Opportunity Title: FDA Computational and Experimental Assessment of Engineered Biotherapeutics: Safety and Regulatory Considerations of Synonymous Gene Recoding
Opportunity Reference Code: FDA-CBER-2026-0017

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

Reference Code FDA-CBER-2026-0017

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 currently available at the Office of Therapeutic Products (OTP), Center for Biologics Evaluation and Research (CBER), 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: You will join a research program focused on elucidating the functional and immunological consequences of synonymous variants in therapeutic proteins using integrated computational and experimental approaches. A central component of the project involves applying and developing advanced bioinformatic tools to model how synonymous sequence changes affect mRNA structure, translation kinetics, codon usage bias, ribosome dynamics, and protein folding trajectories.

You will be able to leverage in silico platforms—including translation efficiency prediction models, RNA secondary structure analysis, codon-pair and harmonization algorithms, and immunogenicity risk prediction tools—to help guide experimental design and variant prioritization. You will research collaboratively with experimental biologists to validate computational predictions through protein expression, structural characterization, and functional and immunogenicity assays.

The following articles in the literature provide examples of the range of

research performed in our group:

- Jankowska, K. I. *et al.* Synonymous ADAMTS13 variants impact molecular characteristics and contribute to variability in active protein abundance. *Blood Advances* (2022).
- Padhiar, N. *et al.* Cell Lines CoCoPUTs: A Database of Codon and Codon-pair Usage Frequencies in Cell Lines. *J Mol Biol*, 169718 (2026). https://doi.org:10.1016/j.jmb.2026.169718
- Katneni, U.K., Liss, A., Holcomb, D., Katagiri, N., Hunt, R.C., Bar, H., Ismail, A., Komar, A.A. and Kimchi-Sarfaty, C.: Splicing dysregulation contributes to the pathogenicity of several F9 exonic point variants. Molecular Genetics & Genomic Medicine E-published; 2019; 00:e840, DOI: 10.1002/mgg3.840). 2019.
- Hettiarachchi G.K., Katneni U.K., Hunt R.C., Athey J.C., Kames J.M., Bar H., Sauna Z.E., McGill J.R., Ibla J.C. and Kimchi-Sarfaty C.: Translational and transcriptional responses in human primary hepatocytes under hypoxia. American Journal of Physiology - Gastrointestinal and Liver Physiology, doi: 10.1152/ajpgi.00331.2018.
- Katneni U.K., Ibla J.C., Hunt R.C., Schiller T. and Kimchi-Sarfaty C.: Von Willebrand Factor/ADAMTS13 Interactions at Birth: Implications for Thrombosis in the Neonatal Period. Journal of Thrombosis and Haemostasis 17(3):429-440, 2019.
- Alexaki A., Kames J., Holcomb D.D., Athey J., Santana-Quintero L.V., Lam P.V.N., Hamasaki-Katagiri N., Osipova E., Simonyan V., Bar H., Komar A.A., and Kimchi-Sarfaty C.: Codon and Codon-Pair Usage Tables (CoCoPUTs): Facilitating Genetic Variation Analyses and Recombinant Gene Design. Journal of Molecular Biology. https://doi.org/10.1016/j.jmb.2019.04.021. 2019.
- Alexaki A., Hettiarachchi G.K., Athey J., Katneni U.K., Simhadri V., Hamasaki-Katagiri N., Nanavaty P., Lin B., Takeda K., Freedberg D., Monroe D., McGill J.R., Peters R., Kames J., Holcomb D.D., Hunt R.C., Gelinas A., Janjic N., DiCuccio M., Bar H., Komar A.A., and Kimchi-Sarfaty C.: Effects of codon optimization on protein translation and structure: Implications for protein therapeutics. 2019. Scientific Reports, in press.

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

- Use of sensitive methods to detect changes in protein structure.
- Understanding how to use prediction methods tools for mRNA.
- Methods for purifying therapeutics.
- Reading papers and understanding the highlights and messages.

Mentor: The mentor for this opportunity is Chava Kimchi-Sarfaty (Chava.Kimchi-Sarfaty@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: May 15, 2026. Start date is flexible and will depend on a variety of factors.

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Appointment Length: The appointment will initially be for seven 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.

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 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;

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- 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 the one of the relevant fields. Degree must have been received within the past five years.

Preferred skills:

- Experience in both experimental methods in protein chemistry.
- Experience with data analysis.
- Strong skills in bioinformatics, computational biology, or data science (e.g., Python/R, sequence analysis pipelines, structural modeling, or machine learning approaches) are highly desirable.
- Familiarity with molecular biology and protein biochemistry is advantageous to support cross-disciplinary integration.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (3 👁)
  - **Computer, Information, and Data Sciences** (6 👁)
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (7 👁)

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.