Opportunity Title: FDA Fellowship in Development and Characterization of a Phage Therapy to Decolonize Vancomycin-Resistant Enterococci
Opportunity Reference Code: FDA-CBER-2024-01

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

Reference Code FDA-CBER-2024-01

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

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

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

Application Deadline 12/31/2024 11:59:00 PM Eastern Time Zone

Description **Applications will be reviewed on a rolling-basis and this opportunity will remain open until filled.**

A research opportunity is currently available in the Office of Vaccine Research and Review (OVRR) at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

A Postbac fellow opportunity is available in the Carlson laboratory at the Food and Drug Administration collaborating on projects designed to assess the potential of bacteriophage therapies against Vancomycin resistant Enterococcus species.

Project Description: Since the advent of antibiotics in the 1920s, these drugs have saved millions of people from diseases such as pneumonias, healthcare associated infections, and foodborne illnesses. However, the continued use of antibiotics has led to several unintended consequences, including disruption of the indigenous beneficial gut bacteria and a rise in antibiotic-resistant bacteria. The Centers for Disease Control and Prevention (CDC) estimates that 23,000 deaths are caused by antibiotic-resistant bacteria each year in the United States, and these organisms constitute a growing problem worldwide. Vancomycin-resistant enterococci (VRE), which have been classified as a serious threat by the CDC, are responsible for 20,000 U.S. infections annually. The inability to treat these infections with common antibiotics necessitates the development of alternative methods of intervention. The objective of this project is to develop and characterize an effective bacteriophage therapy against VRE, including both vancomycin-resistant E. faecalis and E. faecium. The project will include mouse model development as well as assessment of bacteriophage efficacy and pharmacokinetics in this model system. The next few years of this project will focus heavily on the identification of mutations that result in bacterial resistance against bacteriophage and understanding how to overcome this resistance to generate a successful therapeutic. These bacteriophage therapy investigations will have a significant impact on a largely understudied field and contribute to solving the antibiotic-resistant bacteria problem.

Anticipated Appointment Start Date: August 1st, 2024

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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 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 be currently pursuing or have received a bachelor's or master's in the one of the relevant fields or be currently pursuing the degree with completion expected prior to the start of the appointment. Degree must have been received within the past five years.

Preferred skills:

- An interest in microbiology, bacteriology, the microbiome, and/or infectious disease
- Basic understanding of molecular biology/microbiological laboratory techniques

Eligibility Requirements

- **Citizenship:** U.S. Citizen Only
- **Degree:** Bachelor's Degree or Master's Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Engineering** (27 👁)
  - **Life Health and Medical Sciences** (51 👁)

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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.)

I have read the FDA Ethics Requirements.