

Opportunity Title: FDA Postdoctoral Research Opportunity in Immunogenicity of Vectors in Gene Therapy

Opportunity Reference Code: FDA-CBER-2020-0010

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

Reference Code FDA-CBER-2020-0010

How to 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. Your application will be considered incomplete, and will not be reviewed until one recommendation is submitted.

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 8/31/2020 3:00:00 PM Eastern Time Zone

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

A research opportunity is available in the Division of Cellular and Gene Therapies, Office of Tissues and Advanced Therapies (OTAT), at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

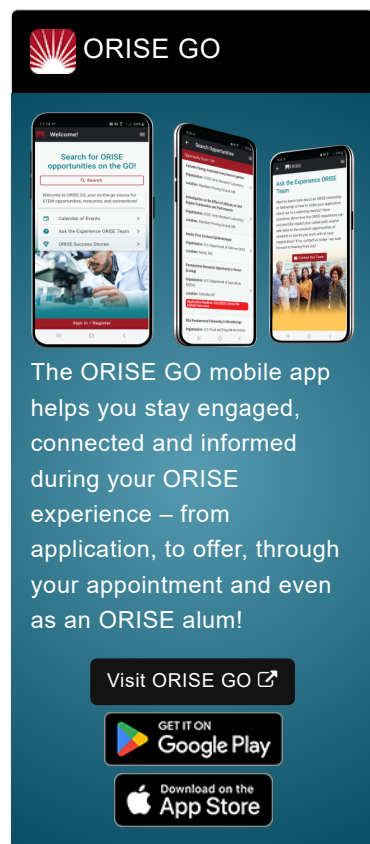
Adeno-associated virus (AAV) is a small viral vector commonly used for gene delivery. AAV based gene therapies are beginning to show clinical successes. However, due to the viral origin of AAV, there is a growing body of evidence demonstrating interactions of AAV vectors with the innate and adaptive immune system which hinders their successful translation from the bench to the bedside.

Our lab's goal is to develop technologies to help evaluate and mitigate the adaptive immunogenicity of AAV vectors in gene therapy. Under the guidance of a mentor, the selected participant will help to rationally design next generation AAV vectors with lower immunogenicity and test the efficacy of these designs in mice models. The participant will perform research in a highly translational and collaborative environment and learn techniques including AAV production and quantification, cloning, mutagenesis, and humoral and cellular immunological assays.

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 five months, 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 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



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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 one of the relevant fields. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Experience in the purification and characterization of proteins in mammalian systems
- Basic recombinant DNA techniques
- Excellent tissue culture techniques
- Experience with computational HLA binding, structural biology and protein design
- Immunological assays including flow cytometry, measuring T-cell mediated immune responses, ELISpot and ELISA
- Willingness to learn new technologies and methods

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
 - **Chemistry and Materials Sciences** ([4](#) 👁)
 - **Engineering** ([4](#) 👁)
 - **Life Health and Medical Sciences** ([15](#) 👁)
 - **Science & Engineering-related** ([1](#) 👁)