

Opportunity Title: FDA Research Opportunity in Molecular Biology of the Zika

Virus

Opportunity Reference Code: FDA-CBER-2020-0019

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

Reference Code FDA-CBER-2020-0019

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

Application Deadline 2/24/2021 3:00:00 PM Eastern Time Zone

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

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.

The project goals involve two specific aims to study Zika Virus (ZIKV) biology of infection/pathogenesis and diagnostic assay development. The recent spread of ZIKV throughout the Americas is responsible for miscarriage and birth defects in unborn humans; as well as neurological disorders in adults. Mosquitoes generally spread ZIKV through the human population, but the virus is also sexually transmitted. ZIKV infects the reproductive organs ovaries and testicles. Reaching the testes, where immune cells are not present, ZIKV infects testicular cells where it replicates and can be spread sexually, even when the virus is no longer detectable in the blood. The Diagnostic for ZIKV virus is very challenging and only molecular techniques can clearly differentiate ZIKV from other flaviviruses such as Dengue Virus (DENV) types 1, 2, 3 and 4. The serological diagnostic is plagued with cross-reactivity that interferes even with gold standard neutralization assays. We have been working on peptide arrays to identify epitopes that would allow discrimination among these viruses and potentially identify antibodies raised specifically against ZIKV.

Specific aim 1 - Development of a microphysiological system for evaluating Zika virus sexual transmission countermeasures

This specific aim is a collaboration with the NCTR. Dr. Petibone's laboratory at NCTR, who has expertise in the development of rats testicular organoids using microphysiological system (MPS) technology. The research aims to develop non-human primate testicular organoids to study ZIKV infection, and replication to assist in the potential countermeasures to prevent sexual transmission. Under the guidance of a mentor, the participant will be involved 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.

Specific aim 2 - Development of reagents for the expansion of specific and sensitive diagnostic devices among flaviviruses

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This specific aim is a collaboration with CDRH. Dr Garcia has been engaged in evaluating ZIKV epitopes compared to other flavivirus including 4 DENV viral types, Yellow fever virus and West Nile virus, search for specific epitopes. Under the guidance of a mentor, the participant will be involved in virology and immunology techniques including but not limited to tissue culture techniques, ELISA, Western blot, immunoblotting, ELISA, PCR and applications, and have bioinformatic skills.

Anticipated Appointment Start Date: May 1, 2020

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 May 1, 2020. Degree must have been received within five years of the appointment start date.

Preferred skills:

- Demonstrated experience in molecular biology, genetics, virology and immunology
- · Additional skills in confocal microscopy, flow cytometry and binding assays
- Eligibility
- Citizenship: LPR or U.S. Citizen
- Requirements
- Degree: Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 5/1/2020 11:59:00 PM.
- Discipline(s):
 - Environmental and Marine Sciences (1.)
 - Life Health and Medical Sciences (45)