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Opportunity Title: FDA Fellowship in Understanding Pathogenesis and Improving Detection of Flaviviruses
Opportunity Reference Code: FDA-CBER-2023-04

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

Reference Code FDA-CBER-2023-04

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
- A cover letter outlining research interests (upload in the Writing Sample area)
- 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 5/31/2023 3:00:00 PM Eastern Time Zone

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

A research opportunity is currently available in the Office of Blood Research and Reviews (OBRR) at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

This project has 2 specific aims focusing on Flaviviruses that threaten the blood supply providing training to the participant in diagnostic assay development and research into ZIKV infection/pathogenesis. In addition, the participant will have the opportunity to participate in other regulatory science applications associated with emerging infectious diseases.

Arbovirus 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 mosquitos, ZIKV is the only known sexually transmitted arbovirus. ZIKV infects the reproductive organs including ovaries and testicles. Upon reaching the immune privileged testes, ZIKV infects testicular cells where it replicates and can be spread sexually, even when the virus is no longer detectable in the blood.

Diagnosis of ZIKV 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.

Aim 1 - Use of a microphysiological system to study ZIKV pathogenesis in the male reproductive system.

This research is a collaboration with Dr. Petibone's laboratory at NCTR, who has expertise in the development of rat 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 identifying potential countermeasures to prevent sexual transmission. The fellow's participation will involve and trained 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.

Aim 2 - Development of specific and sensitive diagnostic devices to discriminate among flaviviruses.

This research is a collaboration with CDRH. Dr Garcia has been engaged in evaluating ZIKV epitopes compared to other flaviviruses including 4 DENV types, yellow fever virus and West Nile virus, in search of specific epitopes. The fellow's participation in this work will involve Virology and Immunology techniques including but not limited to tissue culture, viral isolation, colorimetric assays (ELISA), fluorometric assays (Luminex and nanoparticles), Western blot, immunoblotting, flow-cytometry, and bioinformatic skills.

Anticipated Appointment Start Date: First half of 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. **An allowance for health insurance will be provided.** 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;

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- 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 (e.g. Virology, Immunology) or be currently pursuing the degree with completion expected prior to the appointment starting date. Degree must have been received within the past five years.

Candidates with laboratory experience in molecular biology, genetics, virology, biochemistry, and immunology are encouraged to apply.

Preferred skills:

- Background in virology, genetics, molecular biology, biochemistry, and immunology
- Excellent communication skills
- Experience with cell culture (immortalized cell lines and primary hepatocytes), molecular cloning, recombinant protein expression and purification, SDS-PAGE, immunoblotting, ELISA, RT-qPCR, sequencing and analytical biochemistry techniques

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (48 👁)

Affirmation

I have lived in the United States for at least 36 out of the past 60 months. (36 months do not have to be consecutive.)

I will receive my degree prior to the start of the appointment.