

POLICY: Research Activities		10001
Authorized:		
Original Date:	7/8/20	Reviewed/Revised:
Approved by:	Mary Patterson, MD, MEd; Tom LeMaster, RN, MSN, MEd	

Purpose: This policy applies to all research conducted within the simulation program and/or with support of simulation program investigators, staff, facilities, or equipment.

Policy: CELS encourages academic, interprofessional, and collaborative practice (two or more professions) research. Any research activities that require use of CELS and its resources and/or time from its faculty are reviewed and coordinated with the CELS Research Director. The protocol for any scheduled research is reviewed by the CELS Research Director. In making a decision to approve or reject the proposal, the Director might consult with the other SMEs with significant research experience regarding the merits of the proposed activity. A minimum of three to six month’s lead-time is required for coordinating and scheduling research-related activities. Scheduling must be performed in accordance with the CELS’s scheduling policy.

Procedure:

CELS adheres to the UF COM and UF Shands policies and procedures for research that include but are not limited to:

1. All studies that meet the definition of human research require an approval from the Institutional Review Board (IRB), whether full, expedited, or exempt.
2. Prospective researchers must complete Human Subjects Protection training through the Collaborative Institutional Training Initiative (CITI) and maintain current certification.
3. The policy on the use of protected health information (PHI) in research covers all aspects of conducting research at CELS. Primary investigators (PIs) are encouraged to review them.
4. The initiating investigator must submit a copy of the IRB approval to the CELS Director.
5. All publications and presentations resulting from the projects that use the center’s resources must acknowledge CELS.
6. Compliance with this research policy is monitored and enforced by the CELS’s Research Director.
7. In case of human rights violation or non-compliance with this policy, CELS Research Director suspends the project until a formal institutional investigation is completed.

CELS policy mandates that research coordinated by and conducted within the simulation program is compliant with applicable UF Research Institute policies. The simulation program complies with all applicable governance policy statements.

Funded Research

All contract and grants are accepted in the name of CELS. All legal documents are executed in the name of CELS. All checks, letters of credit, and other financial documents are issued in the name of CELS.

Pre-Awards

All actions taken in the name of CELS prior to awarding of grants or contracts by the funding entity are classified as pre-award procedures. Pre-award procedures differ depending upon the nature of the project and the source of funding.

IRB Submission

The CELS follows the policies and procedures for research as outlined by the P&P Manual. This includes the requirement of the UF Institutional Review Board (IRB) approval, whether for full, expedited, or exempt

status for those studies that meet the definition of human research. Each contract or proposal submitted is viewed as new by the IRB. Similar or resubmitted contracts or proposals will be required to meet all requirements of newly submitted documents. While multiple submissions of the same or similar contracts or proposals are acceptable, it is imperative for reasons of patent rights and other considerations that such multiple submissions be disclosed as a part of all submitted contracts or proposals.

Principal Investigator

The director of a research project is classified as a principal investigator (PI). The investigator must fulfill the ethical obligations and institutional requirements as is IRB standard operating procedure which outlines the general responsibilities of investigators who conduct research involving human subjects at UF. The principal investigator acts in the name of CELS in the direction of the research or training program. The principal investigator directs all such projects in the name of CELS with the approval of the Advisory Board of CELS and its officers.

Co-investigators

Those responsible for portions of the research project are classified as co-investigators. These investigators must fulfill the same ethical obligations and institutional requirements.

Disputes

The CELS Research Director and Research Committee are responsible for mediating matters of dispute regarding any CELS research. The chair of the department in which the research is being conducted shall also be included in the discussions.

Procedure for Research Proposals

Research proposals should be completed by any investigator interested in developing and conducting a research study within, with the support of, or utilizing the services of CELS. The purpose of the proposal is to document the proposed research project goals and objectives to satisfy a research question. It assists in developing sound study design, identifying required resources, and projecting a timeline. Proposed research should be in alignment with CELS's goals. Research proposals should be submitted to the Research Director or designee for review by the Research Committee, including the Director of the Research Program within 4 weeks of submission. Appropriate proposals will be scheduled for presentation by the research study team at a CELS Research Committee Meeting, where feasibility, resources, prioritization, and assistance will be discussed. The study team shall present an update on the research progress to the CELS Research Committee within the first 12 months of data collection to assess effectiveness and efficiency of the study process and to discuss if the study is meeting its timeline and research objectives.