A Process of Quality Improvement: Informed Participation and Institutional Process

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Ethical Justification: Research

- Research is not morally mandatory for institutions;
- Participation in research is not morally mandatory for human subjects; Research is important to advance medical science but participation is morally gratuitous because most research is not necessary for the survival of society;
- The principle of Justice might require the prior beneficiaries of research to repay the benefit that they gained;
- So vital social interest and justice might require participation—most conclude do not;
- Therefore, potential human subjects in research are morally free to consent to or to refuse participation .

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Ethical Justification: Quality Improvement

- Medical professionals are morally required to engage in QI in order to revere the basic ethic of medicine [do no harm];
- Individual health care organizations are morally required to engage in QI –an obligation derived from organizational ethics and the notion or institutional moral agency;
- Patients are morally required to participate in QI [Responsibilities from possible immediate benefit to self and responsibilities from benefits to others]

Definition of Quality Improvement in Medicine:

- “The group defined QI as the systematic, data-guided activities designed to bring about immediate improvements in health care delivery in a particular setting”.

- [The Ethics of Using Quality Improvement Methods in Health Care, Lynn et al, Annals, May 2007, Vol.146, No.9, 666-674]

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Elements of QI

- QI: systemic, data-guided and efficient
- QI: may inadvertently cause harm, waste scarce resources or affect some patients unfairly
- QI: distinguished from research:
- QI: hypothesis, plan, pilot, test, evaluate—repeat—implement
  - [Research: hypothesis, gather data, analyze, discuss]
- QI: uses experience to identify promising improvements, implements change on a small scale and monitors effects
- QI: may review aggregate data impose evidence based methods
- QI: is in intrinsic part of good clinical care

Ethical Requirements for Protection of Human Participants in QI Activities:

- Social or scientific value of the individual QI project;
- Scientific validity in design and methodology;
- Fair participant selection that does not overly burden one population nor stigmatize any population;
- Favorable risk-benefit ratio: basically minimal risk or less than minimal risk;
- Respect for participants
- Informed participation or occasionally in QI efforts that require individual actions, informed consent;
- Independent review by an institutional office authorized to approve or disapprove QI projects, to register these projects, to gather data on completion, to evaluate results and see to the implementation of new systems.

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Similarities between QI and Research:

- Involve human participants;
- Are concerned with inquiry;
- Are processes in which empirical or systematic inquiry generates a question that data collection is designed to answer;
- Propose a set of outcome measures that will support proposal;
- Testing solutions;
- Involve critical evaluation of data.

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Provisions in research for altering or waiving the requirement of Informed Consent:

- Exceptions to Informed Consent: IRB may alter or waive:
- (1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate the subjects will be provided with additional pertinent information after participation.
- §46.111 (d)

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Informed participation:

- Clear statements by the health care institution about QI—obligation to participate in minimal risk QI projects for the immediate benefit to some patients and the long-term benefits for all;
- Oversight structure for QI—review before;
- Structure for accountability—implementation of positive findings after data are collected and analyzed;
- Feedback and Information for patients/participants.

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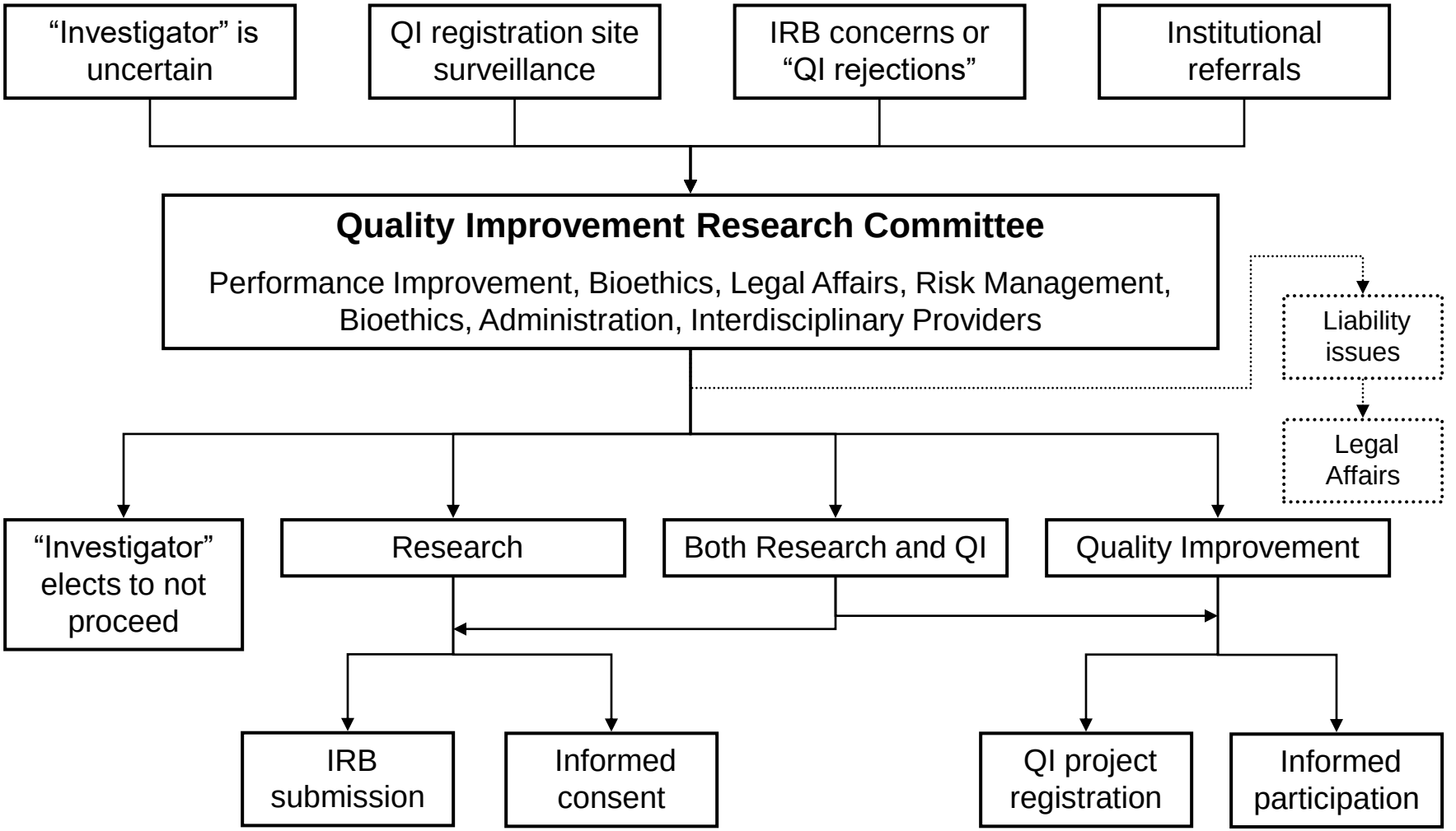
Oversight Structure



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Draft

Registration Form

GENERAL INFORMATION

PI Project Title

Project Description

Department or Service Conducting Project

Primary Project Supervisor — Last First

Phone xxx-xxx-xxxx

Key Project Personnel/Associates

DATA SOURCES

Does this Project Require Data from the LastWord Replicate Database? (Currently Replicated Databases: Merrit, CISLW, Eagle, Unisys/Lab) — Yes No

Analyst Assigned to the Project — Last First

Phone xxx-xxx-xxxx

Primary Data Sources: (Please Check All that Apply)

- Medical Record Reviews
- Project Specific Data Collection Instruments
- Project Specific Survey
- Standardized Survey
- Internal MMC Databases/Reports
- Insurance Claims
- Public Databases (e.g., SPARCS)
- Proprietary Databases (e.g., Press Ganey)
- Other Source

Has a Representative of QM/RM been Contacted Regarding the Project? — Yes No

SCOPE AND USE

Date Project is to Start or was Started On — Jan 2000

Anticipated Project Duration — Less than 6 months

Describe Scope of Project

- Single Service or Department
- Multiple Services, Departments, or Delivery System Components
- Entire Integrated Delivery System

Which Individual and Department will be the Primary User of the Information? — Last First

Department

Does the Project Require Creation of a New Database? — Yes No

Current Project Status? — Active

Submit Clear

Return to Main Page

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Conclusion:

QI is morally mandatory for institutions physicians, and patients: It is part of the social contract of medicine that do no harm implies the need to improve as the skills and tools of improvement are developed. QI is not subject to review as research but is open, transparent and part of the culture of the medical center.

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