

Opportunity Title: Gene Therapy - FDA CBER
Opportunity Reference Code: FDA-CBER-2018-0001

- Organization** U.S. Food and Drug Administration (FDA)
- Reference Code** FDA-CBER-2018-0001
- 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.

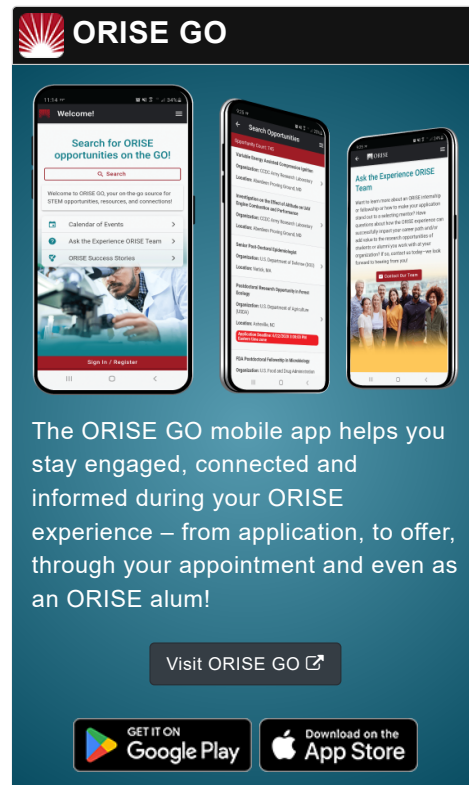
If you have questions, send an email to FDArpp@orau.org. Please include the reference code for this opportunity in your email.

Description A research opportunity is available at the Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), Office of Tissues and Advanced Therapies (OTAT), Division of Cellular and Gene Therapies (DCGT). OTAT/DCGT protects and enhances public health by assuring that gene and cell-based therapeutic products (including stem cell products) and tissue engineered products are safe and effective.

Under the mentorship of a senior scientific staff, the participant will have an opportunity to perform FDA/OTAT mission relevant laboratory research on gene therapy with focus on CAR-T cells. The participant will gain practical experience characterizing intracellular signaling pathways of engineered T cells and assess novel biomarkers to predict safety and efficacy of T cell therapies.

This program, administered by ORAU through its contract with the U.S. Department of Energy (DOE) 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 recommendations 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 Silver Spring, Maryland. Participants do not become employee of the FDA.

The Homeland Security Presidential Directive-12 (HSPD-12) mandates a background check be completed for both U.S. citizens and foreign nationals. Foreign nationals must have

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resided in the U.S. for at least three (3) of the past five (5) years in order to complete a background check.

Qualifications Applicants must have received a Doctoral degree in Biochemistry, Basic Biomedical Science, Cellular and Molecular Biology, Immunology, Microbiology, Virology, Pharmacology, or related disciplines within five (5) years of the desired starting date. Knowledge in gene therapy and T cell immunology, in particular, CAR-T cells is highly desirable. Strong collaborative skills, as well as both written and oral communication skills is also desirable.

Eligibility Requirements

- **Degree:** Any degree received within the last 60 month(s).
- **Discipline(s):**
 - **Life Health and Medical Sciences** (7 👁)
- **Age:** Must be 18 years of age