

Opportunity Title: FDA Postdoctoral Fellowship in Computational Metagenomics

Opportunity Reference Code: FDA-CDRH-2023-21

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

Reference Code FDA-CDRH-2023-21

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.

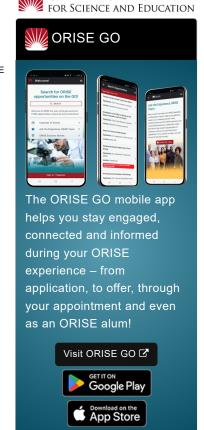
If you have questions, send an email to ORISE.FDA.CDRH@orau.org. Please include the reference code for this opportunity in your email.

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

A research opportunity is available in the Office of In Vitro Diagnostics (OHT7), within the Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration (FDA) located in Silver Spring, Maryland.

The position will engage with scientific staff in a funded project to quantify the effect of reference sequence database structure on the performance of metagenomic classification software with the objective of improving the design of reference sequence databases used.

The research will be computational in nature, using computer simulation and bioinformatic tools (including implementation of Artificial Intelligence models) to describe database features that affect rates of Type I and Type II error when applied to a standardized input of Next Generation Sequencing (NGS) data. The expected outcome of the work will include results that would contribute to FDA guidance to manufacturers developing NGS based diagnostic devices, software tools that can be used by FDA staff to rapidly evaluate reference sequence databases used by industry sponsors, and scientific publications reporting the findings. The candidate will be given creative license to work with FDA mentors to improve experimental design and explore novel objectives as they arise throughout the work. The ideal candidate with be familiar with metagenomics and NGS data analysis, able to code (e.g. python or R languages), and have a track record of scientific publication. Additional qualifications in a successful candidate include expertise in statistics, informatics and a basic understanding of Artificial Intelligence models. Candidates with an interest in the mission of FDA and how scientific breakthroughs contribute to public health will be more strongly considered.



OAK RIDGE INSTITUTE

Generated: 8/30/2024 3:10:07 AM



Opportunity Title: FDA Postdoctoral Fellowship in Computational Metagenomics

Opportunity Reference Code: FDA-CDRH-2023-21

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 two years, 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 on-site for laboratory research at FDA in the Silver Spring, Maryland, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employmentrelated benefits.

Completion of a successful background investigation by the Office of Personnel Management (OPM) 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 Ethics Requirements

If an ORISE Fellow, to include their spouse and minor children, reports what is identified as a Significantly Regulated Organization (SRO) or prohibited investment fund financial interest in any amount, or a relationship with an SRO, except for spousal employment with an SRO, and the individual will not voluntarily divest the financial interest or terminate the relationship, then the individual is not placed at FDA. For additional requirements, see FDA Ethics for Nonemployee Scientists.

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 will have received a Ph.D. from an accredited institution in the subject areas such as Bioinformatics, Genetics, Molecular Genetics, Computational Biology or a field of biology engaged in one or more of those subjects.

> Highly competitive applicants will have education and/or experience in one or more of the following:

- NGS data analysis including experience with Unix and Linux platforms.
- · Proficiency in biological statistics
- · Computational Biology including modeling and familiarity with AI models
- · A track record of scientific publication

Eligibility Requirements

- Degree: Doctoral Degree received within the last 360 month(s).
- Discipline(s):
 - Computer, Information, and Data Sciences (<u>17</u> <a>®)

Generated: 8/30/2024 3:10:07 AM



Opportunity Title: FDA Postdoctoral Fellowship in Computational Metagenomics

Opportunity Reference Code: FDA-CDRH-2023-21

- Engineering (⁴
- Environmental and Marine Sciences (1_♥)
- Life Health and Medical Sciences (<u>48</u> ●)
- Mathematics and Statistics (11 ●)
- Physics (<u>1</u>●)
- **Veteran Status:** Veterans Preference, degree received within the last 0 month(s).

Affirmation I have lived in the United States for at least 36 out of the past 60 months. (36 months do not have to be consecutive.)

and

I have read the FDA Ethics Requirements.

Generated: 8/30/2024 3:10:07 AM