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Opportunity Title: FDA Properties of Bayesian Hierarchical Model Estimators of Subgroup Treatment Effects
Opportunity Reference Code: FDA-CDER-2026-0060

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

Reference Code FDA-CDER-2026-0060

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 5/31/2026 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: Bayesian hierarchical model (BHM) are used to derive more precise estimates of subgroup treatment effects by considering all the data, not just subgroup specific data. A BHM assumes exchangeability in treatment effects across subgroups after adjusting for effect modifiers and other relevant covariates. In this project, we will explore properties of BHM estimators via simulation to address some concerns, such as if the treatment effects are not exchangeable, will use BHM result in more precise but biased estimates for subgroups, how can we tune priors to balance bias and precision.

During the appointment, you will cooperate in investigating mathematical properties of Bayesian hierarchical model estimators through simulation studies, analyze complex statistical scenarios with non-exchangeable treatment effects across subgroups, and research bias-precision trade-offs to optimize statistical inference for regulatory decision-making.

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This educational and developmental program provides you with training opportunities to continue your education and research while enhancing your professional skills. You will also become familiar with CDER research areas and develop interest in future careers related to the FDA's public health mission. Support includes access to an FDA-issued computer with required software and weekly mentor meetings to monitor progress and provide guidance.

Learning Objectives: During the appointment, you will develop expertise in BHMs for clinical trial subgroup analysis while gaining proficiency in computational tools such as R, JAGS, and Stan for both simulation and real-world clinical data analysis. You will also hone presentation skills to effectively interpret and communicate research findings and learn to collaborate with mentors.

Learning experiences to include:

- Participating in educational seminars, contributing to improved statistical methods for subgroup analysis, analyzing real-world clinical data using advanced computational tools under mentorship guidance, and exploring how statistical innovations can enhance regulatory assessments of drug safety and efficacy.
- Developing expertise in Bayesian hierarchical models for clinical trial subgroup analysis.
- Gaining computational proficiency in specialized software and learn research design through simulation studies investigating bias-precision trade-offs.
- Enhancing critical analysis skills for interpreting complex statistical findings, improve scientific communication abilities for presenting research, and develop collaborative research skills through mentorship.

This experience will advance your development by providing structured research training applicable to pharmaceutical and regulatory science careers, facilitating professional network development with FDA scientists, and exposing participants to CDER research areas to foster interest in FDA's public health mission. The program also offers hands-on experience with real-world regulatory challenges in drug development, effectively bridging academic knowledge with practical regulatory science applications.

Mentor: The mentors for this opportunity are Mark Rothmann (mark.rothmann@fda.hhs.gov) and Yun Wang (yun.wang@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentors.

Anticipated Appointment Start Date: May 17 - June 1, 2026. Start date is flexible and will depend on a variety of factors.

Appointment Length: The appointment will initially be for three to four months, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

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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;
- 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.

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Qualifications

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

Preference is towards those who have either:

- Completed a master's degree or;
- Are pursuing a doctoral degree.

Point of Contact

Ashley

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
  - **Mathematics and Statistics** (2 👁)

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.