Opportunity Title: Postdoctoral Research Opportunity in Clinical Trial Design
Opportunity Reference Code: BARDA-DCD-2018-249-0008

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

Reference Code BARDA-DCD-2018-249-0008

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 references – While two references are requested, applications will be considered without reference information. It is preferred that a complete application package contains a minimum of one reference.

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

Application Deadline 10/26/2018 4:00:00 PM Eastern Time Zone

Description The Division of Clinical Development (DCD) within the Biomedical Advanced Research and Defense Authority (BARDA) (part of the U.S. Department of Health and Human Services) provides technical support for 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.

The participant will assist with the innovative clinical trial design development effort. The learning objectives for the participant are: 1) To facilitate research and development of 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, assisting in the development of 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 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 subject matter expertise 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.

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. 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 position 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 applicant should have a Ph.D. or be in the process of pursuing an advanced degree in Statistics or Biostatistics. A strong background in clinical trial research is preferred.

Preference will be given to applicants with experience and training in critical thinking, clinical trial design, and data analysis. Strong programming skills

in R and SAS are highly desired. Excellent oral and written communication skills will be needed. Independence, self motivation, and the ability to take initiative would be considered favorable.

Eligibility Requirements

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