

Opportunity Title: FDA Assessing Safety and Efficacy of Antibody Therapies

Opportunity Reference Code: FDA-CBER-2019-0031

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

Reference Code FDA-CBER-2019-0031

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.CBER@ou.edu. Please include the reference code for this opportunity in your email.

Application Deadline 11/4/2019 3:00:00 PM Eastern Time Zone

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

The research project is focused on assessing safety and efficacy of antibody-based biologic drugs. These drugs are manufactured from complex starting materials such as blood and cell culture media. The purification process includes many steps designed to ensure purity while preserving biologic activity. Our laboratory uses conventional and cutting-edge techniques to assess product attributes essential for the safe and efficacious use of these preparations. Under the guidance of a mentor, the participant will utilize mammalian and viral cell cultures (including Zika virus), live imaging, ELISA and other laboratory techniques to evaluate the potency of these preparations in vitro and in vivo. The participant will also complete all of the institutional training for conducting research safely with pathogens and/or animals and adhering to all the rules and regulations while performing their laboratory activities.

The selected participant will gain in depth understanding of considerations in selecting appropriate models and endpoints to assess therapeutic potential of immune globulin preparations against existing and emerging viral diseases.

***Although the application deadline is November 4, applications will be reviewed on a rolling-basis.**

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



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Silver Spring, Maryland, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

The Homeland Security Presidential Directive-12 (HSPD-12) mandates a background check be completed for both U.S. Citizens and foreign nationals. Foreign nationals must have resided in the U.S. for at least three (3) of the past five (5) years in order for FDA to be able to complete a background check.

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 the degree and will reach completion by September 10, 2019. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Laboratory experience in biomedical research
- Research skills in virology, and cell and molecular biology

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 9/10/2019 12:00:00 AM.
- **Academic Level(s):** Graduate Students, Postdoctoral, or Post-Master's.
- **Discipline(s):**
 - **Life Health and Medical Sciences** (7 )