Opportunity Title: FDA-CDER Research Opportunity in Oncology Bioinformatics
Opportunity Reference Code: FDA-CDER-2024-1432

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

Reference Code
FDA-CDER-2024-1432

How to Apply
To submit your application, scroll to the bottom of this opportunity and click APPLY.

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.

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

Application Deadline
8/26/2024 3:00:00 PM Eastern Time Zone

Description
***Applications will be reviewed on a rolling-basis.**

FDA Office and Location: A research opportunity is available in the Office of Oncologic Diseases (OOD), Office of New Drugs (OND), within the Food and Drug Administration (FDA) located in Silver Spring, Maryland.

The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

Research Project: We will use the genomic data in The Cancer Genome Atlas (TCGA) for in-silico prediction of candidate neoantigens and neoantigen burden across hepatocellular (HCC) etiologies, and to investigate the correlation between the candidate neoantigens and tumor immune microenvironment (TIME) in HCC. TGCA is a well-curated, publicly available, anonymized database of patient-level clinical data and genomic data that includes whole genome sequencing (WGS), whole exome sequencing (WES), and RNA sequencing (RNA-seq) from paired tumor and normal tissue of patients. Using this dataset, we will use an in-silico pipeline that: (a) identifies antigens that are unique to the tumor and are not germline, and (b) use machine learning-based tools to identify those antigens most likely to elicit an immune response based on peptide-human leukocyte antigen (HLA)-binding affinities. We will compare the differences in HLA-binding affinities of candidate neoantigen and neoantigen burden across different etiologies of HCC and investigate whether there is a correlation between the candidate neoantigens and the TIME in HCC.

Learning Objectives: Under the guidance of the mentor, the participant will receive mentoring in bioinformatics and the numerous analytical approaches, including mutation calling and neoantigen prediction models, necessary to complete this project. This opportunity will also provide the participant with expertise in translational oncology research, cancer immunology, and cancer genomics. The participant will be able to attend lab meetings to learn about other ongoing related translational research projects and will have the opportunity to join meetings and events hosted by the Oncology Center of Excellence to learn more about the drug regulation, drug development, and related research areas. The participant will be able to present results on this project in lab meetings, internal poster sessions, and external meetings (when applicable), and will assist with writing the manuscript for publication to gain valuable

experience disseminating research findings to multidisciplinary audiences.

Appointment Length: The appointment will initially be for one year, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

Level of Participation: The appointment is full time.

Citizenship Requirements: This opportunity is available to U.S. citizens, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the Guidelines for Non-U.S. Citizens Details page of the program website for information about the valid immigration statuses that are acceptable for program participation.

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 participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. 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

The qualified candidate should have received a master's or doctoral degree in one of the relevant fields (Pharmaceutical Science, Chemical Engineering, or Chemistry), or be currently pursuing a doctoral degree with completion before August 31, 2024. Qualified post-master's candidates may also be considered provided that the candidate demonstrates strong relevant and analytical experience. Degree must have been received within five years of the appointment start date.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 months or anticipated to be received by 8/31/2024 11:59:00 PM.
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** (1 👁)
  - **Life Health and Medical Sciences** (6 👁)

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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.)

and

I have read the FDA Ethics Requirements.

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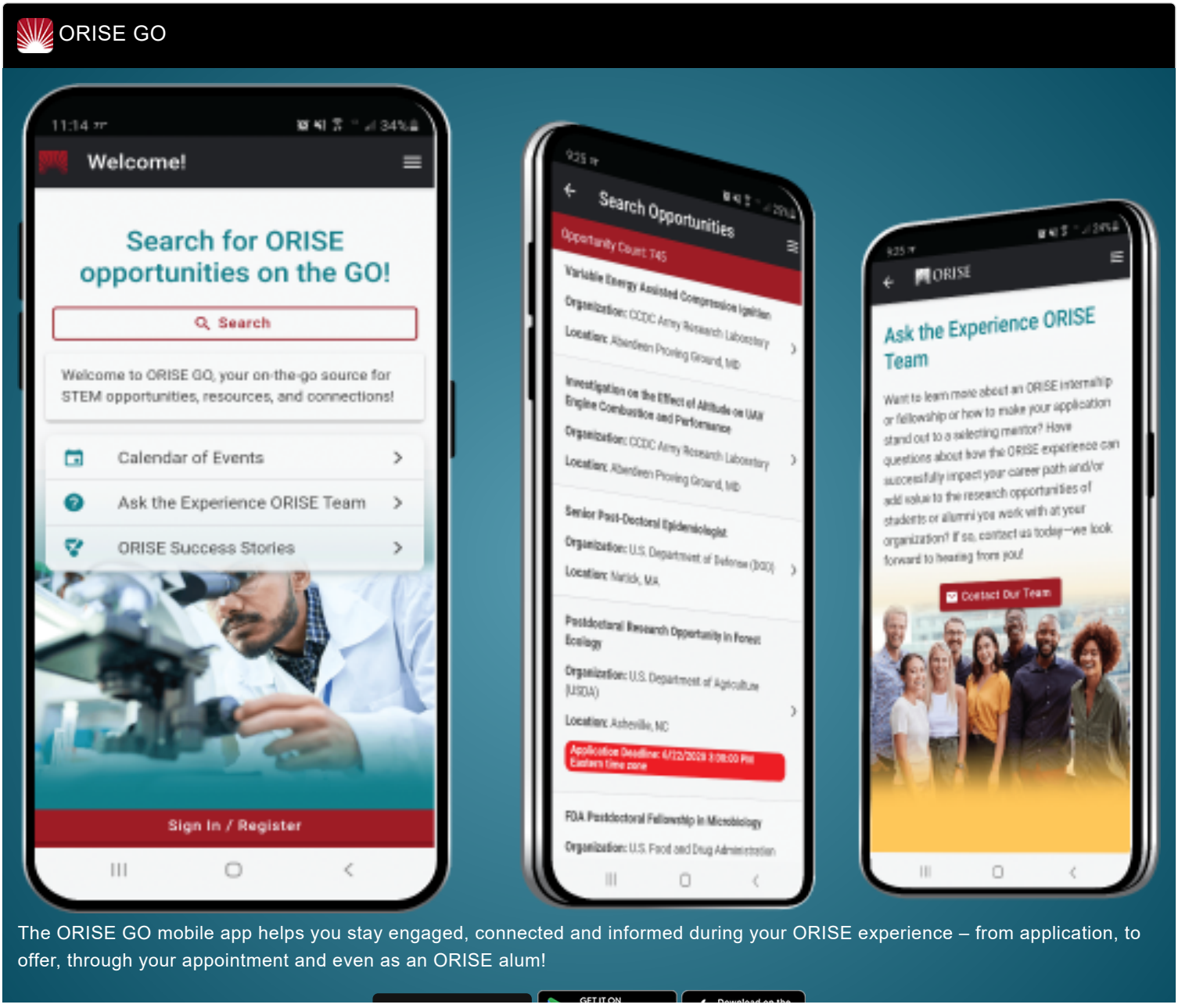

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