

Opportunity Title: MyPAH Fellowship - FDA CDER Opportunity Reference Code: FDA-CDER-2018-0271

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

Reference Code FDA-CDER-2018-0271

How to 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
- Two educational or professional references

All documents must be in English or include an official English translation.

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

Description A research opportunity is available in the Office of New Drugs, Division of Cardiovascular and Renal Products at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA).

> The MyPAH mobile app is the first mobile app developed for patients with pulmonary artery hypertension (PAH). It is intended to leverage state-ofthe-art digital technologies and build on the FDA's Patient-focused Drug Development commitments, while providing a valuable resource for patients, providers, researchers, and the FDA. Development of this mobile app potentially opens clinical trial participation to a segment of the PAH population that is difficult to reach or sustain for clinical trial participation, including pediatric and geriatric patients, as well as other PAH patients that have a difficult time participating in trials due to the severity of their disease.

> Under the guidance of a mentor the participant may be involved in: further developing the prototype to include all the intended capabilities and ensure that it is both Apple and Android ready; deploying the prototype in the Apple and Android stores prototype section and work out prototype testing program with PHA; after completion of prototype testing, addressing issues uncovered in the prototype testing (fixes, enhancements); and finalizing a protocol, post a trial in clinical trials.gov.

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 12 months, 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 or the program administrator, and there are no fringe benefits paid.

The Homeland Security Presidential Directive-12 (HSPD-12) mandates a



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background check be completed for both U.S. Citizens and foreign nationals. Foreign nationals must have resided in the U.S. for at least (3) of the past five (5) years in order for FDA to be able to complete a background check.

## Qualifications

- Currently pursuing or having recently completed a Master's or Doctoral degree in Biomedical Engineering, Electrical Engineering or related fields such as computational biology/bioinformatics, systems biology, biophysics or related fields with a strong emphasis on programming in the context of wireless health and wearable computing, and a familiarity with ordinary differential equations
- Familiarity with coding for mobile apps for both IOS and Android, as well
  as integrating mobile apps with wearables, biosensors, and other
  technology platforms.

## Eligibility Requirements

- **Degree**: Master's Degree or Doctoral Degree received within the last 60 month(s).
- Discipline(s):
  - Computer, Information, and Data Sciences (<u>5</u>.
  - o Engineering (<u>1</u>.●)
  - Life Health and Medical Sciences (10 •)
  - Mathematics and Statistics (3\_●)

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