

Opportunity Title: FDA Fellowship in Pathogenesis and Markers of Flavivirus

Infections

Opportunity Reference Code: FDA-CBER-2023-08

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

Reference Code FDA-CBER-2023-08

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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 <u>ORISE.FDA.CBER@orau.org</u>. Please include the reference code for this opportunity in your email.

Application Deadline 4/14/2023 3:00:00 PM Eastern Time Zone

Description Applications will be reviewed on a rolling-basis, and this opportunity will remain open until filled.

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.

Our laboratory is engaged in multiple projects involving transfusion-transmissible arboviruses. This program has a major focus on flaviviruses, specifically Dengue virus (DENV-1 to -4), yellow fever virus (YFV), West Nile virus (WNV) and Zika virus (ZIKV), aiming to understand the biology of infection, pathogenesis, and to identify biomarkers that allow differential diagnostic among these viruses.

The fellowship opportunities are related to the development of specific and sensitive diagnostic devices to discriminate among flaviviruses. The project will provide training in the development of diagnostic assay for blood-borne viruses and research into physiology of infection and disease development. In addition, the participants will have the opportunity to engage in other regulatory science applications associated with emerging infectious diseases.

Arboviruses outbreaks have increased worldwide and the recent spread of ZIKV throughout the Americas led to the recognition of its association with miscarriage and birth defects in unborn humans, and neurological disorders in adults. Although primarily transmitted among humans by mosquitoes, ZIKV is the only known sexually transmitted arboviruses, known to infect testicular cells where it replicates and can be spread sexually, even when the virus is no longer detectable in the blood, thus PCR testing in blood sample would not detect such infection.

Serological testing can indicate viral exposure but not necessarily active infection; however, antibodies elicited by flaviviruses infections inherently have high degree of cross-reactivity preventing accurate discrimination of virus-specific antibodies elicited during infections, even with neutralization assays.

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The goal of these studies is to develop novel tools and approaches for accurate discrimination of infecting virus. We have engaged in two specific-approach to achieve this goal:

(1) To identify virus-specific epitopes to allow discrimination between flaviviruses namely the 4 DENV serotypes, WNV, YFV and ZIKV. Identifying such epitopes would allow development of assays to assist appropriate medical directive and manage severe cases. Participants in this appointment will be involved in virology and immunology techniques including but not limited to tissue culture, viral isolation, colorimetric assays (ELISA), fluorimetric assays (Luminex and nanoparticles), Western blot, immunoblotting, flow-cytometry, and bioinformatic skills.

(2) Exploring plasma microRNAs (miRNAs) as discriminatory biomarkers during flaviviruses infections (ZIKV, DENV and WNV). The goal of the studies is to identify miRNAs that serves as differential biomarkers induced during infection, which profiles are unique for each flavivirus and evaluate their discriminatory character. That may involve mechanisms responsible for production of inflammatory mediators and/or immune mediators elicited during infection. Such tool will assist the accurate determination of infecting agent. Identification of ZIKV infection will allow appropriate medical pregnancy follow up, and measures regarding perinatal health. Participants in this research will receive training in the execution of techniques used in cell biology, virology and molecular biology including but not limited to cell culture, viral growth curve, viral purification in sucrose gradient, titration for viral load and infectivity, genetic sequencing, etc.

Anticipated Appointment Start Date: March 2023; 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 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 must have received or be currently pursuing a BS, MS or Ph.D. in one of the relevant fields (Life Sciences). The degree must be received before the start of the appointment and within 5 years of the appointment start date.



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Preferred skills/ knowledge:

- Strong drive for lab research and some background in virology and immunology
- Basic bio-informatics skills.
- Excellent communication skills
- Proficiency in using computer MS Windows/Office

The qualified candidate should be familiar with techniques to include, but not limited to: cell culture, molecular cloning, recombinant protein expression and purification, SDS-PAGE, immunoblotting, ELISA, RT-qPCR, flow-cytometry, sequencing and analytical biochemistry techniques. Training will be provided in all techniques but individuals with laboratory experience in molecular biology, genetics, virology, and immunology are encouraged to apply.

 Eligibility
 • Degree: Bachelor's Degree, Master's Degree, or Doctoral Degree

 Requirements
 received within the last 60 months or anticipated to be received by 5/31/2023 11:59:00 PM.

- Discipline(s):
 - Chemistry and Materials Sciences (2.)
 - Life Health and Medical Sciences (48)
- 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.)

and

Do you expect to receive your degree prior to the start of the appointment?