

**THE OAK RIDGE INSTITUTE FOR SCIENCE
AND EDUCATION (ORISE) RESEARCH
PARTICIPATION TRAINING PROGRAM FOR THE CENTER
FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)**

I. PURPOSE

The purpose of this Guide is to establish Center policy concerning the ORISE Research Participation Training Program, as well as to delineate the procedures under which the Fellow and Mentor may engage in mentored scientific studies in a CBER research laboratory or other CBER facility. The purpose of this program is to provide practical scientific training experiences through temporary fellowship appointments.

II. REFERENCES

Interagency Agreement between the Department of Energy and the Food and Drug Administration, dated October 1994

Section 301 of the Public Health Service Act (42 U.S.C. 241)

Economy Act of 1932, as amended (31 U.S.C. 1535), or other statutory authority references and adheres to Federal Acquisition Regulation (FAR) 6.002

ORISE Contract (Non-FTE) Fellowship Research Training Program Frequently Asked Questions: <http://research.cber.fda.gov/ContractFellowship/faq.html>

III. DEFINITION of Non-FTE:

For the purpose of this document, **non-FTE persons** will define individuals in non-civil service appointments, but who are:

- Engaged in scientific studies and investigations using CBER facilities; and/or
- 2) Involved in temporary exchange agreements between CBER and another federal agency or institution of higher education.

IV. BACKGROUND

The ORISE Research Participation Training Program for CBER provides practical scientific training for domestic and foreign scientists and physicians having a background or interest in medical, biological, chemical, toxicological, mathematical/statistical, physics, or other related sciences. Such practical training experience shall be derived through the conduct and support of scientific projects performed on-site. All studies/projects shall be relevant or pertinent to the needs and mission of the FDA.

By supporting this program, CBER will provide Fellows with opportunities to (1) continue their research training/education, (2) enhance their professional development in specific areas, (3) become familiar with the research areas of CBER, and (4) become interested in future careers in fields related to CBER and/or FDA missions. As a result of these research participation appointments, new knowledge and technology will be introduced into programs at academic institutions and other research facilities.

V. POLICY

All appointments are temporary. Fellows selected for appointments in this Program will be hired as contractors (**non-FTEs**) through the Oak Ridge Associated Universities (ORAU). The Fellow receives guest appointments at CBER but does not enter into an employer/employee relationship with CBER, or any other office, organization, or agency. Fellows are administratively associated with the Contractor through a “Letter of Appointment and Terms of Appointment” and must be in residence at CBER or another approved facility during the entire period of the appointment. Fellows receive no salaries or fringe benefits. Fellows are considered “Students-in-Training” and receive a monthly stipend which is considered a fellowship grant for tax purposes. There is no commitment, expressed or implied, to future employment by CBER. All appointments are subject to the availability of funds and may be terminated if appropriated funds are unavailable.

Types of Appointments:

- Pre-doctoral: Allows for college undergraduates, masters and doctoral candidates, and recent post-baccalaureate and post-masters candidates to participate in practical research training at CBER.
- Postdoctoral: Allows individuals receiving a doctoral degree to participate in practical research training at CBER.
- Faculty: Allows qualified U.S. citizens, foreign nationals, and permanent resident alien university faculty to conduct collaborative research on a full or part-time basis, which compliments research, projects, or assessments at CBER.
- Summer Research Program: Allows full-time summer appointment opportunities for second semester freshmen and above and graduate science, engineering, and mathematics students considering a career in science an opportunity to participate in FDA research projects. Summer appointments are normally 10 – 12 weeks and individual must be at least 16 years of age.
- Foreign Nationals Training: Offers recent pre- and post- graduates and full-time college/university faculty from foreign countries an opportunity to participate in practical collaborative research. After the on-site training, the Fellow is expected to return to their country of origin to teach or apply the methods or techniques learned.
- Other applicants, including **established research scientists** (five years or more beyond earning a degree) will be considered on a case-by-case basis with formal justification

from CBER. **The justification should include: 1) How the research participation experience will benefit the established scientist (e.g., will he/she learn a new procedure or gain experience using a new piece of equipment during the appointment?; what will he/she continue to learn and/or accomplish through this participation experience, etc?.); 2) Will the established scientist's participation experience enhance their professional and educational development in specific areas?; and 3) How will the established scientist's work contribute to CBER's mission?**

Eligibility:

Postgraduate applicants should have received a college degree within five years of the appointment start date or expect to complete all requirements for such a degree prior to the appointment start date.

Foreign national appointments (**see below for visa classes accepted in this Program**) may not exceed the duration of their visa.

Former government employees, **excluding former FDA employees**, will be considered on a case-by-case basis, if there are appropriate professional and educational development opportunities for the candidate as part of the appointment. **Written justification is required, to include: 1) How the research experience will benefit the candidate (e.g., will he/she learn a new procedure or gain experience using a new piece of equipment during the appointment?; 2) Will the candidate's participation experience enhance their professional and educational development in specific areas?; and 3) How will the candidate's work contribute to CBER's mission?**

Commissioner's Fellows: Graduates of the Commissioner's Fellowship Program will be considered if they are currently enrolled in or have recently graduated from a degree program (within five years).

Appointments are limited to a total of five years, **inclusive** of all ORISE appointments. Qualified exceptions to this limit will be evaluated on a case-by-case basis with written justification, but may not exceed a maximum of seven years. **Justification for the 6th and 7th year request must include: 1) How the extra year (or two) will be beneficial to furthering the Fellow's research training/education?; 2) Will the Fellow's continued participation enhance their professional and educational development in specific areas?; 3) Why the research project requires continued support from the Fellow?; and 4) How is the Fellow's work contributing to CBER's mission?**

This will be an equal opportunity Program, open to all qualified individuals without regard to race, sex, religion, color, age, physical or mental disability, national origin, or status as a disabled veteran.

The following non-immigrant visa classes are accepted in the ORISE Program:

J1 – A Foreign National entering the U.S. temporarily to study, teach, conduct research or receive training as a Fellow in a sponsor specific Exchange Visitor Program. Time

limitations: Three years, with a possible six-month terminal extension by the contracting organization or on a case-by-case basis an exceptional 4th and 5th year beyond the initial three years, with concurrence from U.S. Immigration and Naturalization Services (INS), Department of Homeland Security (DHS).

- F1 -** A Foreign National entering the U.S. temporarily as a bona fide student to pursue a full course of study at an established college, university, seminary, conservatory, academic high school or other academic institution. Time limitations: for the “duration of status”, that is, to complete an education program. However, if a student must remain in an educational program beyond the date originally estimated for completion of the education program, the student must comply with INS, DHS procedures for program extension.

Program Operations:

Working in cooperation with CBER, ORISE will provide the following support services:

- Develop and implement procedures for recruiting applicants who have backgrounds and experience relevant to CBER’s mission. Specific recruitment efforts may be limited to a single position or be for multiple positions.
- Prepare and distribute position and/or program announcements via mailing/emails to program contacts at CBER.
- List announcements in on-line services, campus newspapers, and professional publications.
- Conduct on-campus visits, including career fairs, and recruit at professional society meetings and conferences.
- Make special efforts to recruit women, minorities, and others who are under represented in science and technical fields.
- Prepare and distribute application materials to program contacts.
- Receive and review applications for eligibility and completeness; and process applications.
- Provide application materials of eligible applicants to CBER for review and selection.
- Make offers to individuals and process appointments of selected individuals.
- Handle administrative activities related to the Fellow’s appointment, including stipends and travel reimbursements.

To assist in the administration of this Program, CBER will provide the following support services:

- Provide ORISE with information on the types of appointments desired, as well as the amount of funding for each appointment.
- Assist in the establishment of Program policies and procedures.
- Assist in preparing descriptions of ongoing projects for distribution to applicants.
- Assist in identifying and recruiting qualified applicants.
- Review candidates for appointments and cooperate with ORISE in the selection process.
- Obtain required approvals and clearances for selected individuals assigned to CBER.
- Identify a coordinator to interact with ORISE, applicants, and Fellows.

- Provide a description of the project for each Fellow and assist him/her in becoming established as functional members of the laboratory to which they are assigned.
- Assist in assessing and reporting program activities by providing information on activities and contributions of Fellows.
- Provide Fellows with appropriate orientation, to include environmental, safety, and health training.
- Provide mentors to interface with Fellows during the appointment.
- Provide funding in a timely manner to support the Program.

Funding:

Funding for Fellows is provided by CBER. Funds will be directly obligated to ORISE/ORAU for each Fellow, to include an agreed upon overhead charge, which is applied to all direct Fellow costs. Contact your Office Program Manager for overhead charges.

Stipend:

Fellowship stipend amounts will be determined by CBER, informed by the General Schedule Pay Scale to reflect the Fellow's experience, years in the position, and scientific contributions. An amount determined by CBER management may be added to a Fellow's stipend to cover yearly health benefits, as ORISE/ORAU does not provide health care directly. Stipends are reported to the Internal Revenue Service (IRS) as fellowship awards. However, no federal income taxes will be withheld by ORISE (except for some foreign nationals). The Fellow is responsible for all applicable taxes.

Reports and Publications:

All published reports, journal articles, or professional presentations that involve an ORISE fellow's participation should carry an acknowledgement such as: "This project was supported in part by an appointment to the Research Participation Program at the Center For Biologics Evaluation and Research administered by the Oak Ridge Institute for Science and Education through an interagency agreement between the U.S. Department of Energy and the U.S. Food and Drug Administration".

Health Insurance and Workers Compensation:

All Fellows must have, and demonstrate proof of, health and medical insurance as one of the conditions of the appointment. Insurance may be secured through the optional ORISE program, the Foundation for Advanced Education in the Sciences (<http://www.faes.org/>), or a private insurance company (e.g., Blue Cross/Blue Shield).

ORISE fellows are not entitled to workers compensation through the US government, Office of Workers' Compensation or ORAU. If injured on-sight, the Fellow must file a claim through their individual insurance company plan.

Disclaimer of Liability:

Neither ORAU, ORISE, CBER, or CBER's sponsoring agency or contractor will be responsible for: 1) Any alleged or actual liability, cost or expense incurred as a result of personal injury to or death of persons, including the Fellow, or damage to or destruction of property, or for any other loss, damage, or injury of any kind whatsoever, except where such death, injury, loss, or damage is the result of willful negligence or intentional misconduct of an employee of ORAU, ORISE, CBER, or CBER's sponsoring agency or contractor; 2) Any claims, losses, expenses (except as otherwise provided to the Fellow in the Terms of Appointment) or damages including but not limited to, bodily injury, death, or property damage caused by the negligence or misconduct of the Fellow; and 3) Any claims, losses, expenses, or damages including but not limited to, bodily injury, death, or property damage arising out of or resulting in any way from, the use or misuse of information acquired by the Fellow during the appointment.

Travel:

Fellows may travel to one domestic and one foreign scientific meeting per year as part of the training experience, pending supervisory and administrative approval. Domestic travel requests must be submitted to the sponsoring Office (at least) 45 days prior to the anticipated start date of the meeting. Foreign travel requests must be submitted to the sponsoring Office (at least) 60 days prior to the anticipated start date of the meeting. Decisions to send Fellows to meetings beyond this limit should be balanced with time, available resources, and adequate data to present, as well as approved by appropriate supervisory and administrative staff. For more details, see the ORISE Frequently Asked Questions (FAQ):

<http://research.cber.fda.gov/ContractFellowship/main.htm>.

Excused Absence with Stipend:

Contract Fellows, because they are not employees, do not earn annual or sick leave. However, they may be excused for: 1) Federal holidays, 2) illness, 3) personal emergencies, and 4) vacations when appointments are for more than 90 days. For vacations, Fellows receive a minimum of two weeks excused absence per year. That number of days should be prorated for appointments of 90 days or less. The immediate supervisor may exercise discretion in granting additional short absences as they deem appropriate.

Generally eight weeks of excused absence, **with stipend**, will be granted for the birth or adoption of a child or for other family health care. Maternity/Paternity leave with stipend for more than eight weeks may be granted at the discretion of the immediate supervisor. In addition, the immediate supervisor and supervisory chain of command (i.e., Div and/or Office Director) must excuse absences to accommodate a fellow's military obligations, e.g. active duty, active duty training, and inactive duty training.

Excused Absence without Stipend:

Absence without stipend may be approved by the immediate supervisor with concurrence from the supervisory chain of command (i.e., Div and/or Office Director). Leave of absence without stipend requires notification to ORISE through the Fellow's Office administrative staff, prior to

the absence. Absence without stipend for more than 12 months will require a new appointment upon return.

Stop-the-Appointment-Clock:

A Stop-the-Appointment-Clock provision may be granted for the birth or adoption of a child or for other family health care with approval from the immediate supervisor and supervisory chain of command (i.e., Division and/or Office Director, Center Associate Director for Research, and Office of Management), as well as notification to ORISE through the Fellow's Office administrative staff. At the discretion of the immediate supervisor, a Stop-the-Appointment-Clock may be granted with or without stipend. A Stop-the-Appointment-Clock for more than 12 months will require a new appointment upon return.

VI. Scope

The policies, responsibilities, procedures, and criteria found in this Guide apply to all CBER employees and other individuals who participate in the ORISE Research Training Participation Program.

VII. Forms Used (see Office administrative staff for forms)

- ORISE Program: Postgraduate Research Program application
- ORISE Routing Form
- ORISE Selection/Renewal Form
- ORISE Funding Summary Sheet
- FDA 3398 Form – Commitment to Protect Non-Public Information
(<http://inside.fda.gov:9003/downloads/Administrative/Forms/FDA/UCM013733.pdf>)
- HHS Form-745, HHS ID Badge Request
(http://intranet.hhs.gov/hr/ohr/forms/hhs_forms/hhs-745.pdf)
- EASE Checklist
- All electronic from FDA Security
- E-QIP Initiation Form
- CBER Personnel Information Checklist
<http://inside.fda.gov:9003/downloads/Administrative/Forms/FDA/UCM289459.pdf>

- DCC-101 Form – Notification of Personnel Change or Correction for CBER Document Control Center and CBER Staff Directory
(<http://inside.fda.gov:9003/downloads/Administrative/Forms/CBEROfficeTemplates/UCM023737.pdf>)

VIII. Documents Required in the Initial/New Package

Original Forms:

- ORISE Routing Form
- ORISE Selection/Renewal Form
- ORISE Funding Summary Sheet
- FDA 3398 Form – Commitment to Protect Non-Public Information Form
- Current Curriculum Vitae (CV)
- Proof of legal status in US, if foreign national

Copies of Forms:

- Postgraduate Research Program application
- CBER Personnel Information Checklist

IX. Documents Required in a Renewal Package

- ORISE Routing Form
- ORISE Selection/Renewal Form
- ORISE Funding Summary Sheet
- Progress Report from Fellow, signed by mentor/sponsor
- Proof of legal status in US, if foreign national

Copy of:

- CBER Personnel Information Checklist

X. Fellows Responsibility/Routing

ORISE Fellow must:

- Adhere to all established policies and procedures set forth by CBER for the ORISE Contract Fellowship Training Program.
- **Before reporting to CBER, the Fellow must:**
 - Complete and sign:
 - Postgraduate Research Programs application;
 - CBER Personnel Information Checklist;

- FDA 3398 Form – Commitment to Protect Non-Public Information (see link in Section VII).
 - Return completed application to the Office Program Manager, who reviews for completeness and routes the ORISE package for approval and processing.
 - Receive Letter of Appointment and Terms of Appointment from ORISE/ORAU;
 - Sign Terms of Appointment form and return to ORISE/ORAU with a copy sent to the Office Program Manager;
 - Receive confirmation of appointment from ORISE/ORAU.
 - Attend the FDA/CBER New Employee Orientation
- **After reporting to CBER, all Fellows must:**
 - Complete and sign:
 - HHS Form-745, HHS ID Badge Request;
 - DCC-101 Form: Notification of Personnel Change or Correction for CBER Document Control Center and CBER Staff Directory
 - Satisfactorily complete all laboratory safety training requirements, if applicable;
 - Obtain appropriate training certifications, for new Fellows and yearly re-certification (tracked by FDA Ethics):
 - Computer security;
 - Economic espionage;
 - Ethics training.
- **If the Fellow will be in a CBER Facility for more than 30 days, the Fellow must:**
 - Complete and sign:
 - HHS Form-745E-QIP Initiation Form.
 - Report to BOS with the following:
 - HHS Form-745;
 - E-QIP Initiation Form;
 - Two forms of ID (State issued photo ID or passport, and one ID from the list of acceptable IDs shown on the U.S. Citizenship & Immigration Services, Department of Homeland Security (DHS) website under Form I-9, Employment Eligibility Verification (<http://www.uscis.gov/files/form/i-9.pdf>).

- BOS Staff reviews documents for completion and forwards to the FDA Personnel Security Branch;
- After receiving documents, FDA Personnel Security Branch forwards the Fellow, via email, information needed to complete a background investigation, to include the website containing instructions and a list of additional online forms necessary for the background investigation;
- Fellow completes online forms;
- FDA Personnel Security Branch reviews online forms for completion and contacts the Fellow to schedule fingerprinting appointment;
- Fellow reports to the FDA Personnel Security Branch to be fingerprinted;
- Once the Fellow's background investigation is cleared by the FDA Personnel Security Branch, the Fellow reports to the FDA Badging Office for badge issuance.
- Foreign Nationals must adhere to all requirements applicable above, as well as provide copy of appropriate documents as proof of DHS sanction.
- At the end of each appointment:
 - Fellows should prepare a progress report based on their participation in the Fellowship Training Program.

Students in the ORISE Program:

- All requirements applicable above, as well as:
 - Provide proof of current enrollment in an accredited school or university;
 - Must be at least 16 years of age
 - If 16 – 18, Secure signature of parent or guardian on all required forms.

CBER Mentor/Sponsor:

- Adheres to all established policies and procedures set forth by CBER for the ORISE Research Participation Training Program;
- Interviews candidate(s) and review candidates for appointments and cooperate with ORISE/ORAU on the selection process;
- Receives copy of ORISE application package with Selection Form from ORISE/ORAU;
- Completes Selection Form and returns to Office Program Manager

- Delineate statement of duties and purpose of assignment, monthly stipend, and proposed appointment period;
- Ensures Fellow successfully completes appropriate safety training requirements, if applicable;
- Provides training in ongoing research projects and supervise all research activities;
- Provides supervision, training, and mentoring in the relevant federal statutes, regulations, principles, and practices of FDA medical product review, including issues related to product development, if applicable.

Office Program Manager:

- Provides Fellow with appropriate forms (see **Section VII**);
- Ensures Fellow and sponsor complete all forms;
- Assembles complete package;
- Secures approval from Branch/Division/Office Directors, where applicable;
- Enters appropriate information in AIMS;
- Forwards completed application package to their servicing Personnel Liaison;
- Forwards to Fellow any additional forms, as appropriate;
- If the Fellow’s tour of duty is less than 30 days, network and email accounts will not be granted unless the supervisor provides a business justification to the CBER Information Systems Security Officer (ISSO) and it is approved;
- If the Fellow’s tour of duty is 30 days or more, a network account should be requested. Instructions on “How to Complete the Network Account Request Form” can be found at <http://inside.fda.gov:9003/it/ITServices/HowToGuides/ucm031391.htm>
 - All staff that utilize computers must take the FDA Security Awareness Training within 5 business days;
 - All Fellowship network accounts will be set to expire on the “Not to Exceed” (NTE) date, set in the Enterprise Administrative Support Environment (EASE).
- Sends an email notification to the CBER Internal Exit Checkpoint prior to the Fellow’s NTE date to initiate CBER’s staff exit procedures.

Personnel Liaison (PL) Specialists, Program Operations Branch, Division of Program Services, Office of Management (POB, DPS, OM):

- Reviews package for completeness, to include all appropriate signatures;
- Files copy of application packages in POB/OM;
- Forwards original (ORISE) package to OM/DBRM/RMB;
- Enters name and appropriate information in EASE/eArrive;
- Advises Building Operations Staff, Office of Management (BOS) of Fellow's start and end dates.

Building Operations Staff, Office of Management (BOS)

- Reviews completed HHS-745 Form and E-QIP form with Fellow;
- Sends all required documents to the FDA Personnel Security Branch.

Office of Management/Division of Budget and Resource Management/Resource Management Branch (OM/DBRM/RMB)

- Files copy of FDA 3398 form;
- Approves all funding;
- Sends approved package to ORISE/ORAU via email

Associate Director for Research, CBER

- Establishes policies and procedures for participation in CBER's ORISE Research Participation Training Program;
- Receives and reviews all packages submitted to the Office of the Center Director for scientific qualifications and contributions;
- Signs all required forms in the application package;
- Returns all incomplete packages to the Office Program Manager, with explanation.

XII. Conditions for Acceptance

An ORISE Fellow: 1) May begin the training program if, a) all required forms are filled out and sent to the appropriate departments; b) CBER mentor is notified by the Office Program Manager of the Fellow's approved start date; 2) Can only work under the direct guidance of an appropriate CBER mentor or designee; and 3) Must meet all safety and security requirements, as applicable.

XIII. Extension of Appointment

At the conclusion of the initial appointment, a Fellow's appointment may be extended on a yearly basis up to the maximum terms allowed by the Program (**see Section V**). Extension requests must be in writing and signed by the Mentor, Division Director, and Office Director, and approved by the Associate Director for Research. Completed extension packages are then forwarded to the POB/DPS/OM for processing, no less than 30 days prior to the appointment NTE date.

XIV. Termination of Appointment

An ORISE Fellow's appointment ends on the NTE date. Please follow the exit procedures outlined in CBER SOPP 6501, Transfer/Exit Procedures, which can be found at the following link: <http://inside.fda.gov:9003/PolicyProcedures/SOPsbyProgram/Biologics/ucm016420.htm>. Please note: On FDA Form 2277, Employees Exit Clearance Record (in link above), Fellows are not required to clear through #8, Ethics.

The Fellow's appointment may be terminated prior to the NTE date, without prior notification, for a number of reasons, including but not limited to: 1) the services of the Fellow are no longer needed; 2) realignment or loss of resources; 3) concerns about the quality or productivity of the Fellow, or any other performance deficiency and/or inappropriate conduct.

A Foreign National Fellow's appointment will be terminated immediately if at any time their visa expires or is cancelled for any reason.

XV. Contacts

The ORISE program is administered through the Resource Management Branch, Division of Budget and Resource Management, Office of Management (301-827-1414) and the Associate Director for Research offices (301-827-0833).

XVI. Effective Date – May 2012