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Opportunity Title: FDA Fellowship in Blood Platelet and Protein Particle Research
Opportunity Reference Code: FDA-CBER-2024-0024

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

Reference Code FDA-CBER-2024-0024

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 8/31/2024 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: A research opportunity is currently available in the Office of Blood Research and Review (OBRR) at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

The Center for Biologics Evaluation and Research (CBER) is one Center within the Food and Drug Administration, an Agency within the United States Government's Department of Health and Human Services. CBER's mission is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

Research Project: The first research project the participant will be involved with is focused on cellular and molecular aspects of new methods of long term storage of blood platelets for transfusion. Platelets for transfusion can only be stored for 5 to 7 days. Platelet cryopreservation would improve platelet availability in remote locations and military operations and building a platelet inventory for refractory patients. The state of the art platelet cryopreservation method uses 6% dimethylsulfoxide (DMSO) as a cryoprotectant. Platelets, however, undergo major damage during DMSO-cryopreservation, including membrane transition and release of different populations of platelet membrane vesicles. Content and activities of platelet membrane vesicles in DMSO cryopreserved platelets (CPP) may significantly impact safety and efficacy of CPP. The proposed project is focused on development and optimization a panel of assays for characterization and in vitro potency for quality control of CPP products. In addition, the project will investigate cryoprotective effects of various novel cryoprotectants including engineered nanomaterials for platelet cryopreservation.

The second research project the participant will be involved with is focused on characterization of protein and lipid particles in blood transfusion products, such as freeze-dried plasma, and plasma derivatives, particularly in intravenous immunoglobulin (IVIG) products. The presence of subvisible protein particles in IGIV products has been implicated to play a significant role in IVIG-associated

adverse events. We have initiated a collaborative project to investigate IGIV protein particle characteristics in relation to their vascular toxicity effects.

Learning Objectives: The participant will gain theoretical knowledge in platelet biology and platelet transfusion science, including current methods of platelet processing and storage and needs for long term platelet storage. The participant will gain theoretical knowledge and practical experience in laboratory assays for evaluation of quality of platelets for transfusion, characterization of platelet membrane vesicles, and other membrane changes in platelets stored for transfusion and new methods of platelet cryopreservation. The participant will gain theoretical knowledge and practical experience in laboratory methods for analysis and characterization of subvisible protein and lipid particles and evaluation their biological activities in tissue culture models.

Anticipated Appointment Start Date: June 27, 2024. 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.

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;

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- 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 or master's degree in one of the relevant fields (Life Sciences, Biology, Chemistry, Physics or related sciences). Degree must have been received within the past five years.

Preferred skills:

- Excellent communication skills.
- The candidate must have a strong drive for lab research and some background in life sciences.
- Training will be provided in all techniques but individuals with laboratory experience in biomedical research, skills in cell biology, hematology, cryobiology, or protein chemistry will be preferred.

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Bachelor's Degree or Master's Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12 👁)
  - **Life Health and Medical Sciences** (51 👁)
  - **Physics** (16 👁)
  - **Science & Engineering-related** (1 👁)

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.