Survey to Assess Ethical Framework of Minimal Risk Studies

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ABATE Infection Project

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

Core Investigative Team and Liaisons

Investigator	Affiliation	Expertise
Susan Huang, MD MPH	UC Irvine, Assoc Professor Director, Epidemiology & Infection Prevention	Quality improvement, infection prevention, healthcare epidemiology, infectious diseases, CER
Jim Sabin, MD	Harvard Pilgrim Health Care Institute Professor, Population Med & Psychiatry Director, Ethics Program	Psychiatry, ethics in patient care and research, including CER and clinical trials
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
Sheila Fireman, JD	Director, IRB Harvard Pilgrim Health Care	IRB Liaison, Ethics Core, NIH Collaboratory
Adrijana Gombosev, BS	UC Irvine	Project Coordinator
Lauren Heim, MPH	UC Irvine	Project Coordinator
Becky Kaganov, BS	Harvard Pilgrim Health Care Institute	Research Associate
Julie Lankiewicz, MPH	Harvard Pilgrim Health Care Institute	Project Coordinator, ABATE Infection Trial liaison to Collaboratory Ethics Core

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:

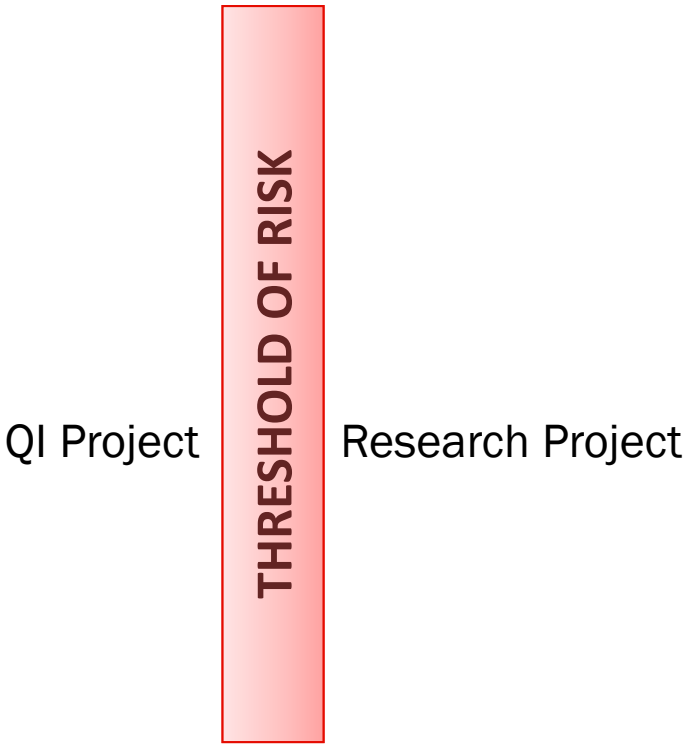
    1) That hospitals are dedicated to improving medical care

    2) That participating in QI initiatives and research helps improve health care for current and future generations

Survey Constructs

Hypothesis: Threshold of Risk

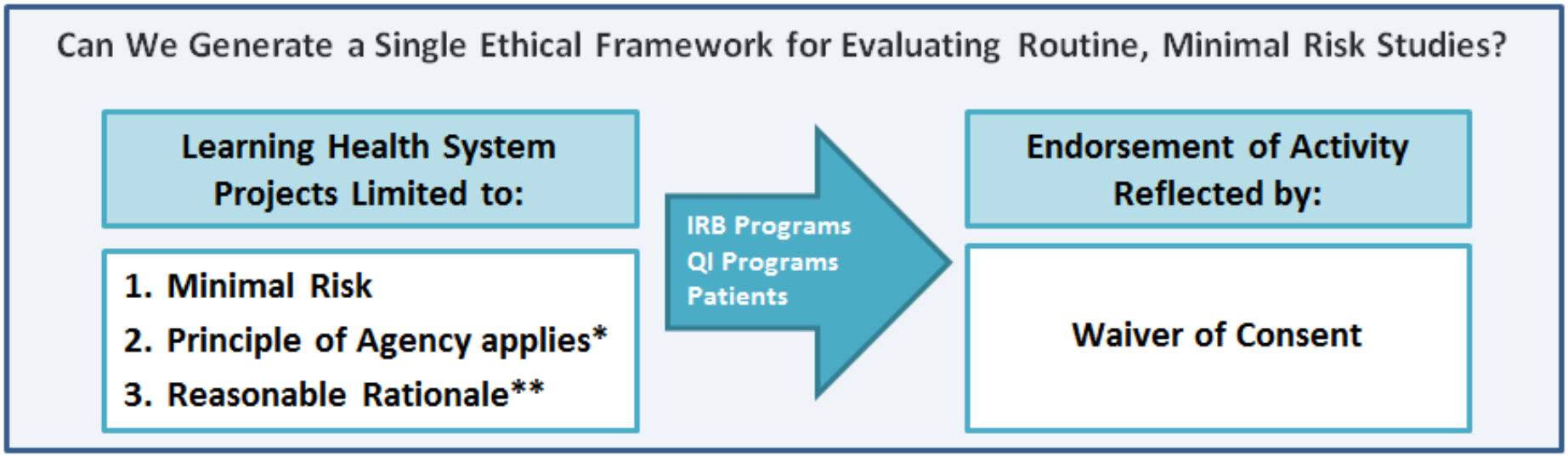
Current Prevailing Concept



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



*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

Questions for the Group

- How to best assess consent among 3 groups?

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

Survey Introduction

We are conducting this study to find out how patients feel about being asked for their written permission when hospitals look to make changes to policies, procedures, practices, and the physical environment to improve patient care.

Hospitals regularly look to make changes to improve the care they provide to patients. Some of these changes may seem minor and may not need written permission from patients before they are made. Other changes may seem more important and need written permission from patients. “Written permission” would require that patients read and sign a document agreeing that the changes can be made.

Questions for the Group

- How to best assess consent among 3 groups?
- What categories of studies provide value?

Survey Sub-Constructs

- Hospital Environment
- Products Used on or by Patients
- Medication, Health Equipment ,and Devices
- Policies and Procedures
- Data Sharing

Questions for the Group

- How to best assess consent among 3 groups?
- What categories of studies provide value?
- Are the examples within categories useful?

Hospital Environment

- Looking at different ways to reduce noise level at night
- Trying out special types of lighting at night to improve patients' sleep
- Comparing different types of privacy curtains
- Trying out different placement options for handrails in patient rooms to prevent falls

Products Used On Or By Patients

- Trying out different types of bathing soap to reduce risk of infections
- Seeing how long patients should wear stockings to prevent blood clots in leg
- Trying out different thermometer types for taking temperature
- Comparing different types of bandages to improve healing or reduce irritation

Medication, Health Equipment & Devices

- Comparing use of generic vs. name brand drugs
- Comparing different types of crutches or walkers
- Comparing different types of blood drawing needles or methods of drawing blood
- Comparing automatic blood pressure monitors to manual check by nurses

Policies and Procedures

- Trying out different post discharge teaching materials or education methods
- Trying out the use of tiny robots to guide surgery compared to large incisions
- Seeing whether having nurses call patients after they go home improves their care at home
- Trying out ways to reduce patient wait time in the emergency room

Data Sharing

- Changing to computerized vs. paper medical records
- Including patient data in disease registries
- Trying out different ways to help patients understand their own medical record information
- Using patient data to improve care at only the hospital where they were seen
- Using patient data to improve care at other hospitals that take care of similar patients

Survey Design

- Survey built to have internal validity
- General section: overall questions re: sub-constructs
- Followed by more detailed questions/examples per sub-construct to assess internal validity

Questions for the Group

- 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?

Response Options

2. Hospitals often look for ways to improve patient care. Should you be asked for your **written permission** before hospitals can do the following activities:

(circle one number on each line)

	YES, DEFINITELY	YES, PROBABLY	MAYBE	NO, PROBABLY NOT	NO, DEFINITELY NOT
a. XXXXXX.....	1	2	3	4	5

2. Hospitals often look for ways to improve patient care. For each of the following, please answer whether you would like to know or give permission before these activities occur:
(*Publicly available means you can ask for it or it's on the hospital website)

(circle one number on each line)

	I DON'T NEED TO BE ASKED (GO AHEAD)	I DON'T NEED TO BE ASKED, INFO PUBLICLY AVAILABLE (CAN LOOK UP)	I DON'T NEED TO BE ASKED, POST INFO IN ROOM (SIGNAGE)	DON'T DO UNLESS I SAY OK (ASK ME)	DON'T DO UNLESS I SIGN SOMETHING (SIGNATURE)
a. XXXXXX.....	1	2	3	4	5

Questions for the Group

- 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”?

Hospital Environment

SECTION 2. Asking for Your Permission to Study Specific Types of Changes in the Hospital Setting or Environment to Improve Patient Care or Experiences

2. 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 involves the physical surroundings:

(circle one number on each line)

	YES, DEFINITELY	YES, PROBABLY	MAYBE	NO, PROBABLY NOT	NO, DEFINITELY NOT
a. Comparing ways to reduce noise levels in hospitals at night.....	1	2	3	4	5
b. Testing two types of patient beds for comfort OR color of walls to improve patient mood.	1	2	3	4	5
c. Comparing two types of privacy curtains around patient beds	1	2	3	4	5

Products Used on or by Patients

SECTION 3. Asking for Your Permission to Study Changes in Things that are Put On or Used by Patients to Improve Patient Care Or Experiences

3. These questions ask about whether you would like to know or give permission before hospitals make changes in things that are used by or put on patients.

(circle one number on each line)

	I DON'T NEED TO BE ASKED (GO AHEAD)	I DON'T NEED TO BE ASKED, INFO PUBLICLY AVAILABLE (CAN LOOK UP)	I DON'T NEED TO BE ASKED, POST INFO IN ROOM (SIGNAGE)	DON'T DO UNLESS I SAY OK (ASK ME)	DON'T DO UNLESS I SIGN SOMETHING (SIGNATURE)
a. Comparing different types of bathing soaps to reduce the risk of infections?	1	2	3	4	5
b. Comparing different types of wound bandages to improve healing or reduce irritation?	1	2	3	4	5
c. Comparing different types of thermometers (oral, underarm, ear) for taking temperature?	1	2	3	4	5

Medication, Health Equipment and Devices

SECTION 4. Asking for Your Permission to Study Changes in Types of Medications or Health Equipment to Improve Patient Care or Experiences.

4. The following questions ask about if you would like to be asked for your **written permission** when comparing the ways hospitals use already approved medications, health products, or equipment to improve patient care or experiences:

(circle one number on each line)

	YES, DEFINITELY	YES, PROBABLY	MAYBE	NO, PROBABLY NOT	NO, DEFINITELY NOT
a. Trying out the use of generic or cheaper versions of drugs vs. brand name drugs?	1	2	3	4	5
b. Comparing different types of crutches or walkers for patients who need them?	1	2	3	4	5
c. Comparing different types of blood drawing needles or methods to draw blood?	1	2	3	4	5

Policies and Procedures

SECTION 5. Asking for Your Permission to Study Changes in Hospital Policies or Procedures to Improve Care or Experiences

5. These questions ask about whether you would like to know or give permission before hospitals make changes in certain types of procedures, policies, or ways they are done.

(circle one number on each line)

	I DON'T NEED TO BE ASKED (GO AHEAD)	I DON'T NEED TO BE ASKED, INFO PUBLICLY AVAILABLE (CAN LOOK UP)	I DON'T NEED TO BE ASKED, POST INFO IN ROOM (SIGNAGE)	DON'T DO UNLESS I SAY OK (ASK ME)	DON'T DO UNLESS I SIGN SOMETHING (SIGNATURE)
a. Comparing different teaching materials or methods for educating patients about what to do after they leave the hospital?	1	2	3	4	5
b. Comparing whether robotic or open surgery is better for patient outcomes? ...	1	2	3	4	5
c. Comparing whether getting patients up and walking sooner after surgery reduces problems (such as pneumonia, blood clots, etc.)?	1	2	3	4	5

Data Sharing

SECTION 6. Asking for Your Permission to Study Changes in the ways Hospitals Collect, Use, or Share Patient Information to Improve Patient Care or Experience

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.

(circle one number on each line)

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

Next Steps for Survey

- Revise
- Vet
- Pilot
- Conduct

Questions for the Group

- 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”?