

**Opportunity Title:** Comparing Neonatal Adverse Drug Events from the Literature with FDA Labels

**Opportunity Reference Code:** FDA-CDER-2026-0068

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

**Reference Code** FDA-CDER-2026-0068

**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](mailto: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:** Despite tremendous strides in pediatric drug development prompted by the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, exceedingly few drug development programs include neonates. As a result, a relatively small number of drugs have the safety and efficacy data necessary to support approval for use during the first month of life despite appreciable off-label use. The lack of data combined with the rapid growth and development of these physiologically complex patients leaves neonates vulnerable to adverse drug events (ADEs). This project entails an extensive literature search of ADEs reported in neonates and examining the extent to which these findings are reflected in current FDA labeling with the goal of informing strategies for inclusive safety labeling for drugs used in the neonatal population.

You will collaborate with mentors in the following activities related to the

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research project: participate in data collection from published sources, create a system to organize and analyze collected data, review and apply relevant statistical tests, and prepare and present research findings. In addition to the project, you will participate a variety of educational activities, such weekly journal club meetings and project meetings, to better understand pediatric drug development and clinical pharmacology concepts.

The Office of Clinical Pharmacology is involved in educational and research programs which promote the Agency as a career option for students and fellows. This is part of our public health mission in order to have a future of highly trained regulatory scientists in clinical pharmacology. Students and fellows can observe, but not participate in, the regulatory review process.

**Learning Objectives:** Under the guidance of the mentor, you will develop the following skills during the fellowship;

1. Develop advanced information search strategies to identify and organize data relevant to the question at hand,
2. Evolve the critical thinking skills required to synthesize and analyze information from a variety sources while establishing accuracy and validity,
3. Expand their written and verbal communication skills to construct a clear and coherent overview for their findings, and;
4. Conceptualize and propose recommendations for expanding neonatal labeling in the concept of current regulatory and legislative frameworks.

All of these skills are important to learn for a future as an effective regulatory scientist and for understanding drug labeling which is a part of FDA's public health mission.

**Mentor:** The mentor for this opportunity is Susan Abdel-Rahman ([susan.abdel-rahman@fda.hhs.gov](mailto:susan.abdel-rahman@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.

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This program, administered by ORAU through its contract with the U.S.

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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 bachelor's, master's, or doctoral degree in the one of the relevant fields.

**Point of Contact** [Ashley](#)

**Eligibility Requirements**

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree.
- **Discipline(s):**
  - **Life Health and Medical Sciences** ([51](#) )

**Affirmation** I am a U.S. citizen, or I have lived in the United States for at least 36 out of

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the past 60 months. (36 months do not have to be consecutive.)  
and  
I have read the FDA Ethics Requirements.