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
 - **Discipline(s):**
 - **Computer, Information, and Data Sciences** ([5](#) 👁)
 - **Life Health and Medical Sciences** ([19](#) 👁)
 - **Mathematics and Statistics** ([4](#) 👁)
 - **Social and Behavioral Sciences** ([6](#) 👁)