



Office of Research Integrity and Compliance

Compliance Connection

April 2023

The **Office of Research Integrity and Compliance (ORIC)** is responsible for regulatory compliance related to a number of research and non-research areas. This includes conflicts of interest, export controls and customs, responsible conduct of research, and research misconduct. This edition of our newsletter provides regulatory information regarding conflicts of interest, responsible conduct of research and information for those faculty interested in Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) Awards.

Conflicts of Interest

Training

ECU requires that all EHRA employees complete COI training in [Cornerstone](#). (New EHRA employees must complete the training within thirty (30) days of beginning employment; all EHRA employees must complete it once every four (4) years.)

In addition ECU's requirement, both the Public Health Service (PHS) and Department of Energy (DOE) Interim COI Policy regulations require COI training for all investigators* prior to engaging in PHS- or DOE-funded research. **This requirement also applies to sponsors who have adopted the PHS regulations.** This specific training requirement is satisfied by completing the Conflicts of Interest Basic Course available in CITI. The course may be accessed [here](#).

Training is also required when:

- There is a change in conflicts of interest policy that affects investigator's responsibilities
- The institution determines that an investigator is not compliant with COI policy
- The institution determines that an investigator is not compliant with a COI management plan

*Investigator is defined as anyone engaged in the design, conduct, or reporting of research.

FAQ

Q: When does my Annual COI Disclosure need to be submitted?

A: All EHRA employees must submit their Annual COI Disclosure by April 30th in [COI Risk Manager](#).

Q: Who should complete a [Project Specific Disclosure](#)?

A: The Principal Investigator/Co-Principal Investigators, regardless of compensation, and any other ECU personnel who will receive compensation from the grant (excluding undergraduate students) must complete a Project Specific Disclosure.

Q: When should I complete a Notice of Intent?

A: A Notice of Intent should be completed at least ten (10) days prior to the start of your external professional activity for pay. Your direct supervisor should follow appropriate steps to approve your submission in COI Risk Manager before you begin the activity.



Are You a Faculty Member with a Start-up Looking to Apply for a Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) Award?

To participate in the SBIR or STTR program, an applicant must meet a number of eligibility and project performance requirements. These requirements pertain to the applicant itself (the small business concern), its principal investigator, and its subcontractors.

Proposal/Project Requirements

To start, only [certain types and sizes](#) of small businesses may apply for and receive SBIR or STTR awards. SBIR and STTR proposals must be submitted by the eligible Small Business Concern (SBC). The University CANNOT prepare and/or submit the proposal on the SBC's behalf. In the case of STTR proposals, collaboration is required with a university or other non-profit research institution participating on the STTR project. Remember that both programs require the small business to be the applicant, as well as the responsible business and technical lead, on the proposal.

Phase I SBIR and STTR funding supports **R&D** that focuses primarily on the development and feasibility testing of prototypes (e.g., compounds, products, and services). The goal is to establish technical merit, feasibility, and potential for commercialization. SBIR/STTR Phase I funds cannot be used for business development, marketing and sales, production, patent costs, or entertainment. Equipment purchases also are not permitted on a Phase I award.

Phase II funding supports additional R&D of prototypes. Phase II projects can also accommodate simple between-group comparisons to demonstrate hypothesized features/benefits of the prototype. Applicants must supply a commercialization plan in their submission.

PI Eligibility Requirements

The principal investigator has to meet certain eligibility requirements on an SBIR/STTR proposal. For SBIR projects, the PI must be "primarily employed" by the applicant small business during the SBIR award period. The agencies don't agree on all the specifics as to what "primarily employed" means, but all do agree that this means the PI cannot be employed full time elsewhere, such as at ECU, during the SBIR award period. In addition, the PI must commit a **minimum level of effort to the project described in the application** (not to be confused with the greater than 50 percent employment requirement). The minimum level of effort for the PI to commit to a Phase I SBIR or STTR project is one month of effort (173 hours).

A careful read of the agency's solicitation will help ensure that you stay in compliance with the eligibility requirements for the PI.

The PI is responsible for communicating with the cognizant Program Director and staff during the course of the award and for monitoring the project to assure adherence to performance goals, time schedules, or other requirements as appropriate to the project or the terms of the grant. The PI is also responsible for submitting required reports to the funding agency.

In most cases, employment as an ECU faculty member conflicts with the primary employment requirement for the PI of an SBIR project. It also sometimes conflicts with the requirement for an STTR project. In some cases, however, a leave of absence may be granted to permit employment of the faculty member by the small business for the duration of the award.

Are You a Faculty Member with a Start-up Looking to Apply for a Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) Award? Continued

Subcontractor Eligibility

On a Phase I SBIR project, up to 33% of the research can be subcontracted to another entity. That entity can be anything from a non-profit research institution, such as a university or federal laboratory, to an individual consultant or a larger contractor.

On Phase I or II STTR projects, the applicant small business must perform at least 40% of the R&D on the project. At least 30%, but no more than 60%, of the research must be performed by a non-profit entity referred to as the Research Institution or RI. The RI typically is a university (public or private) or a federal laboratory (provided it qualifies as a Federally Funded Research and Development Center).

Institutional Requirements for a Faculty Owned Business - Getting Started

The proposing small business must be a legal entity at the time of proposal submission. A legal entity is required to complete all of the necessary registrations.

- The company must meet the SBC requirements under the intended sponsor.
- The company must have at least one employee who is NOT an ECU employee and can act on behalf of the company (i.e., sign contracts, ensure the company R&D efforts are completed as conveyed in the proposal).
- The faculty member CANNOT serve as both PI of the company (project) and PI on the ECU subcontract.
- The company must have its own lab space to conduct the R&D effort, or SBCs may use ECU facilities for their portion of the work provided the SBC is charged the standard rate applicable to other non-University entities. There must be a documented agreement between the SBC and University relating to the use of space, equipment, etc. SBC work may NOT, however, be conducted by the SBC in the PI's University laboratory. The PI's University laboratory may only be used for work subcontracted to the University by the SBC.
- Currently enrolled ECU students under the mentorship of or taught by the faculty member CANNOT work for the SBC.
- Effective July 1, 2023, you must submit or update your annual COI disclosure indicating your intention to have your start-up (SBC) apply for an SBIR or STTR - ORIC will simultaneously route this information to ORA, OLC, University Counsel, Facilities Management and HR, when applicable, to review any potential conflicts of interest.

NOTE: All SBIR/STTR **awards** require an associated management plan. The Office of Research Integrity and Compliance will work with you to complete this plan.

Responsible Conduct of Research

Training in the Responsible Conduct of Research (RCR) often differs depending upon the federal agency that is providing a research project's funding. The following chart depicts the minimum institutional training requirements by funding source.


Funding Source	Career Stage				
	<u>Undergrad</u>	<u>Master's</u>	<u>Doctoral</u>	<u>Postdoc</u>	<u>Faculty and Staff</u>
<u>NSF</u>	Online OR 1 hour In-Person	Online OR 2 hours In-Person	HUMS 7004 Course	8 hours In-Person Postdoc Course	(Encouraged but not required)
<u>NIH</u>	8 hours In-Person	8 hours In-Person	HUMS 7004 Course	8 hours In-Person Postdoc Course	(Encouraged but not required)
<u>NIFA</u>	Online (In-Person is encouraged but not required)	Online (In-Person is encouraged but not required)	Online (In-Person is encouraged but not required)	Online (In-Person is encouraged but not required)	Online (In-Person is encouraged but not required)


*Chart adapted from the Georgia Institute of Technology RCR matrix with permission.

When allowed, online training is available through the CITI program. In person RCR training is provided periodically on campus. Please contact Tammy Drapeaux at drapeauxt22@ecu.edu to coordinate in person training or if you require additional information about RCR.

Contact Us

Office of Research Integrity
and Compliance

 rede.ecu.edu/oric

 252-744-4140

 oric@ecu.edu
ecuexportcontrols@ecu.edu

ORIC Team

Tony Rowe
Assitant Director

Christiana Shoopman
Export Controls

Tammy Drapeaux
Responsible Conduct
of Research

Erik Baker
Conflicts of Interest