Opportunity Title: FDA Drug Safety Research Fellowship
Opportunity Reference Code: FDA-CDER-2019-0469

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

Reference Code FDA-CDER-2019-0469

How to 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. Your application will be considered incomplete, and will not be reviewed until one recommendation is submitted.

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 3/31/2020 3:00:00 PM Eastern Time Zone

Description

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

A research opportunity is available in the Office of New Drugs/Office of Drug Evaluation I, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) located in Silver Spring, Maryland.

This project is a collaboration between the Office of New Drugs/CDER and the Office of Science and Engineering Laboratories/CDRH. The agency receives submissions on newly evolving bioresorbable polymer-based drug formulations for endovascular interventions, open vascular wraps, and hemodialysis access grafts. To better understand the suitability of bioresorbable polymers, a rapid assay will be developed to determine cytocompatibility of bioresorbable polymer formulated drugs. The proposed study will identify predictive biomarkers of biocompatibility that include prothrombotic factors, proinflammatory mediators, proadhesion molecules, and prooxidant species. The results of the proposed study will provide 1) a rational basis for the assessment of safety of polymer carriers and 2) requirements for biocompatibility testing.

Under the guidance of a mentor the participant will receive training on the critical role of biocompatibility testing in the assessment of safety for biomaterials that interact with the human body. The laboratory project will then evaluate various biodegradable polymers in cultured endothelial cells to determine their effects on the release of markers of inflammation and thrombosis. The participant will learn how to conduct laboratory research to develop in vitro screening assays to evaluate and optimize biocompatibility of polymers that are used as drug carriers, utilizing techniques such as cell culture, quantitative real-time polymerase chain reaction (RT-PCR), flow cytometry, immunoblotting, mRNA expression, ELISA, immunofluorescence, and Luminex assays.

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

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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.

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 bachelor's degree in one of the relevant fields. Degree must have been received within five years of the appointment start date.

Familiarity with cell and molecular biology laboratory techniques (e.g., cell culture, mRNA extraction, preparing sterile solutions), endothelial cell cultures, in vitro cytocompatibility assays, biocmpatability testing protocols, bioresorbable polymers is desired.

Eligibility Requirements

- **Degree:** Bachelor's Degree received within the last 60 month(s).
- **Academic Level(s):** Post-Bachelor's.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Life Health and Medical Sciences** (5 👁)