# **Interprofessional Clinical Simulation Center**

# **Standard Operating Procedures**

# 20. Research, Grants, and Scholarly Activity

## General Research Guidelines

The ICSP faculty and staff should be involved in the research project design prior to the study. The investigator should share the proposed written protocol with the Assistant Dean prior to designing the study so that he/she may determine if the Center has the resources to do the project, if simulation is an appropriate method for the study, and if the study aligns with the ICSP’s mission. This discussion also includes a plan for presenting scholarly activity (dissemination plan) and including appropriate individuals.

A research guide and helpful resources are listed on the ICSP’s website. Persons interested in doing a simulation-related research project should review and complete written sections of this guide. Once the idea is outlined in the guide, he/she may attend a Simulation Education Research Group (SERG) meeting, meet with the Assistant Dean of Medical Education and Outcomes, or meet with the Assistant Dean of Clinical Simulation to discuss the project. SERG meeting dates can be obtained by contacting the Program Coordinator or (csc@ecu.edu).

All rules in the Guidelines for Use of the Clinical Simulation Center will apply to research activities. A copy of these guidelines will be shared with all research team members. Deviations from the Guidelines will be made at the discretion of the Assistant Dean and if they do not degrade the integrity of the ICSP. No deviations from the Guidelines that adversely affect physical or psychological safety of researchers, participant’s, faculty, staff, or any personnel will be permitted.

## Requirement for Human Subjects Research (Institutional Review Board)

All human subjects research being conducted in conjunction with the ICSP must comply with the University and Medical Center Institutional Review Board (IRB) requirements [(https://www.ecu.edu/cs-acad/rgs/irb/).](https://www.ecu.edu/cs-acad/rgs/irb/) If ICSP faculty and staff will be actively engaged in the research project, they should be included on the IRB submission.

All key research personnel must complete the required Collaborative Institutional Trainings Initiative (CITI) courses on the ECU IRB website. Key research personnel include principal investigators, sub-investigators, research coordinators, and any other research team members that have contact with research participants, and their research data or private information.

Prior to the start of the study, the investigators should give ICSP staff copies of the following documents, which will be stored in the department shared drive for reference (Z > Simulation Center > Research and Scholarly Activity):

* IRB approval letter
* IRB submission packet
* Consent forms
* Written protocol (if the study has one)

If the research study has not been approved by the IRB, the ICSP faculty and staff may halt the research activity until it is properly authorized.

## Data Collection Responsibility

Investigators are responsible for data collection, storage, and analysis. The ICSP staff can assist with data acquisition and storage. Furthermore, it is not the responsibility of the ICSP staff to consent participants for research. The investigators should plan to consent participants.

Per regulations specified by the Office of Human Research Protections (OHRP):

* Informed consent documentation for studies that do not contain protected health information will be kept by the investigator three years after the conclusion of the study.
* Informed consent documentation for studies that do contain protected health information will be kept by the investigator six years after the conclusion of the study.

All data must be stored to meet HIPAA compliance standards. Video recordings will be stored according to the guidelines in the Video Recording and Photo Release section of this manual. Printed material will be stored in a locked cabinet in the Assistant Dean’s or Director’s office. Electronic information will be kept on the study team member’s individual Piratedrive and not shared with others outside of the study team.

## Research Oversight

Research in the Center is overseen by the Simulation Education, Research, and Grants (SERG) Committee. Members of this committee have experience in simulation-based research and will assist in development of the research plan. An investigator with an active research project in the Center will attend the SERG meetings and provide updates to the Committee.

## Authorship and Citations in the Publication of Research

All publications involving the use of the Center resources should acknowledge the ICSP and include participating faculty and staff as contributing authors. Authorship will be discussed during the planning process of the study and agreed upon prior to implementation. Authorship, Contributors, and Acknowledgements will follow the International Committee of Medical Journal Editors (ICMJE) guidelines. The ICSP will retain a copy of the final publication or poster (digital copy is acceptable).

Per the Office of Research and Graduate Studies (August 2019): The Brody School of Medicine places strong emphasis on its scholarship activities, especially research. Publications are an integral aspect of these activities. In order to efficiently track the impact of the school, departments, divisions, and center/institutes, it is most helpful to cite affiliations correctly and consistently. Please include all the following relevant criteria when citing your author affiliation in publications:

1.            Brody School of Medicine at East Carolina University

2.            Your Department

3.            Your Division (if applicable)

4.            Your Center or Institute (if applicable)

Example: Brody School of Medicine at East Carolina University, Department of Academic Affairs, Division of Health Sciences, Greenville, NC.

Example: Brody School of Medicine at East Carolina University, Department of Internal Medicine, Division of Endocrinology, and East Carolina Diabetes and Obesity Institute, Greenville, NC.

## Fiscal Impact of Research

The principal investigator is responsible for ensuring appropriate staffing, equipment, supplies, and other resources for the research project or grant. If a financial incentive accompanies the project or grant, the ICSP will receive appropriate compensation for its resources. The principal investigator will work with the Assistant Dean and Director to ensure the financial components are clear prior to starting the research activity.