Opportunity Title: FDA Non-clinical Identification and Mitigation of Safety Risks During the Development and Licensure of Protein-therapeutics
Opportunity Reference Code: FDA-CBER-2026-0005

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

Reference Code FDA-CBER-2026-0005

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

Application Deadline 5/22/2026 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: A research opportunity is available in the Division of Plasma Protein Therapeutics (DPPT), Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) in Silver Spring, 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.

Research Project: Under the guidance of a mentor, you will receive training in cutting edge technologies directly relevant to promoting public health, opportunities to attend seminars and formal training programs. you will participate in collaborative projects with academia and/or industry and will thus be well positioned for diverse career options after the training period. Flexibility and a willingness to learn new techniques is a desirable quality in the applicant. An allowance for training and/or scientific conference attendance may also be available, contingent upon available funding and DHHS, FDA, CDC, and local and/or state public health alerts related to the COVID-19 pandemic.

You will join a research program that broadly investigates unwanted immune responses to proteins used in therapeutic applications. The specific focus will be immune responses to Cas proteins used in gene editing. Cas9 proteins derived from human pathogens are the most extensively studied CRISPR-Cas gene editors. An important hurdle when developing and licensing a protein for clinical applications is the potential

for immune responses to the protein. We have previously demonstrated both T- and B-cell immunity to diverse Cas proteins. You will help identify promiscuous immunogenic epitopes in emerging Cas proteins and develop new tools to understand the safety consequences of immune responses to neo-epitopes generated due to off-target gene editing.

The following articles from our laboratory provide examples of research performed in our group:

1. V.L. Simhadri, J.R. McGill, & Z.E. Sauna. Endotoxin contamination in commercially available Cas9 proteins potentially induces T-cell mediated responses. Gene Therapy. 2022
2. V.L. Simhadri, L. Hopkins, J.R. McGill, B.R. Duke, S. Mukherjee, K. Zhang, & Z.E. Sauna. Cas9-derived peptides presented by MHC Class II that elicit proliferation of CD4(+) T-cells. Nat. Commun. 12: 5090, 2021
3. J.R. McGill, O.N. Yogurtcu, H. Yang, D. Verthelyi, & Z.E. Sauna. SampPick: Selection of a cohort of subjects matching a population HLA distribution. Front. Immunol. 10: 2894, 2019
4. V.L. Simhadri, J. McGill, S. McMahon, J. Wang, H. Jian & Z.E. Sauna. Prevalence of Pre-existing Antibodies to CRISPR-associated Nuclease Cas9 in the US Population. Mol Ther Methods Clin Dev. 10: 105-112, 2018.

Learning Objectives: Under the guidance of a mentor, you will receive training in cutting edge technologies directly relevant to promoting public health, opportunities to attend seminars and formal training programs. The candidate will participate in collaborative projects with academia and/or industry and will thus be well positioned for diverse career options after the training period. Flexibility and a willingness to learn new techniques is a desirable quality in the applicant.

Mentor: The mentor for this opportunity is Zuben E. Sauna (zuben.sauna@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, 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.

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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 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 have received a master's or doctoral degree in one of the relevant fields (e.g. Immunology, Biochemistry, Biology, Pharmacy or Pharmaceutical Sciences), or be currently pursuing one of the degrees with completion before the appointment start date. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Experience in mammalian cell culture, cell-based assays, and flow cytometry
- Experience in advanced techniques in immunology, biochemistry, molecular biology, cell

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biology

- Familiarity with basic techniques and principles in cell and molecular biology and biochemistry
- Willing to learn new technologies and methods and operate outside their comfort zone

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Life Health and Medical Sciences** (48 👁)
  - **Mathematics and Statistics** (11 👁)

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.