Research

Policy

The CSL is committed to furthering the knowledge of the community regarding the practice of simulation based education. Prior to any scheduled research, the protocol will have to be approved for use in the CSL the by Director of Simulation Education and Operations, and if helpful by the Director of Clinical Simulation.

Procedure

UVM's Research Protections Office (RPO) is responsible for the review/oversight programs that support the institution's conduct of safe and ethically sound scientific research involving human participants, vertebrate animals and biohazards. If a faculty/staff instructor has a research question they are looking to answer using simulation based education in the CSL then they must have the Institutional Review Board (IRB) review. In most cases the IRB will deem the project is not research and/or is exempt. The Director of Simulation Education and Operations can help faculty/staff instructors through the process.

The UVM Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted by faculty, staff, or students. The IRB is composed of more than 50 members representing University faculty and staff, as well as the local community. The IRB reviews research which involves human subjects to ensure that two broad standards are upheld: 1) participants are not unnecessarily exposed to risk; 2) participants willingly give, without undue influence or coercion, informed consent to participate in the research. A project is first reviewed in its proposal stage before participants are recruited.
https://www.uvm.edu/rpo/uvmclick-irb-forms-library

IRB Policy

https://www.uvm.edu/rpo/human-subjects-research

UVM and the UVM Medical Center are involved in important behavioral and biomedical research and are committed to assuring that all research activities are conducted in a manner that promotes the rights and welfare of the participants. The two Committees listed below are responsible for reviewing and overseeing all research activities, and are known as the Institutional Review Boards (IRBs).

1. The "Committee on Human Research in the Medical Sciences" (CHRMS) is authorized to review all proposals to use human subjects in biomedical research. CHRMS also functions as the Privacy Board for UVMMC for the Health Insurance Portability and Accountability Act (HIPAA) by reviewing all authorizations or requests to waive authorization for research undertaken at both institutions.
2. The "Committee on Human Research in the Behavioral and Social Sciences"

(CHRBSS) is authorized to review all proposals to use human subjects in the social sciences, education, psychology and other non-medical fields.

Required Training through CITI

All faculty, students and staff involved in the conduct of research with human subjects, regardless of funding source, must complete the Human Subjects Training through CITI. In addition, principal investigators or key personnel working on a clinical trial involving human

Subjects and all personnel affiliated with the UVM Larner College of Medicine will need to complete the Good Clinical Practice Training. Every three years, all personnel still listed on an active protocol are required to retake the training. Follow the link below for instructions on how to access CITI and add the appropriate course to complete.
https://www.uvm.edu/rpo/human- subjects-research

Data Collection Responsibility

- The CSL staff is there to assist in research by providing space/resources and simulation operations consulting for your research project. CSL staff roles include scheduling and running the simulation session as the operator.
- The CSL staff will not consent subjects regarding research and will not be stewards of any research paperwork.
- No research data may be stored on site, with the exception of any video/audio recording captured for the research. The simulation staff may take part in the rough and final write-ups for the research and help with processing the final product, but will do so as the simulation schedule allows.

Publication Policy

When resources provided by the Clinical Simulation Laboratory (CSL) contribute to the development or implementation of scholarly work, the name "The Clinical Simulation Laboratory at the University of Vermont" and or a specific member of the CSL staff will be acknowledged in any work intended for the public audience including: presentations of unpublished works, workshops discussing the research and protocols of said research, on abstracts, and in peer-reviewed and non-peer-reviewed articles.

Authorship Rules

Authorship is best decided by standard guidelines. We follow the Vancouver guidelines to ensure good publication ethics.[10]An author is an individual who has made substantial intellectual

Contributions to a scientific investigation. All authors should meet the following four criteria, and all those who meet the criteria should be authors.

[10] Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Ann Intern Med. 1997; 126:36– 47. doi: 10.7326/0003-4819-126-1-199701010-00006

1. *Scholarship*: substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work;
2. *Authorship*: drafting the manuscript or revising it critically for important intellectual content;
3. *Approval*: final approval of the version to be published; and
4. *Agreement* to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is not sufficient for authorship.[11] 11

Industry Research/Usability/Beta Testing

Policy

The CSL works closely with the UVMMC and outside organizations to provide access to the facilities and staff necessary to conduct industry research or usability or beta testing.

Procedure

The client point person will contact the Director of Simulation Education and Operations to discuss the goals and objectives of the project and to determine if the CSL can meet these needs.

If the answer is "yes", then the next step is to involve all parties in a planning discussion using the Curriculum Planning Template.

The CSL will assess a fee based on the fee structure and internal calculations based on the scope of work required by the CSL and staff.

Once that is Complete the client will work with the Senior Simulation Specialist, or an SP educator, to fully develop the project. The Simulation Specialist will be contacted regarding scheduling.

Use of the University of Vermont IRB Process

The use of the UVM IRB for industry research/usability/beta testing will be on a case by case basis only.

Research Recordkeeping

The lead researcher is required to maintain all recordkeeping functions. The University of Vermont Clinical Simulation Laboratory at the University of Vermont (CSL) will only submit IRB applications for projects that list the Director of Simulation Education and Operations or the Director of Clinical Simulation as the principal investigator.

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[11] Tarkang EE, Kweku M, Zotor FB. Publication Practices and Responsible Authorship: A Review Article. *J Public Health Afr.* 2017; 8(1):723. Published 2017 Jun 27. doi:10.4081/jphia.2017.723