

Opportunity Title: FDA Summer opportunity: Investigation of Sex Difference in Immunogenicity and Efficacy of AAV-Mediated Gene Therapy

Opportunity Reference Code: FDA-CBER-2024-0019

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

Reference Code FDA-CBER-2024-0019

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

Application Deadline 8/31/2024 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 at the Center for Biologics Evaluation and Research (CBER), in the Office of Therapeutic Products(OTP), at the Food and Drug Administration (FDA) in Silver Spring, Maryland.

Research Project: The project will include investigation of the differences between males and females and their innate and adaptive immune response to gene therapy products. The qualified candidate will collaborate with an experienced post doctoral fellow and will learn novel methods in gene therapy vector production as well as immunological methods. The research will be conducted in a highly translational and collaborative laboratory. Applicants should have some lab experience including pipetting, and preparation of buffers and solutions. Candidates are expected to be highly organized, responsible and self motivated.

Learning Objectives: The participant will learn how to manufacture gene therapy vectors, how to execute immunological assays. In addition, if time allows, the participant will learn to handle and restrain research animals.

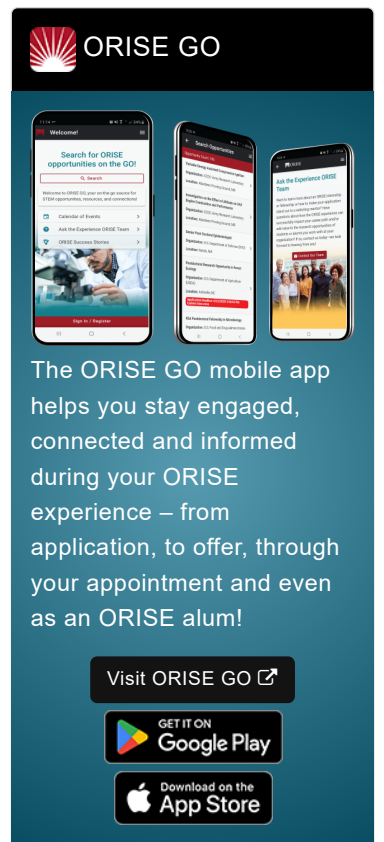
Anticipated Appointment Start Date: May 13, 2024. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for 6 months, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is full time or part time.

Citizenship Requirements: This opportunity is available to U.S. citizens and Lawful Permanent Residents (LPR) 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



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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 be pursuing or completed a bachelor, master or doctoral degree in a relevant field. Degree must have been received within the past five years.

Preferred skills:

- Lab experience including pipetting and preparation of buffers and solutions
- Handling of laboratory animals, and mouse tissue collection is preferred
- Experience with ELISA or other immunological assays is a big advantage
- Theoretical experience with immunological assays is also acceptable
- Self motivation and willingness to learn new technologies and methods are critical

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- **Academic Level(s):** Graduate Students, Post-Bachelor's, Postdoctoral, Post-Master's, or Undergraduate Students.
- **Discipline(s):**
 - **Chemistry and Materials Sciences** (4 )
 - **Engineering** (27 )
 - **Life Health and Medical Sciences** (16 )
 - **Science & Engineering-related** (2 )

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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.