Opportunity Title: FDA Development of a Cell-based Potency Assay for Reproductive Hormone Therapies
Opportunity Reference Code: FDA-CDER-2026-0081

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

Reference Code FDA-CDER-2026-0081

How to Apply ***To submit your application, scroll to the bottom of this opportunity and click 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
- One educational or professional recommendation

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. Please include the reference code for this opportunity in your email.

Application Deadline 5/31/2026 3:00:00 PM Eastern Time Zone

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

FDA 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 White Oak, 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 effort covers more than just medicines.

Research Project: You will cooperate in developing bioassays to assess the potency of fertility hormones. This will include follicle stimulating hormone, Luteinizing hormone and human chorionic gonadotropin hormones. During the project, you will participate in developing cell lines that expresses specific receptor and develop reporter assays and functional assays to characterize the bioactivity of hormones. In addition, you will also help with the validation of bioassays. Lastly, you will use advanced analytical characterization techniques to help assess product quality attributes of hormones and develop a comprehensive product quality control strategy for fertility hormones.

Learning Objectives: During the appointment, you will be trained in:

1. The development of cell lines for bioassays. This includes cloning of specific genes, monitoring gene expression, selection of clones, single cell cloning, storage retrieval and routine maintenance.
2. Validation of bioassays. This will include testing for sensitivity, specificity, selectivity, accuracy and precision.

3. Using advanced analytical characterization techniques to assess product quality attributes of hormones.
4. Presenting the results in scientific forums like FDA ORISE seminar series, CDER science day and FDA science forum.

Mentor: The mentor for this opportunity is Mohanraj Manangeeswaran (mohanraj.manangeeswaran@fda.hhs.gov). If you have questions about the nature of the research, please contact the mentor.

Anticipated Appointment Start Date: As soon as possible, 2026. Start date is flexible and will depend on a variety of factors.

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

Level of Participation: The appointment is full time.

Participant Stipend: The participant will receive a monthly stipend commensurate with educational level and experience.

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.

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.

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.

Opportunity Title: FDA Development of a Cell-based Potency Assay for Reproductive Hormone Therapies
Opportunity Reference Code: FDA-CDER-2026-0081

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 or be currently pursuing a master's or doctoral degree in one of the relevant fields.

Point of Contact Ashley

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree.
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1)
  - **Life Health and Medical Sciences** (51)

Affirmation I am a U.S. citizen, or 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.)
and
I have read the FDA Ethics Requirements.