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Opportunity Title: FDA Research Opportunity - Assessment of Bayesian Statistical Methods Applied in Regulatory Contexts
Opportunity Reference Code: FDA-CDRH-2026-0021

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

Reference Code FDA-CDRH-2026-0021

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

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!

Application Deadline 9/30/2027 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 Devices and Radiological Health (CDRH), located in Silver Spring, Maryland.

The mission of CDRH is to protect and promote public health. CDRH assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. CDRH provides consumers, patients, caregivers, and providers with understandable and accessible science-based information about products. CDRH facilitates medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

Research Project: You will be a part of the following activities:

- Landscape Analysis: Survey Bayesian designs used in CDRH device approvals to identify successes, limitations, and recurring challenges.
- Reviewing Guidance and Literature Review: Evaluate the CDER/CBER draft guidance and stakeholder commentaries. Conduct systematic literature reviews to identify novel Bayesian methodologies aligned with the draft guidance that demonstrate potential utility for medical device regulation.
- Methodological Evaluation via Simulation: Assess novel approaches—such as Bayes factors and Calibrated Bayes—through simulation studies to evaluate their performance and suitability for regulatory

decision-making.
- Assessment of Prior Data Conflict: Examine historical challenges related to prior-data conflict in Bayesian designs and evaluate whether newer methods (e.g., adaptive borrowing or discounting) mitigate these issues.
- Evaluation of Interim Decision Metrics: Conduct simulation studies to assess uncertainty and operating characteristics of PPoS-based interim decision rules across various endpoint types (binary, continuous, time-to-event), modeling assumptions, and data-borrowing strategies.

Learning Objectives: Under the guidance of a mentor, you will be a part of a time-sensitive, high-impact regulatory science initiative while gaining:

- Direct experience with FDA guidance interpretation and impact assessment
- Insight into regulatory applications of Bayesian methods in medical devices
- Hands-on experience evaluating novel statistical methodologies
- Mentorship and skills that help you develop your future goals

Mentor: The mentor for this opportunity is Rajesh Nair (Rajesh.Nair@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 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.

Completion of a successful background investigation by the Office of

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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 degree in the one of the relevant fields.

Preferred skills:

- Bayesian statistics, clinical trial design, and simulation methodology.
- Strong quantitative training.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Master's Degree.
- **Discipline(s):**
  - **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.