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Opportunity Title: FDA Immunoglobulin Products Research Fellowship
Opportunity Reference Code: FDA-CBER-2021-0019

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

Reference Code FDA-CBER-2021-0019

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.**

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

The selected participant will join a research program that studies the mechanism of immunoglobulin - mediated hemolysis, developing assay protocols for intravenous and extravascular hemolysis, and characterizing hemolysis-implicated immunoglobulin intravenous (IGIV) products.

Learning objectives for the participant:

- Theory of Immune Globulin (IG) mediated hemolytic adverse reaction and its impact on patients' safety
- Understanding and Testing of the complement-dependent microplate-based hemolysis assay on the IGIV products, and interpretation of the assay results.
- Method development and optimization of the extravascular hemolysis. This will involve in cell culture (mammalian cells), isolation and differentiation of human monocyte into macrophage, opsonization of red cells, and phagocytosis analysis using microscope.
- Characterization of hemolysis implicated IGIV products by using Fast protein liquid chromatography (FPLC), hemagglutination test, and the established hemolysis assays.
- Strategies for development of reference standards, such as, how international standards are developed. This may involve in the participation of the establishment of international WHO reference standards.
- Techniques of Surface Plasmon Resonance methods for binding detection and characterization by collaborating with the team members.

The following articles in the literature provide examples of the range of work performed in our group:

- Scott DE, Epstein JS. Hemolytic adverse events with immune globulin products: product factors and patient risks. Transfusion. 2015;55 Suppl 2:S2-5.
- Scott DE, Epstein JS. Safeguarding immune globulin recipients against hemolysis: what do we know and where do we go? Transfusion. 2015;55 Suppl 2:S122-6.
- Bellac CL, Hottiger T, Jutzi MP, Bogli-Stuber K, Sanger M, Hanschmann KM, et al. The role of isoagglutinins in intravenous immunoglobulin-related hemolysis. Transfusion. 2015;55:S13-S22.
- Jacobs J, Kneib J, Gabbard A. Intravenous Immunoglobulin-Associated Hemolytic Anemia. Lab Med. 2020;51:e47-e50.
- Romberg V, Hoefferer L, El Menyawi I. Effects of the manufacturing process on the anti-A isoagglutinin titers in intravenous immunoglobulin products. Transfusion. 2015;55 Suppl 2:S105-9.
- Thorpe SJ. Specifications for anti-A and anti-B in intravenous immunoglobulin: history and rationale. Transfusion. 2015;55 Suppl 2:S80-5.
- Flegel WA. Pathogenesis and mechanisms of antibody-mediated hemolysis. Transfusion. 2015;55 Suppl 2:S47-58.
- Tong TN, Burke-Murphy E, Sakac D, Pendergrast J, Cserti-Gazdewich C, Laroche V, et al. Optimal conditions for the performance of a monocyte monolayer assay. Transfusion. 2016;56:2680-90.

Anticipated Appointment Start Date: October 2021

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, or be currently pursuing one of the degrees with completion by the end of May 2021. Degree must have been received within the past five years.

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Preferred skills:

- Experience in cell culture, flow cytometry, Fast protein liquid chromatography (FPLC)
- Experience and lab experience in molecular and cell biology, immunology, and/or hematology
- Willingness to learn new technologies and methods

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 5/31/2021 11:59:00 PM.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (46 👁)