

Opportunity Title: FDA Research Opportunity in Defining the Antigenic Topology

of Highly Diverse RNA Viruses

Opportunity Reference Code: FDA-CBER-2024-0030

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

Reference Code FDA-CBER-2024-0030

How to Apply Connect with ORISE...on the GO! Download the new ORISE GO mobile app in the Apple App

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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 <a href="mailto:ORISE.FDA.CBER@orau.org">ORISE.FDA.CBER@orau.org</a>. Please include the reference code for this opportunity in your email.

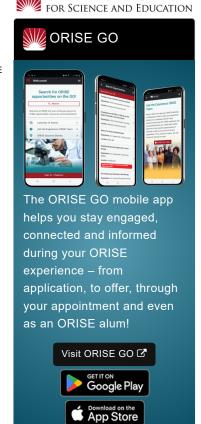
Application Deadline 10/31/2024 3:00:00 PM Eastern Time Zone

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

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

The ORISE Research Participation Program at the U.S. Food and Drug Administration is an educational and training program designed to provide college students, recent graduates, and university faculty opportunities to connect with the unique resources of the FDA. With the support of an assigned mentor, participants have authentic hands-on research experience and allows them access to unique research opportunities, top scientists and engineers, and state-of the art facilities and equipment. The Center for Biologics Evaluation and Research (CBER) is one Center within the Food and Drug Administration, an Agency within the United States Government's Department of Health and Human Services. CBER's mission is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

Research Project: RNA viruses present extraordinary diversity that could impact vaccine design. Despite the extreme diversity, broadly neutralizing antibodies have been described for several RNA viruses, such as human immunodeficiency virus, influenza, hepatitis C virus and noroviruses Unfortunately, most of these antibodies target subdominant epitopes. For this research project, under the guidance of a mentor, the participant will use a large set of reagents (monoclonal antibodies, and polyclonal sera) and different protein expression approaches to assess antibody responses, define epitopes and understand the rules of antibody immunodominance from two distinct highly diverse RNA viruses, hepatitis C virus and norovirus. The team hopes this project will provide new insights on the presence of broadly neutralizing epitopes and inform future immune-focusing vaccine approaches.



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Learning Objectives: The participant will be trained in classic molecular biology and protein analysis techniques. They will gain an understanding of protein expression systems, protein structure and purification and how amino acid variation impacts reactivity with antibodies.

Anticipated Appointment Start Date: July 15, 2024. Start date is flexible and will depend on a variety of factors.

**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, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the <u>Guidelines for Non-U.S. Citizens Details page</u> of the program website for information about the valid immigration statuses that are acceptable for program participation.

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 <u>FDA Ethics for Nonemployee Scientists</u>.

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. The degree must have been received within 3 years of the appointment start date.

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## Preferred Skills/Knowledge:

• Candidates with research experience in molecular biology, cell culture and immunology are encouraged to apply.

## Eligibility Requirements

- Degree: Bachelor's Degree or Master's Degree received within the last 36 months or currently pursuing.
- Discipline(s):
  - Life Health and Medical Sciences (51 ♥)

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.

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