Opportunity Title: FDA Postdoctoral Fellowship / Research Fellowship: Enhancing the Review of Mediation Analyses—Developing a Regulatory Checklist and AI Support Tool
Opportunity Reference Code: FDA-CDER-2026-0093

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

Reference Code FDA-CDER-2026-0093

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 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 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. This effort covers more than just medicines.

Research Project: The ORISE Fellow will be a part of a regulatory science initiative aimed at enhancing the review of mediation analyses in clinical trial submissions to the U.S. Food and Drug Administration (FDA). The project focuses on developing a structured framework to guide statistical reviewers in evaluating mediation analyses at key checkpoints—specifically, the study protocol, statistical analysis plan (SAP), and clinical study report (CSR).

You will use the AGReMA (A Guideline for Reporting Mediation Analyses) statement—an international consensus guideline that promotes transparency and reproducibility in mediation analyses (JAMA 2021;326(11):1045–1056; https://jamanetwork.com/journals/jama/fullarticle/2784353)—as the methodological foundation. You will help analyze a sample of published mediation studies and publicly available FDA reviews (e.g., Drugs@FDA

approval packages) to identify methodological and reporting checkpoints that are most relevant to regulatory review. Building on this analysis, you will help develop an evidence-based Reviewer Checklist for evaluating mediation analyses and will help prototype a custom internal GPT tool that integrates these checkpoints into an interactive platform, allowing FDA statisticians to query best practices in real time.

Learning Objectives: The fellowship will include structured learning and mentorship within the FDA's Office of Biostatistics. During the appointment, you will learn how to:

- Participate in seminars and meetings focused on statistical review practices, causal inference, and regulatory science applications.
- Evaluate clinical trial submissions, with emphasis on assessing mediation and causal modeling approaches.
- Use AI-assisted tools to support regulatory decision-making and learn about emerging technologies within the FDA's Digital Health and AI ecosystems.
- Collaborate with experienced FDA statisticians to refine the checklist and GPT prototype, receiving iterative feedback on both methodological and regulatory aspects.

This experience will strengthen your expertise in regulatory biostatistics, causal inference, and applied data science, while providing direct exposure to FDA's review processes. The project offers a unique opportunity to bridge methodological research with practical regulatory application and to learn about the agency's modernization efforts through responsible AI. You will be a part of creating a Reviewer Checklist and a prototype AI assistant that demonstrate how analytical rigor and technology can advance FDA's public health mission. This experience will prepare you for future roles in regulatory science, government service, or quantitative research supporting evidence-based public health decisions.

Mentor: The mentor for this opportunity is Jae Joon Song (jaejoon.song@fda.hhs.gov) and Brian Gilbert (Brian.Gilbert@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 eight 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-

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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;
- 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 doctoral degree in the one of the relevant fields.

Point of Contact Ashley

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Eligibility Requirements

- **Degree:** Doctoral Degree.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (3 👁)
  - **Mathematics and Statistics** (3 👁)

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.