

Opportunity Title: CDER Program, Policy and Operational Analysis Fellowship -

CDER

Opportunity Reference Code: FDA-CDER-2018-0240

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

Reference Code FDA-CDER-2018-0240

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 at the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Strategic Programs/Office of Program & Strategic Analysis.

> The Center for Drug Evaluation and Research (CDER) Office of Strategic Programs (OSP) Office of Program and Strategic Analysis (OPSA) proposes a project to participate in, support and analyze a broad range of proposed and current CDER programs and policies. This project's objective is to assess the impact and efficiency of CDER initiatives and programs; design and implement new programs; advance structured benefit-risk assessment in regulatory decision making; and evaluate key business processes using an evidence-based approach that assesses the value of each step and leads to sustained practical solutions for complex problems.

> Under the guidance of a mentor the participant may be involved in: consulting stakeholders and conducting background research related to a policy or data need identified by the mentor; assisting mentor in development of research methodology and project plan through contributing to relevant research; compiling and analyzing relevant qualitative and quantitative data; and synthesizing and presenting findings, recommendations and implementation insights.

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, MD area. Participants do not become employees of FDA or the program administrator, and there are no fringe benefits paid.

Qualifications Applicants must have received a Bachelors or Master's degree in



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Biomedical Sciences within five (5) years of the desired starting date. Familiarity with statement of problem, project analysis plan, data and analysis documentation, and synthesis of results and findings is desired.

Eligibility Requirements

- **Degree**: Bachelor's Degree or Master's Degree received within the last 60 month(s).
- Discipline(s):
 - Environmental and Marine Sciences (1_●)
 - Life Health and Medical Sciences (45 ●)

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