Procedure Title: Quality Improvement Versus Research

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	5/4/2018	**Executive Lead:**	Chief Research Officer
Effective:	05/04/2018	**Revision History:**	.01 – 10/03/2019; .02 – 04/07/2020; .03 – 03/11/2021; .04 – 3/7/2023
Approved by:	Institutional Review Board		
Procedure Number:	121.04		
Key Words:	Publication intent; Quality Improvement, QI; Research; Human Subject		
Purpose:	To meet the responsibilities for protecting human subjects as issued by the Office for Human Research Protections (OHRP) requirement for individuals involved in the conduct or review of human subjects research at institutions holding OHRP-approved Federal Wide Assurances (FWAs)		

Process:
This SOP serves to inform all agents, offices, departments, and affiliate sites of PNWU regarding the difference between quality improvement (QI) and research.

This SOP must be used as a guide in parallel with OSA Policy 1.0, to comply with human subject research protections. SOPs are not intended to supersede existing institutional policies, and local, state, and federal laws and regulations.

General Information
Quality Improvement (QI) and research are easily confused because they share similar characteristics. Both activities ask clinically important questions, use patient data, may apply complex statistical analyses to those data, and have improvement of patient care as a goal.

Research, as defined by the Department of Health and Human Services (DHHS), is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. For the knowledge "to be generalizable, the intent of the activity must be to extrapolate findings from a sample (e.g., the study subjects) to a larger (reference) population to define some universal truth".

QI is a systematic process that involves activities designed to bring about immediate or nearly immediate improvement to health care delivery or processes in a local setting. Improvements are achieved through interventions that target health care providers, practitioners, plans, and/or beneficiaries. These projects use the traditional Plan, Do, Study/Survey, and Act (PDSA) cycle.

Regardless of whether the activity is QI or research, both activities involve human subjects and must be carried out ethically and in a manner that respects the rights and welfare of the human participants.

Responsible Parties

The Institutional Review Board (IRB) is responsible for:

- Protecting the rights and welfare of human research participants;
- Impartiality when reviewing of human subject research;
- Remaining immune from pressure by the institution's administration, the investigators whose protocols are brought before it, or other professional and non-professional sources;
- Assessing risk and other considerations per federal regulations in the determination of exempt versus non-exempt studies;
- Communicating with the investigator as to the application status and modifications needed to ensure protection of human subjects.

The Office of Scholarly Activity (OSA) is responsible for:

- Supporting the investigator in the development of scholarly activity;
- Monitoring compliance with this SOP;
- Posting this SOP for the PNWU community;
- Working with the investigator and providing them instructions for determination of QI versus research processes.

The Investigator is responsible for:

- Being a steward of a research environment that promotes the responsible conduct of research;
- Ensuring compliance with the IRB-approved protocol, federal regulations, state laws, good clinical practice, and FDA guidance (when applicable);
- Seeking support from OSA and the IRB when questions arise;
- Ensuring no research is conducted prior to IRB approval;
- Practicing good judgment when it comes to determination of a QI project question versus a research study driven by a hypothesis;
- Being sure the QI project is not used as loophole to avoid prior IRB review.

The Office of Institutional Effectiveness (OIE) is responsible for:

- Retrieving, compiling, storing institutional data;
- Ensuring protection of student identities, complying with FERPA laws, minimizing risk to PNWU, when sharing institutional data for the purpose of research and/or quality improvement.

Definitions

Please reference the Glossary for complete definitions of the following terms and additional terms not listed.

- Evidence-based Practice
- FERPA
- Generalizable Knowledge
- Health Information Portability and Accountability Act (HIPAA)
- Human Subject
- PDSA Cycle
- Principal Investigator (PI)
- Quality Improvement (QI)
- Research
- Systematic Investigation

Investigator Procedures:

1. Review PNWU OSA SOP 103.0, which defines the institution's process for determining whether Health and Human Services-conducted or -supported research studies qualify as exempt or non-exempt from the HHS regulations.
2. Fill out and submit the OIE Request for Data/Information Form for any project that involves student data protected by the Family Education Rights and Privacy Act (FERPA).
3. Fill out and submit a request for determination of not human subjects' research in the electronic IRB system to request that the IRB make a determination as to whether or not the project meets the criteria for research with human subjects. Note: Projects that collect data about human participants must be submitted and reviewed prior to collecting actual data.

IRB Procedures:

1. Review requests for determination of not human subject research in a timely manner.
2. Request additional information about project as needed.
3. Provide determinations to the individual submitting the form in writing.

Additional Guidance:

1. Some indications of when an activity might NOT be quality improvement include:
   a. treatments/interventions that are more than minimal risk;
   b. the intent to generate new scientific knowledge;
   c. the intent to validate a new treatment and/or intervention;
   d. protocols that have distinct goals, methods, populations and time periods;
2. QI projects may include, but are not limited to, performance measures, compliance checks, examination of intervention use at local hospitals to attempt to decrease patient falls. QI typically uses the Plan, Do, Study, Act (PDSA) Cycle
3. Results are typically disseminated internally (e.g., within the business, clinic, or hospital)
4. Some differences between QI and Research:

Points to Consider	Research	QA/QI
Design	• Systematic data collection • Hypothesis driven • May include randomization to different interventions • May involve placebo or sham treatment • May evaluate drug and/or device safety and/or efficacy • May differ from standard of care • Single-site or multi-site	• Systematic data guided activities to improve performance • Uses the Plan, Do, Study, Act Cycle (a cyclical program to plan, implement, test, and make modest changes in the delivery of patient care) • Typically involves a single site, but may be multiple sites of the same business
Purpose/Intent	• Test a hypothesis/answer a research question • To develop and/or contribute to generalizable knowledge	• To assess and bring about immediate or nearly immediate improvement in a specific process, program, or system • To improve performance as measured by accepted or established standards (may include consistency of patient care in a clinic or a specific care unit of a hospital)
Population	• Defined through study protocol inclusion and exclusion criteria • Participation must be voluntary	• Commonly includes all patients/participants of the business/practice (e.g., patients and healthcare providers) • Participation may or may not be voluntary.
Benefits	• Primary benefit is usually the scientific knowledge gained • Participants may or may not directly benefit from the research	• All patients are likely to benefit from QA/QI
Risks	• May place subjects at risk of harm and will be	• Does not place a subject at risk of harm

Points to Consider	Research	QA/QI
	stated as such during subject consent to participate in the study	
Funding	• Unfunded OR funded by a research grant, award or contract. When funded as research, all activities supported by the funding must be considered research	• Normally is not funded
Analysis and Impact	• Findings are not expected to directly impact or directly benefit the institution, program, or practice. • Data analyzed to prove or disprove a hypothesis	• Findings of the project are expected have immediate impact and directly improve institution practice, programs, or processes • Data compared to program, process, system, or established standards
Publication	• Clear intent to publish the results as research (e.g., in scientific journals, research poster/abstract, or another research forum.) • Part of professional and scholarly expectations and/ or obligations.	• Results are typically disseminated internally (e.g., within the business, clinic, or hospital) • Project findings are reviewed to determine if the changes improved care delivery or other business practices and inform business decisions or operations • Interesting project results may result in publication. Any publication must make it clear that the project was carried out as quality improvement

5. Publication intent and lack of IRB review/approval for a research study do not automatically qualify the investigation as QI (e.g. "well, we didn't get IRB approval, so, let's call it QI" or "we can't publish it because it is QI").
6. QI findings are typically kept within the confines of the sponsoring institution. Sometimes, however, it is reasonable to publish an appropriately designed and administered QI project if the project's findings are desirable. Ultimately, dissemination of information outside the project's institution has implications for demonstration of oversight regarding risk and privacy.

References:

1. Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services Part 46, Protection of Human Subjects, Revised January 15, 2009, Effective July 14, 2009
2. Department of Health and Human Services, Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection, May 5, 2004.
3. Code of Federal Regulations, Title 42 Policies of General Applicability, Department of Health and Human Services, Part 50 Subpart F – Promoting Objectivity in Research
4. Code of Federal Regulations, the Family Educational Rights and Privacy Act (FERPA), 20 U.S.C.§ 1232g; 34 CFR Part 99. https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html
5. Principles of Research Methodology: A Guide for Clinical Investigators. Springer New Your 2012; ISBN 978-1-4614-3359-0
6. Peter E. Morris, Kathleen Dracup; Quality Improvement or Research? The Ethics of Hospital Project Oversight. Am J Crit Care 1 September 2007; 16 (5): 424–426. doi: https://doi.org/10.4037/ajcc2007.16.5.424Office of Human Research Protections, Quality Improvement Activities FAQ. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html
7. Release of FERPA Protected Data from Office of Institutional Effectiveness for Research Purposes Policy. https://www.pnwu.edu/inside-pnwu/about-us/policies-and-procedures/policy-release-ferpa-protected-data-oie-research-purposes

8. Department of Health and Human Services, Quality Improvement Activities Frequently Asked Questions, https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html
9. PNWU SOP 103 Activities Subject to Human Protection

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 05-04-2018	M. McCarroll	Original SOP
.01 / 10-03-2019	C. Case	Put into new PNWU SOP Format
.02 / 04-07-2020	C. Case	Reworked the SOP format to include the General Information section; added standard responsibilities for the IRB, the PI and OSA; Added responsibilities for Office of Institutional Effectiveness regarding FERPA data; removed definitions not applicable to this SOP; renamed the procedures section to Investigator procedures and revised the content to be more procedural in nature; Added an IRB procedures section; added a new section for Additional Guidance; added citations 6-11 to the reference section.
.03 / 04-26-2021	C. Case	•Added requirement to submit NHSR request to the IRB prior to data collection when human participant data is being collected. •Deleted reference hyperlink University of Colorado Denver as it no longer worked. •Deleted reference hyperlink to University of Kansas City as it no longer worked. •Added a reference to PNWU SOP 103 Activities Subject to Human Protections. •Replaced the table with Research and QA/QI differences.
.04 / 4-3-2023	C. Case	• Added item 3 under additional guidance regarding QI results typically being distributed internally. • Added reference #8 to the HHS Website information regarding Quality Improvement Frequently Asked Questions.

Appendices:
None