zintellect
climb higher

Opportunity Title: FDA Fellowship - In Silico and In Vitro Approaches to Inform Polypharmacy and Patient Effects on Opioid Overdose
Opportunity Reference Code: FDA-CDER-2026-0054

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

Reference Code FDA-CDER-2026-0054

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.CDER@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 4/30/2026 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: Three research opportunities are available immediately with the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), located in White Oak, Maryland.

The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. These efforts cover more than just medicines.

Research Project: The overarching research project supports efforts in the polypharmacy space and will be split into three project components for each ORISE fellow (computational, complex in vitro modeling - CiVM and bioanalytical).

- **Computational:**
  - The participant will assist in the development of quantitative systems pharmacology models and become efficient in using various computing languages, such as R, C, and Python, to develop mechanistic models to simulate human pharmacology and utilize High Performance Computing for data analysis.
  - The goal of these quantitative systems pharmacology models is to define a data processing pathway and model validation method that will be used in various areas with particular emphasis on drug polypharmacy.

- **CiVM:**
  - The participant will contribute to research on opioid pharmacology using human-relevant in vitro models. The core project focuses on extending previous studies that have demonstrated the concentration-dependent response of human induced pluripotent stem cell-derived neural new approach methodologies (NAMs) to opioids and their reversal by naloxone.
  - The participant will contribute to expanding this research into broader chemical space and will actively participate in laboratory-based research activities, including the cultivation and maintenance of human induced pluripotent stem cell-derived neural cultures. They will investigate the electrophysiological effects (e.g., multielectrode array MEA) of various opioids and drug combinations and analyze the mechanism of safety and efficacy of opioid reversal agents.
- **Bioanalytical:**
  - The Bioanalytical is involved in number of projects related to the pharmacokinetic evaluation of both small and large molecules. Division of Applied Regulatory Science (DARS) provides bioanalytical support for in vitro and clinical in vivo projects including drug transport and metabolism investigations.
  - Division of Applied Regulatory Science (DARS) can provide training in a variety of advanced analytical and bioanalytical assays from method development to experimental or test sample analysis including the process of method validation.

Learning Objectives:

- **Computational:** Through this opportunity you will;
  - Establish collaboration framework with FDA internal and external stakeholders for various specific domains including opioids and polypharmacy;
  - Learn to process diverse and high-volume data to prepare for modeling;
  - Learn how to adjust model structures/parameters based on calibration data, and evaluate model credibility using validation data;
  - Learn how to execute modeling & simulation to predict various outcomes, including efficacy and safety for opioid overdose reversal agents.
  - Note: you will not be involved with any regulatory decision making and policy discussions.

- **CiVM:** Through this opportunity you will;
  - Receive comprehensive training in human induced pluripotent stem cell-derived neural handling and culture techniques, gaining hands-on experience with cutting-edge cellular models. You will participate in specialized training programs focused on in vitro neural functional readouts, including electrophysiology and calcium handling

methodologies.
  - Develop comprehensive competencies in neural physiology laboratory techniques specifically applied to regulatory assessment and drug safety evaluation. You will gain in-depth understanding of how human-relevant in vitro models can replace traditional animal studies in opioid research, advancing the principles of regulatory science and public health protection.
  - Gain exposure to government regulatory science and advanced research methodologies. You will develop expertise in emerging methodologies and have networking opportunities.

- **Bioanalytical:** Through this opportunity you will;
  - Gain experience and training in bioanalytical techniques including familiarity with liquid chromatography, mass spectrometry, immunocapture sample clean-up, and ligand binding assays.
  - Learn development and validation of new and novel methods.

Mentor: The mentors for these opportunities are Computational: Zhihua Li (zhihua.li@fda.hhs.gov) CiVM: Tromondae Feaster (tromondae.feaster@fda.hhs.gov), Bioanalytical: Ryan DePalma (Ryan.DePalma@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentors.

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.

Opportunity Title: FDA Fellowship - In Silico and In Vitro Approaches to Inform Polypharmacy and Patient Effects on Opioid Overdose
Opportunity Reference Code: FDA-CDER-2026-0054

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 be currently pursuing or have received a master's or doctoral degree in the one of the relevant fields.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17)
  - **Engineering** (29)
  - **Life Health and Medical Sciences** (51)
  - **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.