

Opportunity Title: FDA Postgraduate Fellowship in Understanding Pathogenesis and Improving Detection of Hepatitis Viruses that Threaten Blood Safety

Opportunity Reference Code: FDA-CBER-2022-05A



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

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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
- 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 8/3/2022 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 hepatitis viruses that threaten the blood supply providing training to the participant in diagnostic assay development and the study of pathogenesis of blood-borne hepatitis viruses. In addition, the participant will have the opportunity to participate in other regulatory science applications associated with emerging infectious diseases.

1. Development of cell culture systems, novel detection assays and reference reagents for hepatitis E virus genotypes with zoonotic potential.

In industrialized countries sporadic HEV infections are caused by genotypes 3, 4 and 7 HEV. These viruses primarily infect animals such as pigs and deer but can be transmitted to humans by consumption of undercooked meat from infected animals. Most infections with these food-borne HEV strains have no symptoms so infected individuals may feel well enough to donate blood. When blood products containing HEV are given to immune suppressed persons (e.g. organ transplant recipients), the virus can establish chronic infection and cause progressive liver disease. For this reason, HEV is considered an emerging threat to blood safety. Goals under this specific aim include (i) improvement of cell culture systems for HEV genotype 3, 4 and 7 as well as rat HEV (Orthohepevirus C) (ii) development of novel and sensitive methods for detection of HEV in blood using assays that target a secreted form of the viral capsid (iii) development of reference reagents for the standardization of diagnostic tests between different laboratories. The participant will receive training in molecular virology and cell biology methods including virus propagation in cell culture, virus detection and quantitation, infectivity assays, virus purification and biochemical characterization, genetic sequencing, protein expression, ELISA, RT-qPCR, etc.

2. Studies of pathogenesis of blood-borne hepatitis viruses.

Disease progression and outcomes are variable following exposure to and infection with blood-borne hepatitis viruses. This study will identify mechanisms of pathogenesis during acute and chronic infection with HBV and HCV. The study is a collaboration with NIH and makes use of well-characterized clinical specimens from patients with acute and chronic viral hepatitis with a wide range of disease outcomes. The participant will use multidisciplinary approaches (including in vitro and animal studies as well as characterization of clinical specimens) to investigate the molecular mechanisms that contribute to disease progression. The participant will receive training in the use of ex vivo (primary hepatocyte) models of HBV and HCV infection, RT-qPCR, in situ hybridization, confocal microscopy, etc.

Anticipated Appointment Start Date: July 11, 2022; start date is flexible

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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. **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;
- 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 bachelor's or master's degree in one of the relevant fields (e.g. Molecular Biology). Degree must have been received within the past five years.

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

Preferred skills:

- Background in virology, genetics, molecular biology, 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:** Bachelor's Degree or Master's Degree received within the last 60 month(s).
- **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.)