Opportunity Title: FDA Advancing Pathogen Reduction Technologies Fellowship
Opportunity Reference Code: FDA-CBER-2021-0034

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

Reference Code FDA-CBER-2021-0034

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 12/31/2021 3:00:00 PM Eastern Time Zone

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

Three research opportunities are 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.

Transfusion-transmitted infections (TTIs), while rare, remain a significant risk of blood transfusion. Although advances in donor screening and laboratory testing have decreased this risk, emerging transfusion-transmitted infections remain a threat to the safety and availability of the blood supply. One approach to address the risk of TTIs is the use of pathogen reduction technologies that can inactivate potential infectious agents. While pathogen reduction technologies for blood components have been investigated and, in some components, approved for use, pathogen reduction technologies may be associated with several limitations including, inadequate inactivation of certain pathogens, suboptimal recovery of treated products, or impaired product effectiveness after transfusion. Current technologies also largely target pathogens in individual blood components (such as platelets or plasma). A more attractive, and potentially more broadly applicable approach would be to apply pathogen reduction to whole blood and then separate the parent unit into components. However, to date, there remain significant technical and scientific challenges that have limited successful use of this approach.

To address these challenges, the OBRR is establishing a research program in pathogen reduction of whole blood. This program is expected to both advance existing technologies and develop novel technologies that can be used in the manufacturing of blood components for transfusion.

The pathogen reduction technologies (PRT) research program at CBER aims to both:

1. further characterize and advance existing technologies for pathogen reduction of whole blood, and
2. to develop novel approaches to pathogen reduction of whole blood

The participant will contribute substantially to aim (1) by:

- applying current technologies to whole blood under various experimental conditions, and
- examining the effects of pathogen reduction on in vitro parameters of component quality (such as platelet function testing, coagulation function testing, and assays of RBC function and viability) and the ability of pathogen reduction technologies to inactivate model pathogens (such as parasites and hepatitis viruses)

Upon completion of the first phase of the project, the participant will have the opportunity to extend their appointment and apply the scientific knowledge gained and experimental protocols developed in aim (1) to aim (2). In aim (2), the participant would transition research to the laboratory of newly established investigators at CBER/OBRR to further assess how novel approaches to pathogen reduction, including novel devices and novel biochemical approaches, are able to inactivate pathogens and how these impact the quality of subsequent components such as red blood cells, platelets, and plasma.

Anticipated Appointment Start Date: August 1, 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.

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 master's or doctoral degree in one of the relevant fields. Degree must have been received within the past five years.

Preferred skills:

- Strong background in molecular and cellular biology and biochemistry
- Additional experience in microbiology and virology
- Treatment of human donor blood specimens with pathogen reduction devices and reagents
- Preparation of derivative components from treated whole blood (e.g., platelets, plasma, and red blood cells)
- Assays of component quality and activity (e.g., platelet aggregometry, coagulation factor

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activity, RBC ektacytometry)
- Application of these techniques to novel strategies for pathogen inactivation
- Training will be provided in all laboratory techniques, but some prior experience in any of the following areas is helpful: cell culture, virus propagation, PCR, ELISA, flow cytometry, and general hematology.

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Life Health and Medical Sciences** (46 👁)

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.)