Opportunity Title: Biostatistics Research Opportunity in Clinical Studies
Opportunity Reference Code: HHS-BARDA-2019-0001

Organization U.S. Department of Health and Human Services (HHS)

Reference Code HHS-BARDA-2019-0001

How to Apply A complete application package consists of:

- An application
- Transcript(s) – For this opportunity, an unofficial transcript or copy of the student academic records printed by the applicant or by academic advisors from internal institution systems may be submitted. Selected candidate must provide proof of completion of the degree before the appointment can start. Proof must be sent to ORISE directly from the academic institution including graduation date and degree awarded. All transcripts must be in English or include an official English translation. Click **Here** for detailed information about acceptable transcripts.
- A current resume/CV
- Two recommendations – While two recommendations are requested, applications will be considered without recommendation information. It is preferred that a complete application package contains a minimum of one recommendation.

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

Application Deadline 5/31/2019 3:00:00 PM Eastern Time Zone

Description The Division of Clinical Development (DCD) within the Biomedical Advanced Research and Development Authority (BARDA) (part of the U.S. Department of Health and Human Services) provides technical support for all the clinical studies funded and sponsored by BARDA, and the application of innovative clinical trial design is critical in meeting the challenges of the advanced development of medical countermeasures for emerging health threats of the US population.

Under the guidance of a mentor, the participant will be involved with innovative clinical trial design development effort. The learning objectives for the participant are: 1) To collaborate with their mentor to conduct research and develop innovative clinical trial designs for medical countermeasures. 2) To gain hands-on experience with the implementation of clinical trials in real-time.

Main activities will include contributing to discussions on developing and applying new methodologies on innovative clinical trial design and analysis, and conducting simulation studies to assess the performance of the proposed trial designs and data analyses. Other opportunities may include providing technical support for DCD projects, learning how to develop relevant study documents such as clinical study protocols and statistical analysis plans, interacting with program officers, participating in team communications with regulatory authorities and other federal partners, drug developers, academic centers, and Contract Research Organizations, all to ensure progress on the mission of BARDA.

Areas of interest include:

1. Literature research: perform literature research on innovative trial design methodology, such as adaptive trial design and Bayesian trial design, with the goal of identifying appropriate trial design candidates for a clinical trial for the development of novel therapeutics for serious influenza illnesses.
2. Simulation study: conduct simulation studies with R and SAS to capture the operating characteristics of candidate novel trial designs, with the goal of identifying the best trial design

in terms of trial performance utilities.

3. Comparative research: compare the proposed novel design with the conventional designs, with the goal of characterizing the advantages and disadvantages of the novel trial design.
4. Data analysis: apply the novel trial design methodology to real clinical trial data to access the feasibility and performance of the novel trial design.
5. Provide statistical support: help develop task orders and study protocols to support an integrated summary of safety of pandemic influenza vaccines and adjuvants to be conducted by DCD's clinical study network
6. Technical support for representative clinical trials supported by DCD: actively participate in selected Project Coordination Team (PCT) meetings to provide technical advice related to clinical study design; participate in team communications with FDA, sponsors, CROs, and other partners to ensure progress.

Travel for presentations at conferences/meetings may be required.

Anticipated Appointment Start Date: September 1, 2019

This program, administered by ORAU through its contract with the U.S. Department of Energy (DOE) to manage the Oak Ridge Institute for Science and Education (ORISE), was established through an interagency agreement between DOE and BARDA. The initial appointment is for one year, but may be renewed upon recommendation of BARDA and is contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience, a monthly health insurance stipend supplement, and a travel allowance. Proof of health insurance is required for participation in this program. The appointment is full-time at HHS in the Washington, DC, area. Participants do not become employees of HHS, BARDA, DOE or the program administrator, and there are no employment-related benefits.

While participants will not enter into an employment relationship with BARDA, this appointment requires a pre-appointment check and a full background investigation.

This opportunity is available to U.S. citizens and Lawful Permanent Residents (LPR).

Qualifications

The qualified candidate should have a master's or doctoral degree, or be in the late stage of pursuing an advanced degree in statistics or biostatistics.

Preferred skills:

- Experience in clinical studies and data analysis
- Proficiency in programming languages R and SAS
- Excellent oral and written communication skills
- Critical thinking, data analysis, and protocol/study design skills
- Independence, self motivation, and the ability to take initiative

Eligibility Requirements

- **Citizenship:** LPR or U.S. Citizen
- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
  - **Mathematics and Statistics** (10 👁)

Affirmation

I have received a master's or doctoral degree, or am in the late stages of completing a master's or doctoral degree.