

**Opportunity Title:** FDA Fellowship - Developing Novel Strategies to Improve Safety, Efficacy and Quality of Gene Therapy Products

**Opportunity Reference Code:** FDA-CBER-2026-0023

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

**Reference Code** FDA-CBER-2026-0023

**How to Apply** *To submit your application, scroll to the bottom of this opportunity and click APPLY.*

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](mailto:ORISE.FDA.CBER@orau.org). Please include the reference code for this opportunity in your email.

**Application Deadline** 6/26/2026 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), Food and Drug Administration (FDA), in White Oak, Maryland.

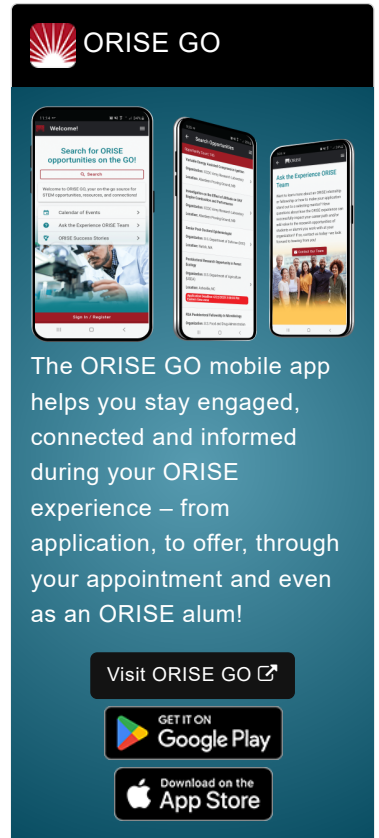
The Center for Biologics Evaluation and Research (CBER) is one Center within the Food and Drug Administration, an Agency within the United States Government's Department of Health and Human Services. CBER's mission is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

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.

**Research Project:** AAV is a small viral vector commonly used for gene delivery. AAV based gene therapies are beginning to show clinical successes. As the field rapidly expands, with an increasing number of investigational new drug (IND) applications and biologics license applications (BLA) being submitted to the FDA, there is a need to develop innovative analytical methods and regulatory science approaches to comprehensively evaluate the safety, efficacy, and quality of these complex biological products.





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This project addresses gaps in our ability to assess AAV-based gene therapy products by developing advanced in vitro models and analytical methodologies. In joining this project, you will focus on two interconnected research areas:

1. **Development of three-dimensional (3D) cell culture systems** to evaluate AAV product potency and immunogenicity. Unlike traditional two-dimensional cultures, 3D models better recapitulate the complex tissue architecture, cell-cell interactions, and microenvironmental conditions found in vivo, potentially providing more physiologically relevant data for regulatory decision-making.
2. **Establishment of novel in vitro models** for comprehensive safety and efficacy assessment. These models will serve as tools for evaluating product quality attributes, predicting clinical outcomes, and identifying potential safety concerns early in product development.

**Learning Objectives:** If selected, you will join a highly translational and collaborative environment and will gain practical experience in the cutting-edge fields of gene therapy and immunogenicity. You will learn new methods include ELISpot assay, in vivo animal experiments, computational epitope analysis, and AAV purification and production. These methods can be utilized to study immunogenicity of proteins in many fields including drug and vaccine development or gene therapy.

**Mentor:** The mentor for this opportunity is Ronit Mazor ([ronit.mazor@fda.hhs.gov](mailto:ronit.mazor@fda.hhs.gov)). If you have questions about the nature of the research, please contact the mentor.

**Anticipated Appointment Start Date: 2026.** 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.

**Participant Stipend:** The participant will receive a monthly stipend commensurate with educational level and experience.

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

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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 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

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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 doctoral degree in the one of the relevant fields.

**Point of Contact** [Ashley](#)

- Eligibility Requirements**
- **Citizenship:** LPR or U.S. Citizen
  - **Degree:** Doctoral Degree.
  - **Discipline(s):**
    - **Life Health and Medical Sciences** ([51](#) )

**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.