

Simulation Training and Education for Patient Safety (STEPS): Submitting Approval for Educational Investigations of Simulation and its Impact on Learners

Multi-disciplinary educators are using the STEPS facilities to adopt simulation as an educational approach. Simulation is a learning opportunity that replaces real patient encounters with guided experiences, allowing learners to acquire knowledge and skills in a realistic setting without compromising patient safety. Educators from all of the schools of the Health Science Center and educators from Ruby Memorial Hospital may couch implemented simulations as an opportunity for an educational investigation. Research can explore the extent that simulation is an efficient, effective and valid methodology to advance learners' ability to meet expected program and course competencies. Some educators will seek to publish their innovative educational simulations along with documentation of the learning outcomes. Accordingly, **STEPS has created a research protocol to facilitate investigations of normal educational practices related to simulation.** In coordination with West Virginia University's IRB, the emphasis of this protocol is to encourage multi-disciplinary research in the STEPS program, while protecting learners and educators and other constituents. In addition, most educational conferences and journals require investigators to be in compliance with their institutional IRB. **The goal of this broad protocol is to coordinate multiple-disciplinary educational studies that will help answer important questions about simulation and its impact on learners' development.**

The STEPS Research Advisory Committee will review all educational research studies utilizing the facility to assure that they meet the standards of our protocol. In order to be considered by the Research Advisory Committee, the principal investigator (PI) must submit a formal application, detailed below. All applications must meet, at a minimum, 4 general standards:

1. Learners (who must be 18 years or older) will be given a cover letter (Appendix A) that outlines the purpose of simulation and details how data will be collected, analyzed and reported.
2. Anonymous learner evaluations of simulations will be collected through tools, (e.g., SOLE, E-value) that are currently being utilized as a normal educational practice. If paper evaluations are collected, learners are not to supply their name. A learner's participation in the evaluation of simulations will not be used to calculate a grade or figure into any other evaluation of the learner's performance. The purpose of collecting learner evaluations is to allow educators to make informed changes to future simulations.

3. Formative and summative assessment data (e.g., standardized patient rating forms) may be used to collect information about whether learners are meeting expectations of the course and/or program; however, all data must be presented in aggregate for scholarly projects to ensure learner confidentiality.
4. The protocol requires that learners have an option to remove individual data from educational research analyses, which is beyond the scope of using data for formative and summative assessment purposes. It is also imperative to protect a learner from being penalized for deciding not to participate. Therefore, the cover letter will detail how learners may request the STEPS staff to purge individual assessment data from the database that will be used for research analyses. Project investigators, then, may be required to use confidential data supplied by STEPS staff for research analyses.

The STEPS Research Advisory committee meets regularly to review applications. **PI's must submit an application to be considered for the next committee meeting.** The PI will be notified via email with a proposed date to attend the committee meeting and answer questions about the application. No formal presentation is required. The STEPS Research Advisory committee will judge whether the proposed investigation meets the requirements of our protocol. If the proposed investigation moves beyond the requirements of this study and involves more than a normal educational practice, then the principal investigator will be required to submit a separate protocol to West Virginia University's IRB.

The application should be organized into the following sections:

1. Title
2. Abstract (250 words or less summary of the educational research project)
3. Purpose (Include clear objectives of the study)
4. Background or Literature Review of the Topic
5. Methodology
 - A. Subjects (Who will participate, how long and when?)
 - B. Data collection procedures (How and what data will be collected?)
 - C. Confidentiality (How will you ensure student confidentiality for both verbal and written dissemination of the project's results?)
 - D. Potential risks or discomforts to participants
 - E. Identify any potential financial or other conflicts of interest
 - F. Data analysis (How will data be analyzed to achieve the purpose of your study?)
 - G. Timeframe (How long will it take to collect data for research purposes?)
6. List Principal and Co-Investigators (All investigators must fulfill the IRB CITI Training)

If the STEPS Research Advisory committee approves an application, then a formal acceptance letter will be sent to the PI. PI's must give 6-month follow-up reports to the committee. If the PI makes any significant changes to the study and its methodology, then the PI must submit a revised application to the committee before proceeding with data collection.

Appendix A

Dear Participant:

Simulation has quickly become common to enhance education in the healthcare field. Simulation is a learning opportunity that replaces real patient encounters with guided experiences, which allows students to acquire knowledge and skills in a realistic setting without compromising patient safety.

As educators from all of the schools of the WVU Health Sciences Center and from WVU Medicine Hospitals utilize the West Virginia STEPS facilities, they will be investigating the extent simulation is an *efficient* and *effective* methodology to advance learners' ability to meet expected program and course competencies.

We are asking you to participate in this research study. You must be at least 18 years old to participate. The goal of this study is to answer important questions about simulation and its impact on learners' development.

Your participation is voluntary.

Your responses to evaluations will remain anonymous and confidential. Your performance in the simulation may be judged for ongoing feedback to help improve your skills and knowledge related to this simulation and/or to assign a grade. However, for the purposes of disseminating the results for this study, all data will be reported in aggregate and students will remain anonymous in both written and verbal reports. Your participation in this study will not impact your class standing or grades. You may choose to have your specific assessment data (which would be anonymously reported in aggregate) pulled from the study database and it will not be used for any analyses for this scholarly project.

West Virginia University's Institutional Review Board has acknowledged this study under the auspices of Protocol #1304035754, WV STEPS generalized protocol. Please feel free to contact Dr. Cynthia Graves, M.D., Chair of the WV STEPS research committee, or speak with your course director. If you would like more information regarding the Protocol, please contact Dr. Dorian Williams, principal investigator, by email (dorian.williams@hsc.wvu.edu) or by phone (304-293-5234).

Thanks for considering your participation. You do not have to answer all of the questions and may quit the study at any time. Our goal is to improve simulation education, helping to maximize student learning and development.