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Opportunity Title: FDA Clinical Pharmacology of Novel Modality Biological Products
Opportunity Reference Code: FDA-CDER-2026-0039

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

Reference Code FDA-CDER-2026-0039

How to Apply ***Connect with ORISE...on the GO!*** Download the new ORISE GO mobile app in the Apple App Store or Google Play Store to help you stay engaged, connected, and informed during your ORISE experience and beyond!

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 5/31/2026 12:00:00 AM Eastern Time Zone

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

FDA Office and Location: A research opportunity is available in the Office of Clinical Pharmacology (OCP), Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) in Silver Spring, Maryland. The Center for Drug Evaluation and Research 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, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. These efforts cover more than just medicines.

Research Project: As an ORISE participant, you will engage in research focused on advancing clinical pharmacology understanding of novel modality biological products, including novel structures, novel mechanisms of action, novel delivery methods, etc. This fellowship directly supports FDA's mission of ensuring safety and efficacy of innovative therapeutic modalities. You will investigate pharmacokinetic and pharmacodynamic characteristics of novel biological products through systematic literature reviews, data analysis, and regulatory submission evaluations to identify knowledge gaps and establish best practices for assessment. You will analyze clinical trial datasets to characterize dose-response relationships and biodistribution patterns using advanced statistical modeling approaches. Additionally, you will have the opportunity to collaborate with clinical pharmacologists and regulatory reviewers to evaluate innovative

study designs for assessing novel modality clinical pharmacology and research regulatory precedents and contribute to guidance document development for emerging therapeutic modalities.

Learning Objectives: Under the guidance of the mentor, you will participate in specialized training programs covering regulatory science principles and FDA's review processes for novel biological products, engage in mentorship relationships with senior FDA scientists to develop expertise in regulatory decision-making and scientific evaluation, attend scientific seminars focused on clinical pharmacology, model-informed drug development, and innovative trial designs, and collaborate on manuscript preparation to develop scientific communication skills.

Mentor: The mentor for this opportunity is Yow-Ming Wang (wangyow@fda.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 twelve 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 and Lawful Permanent Residents (LPR). 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

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

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Engineering** (2 👁)
  - **Life Health and Medical Sciences** (51 👁)

Affirmation Have you 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.