Opportunity Title: FDA Postdoctoral Fellowship in Live Attenuated Rubella Viral Vectors
Opportunity Reference Code: FDA-CBER-2022-29

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

Reference Code FDA-CBER-2022-29

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 11:59:00 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 Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) in Silver Spring, MD.

The goal of the project is to enhance vaccine potency by expressing a desired vaccine antigen in a live viral vector. The vector is based on the rubella vaccine strain, which is given to nearly every child as part of the MMR vaccine. The vaccine has demonstrated its safety and potency in millions of children. The project is to insert a foreign gene into the structural insertion site of the rubella virus genome to create a new viral vaccine. Each time the rubella vector infects a cell, it expresses its own proteins plus the new vaccine insert. This combines the safety and potency of the vector with the antigenicity of the new vaccine insert

For example, the insert can be Simian Immunodeficiency Virus (SIV) gag protein. Rubella can accommodate the entire SIV gag protein p27, and the insert is stably expressed for more than 10 passages in cell culture. The vector also grows well in vivo, and it elicits antibodies and T cell immunity against SIV gag that are comparable to natural SIV infection. The result may be protection against SIV infection.

Similarly, the insert can be malaria Circumsporozoite Protein (CSP). Antibodies specific for CSP can protect against malaria infection. One quarter of the world's population are exposed to malaria, and there is no vaccine. The rubella/CSP vectors may establish sufficient immunity in young children to prevent the severe disease that occurs in this age group.

Recently, we have found that certain host cell proteins can be expressed by

rubella. By immunizing against cell proteins on the surface of lymphocytes, we may knock out selectively the function of an entire cell subset. For example, antibodies to CD20, CD4, or CD8 could wipe out the effector functions of B cells, helper T cells, or cytolytic T cells if given separately. But, given together, they could modulate the function of all lymphocytes.

The selected participant's research project will start by identifying target antigens. The participant will assist to incorporate targets of protection into the vectors and select for growth and immunogenicity. CBER has animal facilities that provide a unique opportunity to study macaques for immunization and protection by live viral vectors.

Under the guidance of a mentor, learning objectives will include: vaccines based on experiential learning, molecular biology, vector growth and protein expression, and measuring neutralizing antibodies that predict immunity and protection against live viral challenge.

Anticipated Appointment Start Date: June 2022; 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 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 (e.g. Molecular Biology, Virology, Immunology), or be currently pursuing the degree with completion by the appointment start date. Degree must have been received within the past five years.

Preferred Skills:

- Training in molecular biology, virology, and immunology
- Experience with vaccine design and vector construction, reverse genetics and vector growth, protein expression and immunological

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assays to evaluate antiviral antibodies and T cells
- Excellent problem-solving, planning, and analyzation skills
- A desire to solve difficult problems in protein expression and stability

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Communications and Graphics Design** (1 👁)
  - **Computer, Information, and Data Sciences** (3 👁)
  - **Engineering** (1 👁)
  - **Life Health and Medical Sciences** (48 👁)
  - **Science & Engineering-related** (1 👁)

Affirmation Have you lived in the United States for at least 36 out of the past 60 months? (36 months do not have to be consecutive.)