Sharing Quality Data Outside of UCM/BSD

Quality Improvement vs. Human Subjects Research

Background

Human subjects research protections are governed by the Institutional Review Board (IRB) and other applicable policies. Quality improvement is not human subjects research. Having a process to ensure clear distinctions between the two is important for patients, for investigators, and for the institution.

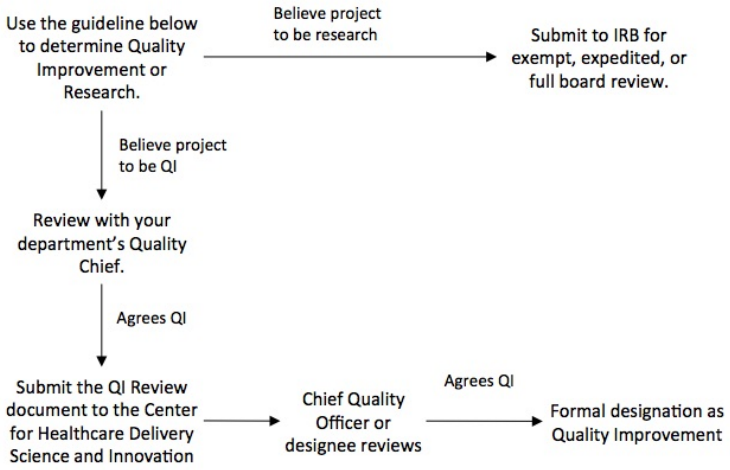
Policy

- Sharing of quality improvement data and results outside of the University of Chicago (e.g. presentation at meetings, poster presentations, abstracts, and publications) requires approval via the procedure described below.
- This policy articulates the institution's approach to distinguishing between quality improvement and human subjects research that will be shared outside of the institution.
- No individual alone shall make the determination for themselves as to whether an individual project is quality improvement or human subjects research.
- Data must always be handled in accordance with UCM/BSD information security policies.
- Governing structures
    - Human subjects research protections are governed by the Institutional Review Board and other applicable policies.
    - Quality improvement is governed by organizational structures and committees, culminating in the University of Chicago Medicine Quality Committee. The senior institutional officials responsible for quality improvement and patient safety are the Chief Quality Officer and the Vice President of Risk Management and Patient Safety.
- Neither this process nor the IRB allocate resources for acquiring or extracting data.

Scope

- This policy applies to quality improvement results and analyses that will be shared outside of the institution (e.g. presentation at meetings, poster presentations, abstracts, and publications).
- Quality improvement occurs on a continuous basis throughout the institution. Most quality improvement efforts are very local and will not be shared outside of the institution (e.g. Managing for Daily Improvement huddles). This type of quality improvement is out of scope for this policy.

Procedure Overview



Key Points

- The IRB governs human subject research.

- **Neither this process nor the IRB provides or guarantees resources for acquiring or extracting data.**

- Regardless of whether an activity is quality improvement or human subjects research, teams must:
    - Follow Institutional Security Policies
    - Follow HIPAA regulations for protecting the information, including ensuring that appropriate legal and business associates agreements are in place prior to sharing any individual or identifiable information outside of the institution

- **The intent to publish the results of a project does not determine whether it is research nor whether it needs IRB review. However, at a minimum, it requires this process to be completed.**
    - Publication of a quality improvement project does not necessarily mean it fits the definition of human subjects research. You may wish to publish something if you believe others would be interested in learning about your activities without it being human subjects research.
    - Conversely, some improvement projects are in fact better classified as human subjects research even when there is no intention of disseminating or publishing the findings.

- Depending on volume of requests, the Associate Chief Medical Officer may designate another individual to evaluate requests. If the Associate Chief Medical Officer for Clinical Quality is individually involved in the project under discussion, determinations will be handled by the Vice President of Risk Management and Patient Safety, or the Chief Medical Officer.

- If the project is deemed a quality improvement project, it must be described in any dissemination of information (publications, posters, presentations, etc.) as a quality improvement project/ initiative and not as research or a study.

Definitions and Examples

- The IRB governs human subjects research. Human subjects research is defined in CFR §46.102 as
    - Research: a systematic investigation … designed to develop or contribute to generalizable knowledge.
    - Human subject: living individual about whom an investigator conducting research obtains
        1. Data through intervention or interaction with the individual, or
        2. Identifiable private information.

- Quality improvement is sometimes defined in the following ways:
    - "Quality improvement (QI) consists of systematic and continuous actions that lead to measurable improvement in health care services and the health status of targeted patient groups."[1]
    - Quality improvement is "the combined and unceasing efforts of everyone—healthcare professionals, patients and their families, researchers, payers, planners and educators—to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development"[2]
    - The pursuit of the triple aim: "Improving the U.S. health care system requires simultaneous pursuit of three aims: improving the experience of care, improving the health of populations, and reducing per capita costs of health care."[3]

- As examples, the following projects are examples of quality improvement:
    - A team changes the approach of scheduling in clinic and uses Lean principles to reduce waiting. To assess impact, they measure throughput, potentially preventable hospital admissions, and patient satisfaction with care, all of which are collected as part of routine operations.
    - A guideline for managing pneumonia is published by a national specialty society. A multidisciplinary team adapts this guideline to UCM and implements it using PDSA tools. To assess improvement, the team uses data from the electronic health record on compliance with the guideline, patient outcomes and costs of care.

Resources

- CITI Training: human subjects research training required to submit an IRB proposal

- Hastings Center reports for further information:
    - *The Ethics of Using QI Methods to Improve Health Care Quality and Safety,* at http://www.thehastingscenter.org/uploadedFiles/Publications/Special_Reports/using_qi_methods_to_improve_health_care_quality_safety.pdf
    - *Health Care Quality Improvement: Ethical and Regulatory Issues*, at http://www.thehastingscenter.org/uploadedFiles/Publications/Special_Reports/Health%20Care%20Quality%20Improvement.pdf

[1] U.S Department of Health and Human Services, Health Resources and Services Administration. Quality improvement. 2011. Accessed 29 October 2015 at http://www.hrsa.gov/quality/toolbox/508pdfs/qualityimprovement.pdf.
[2] Batalden P, Davidoff F. What is ''quality improvement'' and how can it transform healthcare? *Qual Saf Health Care* 2007;16:2–3
[3]Berwick D, Nolan TW, Whittington J. The Triple Aim: care, health, and cost. *Health Affairs,* 27, no.3 (2008):759-769.
[3] Berwick D, Nolan TW, Whittington J. The Triple Aim: care, health, and cost. *Health Affairs*, 27, no.3 (2008):759-769

Determination of Quality Improvement Application

Process for Determining Quality Improvement vs. Human Subjects Research

Revised 02/08/2016

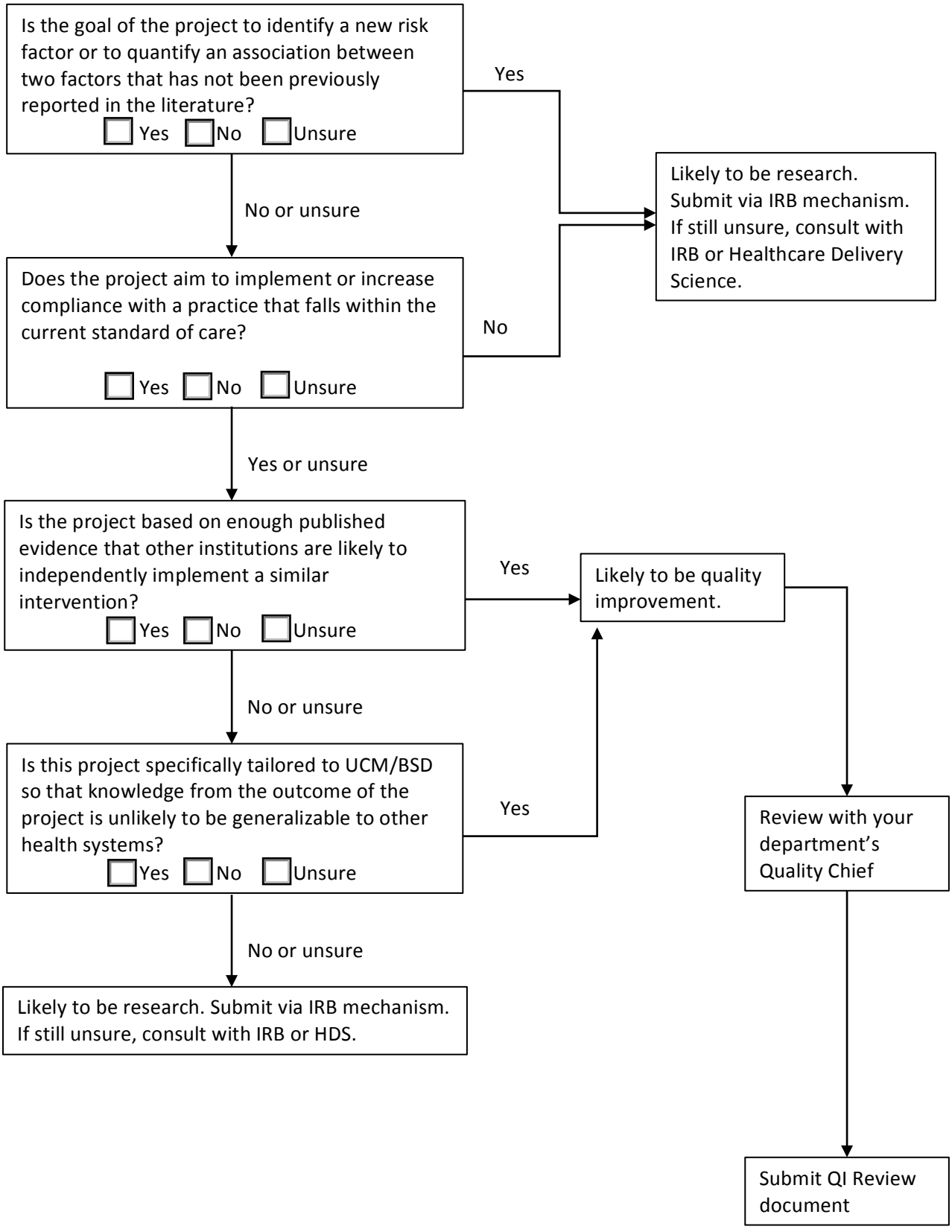
Name:	
Email:	
Project Title:	

Project description (detailed enough to understand the major points of the project):

Describe why you believe this project is quality improvement and not human subjects research:

If you could not disseminate these results outside of UCM/BSD, would you conduct the work? How would it differ from what you plan now?

Complete the following flow chart (yes/no boxes are clickable):



Answer the following by initialing in the appropriate spots:

The goal of this project is to improve care. All patients will receive the standard of care.	☐ Agree	☐ Disagree
This project involves implementing care practices that are evidence- or consensus-based. It does not test an intervention that is beyond current science and experience.	☐ Agree	☐ Disagree
If publishing or presenting your work, you are comfortable with the following statements in your methods section: "This project received a formal Determination of Quality Improvement status according to University of Chicago Medicine institutional policy. As such, this initiative was deemed not human subjects research and was therefore not reviewed by the Institutional Review Board."	☐ Agree	☐ Disagree

Attestations:

- I have provided correct, accurate, and truthful information above.
- As the project leader, I have completed the institution's required Human Subjects Research training (i.e. CITI program, NIH training).
- If I have any further questions, I will reach out to the IRB and/or to Healthcare Delivery Science.
- In all cases, I will follow institutional guidelines for information security and HIPAA guidelines. If I do not understand them, I will reach out to the HIPAA office and to the Office of the Chief Information Security Officer for clarification.
- I understand that this process does not provide approval for resources to perform quality improvement projects or data extraction.
- I attest that I have read this policy in its entirety.
- I agree to resubmit my project to this process should the procedures change.

_____ _____

Project Leader Date

Approvals

Department Quality Chief (or equivalent area quality leader) Approval

Comments:

I have reviewed this project and agree that it represents quality improvement, not human subjects research.

_____ _____

Department Quality Chief (or equivalent) Date

Chief Quality Officer, University of Chicago Medicine (or designee)

Comments:

I have reviewed this project and agree that it represents quality improvement, not research.

_____ _____

Chief Quality Officer (or designee) Date

Please submit this form to: hds@medicine.bsd.uchicago.edu