Opportunity Title: FDA Research Opportunity - Developing Methods for Efficient Gene Editing in Hematopoietic Stem Cells (HSCs)
Opportunity Reference Code: FDA-CBER-2026-0051

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

Reference Code FDA-CBER-2026-0051

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 6/19/2026 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 immediately in the Division of Cell Therapy (DCT2), within the Office of Cellular Therapy and Human Tissue (OCTHT) at the Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA) located in Silver Spring, Maryland.

The Center for Biologics Evaluation and Research (CBER) is within the U.S. Food and Drug Administration under the U.S. Department of Health and Human Services (HHS). 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: This research project focuses on advancing the development and manufacturing of CRISPR/Cas9-edited hematopoietic stem cell (HSC) therapeutics. Under the mentorship of the Principal Investigator, you will gain experience in cutting-edge genome editing techniques applied to human HSCs and related cell types. You will engage in research at the intersection of stem cell biology, gene therapy, and nanomedicine, addressing one of the most significant challenges in the field: achieving safe and effective delivery of gene editing machinery to HSCs. You will utilize state-of-the-art manufacturing tools and methodologies to investigate and optimize ex vivo HSC-gene editing and expansion protocols. You will gain comprehensive training in the design, development, and optimization of novel lipid nanoparticle (LNP) formulations specifically engineered for efficient gene editing in HSCs. This training opportunity is ideal for individuals seeking to contribute to the advancement of non-viral delivery platforms that could transform the landscape of HSC-based gene therapies and cellular therapeutics.

Opportunity Title: FDA Research Opportunity - Developing Methods for Efficient Gene Editing in Hematopoietic Stem Cells (HSCs)
Opportunity Reference Code: FDA-CBER-2026-0051

Learning Objectives: Under the guidance of a mentor, you will:

1. Develop proficiency in designing, executing, and validating CRISPR/Cas9-mediated genetic modifications in HSCs and other relevant cell types, including understanding guide RNA design, delivery methods, and assessment of editing efficiency and specificity.
2. Gain experience in the rational design and synthesis of lipid nanoparticle components for gene editing applications.
3. Develop technical skills in LNP formulation techniques and optimization strategies.
4. Understand the biological barriers to HSC gene editing and develop strategies to overcome them.
5. Acquire skills in evaluating gene editing efficiency and safety in hematopoietic stem cells.

Mentor: The mentor for this opportunity is Pankaj Kumar Mandal (pankaj.mandal@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.

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

Opportunity Title: FDA Research Opportunity - Developing Methods for Efficient Gene Editing in Hematopoietic Stem Cells (HSCs)
Opportunity Reference Code: FDA-CBER-2026-0051

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 Ph.D. or equivalent degree with an educational background in molecular and cell biology, pharmacology and drug discovery/development.

Preferred skills/experience:

- Lab skills in common molecular and cell biology techniques are preferred.

Point of Contact

Ashley

Eligibility Requirements

- **Degree:** Doctoral Degree.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Engineering** (2 👁)
  - **Life Health and Medical Sciences** (11 👁)
  - **Science & Engineering-related** (1 👁)

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.