
Research Process

Purpose:

The purpose of this policy is to outline the process for conducting research projects through the David and Joann Shaw Center for Simulation Training and Education for Patient Safety (STEPS) including proposal development, mentorship, and project management. The policy details each step of the research process, while providing guidance as to how to access the resources available along the way.

Scope:

With the increase in research productivity, largely due to the success of the interdisciplinary STEPS research committee, investigators are requesting additional assistance with their research projects, beyond committee review and timeline assistance. This policy will provide information to investigators who wish to utilize STEPS research resources for their projects.

Responsibilities:

Conducting research can be a daunting process for some investigators. Therefore, this policy will provide step-by-step research guidance from the initial conception of an idea to the end product of a publication in a peer-reviewed journal of the investigator's choice. Should an investigator desire to conduct research through STEPS, this policy will be provided to them upon notification of their interest, with certain steps in the policy being mandatory to STEPS.

Definitions:

Term or Acronym/Abbreviation	Definition
IRB	Institutional Review Board
Project	Specific Educational research being performed under the STEPS IRB-approved umbrella protocol
Protocol	The STEPS general IRB-approved protocol that describes the essential steps necessary for educational research projects approved by the committee.

Procedures:

Upon notification by the investigator of interest in conducting simulation-focused research via STEPS, the following procedures are in place to guide the investigator through the research process. See Appendix A for complete contact list for all positions listed in this document.

**Indicates mandatory steps for investigators to participate in STEPS research projects*

Pre-IRB Approval –

1. Research Design Development

- a. Should an investigator desire assistance with solidifying the appropriate design that best fits the outcomes for their project, STEPS has a research coordinator that can provide guidance.
- b. Contact: Administrative Research Coordinator

2. Research Question / Hypothesis Development

- a. Ensuring the success of a research project at STEPS begins with the solid foundation of a research question and hypothesis. STEPS has a research

coordinator that can assist investigators with proper question and hypothesis development.

- b. Contact: Administrative Research Coordinator

3. Proposal Development

- a. Available for investigators who seek to develop a proposal for review by the STEPS Research Committee. The submission of a formal application to the STEPS Research Committee is **mandatory** in order to conduct research in STEPS.
- b. Must be sent to Administrative Research Coordinator at least 10 days prior to next committee meeting in order to be on agenda, or else it will be slotted for the following meeting.
- c. Please see the Research Committee SOP for further information regarding the formal application.
- d. Contact: Administrative Research Coordinator

4. STEPS Research Mentor Placement*

- a. Mentors will provide support and accountability to principle investigators. They can assist with appropriately articulating research questions, design, hypothesis and objectives, as well as providing recommendations for methodology and implementation.
- b. Contact: Assistant Director of Education and Assessment

5. Mandatory Pre-Review Meeting*

- a. The administrative research coordinator, simulation specialist, mentor and PI of project will meet to review the proposal.
- b. A review of the project's research design, surveys and assessment tools will be provided to finalize the proposal before submission to the research committee
- c. Contact: Administrative Research Coordinator

6. STEPS Research Committee Review*

- a. This interdisciplinary group monitors the educational research conducted in STEPS in order to assure compliance with IRB policies and promote

high-quality research. The committee also provides assistance with establishing a timeline for project completion.

- b. At least one member from the research team proposal (preferably the principle investigator) **must** be in attendance at the Research Committee Review in order to present the team's proposal and answer any committee questions.
- c. For more information, please see the Research Committee SOP for further information regarding the committee.
- d. Contact: STEPS Medical Director

7. IRB Approval Notification

- a. Upon Research Committee review of the proposal, the principle investigator will receive an update regarding the status of their proposal. Should there be any revisions requested from the committee, the research team will have until the next scheduled committee meeting to conduct changes and submit for final review.
- b. Once a proposal has been reviewed and approved, investigators will be sent an official approval letter from the committee, providing the investigators with brief next steps, as well as a STEPS research number to be used when referencing their project in the future.
- c. Please see Appendix B for a template approval letter.
- d. Contact: Administrative Research Coordinator

Post-IRB Approval –

8. Pre-Implementation Team Meeting*

- a. The purpose of this meeting is to finalize the implementation plan for the project, and organize the equipment and/or rooms needed for the project, as detailed in steps 9-10 above.
- b. It is recommended that investigators schedule a time that includes their STEPS research mentor and the principle investigator, as well as necessary STEPS research team members, such as a simulation specialist, assistant director of education and evaluation and the learning space specialist.
- c. Contact: Administrative Research Coordinator

9. Materials and/or Other Simulation-Related Requests*

- a. The materials needed for your simulation or any special items for your event will be addressed on the request form located on the STEPS Website (www.hsc.wvu.edu/STEPS) noted above in step 8.
- b. Contact: STEPS Scheduler

10. Simulation Scheduling Requests*

- a. To schedule a simulation you must fill out the request form located on the STEPS website (www.hsc.wvu.edu/STEPS).
- b. Select “Schedule” at the bottom of the page – This will take you to the instruction page, which will provide directions as to which log-in you should use to complete the form.
- c. Once complete, select “Schedule Event” – This will advance you to the formal event request form. Complete the form, and submit request for approval of event and date.
- d. Contact: STEPS Scheduler

11. Project Implementation*

- a. Upon steps 8-10 being completed, investigators may implement and conduct their research project at STEPS.
- b. Contact: Administrative Research Coordinator

12. Post-Implementation Follow-Up*

- a. Investigators are expected to provide semi-annual updates, 6 months from initial approval date, regarding project progression.
- b. Follow-up can be conducted in the form of a team meeting, with the STEPS Research Coordinator present, or by having the principle investigator attend the monthly Research Committee meeting that same month. This must be scheduled with the Research Coordinator at least 10 days prior to the next Committee meeting.
- c. Contact: Administrative Research Coordinator

13. Annual Re-Approval*

- a. Principle investigators are expected to provide an annual update, every 12 months from initial approval date, to the STEPS Research Committee. The principle investigator is expected to attend the monthly Research Committee meeting during that month in order to provide a brief summary of the project's progression in the past 12 months.
- b. If requested by the principle investigator, and upon satisfaction from the Research Committee, the investigator will be granted a 12 month renewal for the research project.
- c. Contact: Administrative Research Coordinator

14. Data Analysis

- a. The researcher can contact a statistician through the iLab system in the WV Clinical Translational Sciences Institute (CTSI).
- b. Other respective schools within the Health Sciences Center may have a statistician or other resources within their department to assist with this need.
- c. Contact: Administrative Research Coordinator

15. Abstract & Presentation Development

- a. STEPS center has personnel that are able to assist in the development and editing of abstracts for submission to regional, national, and/or international conferences.
- b. Upon acceptance to the conference, STEPS can also assist in presentation development, including electronic and/or printed posters, or oral presentations.
- c. It is recommended that the principle investigator, or the presenting member of the research team, practice their presentation in a monthly Research Committee meeting. The purpose of this practice presentation is to provide presenter's with appropriate feedback.
- d. Contact: Administrative Research Coordinator

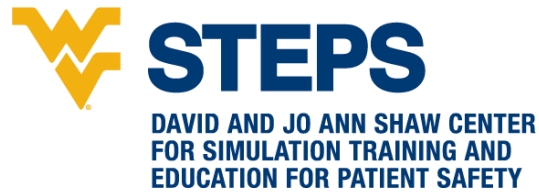
16. Manuscript Development

- a. STEPS center has personnel that are able to assist in the development and editing of manuscripts for submission to peer-reviewed journals.

- b. STEPS can assist in the submission process to the journal of the investigators choosing, as well as the revisions and re-submission process.
- c. It is an expectation of the principle investigator to submit any manuscripts published in peer-reviewed journals to the Research Committee for their records.
- d. Contact: Administrative Research Coordinator

17. Closing Procedure for Projects

- a. Upon completion of the research project, the principle investigator is expected to notify STEPS of any publications and presentations that were a product of the research conducted in STEPS, as noted in steps 15-16.
- b. To provide formal notification, email the Administrative Research Coordinator with the specific details of the conference where the project was presented, and the peer-reviewed journal where the research was published. Attach electronic copies of presentations and/or publications with the formal citations.



Policy: RE02
Adopted: April 19, 2019
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Author: Russell Doerr
Approver: Daniel Summers

Appendix A: Research Process Contact

Administrative Research Coordinator:

Amy Summers [Contact Information: amy.summers1@hsc.wvu.edu (304) 293-7596]

Assistant Director of Education and Assessment:

Lee ann Miller [Contact Information: lamiller@hsc.wvu.edu (304) 293-5533]

Medical Director:

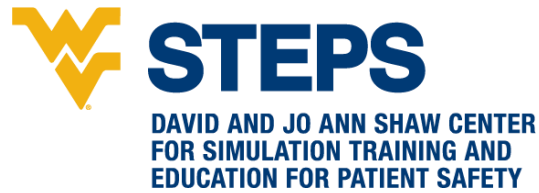
Dorian Williams, MD [Contact Information: dorian.williams@hsc.wvu.edu (304) 293-5234]

STEPS Scheduler:

Leigh Ann Bean [Contact Information: leighann.bean@hsc.wvu.edu (304) 293 -2665]

Simulation Specialist:

Rusty Doerr [Contact Information: rdoerr@hsc.wvu.edu (304) 293 –1703]



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Approver: Daniel Summers

Appendix B: Template STEPS Research Committee Approval Letter.

<Date>

<Faculty>
West Virginia University

Dear <faculty>

This letter is to confirm that the project you submitted titled < title > was discussed at our <date> Research Meeting. The proposal was determined to meet criteria for approval by the committee under our IRB Protocol #1304035754. Your project number is < > please use this when referencing your project going forward. This project meets the guidelines set forth and has been approved.

Congratulations, we look forward to hearing the results of the study.

Kind Regards,

Amy Summers
Administrative Research Coordinator
STEPS – David and Jo Ann Shaw Simulation Training and Education for Patient Safety
(304) 293-7596

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Approver: Daniel Summers

Approval to Issue: Please sign and date in spaces provided below to indicate your approval for issuance of this SOP.

X Russell Doerr

Author

April 19, 2019

Date

X Daniel Summers

Approver

April 19, 2019

Date

Policy: RE02
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Chronological Revision History

Version	Modification	Date
1.0	New SOP	April 19, 2019