Opportunity Title: FDA Postdoctoral Fellowship in Evaluation of Drug Toxicity
Opportunity Reference Code: FDA-CBER-2021-0037

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

Reference Code FDA-CBER-2021-0037

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

Application Deadline 9/6/2021 3:00:00 PM Eastern Time Zone

Description ***Applications will be reviewed on a rolling-basis.**

A research opportunity is currently available in the Office of Tissues and Advanced Therapies (OTAT) at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

Many pregnant women take prescription drugs to treat health problems, such as chronic pain, diabetes, and high blood pressure. In addition to their direct adverse effects on the fetus, these drugs may be toxic to the placenta barrier and impair its ability to provide protective immunity to the fetus. This ability is attributed to the placenta's resistance to microbial and viral infections and ability to transfer of protective maternal antibodies to the fetus. It is critical to understand how prescription drugs adversely affect the placenta's ability to provide immune protection to the fetus.

The participant will receive training on how to develop a reliable, high-throughput screening platform to evaluate drug transport from maternal blood across the placenta barrier to fetal blood. Using the platform, the participant will also receive training on how experimental models can be used to understand the effect of a drug on placenta immunity, which may contribute to determining safe drugs that pregnant women could take. Training in this area will provide the participant with regards to how the newly developed assays could be employed in the assessment of various products regulated at the FDA.

Anticipated Appointment Start Date: September 2021; start date is flexible

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 initial appointment is for one year, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Silver Spring, Maryland, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

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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 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 have received a doctoral degree in one of the relevant fields, or be currently pursuing the degree with completion by the appointment start date. Degree must have been received within the past five years.

Preferred skills:

- Experience in microfluidics, 3D in vitro system, cell and molecular biology
- Understanding of high-throughput screening, immunology, and tissue engineering
- Experience in various imaging technologies and molecular biology technologies

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Doctoral Degree received within the last 60 months or anticipated to be received by 9/30/2021 11:59:00 PM.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Engineering** (27 👁)
  - **Life Health and Medical Sciences** (46 👁)
  - **Physics** (16 👁)
  - **Science & Engineering-related** (1 👁)

Affirmation

Have you lived in the United States for at least 36 out of the past 60 months? (36 months do not have to be consecutive.)