

Opportunity Title: FDA Research Fellowship on Mechanisms of Antibody-

Mediated Neutralization of Hepatitis Viruses

Opportunity Reference Code: FDA-CBER-2023-47

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

Reference Code FDA-CBER-2023-47

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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 including career goals (upload in the writing sample section)
- · One educational or professional recommendations

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

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

Application Deadline 8/30/2024 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 with the Office of Therapeutics Proteins (OTP) at the Center for Biologics Evaluation and Research (CBER), U.S. Food & Drug Administration (FDA) in Silver Spring, Maryland. The successful candidate will join a research program that studies the mechanisms of antibody-mediated neutralization of hepatitis viruses and developing assay protocols to monitor virus-neutralizing activities of immunoglobulin intravenous (IGIV) products.

The following articles in the literature provide examples of the range of work performed in our group:

- 1. P. Zhang et al., Hepatitis C virus epitope-specific neutralizing antibodies in Igs prepared from human plasma. Proc Natl Acad Sci U S A 104, 8449-8454 (2007).
- 2. H. Duan et al., Amino acid residue-specific neutralization and nonneutralization of hepatitis C virus by monoclonal antibodies to the E2 protein. J Virol 86, 12686-12694 (2012).
- 3. L. Deng et al., Structural evidence for a bifurcated mode of action in the antibody-mediated neutralization of hepatitis C virus. Proc Natl Acad Sci U S A, 110, 7418-7422 (2013).
- 4. Z. Zhao et al., A neutralization epitope in the hepatitis C virus E2 glycoprotein interacts with host entry factor CD81. PLoS One 9, e84346 (2014).
- 5. L. Deng et al., A conserved epitope III on hepatitis C virus E2 protein has alternate conformations facilitating cell binding or virus neutralization. Proc Natl Acad Sci U S A 18 (28) e2104242118 (2021).



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6. Tarafdar S et al., Multiple epitopes of hepatitis B virus surface antigen targeted by human plasma-derived immunoglobulins coincide with clinically observed escape mutations. J Med Virol. 94, 649-658 (2022).

This position offers training in cutting edge technologies directly relevant to promoting public health, opportunities to attend seminars and formal training programs. The candidate will work on collaborative projects with academia and/or industry and will thus be well positioned for diverse career options after the training period. Flexibility and a willingness to learn new techniques is a desirable quality in the applicant.

Anticipated Appointment Start Date: February 1, 2024; 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 through August 31, 2024 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 Ethics Requirements

If an ORISE Fellow, to include their spouse and minor children, reports what is identified as a Significantly Regulated Organization (SRO) or prohibited investment fund financial interest in any amount, or a relationship with an SRO, except for spousal employment with an SRO, and the individual will not voluntarily divest the financial interest or terminate the relationship, then the individual is not placed at FDA. For additional requirements, see FDA Ethics for Nonemployee Scientists.

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 A post-doctoral position is available for a highly motivated candidate who will research on a project to study the mechanisms of antibody-mediated neutralization of hepatitis viruses. Applicants must have received a Doctoral degree in one of the relevant fields (Biochemistry or Protein Chemistry), or related disciplines appropriate to the position from a US-accredited institution within five (5) years of the desired starting date. Other degrees will be considered in conjunction with appropriate experience. Current students who expect to receive their degree by the desired starting date may

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apply. Receipt of the degree is required prior to the start of the fellowship.

Experience in surface plasmon resonance, isothermal titration calorimetry, and ELISA is desirable but not essential.

Eligibility

• Citizenship: LPR or U.S. Citizen

Requirements

- Degree: Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 months or currently pursuing.
- Discipline(s):
 - Chemistry and Materials Sciences (12.
 - Life Health and Medical Sciences (51 ♥)

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 expect to receive my degree prior to the start date.

and

I have read the FDA Ethics Requirements.

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