Opportunity Title: FDA Postdoctoral Fellowship in Immunology
Opportunity Reference Code: FDA-CBER-2023-16

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

Reference Code FDA-CBER-2023-16

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 12/31/2023 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 Biostatistics and Pharmacovigilance (OBPV) at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) in Silver Spring, Maryland.

The selected participant will be involved in the development of quantitative models to simulate and predict human immune responses to biologics such as vaccines and cancer immunotherapies. The end goal of this project is the development of computational tools to enhance efficacy and safety evaluation of vaccines, current and next-generation of engineered therapeutic products, leading to personalized and optimal treatment regimens for patients.

Under the guidance of a mentor, the participant will develop and apply novel techniques to model and simulate interactive cellular and molecular components of human immune system. The activities include literature reviews, data collection/curation, model development, presentation of research results, and preparation of scientific manuscripts.

Recent Relevant Manuscripts from the Research Lab:

- 1. Han, Lifeng, et al. "Analysis of tumor-immune functional responses in a mathematical model of neoantigen cancer vaccines." Mathematical Biosciences (2023): 108966.
- 2. Nukala, Ujwani, et al. "Modeling and Simulation of CAR T cell Therapy in Chronic Lymphocytic Leukemia Patients." medRxiv (2022): 2022-12.
- 3. Rodriguez Messan, Marisabel, et al. "Mathematical model of a personalized neoantigen cancer vaccine and the human immune system." PLoS Computational Biology 17.9 (2021): e1009318.
- 4. Nukala, Ujwani, et al. "A Systematic Review of the Efforts and Hindrances of Modeling and Simulation of CAR T-cell Therapy." The AAPS Journal 23 (2021): 1-20.
- 5. Yogurtcu, Osman N., et al. "TCPro: an in silico risk assessment tool for biotherapeutic protein immunogenicity." The AAPS journal 21 (2019): 1-12.
- 6. McGill, Joseph R., et al. "SampPick: selection of a cohort of subjects matching a population

Oak Ridge Institute for Science and Education

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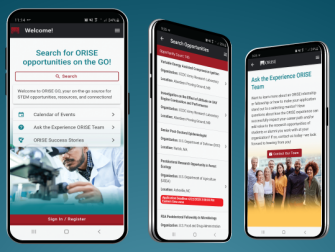

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HLA distribution." Frontiers in Immunology 10 (2019): 2894.

Anticipated Appointment Start Date: June 1, 2023; 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. 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 doctoral degree in one of the relevant fields. The degree must have been received within 5 years of the appointment start date.

Preferred Skills:

- Knowledge of immunology, mathematical/statistical modeling and programming skills
- Experience with differential equations
- Excellent written and oral communication skills
- Solid background and skills in biology and computing science

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (12)
  - **Communications and Graphics Design** (1)
  - **Computer, Information, and Data Sciences** (17)
  - **Earth and Geosciences** (21)
  - **Engineering** (27)
  - **Environmental and Marine Sciences** (14)
  - **Life Health and Medical Sciences** (48)
  - **Mathematics and Statistics** (11)
  - **Physics** (16)

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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.)