

US Food and Drug Administration
Center for Drug Evaluation and Research
Office of Biostatistics

Oak Ridge Institute for Science and Education (ORISE)

Summer of 2023 (May through September)

Full-Time – Virtual (currently)

December/January issue of AmStat St@tTrak

*Other opportunities at www.Zintellect.com

2020 Longitudinal study of 248 FDA* alumni

- 95% are employed in STEM-related occupations
- 46% were retained by FDA* by appointment renewal or full-time employment
- 13% serve as mentor, host, or collaborator to ORISE participants at FDA* and other federal agencies
- 47% continue to collaborate with FDA in various federal, academic, or private sector positions
- 76% recommend program to others

Program Purpose

- An educational and developmental program in science, mathematics, engineering, and/or technology (STEM) to receive related training and provide participants the opportunities to:
 - Continue their education and research training
 - Enhance their professional development
 - Become familiar with research areas conducted at CDER
 - Become interested in future careers related to CDER and/or the FDA's public health mission, or in the case of faculty, enhance this opportunity for their students
- Workforce development through research participant programs
- The ORISE Research Participation Programs are designed to:
 - Be educational/training programs to provide students, recent graduates, and university faculty opportunities to participate in STEM project-specific research and developmental activities
 - Enhance the educational programs offered by academic institutions
 - Strengthen the nation's scientific and technical human resource base
 - Support a growing national commitment to science education

Research participant programs in a virtual environment

- Participants will have more independent time
 - Actively communicate with mentors
 - Ask for the support that you need to have a fulfilling summer research experience
- Specific suggestions
 - Ask your mentor to identify specific learning objectives
 - Work with your mentor to develop an outline of weekly activities and goals
 - Document an individual development plan
 - Meet regularly to review progress towards the outlined plan and individual development plan
- “approximately 75% of our workforce chose to work remote/100% telework with their supervisor’s concurrence, and 25% elected a combination of in person work/telework.” Agency IQ

Status

- Non-employee training and research program
 - You do not earn employee benefits, including leave.
 - If a medical or other emergency requires you to take time off from your appointment, notify your mentor. Then contact ORISE confirming the dates you will be away from your appointment.
 - Your stipend is not a salary. No taxes will be withheld.
 - Your stipend is considered taxable income. You are responsible for paying taxes.
 - Your stipend is considered an educational fellowship, not self-employment.
 - You will not be eligible for unemployment benefits when your appointment ends.
- Fellows are “administratively associated” with ORAU/ORISE through:
 - Letter of Appointment
 - Terms of Appointment
 - Oak Ridge Institute for Science and Education (ORISE) is operated by Oak Ridge Associated Universities (ORAU) under a Department of Energy (DOE) contract
 - FDA/CDER has interagency agreement with DOE for a research and training program under ORISE
- All appointments are temporary and subject to the availability of funds

Hardware

- Basic Regulatory Laptop comes in two sizes: standard (Dell 5520) and lightweight (Dell 7320).
 - Standard 32G RAM, 512 SSD
 - Lightweight 16G RAM, 512 SSD
 - May struggle with large data sets and simulations
- OB Shared Scientific Workstations
 - 192G RAM, 1T+ disk space,
 - Can handle larger data sets, more simulations
 - Accessible via remote desktop application
 - AI workstations have more capacity.
 - Only 5-6 available for ORISE interns at this stage. Permission to use will be required.
- High Performance Computing (HPC) Environments
 - Need to go through approval process, need account
 - Linux command line interface
 - 4400+ cores
 - Good for large scale simulations

Software

- General statistical
 - R (4.2), Rstudio (2022), Rtools (40)
 - SAS Studio on SARGE (SAS Analytics Remote Grid Environment)
 - Stata (limited)
- Power and Sample Size Calculators
 - nQuery (site license)
 - EAST (site license)
- Adaptive Design, group sequential
 - AddPlan
 - EAST
 - FACTS
 - gsDesign, RCTdesign
- Bayesian
 - FACTS
 - OpenBUGS
 - JAGS
 - Stan
- StatXact, LogXact, StatXact Procs
- StatTransfer
- flexMIRT
- Mplus
- Mathematica (3 user network license)
- MATLAB (select workstations)
- Python (Anaconda)
- LaTeX: MikTeX, WinEdt
- SnagIt
- Shiny apps