Penn Medicine

**Simulation at Penn Medicine**

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# Research Policy & Procedure Manual

# 2020

**As a Department within Penn Medicine, Simulation at Penn Medicine honors all Penn University policies and procedures as outlined by the guidelines provided through the Office of the Vice Provost of Research at the University of Pennsylvania. This document outlines the Center's supplemental Policies and Procedures.**

**Policy #1: Research Committee and Meetings**

| | |
|---|---|
| **Type:** | Simulation at Penn Medicine, Policy and Procedures in Research Manual |
| **Applicable to:** | All facilitators, operators, content experts, support staff, researchers, and directors associated with Simulation at Penn Medicine |
| **Department/Unit:** | Simulation at Penn Medicine |
| **Policy owner:** | Director for Research, Simulation at Penn Medicine |
| **Effective Date:** | April 10, 2020 |
| **Approved by:** | Cindy Morgan, VP, Learning & Org Development, Penn Medicine Academy |
| **Accountable for:** ` | Kristoffel Dumon, MD, FACS<br>Director for Research, Simulation at Penn Medicine |

## 1. Policy Statement

Research conducted by Simulation at Penn Medicine is overseen and reviewed by the Director of Simulation Research, Dr. Dumon, with assistance by the Simulation Research Committee. Simulation Research Committee meetings are held quarterly and are open to any investigator, faculty or staff member interested in either presenting their research or participating in the meeting. In addition, the Director of Simulation Research joins the twice monthly Simulation at Penn Medicine Staff meetings to review research productivity. Weekly meetings are held with the standing members of the Simulation at Penn Medicine Research Committee. Monthly meetings are conducted between the Operations Manager of Simulation at Penn Medicine, Christi Jefferson and Dr. Dumon.

The standing members of the Simulation at Penn Medicine Simulation Research Committee include the following:

1. Director of Simulation Research
2. Simulation Fellow
3. Harrison Scholar

Responsibilities of the Simulation Research Committee during the open quarterly meetings include:

1. Review and discuss ongoing research activities.
2. Review the merits of proposed simulation-based research projects and make suggestions regarding protocol amendments
3. Ensure that research conducted is scientifically and ethically sound.
4. Act as a resource for developing solutions for delayed progress.
5. Promote, review and assist in submissions for and presentation resulting from research conducted at or facilitated by Simulation at Penn Medicine staff or its resources, at local, regional, national and/or international forums, as well as for peer-review publications.
6. Act as a resource for posting current status of projects, presentations, publications and grants.
7. Plan and conduct annual research dinners for the presentation of ongoing and proposed activities to the larger Penn Medicine simulation research community.
8. Ensure a wide representation of simulation expertise among various clinical and non-clinical disciplines, e.g., engineering, education, nursing, veterinary medicine and dentistry

## 4. Scope

This Policy applies to all research conducted within Simulation at Penn Medicine and/or with support of Simulation at Penn Medicine investigators, staff, facilities or equipment.

## 5. Exceptions

None

**Policy #2: Research Process and Proposals**

| | |
|---|---|
| **Type:** | Simulation at Penn Medicine, Policy and Procedures in Research Manual |
| **Applicable to:** | All facilitators, operators, content experts, support staff, researchers, and directors associated with Simulation at Penn Medicine |
| **Department/Unit:** | Simulation at Penn Medicine |
| **Policy owner:** | Director for Research, Simulation at Penn Medicine |
| **Effective Date:** | April 10, 2020 |
| **Approved by:** | Cindy Morgan, VP, Learning & Org Development, Penn Medicine |
| **Accountable for:** | Kristoffel Dumon, MD, FACS<br>Director for Research, Simulation at Penn Medicine |

## 1. Policy Statement

It is the policy of Simulation at Penn Medicine that research coordinated by and conducted within Simulation at Penn Medicine is carried out according to applicable Penn Medicine Research Institute policies. Simulation at Penn Medicine complies with all applicable federal policy statements.

Funded Research

All contract and grants are accepted in the name of Trustees of the University of Pennsylvania. All legal documents are executed in the name of Trustees of the University of Pennsylvania. All checks, letters of credit and other financial documents are made out in the name of "Trustees of the University of Pennsylvania".

Pre-Awards

All actions taken in the name of Penn Medicine 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.

In all cases a completed copy of a properly signed portable document format (PDF) version of the Sponsored Projects Proposal and the proposal will be filed with the office of sponsored research

prior to receiving approval for submission in the name of Penn Medicine. As a part of the pre-award process, the office of grants management reviews the proposed budget with regard to Penn Medicine and sponsor requirements.

IRB Submission

The Center follows the policies and procedures for research as outlined by the Office of Regulatory Affairs. This includes the requirement of 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 (P.I.).* This investigator must fulfill the ethical obligations and institutional requirements as in Penn Medicine Guidelines IRB standard operating procedure which outlines the general responsibilities of Investigators who conduct research involving Human Subjects at Penn Medicine.

The *principal investigator* acts in the name of Penn Medicine in the direction of the research or training program. The *principal investigator* directs all such projects in the name of Penn Medicine with the approval of the Board of Trustees of Penn Medicine 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 as the principal investigator.

Disputes

The Director of Simulation Research and the Simulation Research Committee are responsible for mediating in matters of dispute regarding any Simulation at Penn Medicine research with full documentation of the event. The chair of the department in which the research is being conducted

shall also be included in the discussions. A dispute may be escalated to the office of the Vice Provost for Research, if mediation does not lead to full satisfaction of all stakeholders.

Procedure for Research Proposals

Research proposals completed by any investigator interested in developing and conducting a research study within, with the support of, or utilizing the services of Simulation at Penn Medicine are reviewed by the Director of Research and the Simulation Research Committee where necessary.

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.

Research proposals submitted to the Director of Research (or designee) are reviewed within four (4) weeks, with assistance by the Simulation Research Committee where necessary and are continuously reviewed by the Director of Research.

Appropriate proposals are scheduled for presentation by the research study team at a Simulation at Penn Medicine Research Committee Meeting when necessary, where feasibility, resources, prioritization and assistance will be discussed.

The study team presents an update on the research progress to the Simulation at Penn Medicine Director of Research after 12 months of data collection, when necessary, to assess effectiveness and efficiency of the study process and to discuss if the study is meeting its timeline and research objectives. Every research team is provided the opportunity to present their research at the quarterly meetings or annual dinner.

## 2. Scope

This Policy applies to all research conducted within Simulation at Penn Medicine and/or with support of Simulation at Penn Medicine investigators, staff, facilities or equipment.

## 3. Exceptions

None

**Form #1: Research Proposal**

***Outline:***

Any research proposal completed by any investigator interested in developing and conducting a research study within, with the support of, or utilizing the services of Simulation at Penn Medicine are reviewed within four (4) weeks.

The purpose of this 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.

All Research proposals presented are reviewed by the Director of Research, and the Simulation Research Committee.

| | |
|---|---|
| Study Name | |
| Principal Investigator | |
| Relationship to Penn Medicine Blueprint | |
| Prepared By | |
| Date Initiated | |
| Date Reviewed | |
| Date Approved | |
| Date Completed | |

| | |
|---|---|
| | |

***Study (may be contained in attached ppt. presentation)***

| | |
|---|---|
| Research Question | State the big problem that needs to be solved in your own words. |
| Background | State the three important knowns (with refs)<br>Identify the gap in knowledge that you want to fill |
| Significance | State the importance of filling the gap |
| Hypothesis - "PICO" | • Population:<br>• Intervention:<br>• Comparator:<br>• Outcome: |
| Approach | List key methods<br>Identify primary outcome variable<br>List secondary outcome variables<br>Justify selection of primary outcome<br>IRB plan / issues |
| Analysis Plan | Statistical methods<br>Power analysis (justify target number) |
| Potential Limitations | Identify potential limitations to this approach and plan for mitigation |

***Study Research Team (as applicable) (may be contained in attached ppt. presentation)***

| Research Role | Name | Dept | E-mail | Requires Additional Funding (y/n) |
|---|---|---|---|---|
| Principal Investigator | | | | |
| Mentor | | | | |
| Mentee | | | | |
| Lead/Jr. Investigator Regulatory | | | | |
| Data Collection | | | | |
| Data Management | | | | |
| Data Analysis | | | | |
| Sim Resource(s) | | | | |

***Simulation at Penn Medicine Support (may be contained in attached ppt. presentation)***

| | |
|---|---|
| Simulation at Penn Medicine Staff requested (names/roles) | |
| Rooms | |
| Equipment | |
| Disposable Supplies | |
| Additional equipment /supplies needed for study | |

***Proposed Timeline (may be contained in attached ppt. presentation)***

| Proposed Date | Task | Responsible Person |
|---|---|---|

| | | |
|---|---|---|
| | | |
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| | | |
| | | |

***Funding / Dissemination of Information (may be contained in attached ppt. presentation)***

| | |
|---|---|
| Potential Funding Source(s) | |
| Proposed Conference(s) | |
| Proposed Target Publication(s) | |

***Authorization***

*I have read and understand this research proposal assessment. I am in full agreement with the objectives and timeline stated herein and in the aforementioned attachments. I have been made aware of the costs, benefits and risks associated with this research proposal. I believe this project will achieve the stated outcomes and hereby authorize delivery of this project.*

_____

***Principal Investigator Name***

_____ _____

***Principal Investigator Signature*** ***Date***

_____

***Research Director Name***

_____ _____

***Research Director Signature*** ***Date***

**Form #2: Simulation at Penn Medicine Research Proposal Review Form**

| Category | 1 point: Minimal effort made to meet requirements | 3 points: Partially meets requirements/ expectations | 5 points – Fully meets all requirements/ expectations |
|---|---|---|---|

| | | | |
|---|---|---|---|
| **Study Name** | Study name is non-descriptive or absent; does not match research topic. | Study name is reasonable descriptive and matches the research topic. | Study name is concise, complete and well-matched to research topic. |
| **Research Question** | No research question or purpose is stated, or the stated question or purpose are not reasonable; no hypothesis is provided (if applicable) | The research question or purpose is reasonable, but is not precisely or clearly articulated; hypothesis is superficially stated (if applicable). | The research question or purpose is specific, testable, and original and provides a clear sense of the topic of inquiry; a hypothesis is concisely articulated. |
| **Background/ Significance** | Introduction/background is inaccurate, vague, or not pertinent or relevant to the research question.<br><br>No introduction/ background. | Introduction/background provides some information and a sense of the rationale, need, and relevance to the research, somewhat disorganized and could be referenced better. | Introduction/background succinctly describes and appropriately connects the topic and context to the purpose of this research project. |
| **Hypothesis** | Anticipated results of the do not match the study hypotheses or results; the findings are not contextualized with the existing literature; no implications are stated; limitations are not addressed | Conclusions are reasonable given the hypotheses, design and results; the findings are somewhat contextualized with the existing literature; some limitations and implications are stated | Anticipated results are accurately interpreted with respect to the research question or hypotheses and contextualized within the existing literature; the implications of the findings are well articulated; limitations are well described including avenues for future inquiry |
| **Approach** | Discusses the method or resources used to study the topic of investigation but lacks organization, lacks specific details to replicate study and is | Discusses the methods or resources used to study the topic of investigation but is somewhat disorganized, somewhat lacking | Discusses the methods or resources used to study the topic of investigation in an organized, specific and concise manner. |

| | | | |
|---|---|---|---|
| | overly wordy. Or no discussion of method or resources.<br><br>● Quantitative studies: the research design, variables of interest, participants, research tools are not stated, inaccurate, or mis-matched to the research question and hypotheses<br>● Qualitative studies: rationale/ choice of methodology not stated, overarching design and subsequent choice of methods are inappropriate for the research question. | specifics but enough detail to replicate, and rather wordy.<br><br>● Quantitative studies, the research design, variables of interest, participants, research tools are justifiable given the research question and hypotheses<br>● Qualitative studies, the choice of methodology is stated, the overarching design, choice of methods. | Scientific method is replicable.<br><br>● Quantitative studies, the research design, variables of interest, participants, research tools are clearly described, accurate, and suitably matched to the research question and hypotheses<br>● Qualitative studies, the rationale and choice of methodology is clearly articulated, the study design, methods. |
| **Analysis Plan** | ● Quantitative studies, statistical analyses are not stated, inaccurate, or mis-matched to the research question and hypotheses<br>● Qualitative studies, data analysis is poorly described and the role of theory is not explained. | ● Quantitative studies, statistical analyses are justifiable given the research question and hypotheses<br>● Qualitative studies, data analysis are appropriate for the research question, however the role of theory is not explained. | ● Quantitative studies, statistical analyses are clearly described, accurate, and suitably matched to the research question and hypotheses<br>● Qualitative studies, data analysis are well described, and the manner in which the data collection and analyses is informed by theory is clearly articulated |
| **Overall Clarity and Structure** | The abstract is not written in scientific language, contains multiple spelling and/or | The abstract is mostly written in scientific language, contains few spelling and/or | The abstract is clearly written in appropriate scientific language, contains no spelling |

| | | | |
|---|---|---|---|
| | grammatical errors, the sentence structure and flow are difficult to follow, and the overall readability of the abstract is poor | grammatical errors, the sentence structure and flow are reasonably easy to follow, and the overall readability of the abstract is fair | and/or grammatical errors, the sentence structure and flow are easy to follow, and the overall readability of the abstract is excellent |

| Category | Out of 5 | Comments/Suggestions for Improvement |
|---|---|---|
| **Study Name** | | |
| **Research Question** | | |
| **Background/Significance** | | |
| **Hypothesis** | | |
| **Approach** | | |
| **Analysis Plan** | | |
| **Overall Clarity and Structure** | | |
| **Alignment with Simulation at Penn Medicine goal and *Blueprint*:** | | |
| **(out of 40)** | | |

**TOTAL:** _____/40

**RESEARCH DOMAIN:** _____

**REVIEWER:** _____

**Main Research Domains**

- Effectiveness of Penn Medicine Academy (PMA) learning innovation
- Effectiveness of learning technology
- Curriculum development and implementation
- Utility of assessment tools for technical and non-technical skills
- Clinical impact of simulation based interdisciplinary assessment and training
- Innovation in simulation and simulator development

***Closing Report (IRB closing report for study can be used in lieu of report)***

| |
|---|
| Summary of Project |
| Results |
| Limitations |
| Conclusions |
| Next steps |

***Authorization of Closure***

I hereby attest that all research activities are complete and that this research meets one or both of the following conditions: (a) When individually identifiable follow-up data are no longer being collected from subjects enrolled in a protocol and all identifiable private information has been removed from the data set that will be used for analysis purposes, the study may be closed. (b) When the investigator will not be involved in data management and analysis (e.g., multi-center clinical trials), when all data collection is completed at Penn and the study sponsor has completed all closeout activities, the study may be considered complete even if there is research activity at other study sites. I believe that the research has achieved the stated goals, objectives and outcomes and hereby authorize the closure of this research study.

_____

Principal Investigator Name

_____ _____

Principal Investigator Signature Date

**Policy #3: Research Program and Investigator Self-Assessment**

| | |
|---|---|
| **Type:** | Simulation at Penn Medicine, Policy and Procedures in Research Manual |
| **Applicable to:** | All facilitators, operators, content experts, support staff, researchers, and directors associated with Simulation at Penn Medicine |
| **Department/Unit:** | Simulation at Penn Medicine |
| **Policy owner:** | Director for Research, Simulation at Penn Medicine |
| **Effective Date:** | April 10, 2020 |
| **Approved by:** | Cindy Morgan, VP, Learning & Org Development, Penn Medicine |
| **Accountable for:** | Kristoffel Dumon, MD, FACS<br>Director for Research, Simulation at Penn Medicine |

## 1. Policy Statement

It is the policy of Simulation at Penn Medicine to utilize various assessment tools to evaluate the effectiveness and quality of varied elements of Simulation at Penn Medicine Simulation Research Program. These tools include executive review, investigator presentations, meetings, and surveys. By using these tools, program administrators and investigators can examine which aspects of the Simulation Research Program require improvement.

Simulation at Penn Medicine promotes the belief that high-quality research programs tend to be programs that are reflective and willing to improve, change and grow and those that are committed to their mission. Tools have been developed to help programs be reflective, to pinpoint strengths and weaknesses and to target areas for improvement.

Simulation at Penn Medicine Simulation Research Program has recognized eight essential elements that define effective and quality research:

1. Environment/Climate: Safe, healthy and nurturing environment for all researchers and participants.
2. Administration/Organization: Well-developed infrastructure and sound fiscal management to support and enhance worthwhile research activities for all researchers.
3. Relationships: Develops, nurtures and maintains positive relationships and interactions among staff, researchers and collaborators to support the program's

goals.

4. Staffing/Professional Development: Recruits, hires and trains diverse staff and investigators who value each participant, understand their developmental needs, and work closely with administration, staff, researchers and collaborative partners to achieve the program goals.
5. Administration/Researcher/Collaborative Partnerships: Establish a strong partnership with research communities in order to achieve program goals.
6. Program Sustainability/Growth: A coherent vision/mission and a plan for increasing capacity that supplies continuing growth.
7. Measuring Outcomes/Evaluation: A system for measuring outcomes and using that information for ongoing program planning, improvement and evaluation.
8. Dissemination of Information: Ability to interpret study results and present them in a scientifically sound, unbiased and timely manner to the greater research community through local, regional, national and international conferences and peer-reviewed publications.

## 2. Scope

This Policy applies to all research conducted within Simulation at Penn Medicine and/or with support of Simulation at Penn Medicine investigators, staff, facilities or equipment.

## 3. Exceptions

None

## 4. Definitions

None

## 5. Outcome Monitoring

The Simulation at Penn Medicine Simulation Research Program evaluates and assesses its effectiveness on the following levels:

1. Program evaluation: Includes both process evaluation and outcomes evaluation, achieved through a continuous monitoring process. This is achieved through recurrent meetings about all research study activity as referenced in points (2) and (3) below.
2. Process evaluation: Assess whether a program is designed and implemented as

intended, achieved through:

a) Weekly meetings with the standing members of research committee, which any member of the research committee can come to with issues that need addressing
b) Monthly meetings with Christi Jefferson, Director of Operations at the Simulation Center
c) Quarterly meetings open to all research members of the research committee
d) Annual Research dinner: investigator presentation of specific research studies with a summative review by the Director of Research prior to the dinner

3. Outcome evaluations: Assess a program's success in reaching its goals and research objectives, achieved through:
   a) Periodic surveys, as appropriate
   b) Publication output assessed on an annual basis
4. Program quality assessment tools refer to the criteria, standards, or models that are used to assess program quality. These criteria, standards, or models may be used to assess the different components that comprise "quality", achieved through:
   a) Compliance with Penn Medicine IRB rules and regulations
   b) Compliance with FDA reviews, as required
   c) Obtaining funding through competitive grants
   d) Peer-reviewed presentations accepted at local, national and international meetings
   e) Peer-reviewed publications
   f) Internal and External invited peer reviews of programs (e.g. visiting professors, mock and real accreditation reviews)

While evaluation and quality assessment are distinct, they are very complementary and are often used together, as quality assessment may be a piece of a larger program evaluation activity.

**Form #3: Research Program Quality Assessment**

The purpose of the Simulation at Penn Medicine Simulation Research Program Quality Assessment is to evaluate the Simulation at Penn Medicine Simulation Research Program and to help the program be reflective, to pinpoint strengths and weaknesses and to target areas for improvement. This assessment tool is for any research investigator or personnel participating in the development, conduct, and results dissemination of a research study

within, with the support of, or utilizing the services of Simulation at Penn Medicine.

| Please rate your level of agreement with each of the following elements:<br>I. Strongly disagree 2. Disagree 3. Neither agree nor disagree 4. Agree 5. Strongly agree | |
|---|---|
| **1. Environment/Climate:** Safe, healthy and nurturing environment for all esearchers and participants. | **1 2 3 4 5** |
| **2. Administration/Organization:** Well-developed infrastructure and sound iscal management to support and enhance worthwhile research activities for all esearchers. | **1 2 3 4 5** |
| **3. Relationships:** Develops, nurtures and maintains positive relationships nd interactions among staff, researchers and collaborators to support the rogram's goals. | **1 2 3 4 5** |
| **4. Staffing/Professional Development**: Recruits, hires and trains diverse taff and investigators who value each participant, understand their levelopmental needs, and work closely with administration, staff, researchers and ollaborative partners to achieve the program goals. | **1 2 3 4 5** |
| **5. Administration/Researcher/Collaborative Partnerships:** Establish a trong partnership with research communities in order to achieve program goals. | **1 2 3 4 5** |
| **6. Program Sustainability/Growth:** A coherent vision/mission and a plan for ncreasing capacity that supplies continuing growth. | **1 2 3 4 5** |
| **7. Measuring Outcomes/Evaluation:** A system for measuring outcomes and sing that information for ongoing program planning, improvement and valuation. | **1 2 3 4 5** |
| **8. Dissemination of Information:** Ability to interpret study results and resent them in a scientifically sound, unbiased and timely manner to the greater esearch community through local, regional , national and international onferences and peer-reviewed publications. | **1 2 3 4 5** |
| **Please comment on areas which have been particularly helpful or have been lacking in effectiveness:** | |
| **Additional comments:** | |

## Policy #4: Publications

| | |
|---|---|
| **Type:** | Simulation at Penn Medicine, Policy and Procedures in Research Manual |
| **Applicable to:** | All facilitators, operators, content experts, support staff, researchers, and directors associated with the Simulation at Penn Medicine |
| **Department/Unit:** | Simulation at Penn Medicine |
| **Policy owner:** | Director for Research, Simulation at Penn Medicine |
| **Effective Date:** | April 10, 2020 |
| **Approved by:** | Cindy Morgan, VP, Learning & Org Development, Penn Medicine |
| **Accountable for:** | Kristoffel Dumon, MD, FACS Director for Research, Simulation at Penn Medicine |

## 1. Policy Statement

It is the policy of Simulation at Penn Medicine to promote and encourage freedom of the researcher to disseminate results of investigation as a traditional right of a scholar and a vital aspect in academic freedom. The usual form is to make public the results of research through scholarly journals. As such, Simulation at Penn Medicine supports The University of Pennsylvania Policy on Openness in Research stating that instruction, research, and services will be accomplished openly and without restrictions on participation and prohibitions on the publication and dissemination of the results of research activities. In addition, Simulation at Penn Medicine supports the University of Pennsylvania's directive on Authorship Policy and outlines that authorship on research publications is appropriately assigned in a manner that is in keeping with the highest scientific and ethical standards. The Administrative Director or other designated research staff shall maintain documentation of all research publications in The Center Research database under "Publications."

## 2. Scope

This Policy applies to all research conducted within Simulation at Penn Medicine and/or with support of Simulation at Penn Medicine investigators, staff, facilities or equipment.

## 3. Exceptions

None

**Policy #5: Research Investigator and Personnel Requirements**

| | |
|---|---|
| **Type:** | Simulation at Penn Medicine, Policy and Procedures in Research Manual |
| **Applicable to:** | All facilitators, operators, content experts, support staff, researchers, and directors associated with the Simulation at Penn Medicine |
| **Department/Unit:** | Simulation at Penn Medicine |
| **Policy owner:** | Director for Research, Simulation at Penn Medicine |
| **Effective Date:** | April 1, 2020 |
| **Approved by:** | Cindy Morgan, VP, Learning & Org Development, Penn Medicine |
| **Accountable for:** | Kristoffel Dumon, MD, FACS<br>Director for Research, Simulation at Penn Medicine |

## 1. Policy Statement

It is the policy of Simulation at Penn Medicine that all research investigators, research coordinators and research personnel conducting a research study must be properly qualified and trained to perform the procedures as required in the protocol. If requested, Simulation at Penn Medicine Simulation Research Committee will assist the principal investigator (PI) in determining if the research activities are within the scope and level of training and expertise of the investigators and personnel.

All sponsored projects at the University of Pennsylvania must have an individual designated as PI or Project Director (PD) who has sufficient authority; appropriate background, knowledge, training and accountability to carry out all aspects of the project including assumption of fiscal responsibility; and is qualified under the eligibility guidelines herein.

### Documentation of Qualifications

Investigators involved in research coordinated by Simulation at Penn Medicine will have the most recent electronic version of the following documents readily available in the "Research Personnel" folder, which will be maintained by Simulation at Penn Medicine Administrative Director or designee and will be updated at least every two years:

1. CV — dated and initialed by investigator
2. License, if applicable

3. Other pertinent certifications related to research

In addition, documentation of University of Pennsylvania mandatory research education and CITI certification, as required by The Office of Responsible Research, will be filed with the IRB Investigators, research coordinators and research personnel are not eligible to be **added** to a research study unless these requirements are met.

**Delegation of Responsibilities**

The general roles, responsibilities and job descriptions of the following staff are kept with the Administrative Director. More specific study-related responsibilities and tasks are listed on the Study Research Proposal.

1. Research Director
2. Medical Director
3. Administrative Director
4. Research Program Manager
5. Research Coordinator
6. Research Assistant
7. Principal Investigator
8. Co-investigator
9. Research Fellow (Domestic and International) Trainee
10. Other Mentees/Trainees

**Mandatory Education**

Simulation at Penn Medicine adheres to and supports the University of Pennsylvania policy on mandatory education for Penn Medicine faculty, physicians, trainees and personnel engaged in research. All investigators must have completed the appropriate mandatory research education and CITI certification modules as outlined in the Office of the Vice Provost for Research at Penn. Investigators, research coordinators and research personnel are not eligible to be added to a research study unless these requirements are met.

**Research Trainees**

Simulation at Penn Medicine adheres to and supports Penn Medicine's policy that all research

trainees complete formal and informal instruction in responsible conduct of research during their fellowship training in compliance with federal regulations and as outlined in the Responsible Conduct of Research Training Plan, regardless of funding source.

**Protocol Orientation and Training**

The PI will delegate study tasks, per Study Research Proposal, in collaboration with the study's coordinator. Investigators, coordinators and other research personnel conducting the study must be properly qualified and trained to perform the procedures as required in the protocol and will be orientated and trained on new protocols at the initial pre-IRB and post IRB-approval, pre-enrollment study meeting, in accordance with IRB requirements. Additional trainings will be scheduled with specific investigators and staff as needed.

## 2. Scope

This Policy applies to all research conducted within Simulation at Penn Medicine and/or with support of Simulation at Penn Medicine investigators, staff, facilities or equipment.

## 3.Exceptions

None

## 4.Definitions

| Term | Definition |
|---|---|
| Principal Investigator (PI) or Program Director (PD) | An eligible individual designated by the University of Pennsylvania and approved by the sponsor to direct the sponsored project being supported by a grant, contract, or cooperative agreement. The PI is responsible and accountable to both Penn Medicine and the sponsor for the proper programmatic, scientific, or technical conduct of the project, its financial management, and its compliance with the terms and conditions of the award, appropriate regulations, and relevant Penn Medicine and sponsor policies |
| Scientist | A University of Pennsylvania position for employees that have the capability to function as independent researchers based on experience and advanced degree. Typically employees in this position hold a PhD, MD, DVM, PharmD or equivalent degree. |
| Trainee | An individual engaged in pre-doctoral or post-doctoral training at the University of Pennsylvania that provides the opportunity to develop additional research skills and knowledge, learn new techniques and obtain experience in the conduct of research and other sponsored activities. |
| Responsible | As defined by NIH NOT-OD-10-019: The practice of scientific investigation with |

| | |
|---|---|
| Conduct | integrity, of Research (RCR) involving awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research. |
| CITI certification | Collaborative Institutional Training Initiative — Mandatory training for the protection of human research subjects |

**Policy #6: Regulatory Document Management**

| | |
|---|---|
| **Type:** | Simulation at Penn Medicine, Policy and Procedures in Research Manual |
| **Applicable to:** | All facilitators, operators, content experts, support staff, researchers, and directors associated with Simulation at Penn Medicine |
| **Department/Unit:** | Simulation at Penn Medicine |
| **Policy owner:** | Director for Research, Simulation at Penn Medicine |
| **Effective Date:** | April 10, 2020 |
| **Approved by:** | Cindy Morgan, VP, Learning & Org Development, Penn Medicine |
| **Accountable for:** | Kristoffel Dumon, MD, FACS<br>Director for Research, Simulation at Penn Medicine |

## 1. Policy Statement

It is the policy of the Simulation at Penn Medicine that all research study regulatory documents will be kept in accordance with the policy of the Office of the Vice Provost of Research at the University of Pennsylvania. This protocol states that the principal investigator (PI) is responsible for the oversight and management of the essential documents of a research study and ensures that the documents demonstrate compliance with the approved protocol, applicable regulatory requirements, and institutional policies. Note: The PI may delegate the day-to-day management responsibility of essential documents to other members of the study team. All regulatory documents are kept on secured server locations.

## 2. Scope

This Policy applies to all research conducted within Simulation at Penn Medicine and/or with support of Simulation at Penn Medicine investigators, staff, facilities or equipment.

**3.Exceptions**

None

**4.Definitions**

Essential Documents- Specific research study records which individually permit evaluation of the conduct of a study and the quality of the data produced, and collectively create the history of the study.

**Policy #7: Data Management**

| | |
|---|---|
| **Type:** | Simulation at Penn Medicine, Policy and Procedures in Research Manual |
| **Applicable to:** | All facilitators, operators, content experts, support staff, researchers, and directors associated with Simulation at Penn Medicine |
| **Department/Unit:** | Simulation at Penn Medicine |
| **Policy owner:** | Director for Research, Simulation at Penn Medicine |
| **Effective Date:** | April 10, 2020 |
| **Approved by:** | Cindy Morgan, VP, Learning & Org Development, Penn Medicine |
| **Accountable for:** | Kristoffel Dumon, MD, FACS<br>Director for Research, Simulation at Penn Medicine |

## 1. Policy Statement

It is the policy of Simulation at Penn Medicine all research data is kept in accordance with Penn Medicine regulatory requirements, as indicated in each IRB-approved protocol. All research data collection and management is consistent with both the *Office of Research Compliance & Regulatory Affair of Penn Medicine and the Office of the Vice Provost of Research of the University of Pennsylvania.*

## *2.* Scope

This Policy applies to all research conducted within Simulation at Penn Medicine and/or with support of Simulation at Penn Medicine investigators, staff, facilities or equipment.

## 3. Exceptions

None

## 4. Definitions

| Term | Definition |
|---|---|
| Research Data | Research data include laboratory notebooks, as well as any other records that are necessary for the reconstruction and evaluation of reported results of research and the events and processes leading to those results, regardless of the form or the media on which they may be recorded; it often includes materials such as cell lines, vectors, antibodies and the like. |
| Record | Recorded information in any form, regardless of physical form or characteristic, generated or received by or on behalf of the University or the Hospital or Hospital Personnel in their capacity as University Employees or Hospital Personnel and includes information pertaining to University or Hospital Activities and/or Resources. A Record includes all original documents, papers, letters, radiographic images (e.g., X-rays), clinical readings, cards, books, maps, photographs, blueprints, sound or video recordings (e.g., records, CD's, DVD's, audiotape, videotape), microfilm, magnetic tape, electronic media (including information stored on computers), emails and other media for recording information. Original documents means the electronic, digital, microfilmed or other preserved or archived non-hard copy of Records where the University or the Hospital has expressly authorized in writing the destruction of original Records. |

**Policy #8: Mentorship**

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|---|---|
| **Type:** | Simulation at Penn Medicine, Policy and Procedures in Research Manual |
| **Applicable to:** | All facilitators, operators, content experts, support staff, researchers, and directors associated with the Simulation at Penn Medicine |
| **Department/Unit:** | Simulation at Penn Medicine |
| **Policy owner:** | Director for Research, Simulation at Penn Medicine |
| **Effective Date:** | April 10, 2020 |
| **Approved by:** | Cindy Morgan, VP, Learning & Org Development, Penn Medicine |
| **Accountable for:** | Kristoffel Dumon, MD, FACS Director for Research, Simulation at Penn Medicine |

## 1. Policy Statement

It is the policy of the Simulation at Penn Medicine that Mentoring of future leaders in simulation research is coordinated by Simulation at Penn Medicine. The research output and achievement of target benchmarks of the trainees are overseen by the Director of Research. All research conducted is overseen by a designated project mentor. Penn faculty members are required to be in "good standing" in order to participate as designated mentors. Faculty mentor research is conducted in adherence to the research conduct guidelines outlined through the office of the Vice Provost of Research at Penn.

Mentorship at Simulation at Penn Medicine is defined in 4 categories: 1. Formal Mentorship, 2. Peer Mentorship, and 3. Student Mentorship. 4. External Mentorship.

**1. Formal Mentorship:** This involves pairings that meet regularly and have mentor/mentee contracts. These pairings are encouraged to set research goals and benchmarks which they can reflect back on and track progress.

**2. Peer Mentorship:** This consists of two way pairings in which the two medical professionals can learn from the other. These pairings are encouraged to meet regularly and collaborate on research projects.

**3. Student Mentorship:** The aim is to pair medical professionals with a group of students to encourage students to be involved with research and simulation. These pairings meet often at the

simulation center to discuss current projects. Guidelines about mentoring can be found at: https://research.upenn.edu/resources/hub/team/mentoring/

**4. External Mentorship:** In order to foster innovation in research, the Simulation Program strives to integrate the research programs at the Simulation Center in external mentorship programs contingent with the goals and objectives of the specific research. The objective of the external mentorship program is to link the research mentoring to the experience level of the involved research team and the area of research conducted. By integrating our research program with existing mentorship and research training program of the University of Pennsylvania, we strive to increase synergy between our base institutions and to tap into existing knowledge and resources already established.

Examples of external mentorship programs include, but are not limited to:

- External Mentorship through the Masters in Education Program for Education Focused Research. This framework provides an assessment of the research conducted by the research fellows engaged in the Masters of Education program and is a structured and formalized training program in which the Education Fellow participates. The progress of the fellow and his/her achievement of expected benchmarks are established through a carefully designed training program with frequent meetings with the Director of the Master Program.

-External Research Mentoring provided to the Harrison Surgical Simulation Scholar. The Harrison scholar receives external mentoring in research through designated research meeting conducted by the Vice Chair of Research in Surgery. During these meetings, Harrison Scholars in different areas of research present their work, receive feedback and mentoring from research faculty in other disciplines. The Senior Director of Research receives progress reports from the designated mentor of the Harrison Research Scholar, which are shared with the Simulation at Penn Medicine Director of Simulation Research.

-External Research Mentorship provided by the Director of Student Education. Scholarly activities initiated by medical students are overseen by the Director of Student Education who provides external mentorship to the student initiated simulation research projects in conjunction with the Simulation at Penn Medicine Director of Simulation Research.

-External Research Mentorship in Research involving Patient Safety. The scholarly activities of the Fellowship in Patient Safety and Surgical Education is overseen through the Perioperative Patient Safety Executive Leadership which provides mentoring and feedback to patient safety related simulation research projects. Progress of the Research is provided to the Peri-Operative Leadership by the Patient Safety Fellow.

-External Mentorship in Simulation through the Master of Science in Translational Research (MTR). For technology directed Simulation Research. This alignment provides students with in-depth instruction in the fundamental skills, methodology and principles necessary to become well-trained translational investigators in simulation. The program achieves these objectives through the provision of didactic coursework, a formal mentorship program, formal laboratory training and specific ongoing guidance with hands-on exposure to protocol and grant development. Trainees are expected to complete a primary research project of their own design under the supervision of their primary mentor. The primary mentor also plays a role in helping the student identify a feasible research question for a thesis. The thesis consolidates students' knowledge of the principles and practice of translational research or of medical education.

**2. Scope**

This Policy applies to all research conducted within Simulation at Penn Medicine and/or with support of Simulation at Penn Medicine investigators, staff, facilities or equipment.

**3.Exceptions**

None

**4.Definitions**

None