

Opportunity Title: FDA Postgraduate Fellowship in Molecular Biology of COVID-

19

Opportunity Reference Code: FDA-CBER-2020-0036

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

Reference Code FDA-CBER-2020-0036

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

All documents must be in English or include an official English translation.

If you have questions, send an email to ORISE.FDA.CBER@oran.org. Please include the reference code for this opportunity in your email.

Application Deadline 9/24/2020 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available with the Division of Plasma Protein Therapeutics (DPPT), in 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.

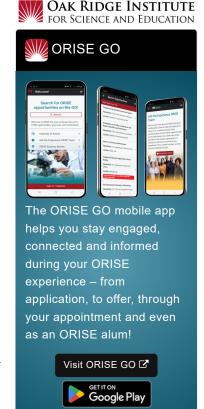
The selected participant will join a research program that studies methods to detect neutralizing antibody activity in serum or plasma against viruses, and the effect of neutralizing antibodies in commercially produced Immune Globulin therapies in animal models. The current efforts of the laboratory are focused upon development of a BSL-2 method to reliably measure neutralizing antibody activity against SARS-CoV-2 in convalescent plasma, to provide a safe and fast method for selection of high-titer donations for COVID-19 therapy. The research team has already developed and tested a similar assay for H1N1 influenza antibodies.

Under the guidance of a mentor, learning objectives for the participant during this appointment include:

- Theory and techniques of Surface Plasmon Resonance methods for binding/binding inhibition detection and characterization; mathematical methods for determining binding characteristics, and protein interaction kinetics
- Methods for measuring antibody-mediated viral neutralization for SARS-CoV-2, such as
 pseudotype virus assays and SARS-CoV-2 virus-based assays (the participant will not be
 required to interact directly with live SARS-CoV-2 virus)
- Optimization of SPR-based methods, including experimental conditions, sample treatment, and reagent requirements
- Methods to ascertain structural characteristics of SARS-CoV-2 binding to its receptors
- Strategies for development of reference standards, how international standards are developed, and how to test candidate reference SARS-CoV-2 antibody reagents

The participant will conduct research in close association with experimental biologists in developing and optimizing the SPR neutralization assay for convalescent human serum/plasma, and animal serum (from animals immunized against SARS-CoV-2).

Anticipated Appointment Start Date: July 1, 2020



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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 and will reach completion by the appointment start date. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Experience in basic lab work, such as sterile tissue culture techniques, protein purification, Western blotting, common molecular biology and virological techniques, and bioassay development
- Experience with advanced methods such as Surface Plasmon Resonance or similar binding detection and characterization 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 7/1/2020 11:59:00 PM.
- Discipline(s):
 - Chemistry and Materials Sciences (4...)
 - Communications and Graphics Design (1...)
 - Computer, Information, and Data Sciences (1...)
 - Engineering (2_②)
 - Life Health and Medical Sciences (11

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