

Office of Clinical Pharmacology

OCP ORISE Fellowship Program for Training in Policy Development and Regulatory Science (OCP Policy and Research Fellowship) 2021-2022

The Office of Clinical Pharmacology (OCP) at the U.S. Food and Drug Administration (FDA) is seeking interested individuals for a **one-year** ORISE (Oak Ridge Institute for Science and Education) fellowship to conduct regulatory research on OCP and FDA policy priority topics that will advance new drug development and promote therapeutic individualization. For more information on timeline and past fellow projects, please visit this site <u>OCP Policy and Research website</u>. Potential project topics are diverse and will be instrumental in informing the development of both scientific and regulatory guidelines and policies. Possible project topics can include programmatic evaluation of clinical pharmacology-informed regulatory decisions (e.g., model informed drug development, citizen's petitions, reviews, regulatory milestone communications, etc.).

At FDA, OCP is housed within the Center for Drug Evaluation and Research (CDER) and is a dynamic organization with a mission to improve public health by enabling patient-centered regulatory decisions of the highest quality. For more information about OCP, please visit <u>OCP's website</u>.

The OCP fellowship will include three components: 1) OCP and FDA regulatory research, 2) self-guided didactic training through the FDA scientific and professional courses, and 3) additional projects and activities for fellow-specific professional development. Fellowship mentoring will also be determined by the fellow's style and professional interests.

For more information about FDA ORISE fellowships, please visit <u>https://orise.orau.gov/fda/</u>. Prospective fellows should have an advanced degree in a STEM or health-related field (e.g., MS, PhD, PharmD, and/or MD) received within 5 years of August 2021. Because of ORISE security requirements, foreign nationals must have resided in the U.S. for at least three of the past five years. Additionally, the candidate should possess excellent analytical, research, and communication skills, and have a profound interest in leading projects that advance regulatory science and public health.

To apply, email the following to <u>CDEROTSHires@fda.hhs.gov</u> no later than <u>April 30, 2021</u>:

- A short introductory paragraph (4-8 sentences)
- Current CV

The subject line should be '<u>OCP Policy and Research Fellowship</u>'. The anticipated fellowship start date is between late Summer to early Fall 2021.