

Opportunity Title: FDA Fellowship Safety and Efficacy of the Emerging Therapeutic Secretary IgA

Opportunity Reference Code: FDA-CDER-2024-1431

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

Reference Code FDA-CDER-2024-1431

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.CDER@oraui.org. Please include the reference code for this opportunity in your email.

Application Deadline 9/30/2024 3:00:00 PM Eastern Time Zone

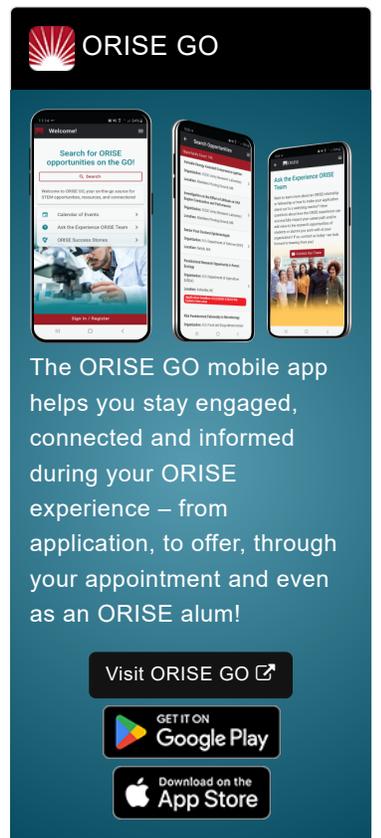
Description *Applications will be reviewed on a rolling-basis.

FDA Office and Location: A research opportunity is available within the Food and Drug Administration (FDA) in The Center for Drug Evaluation and Research (CDER), located at Silver Spring, Maryland.

The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

Research Project: IgA-based drugs, especially secretory IgA, allow novel therapeutic approaches not possible using the existing IgG platform. Secretory IgA has evolved to control mucosal infections, including HIV, influenza virus, and SARS-CoV-2. We investigate the functional consequences and safety implications of secretory IgA binding to a novel receptor, FCRL3, on human T cells. The goal of this research project is identification of functionally relevant proteins and cytokines that could result in adverse reactions.

Learning Objectives: Under the guidance of the mentor, the participant will learn about the scientific issues and rationale of our research program, its relevance to FDA's mission, as well as published and unpublished studies. The participant will participate in daily research activities as appropriate and become familiar among other techniques with the isolation of lymphocytes from human blood and tissues, flow cytometry, multiplex cytokine analysis. The fellow will also be invited to attend research seminars, lab meetings, special seminars and scientific meetings.



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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 [Guidelines for Non-U.S. Citizens Details page](#) 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 [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.

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Qualifications The qualified candidate should be currently pursuing or have received a bachelor's or master's degree in one of the relevant fields (e.g., Biochemistry, Cellular and Molecular Biology, Immunology, or Bioinformatics). Degree must have been received within the past five years.

Preferred skills/experience:

- Research experience is preferred but not necessary
- Experience in handling human tissues and cells and in analyzing large biological data

Eligibility Requirements

- **Degree:** Bachelor's Degree or Master's Degree received within the last 60 months or anticipated to be received by 9/30/2024 12:00:00 AM.
- **Academic Level(s):** Graduate Students, Post-Bachelor's, Post-Master's, or Undergraduate Students.
- **Discipline(s):**
 - **Life Health and Medical Sciences** ([5](#) )

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.