

Opportunity Title: FDA Fellowship in the FcRn-Mediated Dynamics of Anti-SARS CoV-2 IgG

Opportunity Reference Code: FDA-CBER-2022-48A

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

Reference Code FDA-CBER-2022-48A

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
- 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 12/31/2022 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 available in the Division of Plasma Protein Therapeutics (DPPT), Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) in Silver Spring, MD.

CBER's mission is to ensure the safety, purity, potency, and effectiveness of biological products including vaccines, blood and blood products, and cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injury. The selected participant will have the opportunity to learn how biomedical engineering tools would be used in the assessment of regenerative medicine advanced therapeutic products such as cellular and tissue engineered products. The project will employ a variety of approaches including Microfluidics, Biomaterials engineering, Cell-materials imaging, and Molecular biology.

The successful candidate will join a research program that broadly investigates antibody responses to SARS CoV-2. We have investigated whether SARS CoV-2 viral load affects antibody clearance and whether viral load should be taken into account when determining the antibody dose required to treat COVID-19. These studies underscore the importance of monitoring antibody and viral levels during antibody treatment in infected individuals. Our findings could lead to better understanding of the viral load–antibody response relationship and allow for more optimal dosing of antibody-based



Opportunity Title: FDA Fellowship in the FcRn-Mediated Dynamics of Anti-SARS CoV-2 IgG

Opportunity Reference Code: FDA-CBER-2022-48A

therapeutics for COVID-19. The successful candidate will join experimental biologists, computational biologists, immunologists and clinicians to understand the FcRn-mediated trafficking fates of anti-SARS CoV-2 IgG antibodies and immune complexes. They will design and execute assays to determine the levels of anti-SARS CoV-2 IgG recycling and transcytosis.

Under the guidance of a mentor, the candidate will receive training in cutting edge technologies directly relevant to promoting public health, opportunities to attend seminars and formal training programs. The candidate will participate in 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. An allowance for training and/or scientific conference attendance may also be available, contingent upon available funding and DHHS, FDA, CDC, and local and/or state public health alerts related to the COVID-19 pandemic.

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

Clin Infect Dis. 2021 Sep 23:ciab854.

iScience. 2021 Sep 24;24(9):103006.

Drugs R D. 2021 Mar;21(1):1-8.

Antibodies (Basel). 2020 Jun 19;9(2):24.

Anticipated Appointment Start Date: September 1, 2022 (start date is flexible)

Length of Appointment: The initial appointment term is one year, for additional one-year terms on an annual basis, up to a maximum fellowship duration of five years.

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 Ethics Requirements

Opportunity Title: FDA Fellowship in the FcRn-Mediated Dynamics of Anti-SARS CoV-2 IgG

Opportunity Reference Code: FDA-CBER-2022-48A

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 The qualified candidate should have a master's or a Ph.D. in immunology, biochemistry or biology. Degree must have been received within five years of the appointment start date. Candidates who are currently students and expect to receive their degree no later than the projected start date of the fellowship may apply.

Preferred skills:

- Experience in mammalian cell culture, cell-based assays, and flow cytometry
- Experience in advanced techniques in immunology, biochemistry, molecular biology, cell biology
- Familiarity with basic techniques and principles in cell and molecular biology and biochemistry
- Willing to learn new technologies and methods and operate outside their comfort zone

Eligibility Requirements

- **Degree:** Currently pursuing a Master's Degree or Doctoral Degree to be received by 12/31/2022 11:59:00 PM.
- **Discipline(s):**
 - **Chemistry and Materials Sciences** (12 )
 - **Computer, Information, and Data Sciences** (17 )
 - **Life Health and Medical Sciences** (48 )
 - **Mathematics and Statistics** (11 )

Affirmation I have lived in the United States for at least 36 out of the past 60

Opportunity Title: FDA Fellowship in the FcRn-Mediated Dynamics of Anti-SARS CoV-2 IgG

Opportunity Reference Code: FDA-CBER-2022-48A

months. (36 months do not have to be consecutive.)

and

I have read the FDA Ethics Requirements.