BRADLEY University

Quality Improvement: To IRB, or Not to IRB, That Is the Question

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Objectives

- Describe an IRB, quality improvement activities, and human subject research
- Identify how quality improvement activities and human subject research intersect
- Describe an ethical oversight process for quality improvement activities

What is an IRB?

The IRB is an established administrative body mandated by federal regulations to assure that appropriate steps are taken to protect the rights and welfare of human research subjects recruited to participate in research activities

The IRB's function is derived from the DHHS Regulations, Title 45 of the Code of Federal Regulations Part 46 (45 CFR 46)= The Common Rule

(Department of Health and Human Services [DHHS], 2018)

Design Definitions

What is Human Subject Research?

"systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge"

(DHHS, 2018, p.6)

What is Quality Improvement?

Systematic, data-driven activities designed to target immediate improvements in health care delivery or outcomes in a local setting

(Mormer & Stevans, 2019; Stiegler & Tung, 2017)

Research vs. QI: Key Differences

	Research	Quality Improvement
Purpose	Develop or contribute to generalizable knowledge	Improve a process or performance of established standards
Outcome	Generalizable	Relevant to single site
Benefits	May or may not benefit subjects	Benefits a process or program and usually benefits patients
Risks	May put subjects at risk	Low risk to subjects, may have privacy concerns
Methods	Strict protocol	Protocol may need modifications over time
Results	Answer a research question or hypothesis	Improves or creates process/system/program to improve delivery of care, safety, satisfaction

(Fiscella et al., 2015; Mormer & Stevans, 2019)

The Gray Area

DHHS does not define what constitutes “generalizable knowledge.” Lack of clarity requires IRBs to interpret the definition of research and distinguish boundaries of QI and human subject research.

When projects share elements of QI and human subject research, ethical concerns and regulatory oversight become entangled.

(Lee et al., 2016)

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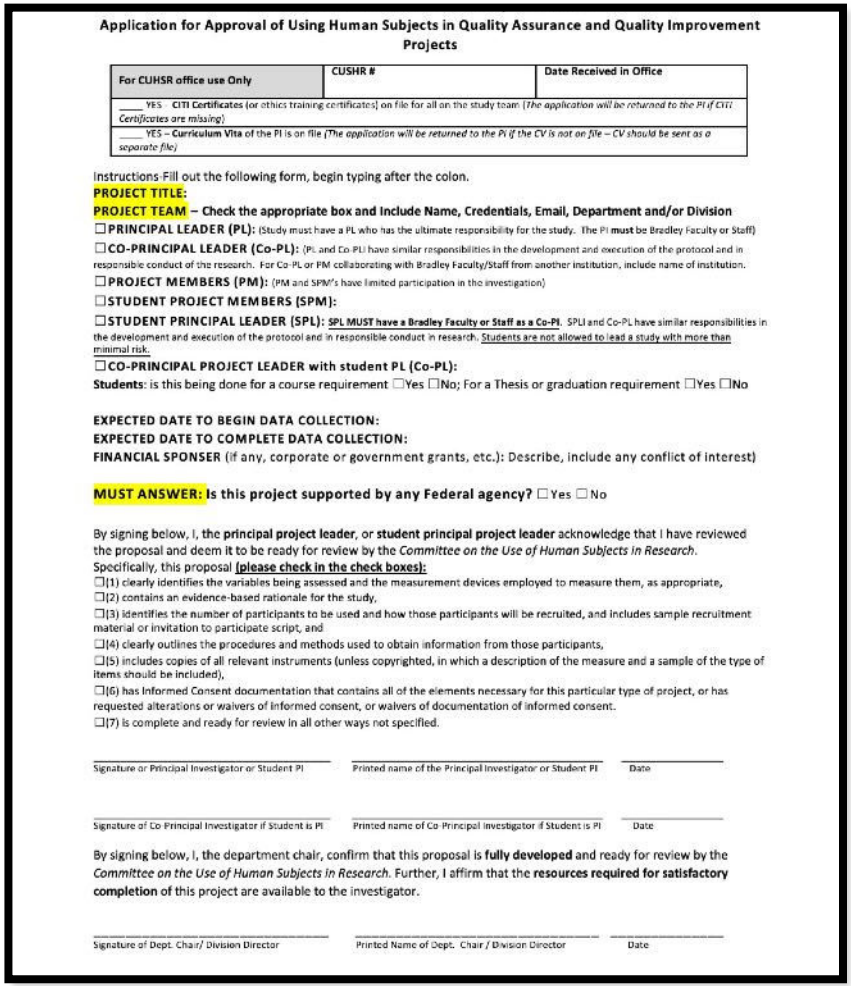
Quality Assurance and Quality Improvement Projects CUHSR Application

- Pilot new application with nursing department for QA/QI projects starting fall 2019 to provide ethical oversight
- Reviewed by CUHSR committee chair
- Determines if project is research or QA/QI
- Human interaction at or below minimal risk



Application for Approval of Using Human Subjects in Quality Assurance and Quality Improvement Projects

For CUHSR office use Only	CUSHR #	Date Received in Office
____ YES – **CITI Certificates** (or ethics training certificates) on file for all on the study team (*The application will be returned to the PI if CITI Certificates are missing*)		
____ YES – **Curriculum Vita** of the PI is on file (*The application will be returned to the PI if the CV is not on file – CV should be sent as a separate file*)		

Instructions-Fill out the following form, begin typing after the colon.

PROJECT TITLE:

PROJECT TEAM – Check the appropriate box and Include Name, Credentials, Email, Department and/or Division

☐**PRINCIPAL LEADER (PL):** (Study must have a PL who has the ultimate responsibility for the study. The PI must be Bradley Faculty or Staff)

☐**CO-PRINCIPAL LEADER (Co-PL):** (PL and Co-PLI have similar responsibilities in the development and execution of the protocol and in responsible conduct of the research. For Co-PL or PM collaborating with Bradley Faculty/Staff from another institution, include name of institution.

☐**PROJECT MEMBERS (PM):** (PM and SPM's have limited participation in the investigation)

☐**STUDENT PROJECT MEMBERS (SPM):**

☐**STUDENT PRINCIPAL LEADER (SPL):** SPL MUST have a Bradley Faculty or Staff as a Co-PI. SPLI and Co-PL have similar responsibilities in the development and execution of the protocol and in responsible conduct in research. Students are not allowed to lead a study with more than minimal risk.

☐**CO-PRINCIPAL PROJECT LEADER with student PL (Co-PL):**

Students: is this being done for a course requirement ☐Yes ☐No; For a Thesis or graduation requirement ☐Yes ☐No

EXPECTED DATE TO BEGIN DATA COLLECTION:

EXPECTED DATE TO COMPLETE DATA COLLECTION:

FINANCIAL SPONSER (if any, corporate or government grants, etc.): Describe, include any conflict of interest)

MUST ANSWER: Is this project supported by any Federal agency? ☐Yes ☐No

By signing below, I, the **principal project leader**, or **student principal project leader** acknowledge that I have reviewed the proposal and deem it to be ready for review by the *Committee on the Use of Human Subjects in Research*.

Specifically, this proposal **(please check in the check boxes):**

☐(1) clearly identifies the variables being assessed and the measurement devices employed to measure them, as appropriate,

☐(2) contains an evidence-based rationale for the study,

☐(3) identifies the number of participants to be used and how those participants will be recruited, and includes sample recruitment material or invitation to participate script, and

☐(4) clearly outlines the procedures and methods used to obtain information from those participants,

☐(5) includes copies of all relevant instruments (unless copyrighted, in which a description of the measure and a sample of the type of items should be included),

☐(6) has Informed Consent documentation that contains all of the elements necessary for this particular type of project, or has requested alterations or waivers of informed consent, or waivers of documentation of informed consent.

☐(7) is complete and ready for review in all other ways not specified.

Signature or Principal Investigator or Student PI | Printed name of the Principal Investigator or Student PI | Date

Signature of Co-Principal Investigator if Student is PI | Printed name of Co-Principal Investigator if Student is PI | Date

By signing below, I, the department chair, confirm that this proposal is **fully developed** and ready for review by the *Committee on the Use of Human Subjects in Research*. Further, I affirm that the **resources required for satisfactory completion** of this project are available to the investigator.

Signature of Dept. Chair/ Division Director | Printed Name of Dept. Chair / Division Director | Date

Developed by Dr. Andrew Struhbar, PhD, PT
Chair Committee on the Use of Human Subjects in Research

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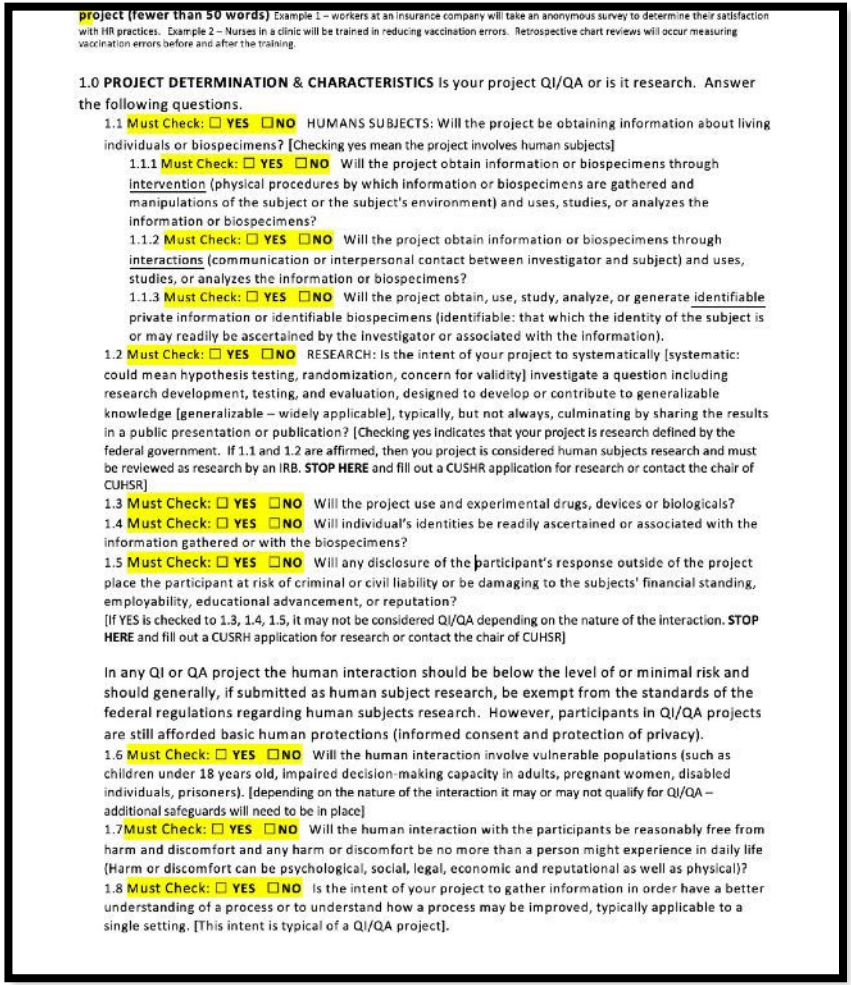
QA/QI IRB Application

- Ensure basic human protections
  - Consent process
    - Autonomy
    - Truthfulness (risks/benefits)
  - Protection of privacy
    - HIPAA
    - Data access and security



project (fewer than 50 words) Example 1 – workers at an insurance company will take an anonymous survey to determine their satisfaction with HR practices. Example 2 – Nurses in a clinic will be trained in reducing vaccination errors. Retrospective chart reviews will occur measuring vaccination errors before and after the training.

1.0 **PROJECT DETERMINATION & CHARACTERISTICS** Is your project QI/QA or is it research. Answer the following questions.

1.1 Must Check: ☐ **YES** ☐**NO** HUMANS SUBJECTS: Will the project be obtaining information about living individuals or biospecimens? [Checking yes mean the project involves human subjects]

1.1.1 Must Check: ☐ **YES** ☐**NO** Will the project obtain information or biospecimens through intervention (physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment) and uses, studies, or analyzes the information or biospecimens?

1.1.2 Must Check: ☐ **YES** ☐**NO** Will the project obtain information or biospecimens through interactions (communication or interpersonal contact between investigator and subject) and uses, studies, or analyzes the information or biospecimens?

1.1.3 Must Check: ☐ **YES** ☐**NO** Will the project obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens (identifiable: that which the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

1.2 Must Check: ☐ **YES** ☐**NO** RESEARCH: Is the intent of your project to systematically [systematic: could mean hypothesis testing, randomization, concern for validity] investigate a question including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge [generalizable – widely applicable], typically, but not always, culminating by sharing the results in a public presentation or publication? [Checking yes indicates that your project is research defined by the federal government. If 1.1 and 1.2 are affirmed, then you project is considered human subjects research and must be reviewed as research by an IRB. **STOP HERE** and fill out a CUSHR application for research or contact the chair of CUHSR]

1.3 Must Check: ☐ **YES** ☐**NO** Will the project use and experimental drugs, devices or biologicals?

1.4 Must Check: ☐ **YES** ☐**NO** Will individual's identities be readily ascertained or associated with the information gathered or with the biospecimens?

1.5 Must Check: ☐ **YES** ☐**NO** Will any disclosure of the participant's response outside of the project place the participant at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation?

[If YES is checked to 1.3, 1.4, 1.5, it may not be considered QI/QA depending on the nature of the interaction. **STOP HERE** and fill out a CUSRH application for research or contact the chair of CUHSR]

In any QI or QA project the human interaction should be below the level of or minimal risk and should generally, if submitted as human subject research, be exempt from the standards of the federal regulations regarding human subjects research. However, participants in QI/QA projects are still afforded basic human protections (informed consent and protection of privacy).

1.6 Must Check: ☐ **YES** ☐**NO** Will the human interaction involve vulnerable populations (such as children under 18 years old, impaired decision-making capacity in adults, pregnant women, disabled individuals, prisoners). [depending on the nature of the interaction it may or may not qualify for QI/QA – additional safeguards will need to be in place]

1.7Must Check: ☐ **YES** ☐**NO** Will the human interaction with the participants be reasonably free from harm and discomfort and any harm or discomfort be no more than a person might experience in daily life (Harm or discomfort can be psychological, social, legal, economic and reputational as well as physical)?

1.8 Must Check: ☐ **YES** ☐**NO** Is the intent of your project to gather information in order have a better understanding of a process or to understand how a process may be improved, typically applicable to a single setting. [This intent is typical of a QI/QA project].

Developed by Dr. Andrew Struhbar, PhD, PT
Chair Committee on the Use of Human Subjects in Research

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