

**Opportunity Title:** Fellowship in Clinical Pharmacology of Monoclonal

Antibodies – Effects of Obesity in Pediatric Patients

**Opportunity Reference Code:** FDA-CDER-2024-1400

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

**Reference Code** FDA-CDER-2024-1400

### How to Apply

**Connect with ORISE...on the GO!** Download the new ORISE GO mobile app in the [Apple App Store](#) or [Google Play Store](#) to help you stay engaged, connected, and informed during your ORISE experience and beyond!

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
- One educational or professional recommendation
- A copy of an abstract or reprint of an article

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

If you have questions, send an email to [ORISE.FDA.CDER@orau.org](mailto:ORISE.FDA.CDER@orau.org). Please include the reference code for this opportunity in your email.

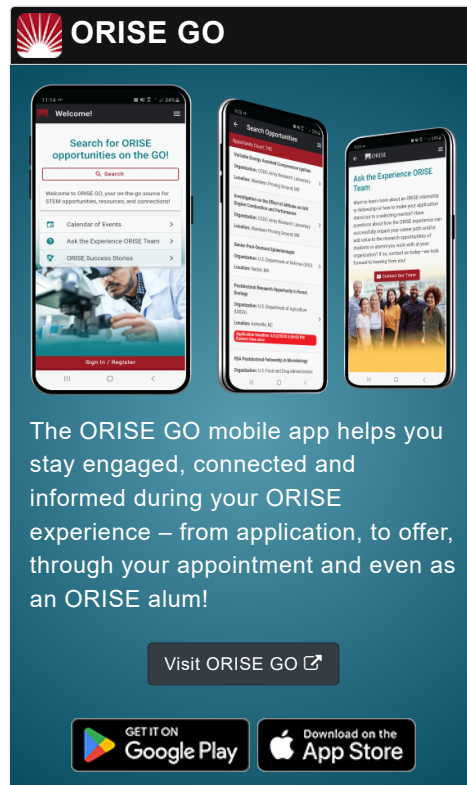
**Application Deadline** 6/28/2024 3:00:00 PM Eastern Time Zone

**Description** **\*Applications will be reviewed on a rolling-basis.**

**CDER Office and Location:** A research opportunity is available within the Food and Drug Administration (FDA) in The Center for Drug Evaluation and Research (CDER), located at Silver Spring, Maryland.

The Center for Drug Evaluation and Research (CDER) performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines.

**Research Project:** This project is in the Office of Clinical Pharmacology (OCP), Office of Translational Sciences (OTS). Monoclonal antibodies are significantly different than standard drugs in that they are much larger, circulate in the body for longer duration of time, and are cleared from the body by the immune system and target cells. Studies suggest that a patient's body size (e.g., weight) affects how the body handles and drug and how the drug works in the body in pediatric and adult patients, especially in obese patients, and that these effects are more pronounced in pediatric patients. In addition, data suggests that individualizing the dose of an antibody based on a patient's weight does not fully account for these effects and the effects are greater with subcutaneous administration. Thus, there is a



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critical need to evaluate the effects of obesity on pharmacology, efficacy, and toxicity of antibodies in pediatric patients.

This project fulfills the need to:

- Evaluate the effect of obesity on the PK and PD;
- Initiate the evaluation of novel individualized dosing strategies; and
- Ultimately address lower exposures and lower clinical response of antibodies in obese pediatric patients.

**Learning Objectives:** Under the guidance of the mentor, the participant will gain in-depth knowledge on

- Clinical pharmacology of monoclonal antibody therapeutics approved by the FDA, including pharmacokinetics and pharmacodynamics,
- Regulations and regulatory evaluation of intrinsic and extrinsic factors influencing the in vivo disposition with an emphasis on the body weight,
- Modeling and simulation methodologies to evaluate the patient covariates on the pharmacokinetics and pharmacodynamics of monoclonal antibodies administered via intravenous and subcutaneous routes in obese and non-obese pediatric subjects , and
- Dose selection strategies for matching the systemic exposure of pediatric subjects to that of the adults over a wide range of body weight, including obese pediatric subjects.

**Appointment Length:** The appointment will initially be for one year, but may be renewed upon recommendation of FDA and is contingent on the availability of funds.

**Level of Participation:** The appointment is full time.

**Citizenship Requirements:** This opportunity is available to U.S. citizens, Lawful Permanent Residents (LPR), and foreign nationals. Non-U.S. citizen applicants should refer to the [Guidelines for Non-U.S. Citizens Details page](#) of the program website for information about the valid immigration statuses that are acceptable for program participation.

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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 participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

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Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.

#### **FDA Ethics Requirements**






If an ORISE Fellow, to include their spouse and minor children, reports what is identified as a Significantly Regulated Organization (SRO) or prohibited investment fund financial interest in any amount, or a relationship with an SRO, except for spousal employment with an SRO, and the individual will not voluntarily divest the financial interest or terminate the relationship, then the individual is not placed at FDA. For additional requirements, see [FDA Ethics for Nonemployee Scientists](#).

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

**Qualifications** The qualified candidate should have received a Doctoral Degree in one of the relevant fields. Degree must have been received within the past five years.

**Eligibility Requirements**

- **Degree:** Doctoral Degree received within the last 60 month(s).
- **Academic Level(s):** Postdoctoral.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (2 )
  - **Computer, Information, and Data Sciences** (1 )
  - **Engineering** (27 )
  - **Life Health and Medical Sciences** (51 )
  - **Mathematics and Statistics** (11 )

**Affirmation** I have lived in the United States for at least 36 out of the past 60 months. (36 months do not have to be consecutive.)

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I have read the FDA Ethics Requirements.