

Ethics Supplement Program Update:
*Survey to Assess Ethical Framework of
Minimal Risk Studies*



Core Investigative Team and Liaisons

Investigator	Affiliation	Expertise
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Sherrie Kaplan, PhD	UC Irvine, Professor Assistant Vice Chancellor for Healthcare Evaluation and Measurement	Expert psychometrician; qualitative and quantitative survey design and evaluation; CER; served on IRB for 15y
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Overview

- Address the ethical gray space related to the interface of minimal risk research and quality improvement studies as they would be applied to Learning Health Systems
 - Identify if a common ethical framework exists
 - Survey IRB chairs, leaders of healthcare quality improvement programs, and patients
 - Common constructs evaluated across all 3 surveys

Project Aims

Aim 1: Survey of IRB Chairs and Directors

- Develop and conduct a survey of IRB directors to assess their experience with and interpretation of minimal risk research activities, including quality improvement research studies as relates to waiver of consent
- Use example scenarios to assess the common range of IRB determinations applied to quality improvement studies and evaluate common drivers of risk determination and consent requirements

Aim 2: Survey of Directors of QI Programs

- Develop and conduct a survey of directors of hospital quality improvement programs to assess the range of QI activities being conducted with and without a research premise to provide context for ethical oversight of such studies
- Use example scenarios to determine the ethical boundaries related to quality improvement research and the assessment of risk and consent requirements

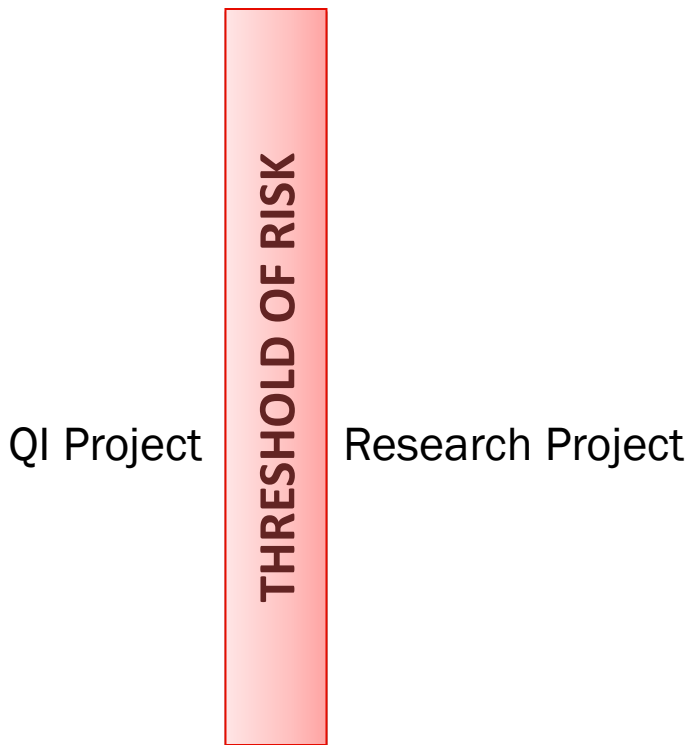
Aim 3: Survey of Patients

- Develop and conduct a structured interview-administered survey of hospitalized patients to evaluate their expectations of consent for hospital activities related to QI and research
- Include questions to evaluate effectiveness of phrases to communicate:
 - 1) That hospitals are dedicated to improving medical care
 - 2) That participating in QI initiatives and research helps improve health care for current and future generations

Survey Constructs

Hypothesis: Threshold of Risk

Current Prevailing Concept



Proposed Concept



Projects below threshold of risk operate under same fundamental principles, regardless if it is a quality improvement project or research project.

Single Ethical Framework

Can We Generate a Single Ethical Framework for Evaluating Routine, Minimal Risk Studies?

**Learning Health System
Projects Limited to:**

- 1. Minimal Risk**
- 2. Principle of Agency applies***
- 3. Reasonable Rationale****

IRB Programs
QI Programs
Patients

**Endorsement of Activity
Reflected by:**

Waiver of Consent

*PI, treating physician, healthcare system provides oversight for respect of patients' rights, welfare, and dignity

**Design and conduct will provide benefit to individuals or generalizable knowledge to improve healthcare

IRB Waiver of Consent Rules

1. Minimal risk
2. No adverse effect to subjects' rights/welfare
3. Research cannot be practicably carried out
4. Subjects provided with additional info

How to Evaluate Consent?

- **IRB Survey**
 - Studies eligible for a waiver of consent
- **QI Survey**
 - Identify reasonable and feasible QI study
- **Patient Survey**
 - Is providing permission necessary



Current Events: Ongoing Survey Design

- How to best assess consent among 3 groups?
 - What categories of studies provide value?
 - Are the examples within categories useful?
 - What are the most meaningful response options?
 - What phrases best convey “study” ?
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- Helpful feedback in response to Dr. Huang’s January GR session resulted in revisions to the the patient survey

Patient Survey: Hospital Environment

SECTION 2. MAKING CHANGES IN THE HOSPITAL ENVIRONMENT

The following questions ask about if you would like to be asked for your written permission before hospitals can make changes in patient care that involve the physical surroundings.

1. Generally, when hospitals change the way patients are cared for, do you think patients should be asked for their written permission in patient care to compare each of the following:

(CIRCLE ONE NUMBER ON EACH LINE)

	YES, DEFINITELY	YES, PROBABLY	MAYBE	NO, PROBABLY NOT	NO, DEFINITELY NOT
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a. Trying out different ways to reduce noise levels in hospitals at night

1 2 3 4 5

b. Comparing two types of privacy curtains around patient beds

1 2 3 4 5

c. Trying out different places to put handrails in patient rooms to prevent falls

1 2 3 4 5

d. Seeing whether using different cleaning products on things patients touch often (doorknobs, call buttons, bed rails) prevents infections

1 2 3 4 5

Patient Survey: Data Sharing

SECTION 6. MAKING CHANGES IN THE WAYS HOSPITALS COLLECT, USE, OR SHARE PATIENT INFORMATION

The following questions ask about when you would like to be asked for your written permission when hospitals compare changes in the ways they collect, use, or share information with other healthcare providers.

1. Which of the following do you think need written permission from patients before hospitals make changes like these?

(CIRCLE ONE NUMBER ON EACH LINE)

	YES, DEFINITELY	YES, PROBABLY	MAYBE	NO, PROBABLY NOT	NO, DEFINITELY NOT
a. Changing from paper to computerized medical records	1	2	3	4	5
b. Including patient data (names and addresses) in disease registries (databases for specific diseases) for <u>research</u>	1	2	3	4	5
c. Sharing pictures of the body <u>without</u> the face with doctors, nurses, or students for teaching purposes	1	2	3	4	5

Patient Survey: Data Sharing

6. How comfortable do you feel sharing your personal information in the following ways?

(CIRCLE ONE NUMBER ON EACH LINE)

	VERY COMFORTABLE	SOMEWHAT COMFORTABLE	SO-SO	SOMEWHAT UNCOMFORTABLE	VERY UNCOMFORTABLE
a. Posting a photo online (Facebook, Twitter)	1	2	3	4	5
b. Emailing personal information (name, address, phone number)	1	2	3	4	5
c. Shopping online	1	2	3	4	5
d. Completing patient forms online	1	2	3	4	5

Next Steps for Patient Survey

- Finalize revisions
- Vet
- Pilot
- Conduct



Project Timeline

- Ongoing: Revise & refine patient survey
- Next: Develop and refine QI and IRB leads survey
- Spring, 2014: Patient survey pilot
- Summer, 2014: Launch all three surveys