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Opportunity Title: FDA Postdoctoral Fellowship on CAR T-cell Neurotoxicity
Opportunity Reference Code: FDA-NCTR-2024-0007

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

Reference Code FDA-NCTR-2024-0007

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.NCTR@orau.org. Please include the reference code for this opportunity in your email.

Application Deadline 4/30/2025 3:00:00 PM Eastern Time Zone

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

FDA Office and Location: A postdoctoral fellowship opportunity is currently available in the Division of Neurotoxicology, National Center for Toxicological Research (NCTR) of the U.S. Food and Drug Administration (FDA) Jefferson Laboratories Campus located in Jefferson, Arkansas.

Research Project: The successful candidate will participate in a multi-disciplinary project to develop and characterize a human-relevant model to evaluate neurotoxicity induced by chimeric antigen receptor (CAR) T-cells. The project aims to evaluate if neurological adverse events observed after CD19 CAR T-cell therapies can be replicated in an in vitro setting, using new alternative methods (NAMs). The model uses patient-derived induced pluripotent stem cells (hiPSCs) and microphysiological systems (organ-chips) to recreate the pediatric and adult neurovascular unit.

The candidate will collaborate with FDA investigators at NCTR and with investigators in other FDA centers. During the project, the candidate will be actively encouraged to present the research at internal and external meetings and publish the findings in peer-reviewed journals.

Learning Objectives:

- Gain hands-on experience with microphysiological systems (brain-chip).
- Gain hands-on experience with the differentiation of hiPSCs into different brain cell types.
- Gain hands-on experience with culture and evaluation of CAR T-cells.
- Gain hands-on experience with different techniques to evaluate neurovascular toxicity, including confocal microscopy, functional and biochemical analysis.
- Training on protocol, abstract, manuscripts and grants writing.
- Acquire knowledge on the non-clinical aspects of the drug/biologic approval process by the FDA.

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Anticipated Start Date: January, 2025. 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.

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.

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 be currently pursuing or have received a doctoral degree in one of the relevant fields (e.g. Neuroscience, Toxicology/Genetic Toxicology, Cellular and Molecular Biology, Biomedical Science). Degree must have been received within the past five years or be currently pursuing with anticipation to receive by the appointment date.

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Preferred skills:

- Knowledge in the areas of Cellular and Molecular Biology, Neuroscience and Toxicology.
- Knowledge of CAR T-cell therapies. • Knowledge in blood-brain barrier/neurovascular unit physiology.
- Prior experience in hiPSCs culture, differentiation, and characterization.
- Prior experience with the use of microphysiological systems or organ-chips is desirable.
- Prior experience with CAR T-cells culture is desirable.
- Prior experience in cellular and molecular biology methods (cell culture, western blot, PCR, ELISA, immunocytochemistry).
- Prior experience in confocal microscopy is desirable.
- Candidates should be highly motivated with demonstrated excellent written and oral communications skills and the ability to work as part of a multidisciplinary team.

Point of Contact Sherry Foster

Eligibility Requirements

- **Degree:** Doctoral Degree received within the last 60 months or currently pursuing.
- **Discipline(s):**
  - **Life Health and Medical Sciences** (7 👁)

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.