Opportunity Title: FDA Quantitative Systems Pharmacology Modeling for Fetal Cardiac Safety Fellowship
Opportunity Reference Code: FDA-CDER-2026-0003

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

Reference Code FDA-CDER-2026-0003

How to Apply ***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!

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 6/19/2026 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 at the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) Office of New Drugs (OND) Office of Immunology and Inflammation (OII), located in Silver Spring, 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: Congenital heart defects (CHDs) are a significant public health concern, with potential long-term implications for affected individuals. Studies have identified a possible association between the use of antidepressants during pregnancy and an increased risk of CHDs in offspring. Studies in cells and animals have suggested that heart defects might be related to disruption of maternal serotonin levels in the fetus which plays a key role in cardiac morphogenesis. Serotonin promotes the growth of fetal heart cells while abnormal or blocked serotonin levels can change heart development. Understanding the mechanisms responsible for this association is crucial for developing effective prevention strategies and minimizing potential risks associated with serotonin modulating drugs used in pregnancy.

Predictions from our QSP model will strengthen associations between drugs and outcome which can lead to interventions that minimize the risk and potentially the incidence of CHD. One potential intervention is

screening for genetic polymorphisms in important proteins identified in this pathway; screening interventions can be done earlier than fetal ultrasounds. Therefore, this research has the potential to reduce the incidence of congenital cardiac anomalies and improve the long-term outcomes for affected individuals and their families. There is also a potential to uncover novel therapeutic targets and interventions to minimize the risk of congenital cardiac anomalies. In turn this project will advance safety and understanding of potential toxicity of FDA-regulated products in the perinatal population.

Learning Objectives: Under the guidance of the mentor, you will gain experience in literature searches and curating datasets. You will also learn basic principles of clinical pharmacology, maternal-fetal medicine, and PK/PD/QSP modeling and simulation methods. Subsequently, you will learn how to effectively communicate their findings and answer questions about their research. You will advance their career by gaining new skill sets in clinical pharmacology, scientific and computational research and communicating scientifically.

The training objectives of this research project will include:

1. Understanding and extracting relevant data from the literature and synthesizing available studies to develop a computation model
2. Introduction to clinical pharmacology and maternal-fetal medicine
3. Building upon participants knowledge of ODE-based modeling and simulation methods using R programming
4. Effective communication of scientific studies

Mentor: The mentor for this opportunity is Blessy George (Blessy.George@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: June 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 and Lawful Permanent Residents (LPR) 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.

Qualifications The qualified candidate should be currently pursuing or have received a doctoral degree in the one of the relevant fields (e.g. Pharmaceutical Sciences, Pharmacology, Pharmacometrics). Degree must have been received within the past five years, or be anticipated to be completed by December 16, 2026.

Point of Contact Ashley

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 12/16/2026 11:59:00 PM.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (17 👁)
  - **Engineering** (29 👁)

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- **Life Health and Medical Sciences** (51 👁)
- **Mathematics and Statistics** (11 👁)
- **Physics** (16 👁)

Affirmation 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.