Opportunity Title: FDA Botulinum Research Fellowship
Opportunity Reference Code: FDA-CFSAN-2024-0024

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

Reference Code FDA-CFSAN-2024-0024

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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

All documents must be in English or include an official English translation.

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

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

FDA Office and Location: A research opportunity is available within the Food and Drug Administration (FDA) in The Center for Food Safety and Applied Nutrition (CFSAN), Office of Regulatory Science (ORS) located in College Park, Maryland.

The Center for Food Safety and Applied Nutrition, known as CFSAN, provides services to consumers, domestic and foreign industry and other outside groups regarding field programs; agency administrative tasks; scientific analysis and support; and policy, planning and handling of critical issues related to food, dietary supplements, and cosmetics.

Research Project: The study aims to sequence 100 selected strains of C. botulinum, focusing on groups I and II, from clinical and food samples using MiSeQ, MinION, and GridION nanopore sequencers. This will improve source-tracking applications, detect serotypes or toxin sequence variants, and highlight geographical prevalence, epidemiology, and antimicrobial resistance characteristics. The study will also evaluate ID-NGS diagnostic devices for biothreat detection, promote innovation, combat global threats, and advance public health. The MinION-based pipeline could reduce genome sequencing costs and enable more laboratories to perform analyses, eliminating barriers posed by cumbersome technologies.

Participants will have an opportunity to utilize their knowledge about molecular genetics and biochemistry from their bioinformatics and/or molecular biology degree to enhance or further their career path by having a hands-on learning experience that will enable them to acquire experience they may need for future endeavors. The project would benefit from some experience with numerous DNA sequence analysis equipment/ biochemical

assay equipment and adjoining computational programs as well as other data analysis software, including proficiency with basic statistical functions of MS Excel.

Learning Objectives: The participant will receive training in the following tasks during the above-specified period. Overall, the participant will gain knowledge and experience in the broader area of regulatory science and bioanalytical research which translate in to protecting the public health through food safety and security. The participant will receive laboratory research training from the mentor during the specified period to conduct experiments as designed by the Principal Investigator, and gain hands-on experience with:

- Food or environmental sample collection, spiking, and sample preparative procedures for downstream analysis and sequencing
- Microbiological techniques (to culture and isolate anaerobic pathogens, and other microorganisms).
- Molecular biological techniques (e.g. total genomic DNA isolation using automated platforms and kits, quality, and quantity determination of nucleic acids, genomic or metagenomic library preparation, MiSeq and MinIon sequencing
- Real-time PCR; whole genome sequencing of repository strains, microbiomes and metagenomes from food and related environmental sample) for their detection and identification.
- Data analysis, Data captured in reports and presentation in meetings. Perform experiments as designed by PI, Maintaining a detailed report and present to PI. The fellow will have opportunity to travel and present data in meetings and conferences.
- The fellow would assist in laboratory hygiene maintenance, maintaining the inventory for select agent, maintaining the laboratory for safety compliance.

Anticipated Start Date: September 1, 2024.

Appointment Length: The appointment will initially be for one year, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is full time.

Citizenship Requirements: This opportunity is available to U.S. citizens only.

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 participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. 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 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 should have received a bachelor's or master's degree in one of the relevant fields. Degree must have been received within the past five years.

Preferred skills:

- Basic aseptic culture technique
- Basic microbiological culturing techniques
- Advance understanding of molecular methods such as PCR, sequencing, assay, Bio informatics

Point of Contact

Ashley Letson

Eligibility Requirements

- **Citizenship:** U.S. Citizen Only
- **Degree:** Bachelor's Degree or Master's Degree received within the last 60 month(s).
- **Minimum Overall GPA:** 3.00

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- **Discipline(s):**
  - **Life Health and Medical Sciences** (8 👁)

Affirmation I am a U.S. citizen, or 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.