

Publishing and Presenting on Quality Improvement (QI)

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Is my QI project a research study?

- Important question to consider when beginning your project!!
- If a project is considered “human subjects research” it is required to undergo ethical review by an Institutional Review Board (IRB)
 - Federal Regulation
 - KP policy

What is the Institutional Review Board (IRB)?

- Committee responsible for reviewing all human subjects research to ensure it is ethical and the welfare and rights of research participants are protected
- If a study requires IRB review, needs to happen **before** the study is conducted
- Research cannot be retrospectively reviewed

Questions to ask to determine if your QI project needs IRB review (in this order!)



Does my project involve research?

Definition of research :

“A systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge”

Generalizable = intend to make results available to the public (outside of KP) - publication, newsletter, PowerPoint presentation or poster presentation

Quality improvement (QI) projects have different purpose and intended audience from research

- Goal is to optimize productivity, quality of care, communication, improve systems, etc.
- Results intended for internal purposes, not designed to be generalized outside of Kaiser Permanente

Does your research involve human subjects?

A human subject is a living individual about whom an investigator conducting research obtains:

1) Data through intervention or interaction with the individual

OR

2) Identifiable private information

If you are collecting identifiable private information (e. g. medical record data, identifiable specimens), your study may be considered human subjects research, even if you are not interacting with human subjects!

If you are unsure, check with the IRB!!

- Fill out the “Human Subjects Research Assessment Form” – short, 2-page form
- Email to Marcela Sanchez, IRB Administrator
Isabel.M.Sanchez@kp.org
626.405.6124
- IRB will make a determination and tell you how to proceed – if your project is not human subjects research, you will get a letter stating this.

Human Subjects Research Assessment Form

Do not use abbreviations in this form- the form will be returned to be amended before it will be considered.

Project Title: <input type="text"/>
Project Leader's Name: <input type="text"/>
Date: <input type="text"/>
KP Mailing Address: <input type="text"/>
Phone #: <input type="text"/>
Email: <input type="text"/>

The purpose of this form is to determine if a given project is human subjects research which requires review and oversight by the Institutional Review Board (IRB) in accordance to federal regulations and institutional policies.

Research - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. §45CFR46.102(d)

Human subject - A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. §45CFR46.102(f)

Projects that do not meet both the definition of research and human subject are not required to be submitted for review to have a formal determination made. However; there are serious consequences for conducting human subjects research without the appropriate oversight and therefore, anyone is encouraged to complete and submit this form to have the assessment made.

<http://irb.kp-scalresearch.org/5/HumanSubjectsResearchAssessment.doc>

An Example....

- **BACKGROUND:** Dextro-transposition of the great arteries (d-TGA) is a form of congenital heart disease, which necessitates intervention within the newborn period to permit survival. There are approximately 1,250 babies, or 1 in 300 children, born with this condition every year. The central feature of this condition lies in the way the major arteries are connected to the heart. In patients with normal anatomy, the aorta connects to the left ventricle, while the pulmonary artery connects to the right ventricle. In patients with d-TGA, these connections are the opposite; the aorta is connected to the right ventricle, while the pulmonary artery is connected to the left ventricle. Within the Kaiser Permanente Southern California system, the volume of obstetric deliveries would presume that many of our youngest patients will have d-TGA. The arterial switch procedure was first successfully performed in 1975, in which, practically, the aorta and pulmonary arteries are detached from their native connections and “switched.” By the late 1980s/early 1990s, the arterial switch procedure became the standard of care for patients with d-TGA and has resulted in improved outcomes in this patient population.
- **STUDY DESIGN:** This will be a retrospective chart review study with a goal of being a quality assurance study for our cardiology department. We plan to include all patients diagnosed within our system since 2005 who have subsequently undergone arterial switch. Exclusion criteria: patients with inadequate records to abstract data from.
- **OBJECTIVES/EXPECTED:** We expect that the grand majority of patients with d-TGA will have survived. We also anticipate that our patients will have survived past the neonatal period and that there may be some factors surrounding this patient population that will allow us to target appropriate interventions.

Considerations for Publishing

- Quality Improvement is very different from Clinical Research; it can be difficult to determine the best ways to organize an article on a QI project.
- QI is fundamentally about human behavior and experiential learning within the high stakes clinical setting.

SQUIRE Guidelines

SQUIRE Guidelines
(Standards for Quality Improvement Reporting Excellence)
Final revision – 4-29-08

Standards for Quality Improvement Reporting Excellence

- These guidelines provide a framework for reporting formal, planned studies designed to assess the nature and effectiveness of interventions to improve the quality and safety of care.
- It may not be possible to include information about every numbered guideline item in reports of original formal studies, but authors should at least consider every item in writing their reports.
- Although each major section (i.e., Introduction, Methods, Results, and Discussion) of a published original study generally contains some information about the numbered items within that section, information about items from one section (for example, the Introduction) is often also needed in other sections (for example, the Discussion).

<i>Text section; Item number and name</i>	<i>Section or Item description</i>
<u>Title and abstract</u>	<i>Did you provide clear and accurate information for finding, indexing, and scanning your paper?</i>
1. Title	<ol style="list-style-type: none">Indicates the article concerns the improvement of quality (broadly defined to include the safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity of care)States the specific aim of the interventionSpecifies the study method used (for example, “A qualitative study,” or “A randomized cluster trial”)
2. Abstract	Summarizes precisely all key information from various sections of the text using the abstract format of the intended publication

http://www.squire-statement.org/assets/pdfs/SQUIRE_guidelines_table.pdf

Journals for QI projects

Journal Title	Version	IF	Type papers	Fee	Comments
American journal of medical quality : the official journal of the American College of Medical Quality http://ajm.sagepub.com/	P/E	1.4	OR,E, C,P (3500 words)	-	Focused in the resources, processes, and perspectives contributing to health care services.
Health and quality of life outcomes http://www.hqlo.com/	E	3.2	OR,E,R,SR,L, C	\$1,8 20	Focusing on the development and clinical application of patient reported outcomes
Healthcare benchmarks and quality improvement	P		E,R,SR,L,C	-	Health services research.
International journal for quality in health care http://intqhc.oxfordjournals.org/	P/E	1.6	OR,E,R,L,C (3,500 words)	-	QI, HSR, qualitative, quantitative studies
International journal of health care quality assurance http://info.emeraldinsight.com/products/journals/journals.htm?PHPSESSID=m91hkpq0n28u0ot1fvi11230h0&id=ijhcga	P/E	NA	OR,E,R,L,C (3,500-6000 words)	-	QI, HSR, qualitative, quantitative studies
Joint Commission journal on quality and patient safety http://www.jcrinc.com/The-Joint-Commission-Journal-on-Quality-and-Patient-Safety/	P/E	1.4	OR,E,R,L,C (2000-4000 words)	-	QI, leadership, HSR, Root analysis, case studies
Journal for healthcare quality : http://www3.interscience.wiley.com/journal/122585946/grouphome/home.html	P	1.6	OR,E,R,L,C (1500-3000 words)	-	QI, HSR. Official publication of the National Association for Healthcare Quality
Journal of nursing care quality http://journals.lww.com/incqjournal/pages/default.aspx	P/E		OR,R,C (18pages)	-	Patient safety, leadership, QI, and the application of quality principles in the clinical setting
Quality & safety in health care http://qshc.bmj.com/	P/E	2.5	OR (2000 words),SR,R, L	-	Leading international journal. Owned by the BMJ Publishing Group Ltd.
Quality in primary care http://www.ingentaconnect.com/content/mp/gpc	P/E	NA	OR,E,R,SR,L, C (3000 words)	-	QI, clinical governance or clinical audit related to primary and prehospital care
Quality management in health care http://journals.lww.com/gmhjournal/pages/default.aspx	P/E	NA	OR,E,R, L	-	HSR, Quality, Management. Call for papers 2010.

Questions?

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