Opportunity Title: FDA Evaluating Consumer Study Regulatory Review Approaches for Applications with Novel Digital Technologies
Opportunity Reference Code: FDA-CDER-2026-0061

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

Reference Code FDA-CDER-2026-0061

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: Evaluating the results of consumer studies [including Label Comprehension Studies (LCSs) and Self-Selection Studies (SSSs) that are increasingly integrating the use of digital apps] is important for determining whether consumers can understand the Drug Facts Label of a nonprescription drug or interact with a digital app to decide if a product is right for them, without a healthcare provider's supervision. Demonstration of consumer comprehension and self-selection is necessary for nonprescription drug approval. Mitigations (rules that may change an incorrect response in a study to a correct response) and participant verbatim information requiring qualitative analysis, complicate consumer study review, making review of consumer studies challenging and time consuming. Notwithstanding these challenges, the review timelines of consumer studies are often compressed. For this reason, it is impractical for FDA to take an in depth look at all study participant outcomes. One approach is to spot check the results. However, the amount of spot

checking required to ensure a reliable assessment has not been established.

The Office of Nonprescription Drugs will conduct exploratory analyses of previously conducted LCSs and SSSs to explore how to improve the efficiency and validity of FDA's review of consumer study results. You would collaborate with FDA reviewers toward the establishment of best practices for FDA review of consumer studies. You will also help design and conduct analyses of consumer study results, including exploring the use of artificial intelligence and evaluate its utility in streamlining FDA's review of verbatim responses. These research activities would involve gaining direct, hands-on experience in social science research design and data analysis within a regulatory context.

Learning Objectives: There will be structured weekly meetings with the mentor (the deputy division director in DNPD II) and co-mentor (the social science analyst in DNPD II). Qualitative and quantitative analysis skills will be an integral part of the training. We will facilitate technical training to ensure that any gaps in your analytical skills are addressed. The nonprescription regulatory environment is unique, and you will be provided with the opportunity to learn about the nonprescription regulations and collaborate with regulatory experts and other scientific and medical experts in our office. You will be invited to participate in internal and sponsor meetings that are applicable to the research project to gain a deeper appreciation of the impact that the research project will have on future regulatory work done in our office.

The opportunity is designed to ensure that you will acquire the skills and competencies to contribute to public health as a social science analyst in our office or in another FDA office. The skills learned during this opportunity will prepare you for a research-focused career. Public service experience is highly sought in academia, where practical experience and federal collaboration will contribute to a well-rounded preparation for research.

You will gain an appreciation of public health and regulatory review through an immersion into nonprescription regulations and the processes of nonprescription drug evaluation and approval. Qualitative and quantitative analytical skills will be honed. You will learn how to investigate consumer studies to determine whether the design and conduct of studies meet criteria for making regulatory decisions.

Mentor: The mentors for this opportunity are Melanie Blank (melanie.blank@fda.hhs.gov) and Jeffrey Cox (jeffrey.cox@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 only.

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. Degree must have been received in the past five years.

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** U.S. Citizen Only
- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
  - **Communications and Graphics Design** (1 👁)
  - **Social and Behavioral Sciences** (27 👁)

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.