

Quality Improvement or Research Worksheet

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SEQ	Issue and Guidance	Rating
1	Are patients randomized into different intervention groups in order to enhance confidence in differences that might be obscured by nonrandom selection? <i>Randomization done to achieve equitable allocation of a scarce resource need not be considered and would not result in a "yes" here.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
2	Does the project seek to test issues that are beyond current science and experience, such as new treatments (<i>i.e.</i> , is there much controversy about whether the intervention will be beneficial to actual patients – or is it designed simply to move existing evidence into practice?). <i>If the project is performed to implement existing knowledge to improve care – rather than to develop new knowledge – answer "no".</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
3	Are researchers who have no ongoing commitment to improvement of the local care situation (and who may well have conflicts of interest with the patients involved) involved in key project roles? <i>Generally answer "yes" even if others on the team do have professional commitments. However, where the project leaders with no clinical commitment are unaffiliated with the project site, it may be that the project site is not engaged – and does not require IRB approval/oversight – even if the project leaders' roles do require IRB oversight at their institutions.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
4	Is the protocol fixed with a fixed goal, methodology, population, and time period? <i>If frequent adjustments are made in the intervention, the measurement, and even the goal over time as experience accumulates, the answer is more likely "no."</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
5	Will there be delayed or ineffective feedback of data from monitoring the implementation of changes? <i>Answer "yes" especially if feedback is delayed or altered in order to avoid biasing the interpretation of data.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
6	Is the project funded by an outside organization with a commercial interest in the use of the results? Is the sponsor a manufacturer with an interest in the outcome of the project relevant to its products? Is it a non-profit foundation that typically funds research, or internal research accounts? <i>If the project is funded by third-party payors through clinical reimbursement incentives, or through internal clinical/operations funds vs. research funds, the answer to this question is more likely to be "no."</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No

Adapted from Hastings Center, "The Ethics of Using Quality Improvement Methods to Improve Health Care Quality and Safety" (June 2006)

If the weight of the answers tends toward "yes" overall, the project should be considered "research" and approved by an IRB prior to implementation. If the weight of the answers tends toward "no," the project is not "research" and is not subject to IRB oversight unless local institutional policies differ. Answering "yes" to sequence #1 or #2 – even if all other answers are "no" – typically will result in a finding that the project constitutes research. *It is important to consult with your local IRB if you are unsure how they would handle a particular case, as the analysis of the above issues cannot always be entirely objective and IRB policies and approaches vary significantly.*

Medical School Institutional Review Boards

(IRBMED)

World Medical Association: Declaration of Helsinki (1964-2004)

- Based on Nuremberg Code
- Interests of subject given higher priority than those of society
- Every subject should be given the best known treatment

Ethical Considerations

Belmont Principles (1979)	IRB Approval
Autonomy	<ul style="list-style-type: none"> • Voluntary participation Consent document and process Privacy Vulnerable subjects
Beneficence	<ul style="list-style-type: none"> • Risks justified by potential benefits Study design minimizes risks Conflicts of interest managed
Justice	<ul style="list-style-type: none"> • Equitable subject selection Likely to benefit not excluded

IRBMED

Mission and Stakeholders

- **Mission**
 1. Protect rights and welfare of human research subjects
 2. Protect ability of institution to conduct human subjects research

– *Achieve in effective and efficient manner*
- **Stakeholders**
 1. Research subjects
 2. Institution and its faculty and staff
 3. Oversight agencies
 4. Society
 - ✓ Provides \$\$\$ to conduct research
 - ✓ Beneficiaries of knowledge produced by research

IRBMED Leadership

- **Co-Chairs**
 - Michael Geisser
 - Alan Sugar
- **Director**
 - Jan Hewett
- **Dean**
 - Raymond Hutchison
- **Vice Chairs**
 - Macdonald Dick
 - William Ensminger
 - Alex Blackwood
 - Steven Taylor

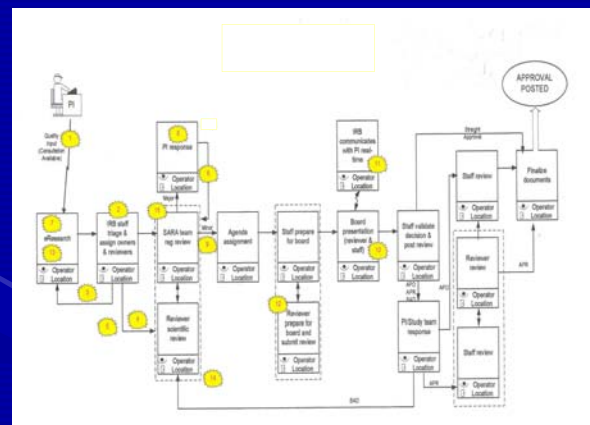
IRBMED Membership

- 80+ colleagues plus non-scientist/community members
- Membership expertise must reflect types of research and subjects

IRBMED Staff

5 Regulatory Teams

- A1
 - Senior Associate Regulatory Analyst (SARA)
 - Junior Associate Regulatory Analyst (JARA)
 - Associate Regulatory Analyst (ARA)
- A2
 - SARA, JARA, ARA
- B1
 - SARA, JARA, ARA (School of Nursing and Nursing @UMHS)
- B2
 - SARA, JARA, ARA
- C1
 - SARA, JARA, ARA



IRBMED Responsibilities

- Know regulations and national standards
- Develop policies and procedures
- **Review proposed and ongoing protocols**
- Provide education and training
- Handle investigator and subject complaints
- Interact with oversight authorities
- Liaison to other institutional entities

IRBMED Authority & Institutional Responsibilities

FDA, OHRP, OCR, ORI, OBA, ICH, AAHRPP, etc.

OVPR (IO)

UMMS ORGS

IRBMED

IRBMED Office

Protocol Review

Volume & System Enhancement

- 13000 submissions per year
 - 200+ per week
 - Includes combination submissions
- 15% are initial reviews of new projects
- Individual IRBMED staff specialists (5) have ~250 submissions in process on any given day
- eResearch will provide immediate and continuous on-line access and system transparency for protocols under review

Other IRBMED Activities

- Education and Training
 - Special topic lectures
 - Regular courses
 - IRBMED staff/member training
 - Special initiative roll-outs
 - IRBMED web site
- 50-100 offerings per year
- 20-40 hours to develop new session
- 5-10 hours to offer each session

Other IRBMED Activities

- Complaints and Concerns
 - IRBMED level
 - Single study
 - Multiple studies
 - Institutional level (OVPR)
 - Federal level
- 50-80 per year
- Can take 1-100s of hours over 2-3 years of IRBMED staff/chair/reviewer time to resolve

PI Responsibilities

- Conduct research responsibly (scientific and ethical integrity)
- Adhere to IRB-approved protocol
- Keep the IRB informed of study progress and submit Scheduled Continuation Renewal well in advance of study expiration
- Ensure the integrity and safeguarding of all collected data

How Can Many of Your Problems be Avoided?

- Well-crafted submission
- Attention to elements and readability of ICD
- Respond to IRBMED requests promptly
- Check IRBMED web site regularly for updated forms and guidance
- Attend IRBMED and other educational offerings

Federal Regulations

DHHS: 45 CFR 46

- Part A Common Rule
- Part B Pregnant Females & Fetuses
- Part C Prisoners
- Part D Children
- Exemptions
- Expedite Reviews

FDA:

- 21 CFR 50 Human subjects
- 21 CFR 56 IRBs
Expedite Reviews
- 21CFR 54 21CFR 600
- 21CFR 312 21CFR812

Veteran Affairs:

38 CFR 16

IRBMED

Q & A

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Ann Arbor, MI 48109-2800
(734) 763-4768
<http://www.med.umich.edu/irbmed>

What is QI and when does it become Research?



Is this regular QI or do I need IRB approval?

Quality Improvement

- Definition:
 - 'systematic, data-guided activities designed to bring out immediate, positive change in the delivery of health care in a particular setting'
- Variety of Methods
 - Deliberate actions to improve care, guided by data reflecting the efforts.
- Type
 - Practical problem-based solving
 - Evidence based management style
- Example
 - Collecting data from multiple organizations & analyzing it to understand what drives a change in activity
 - Then based on these results design and implement a strategy to achieve a specific improvement across the organization

Quality Framework

- **Quality** – defined as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge
- **Safety** – avoiding injuries to pts from the care that is intended to help them
- **Effectiveness** – providing services based on scientific knowledge to all who could benefit, & refraining from providing services to those not likely to benefit
- **Patient-centeredness** – providing care that is respectful & responsive to individual pt preferences, needs & values
- **Timeliness** – reducing waits and sometimes harmful delays for both those who receive and those who give the care
- **Equity** – providing care that does not vary in quality b/c of personal characteristics such as gender, ethnicity, geographic location, & socioeconomic status
- **Efficiency** – avoiding waste, including waste of equipment, supplies, ideas and energy.

QI vs. Research

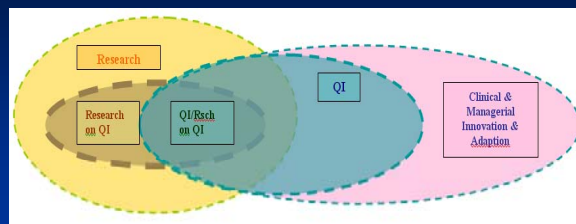


Figure 1 – "The Ethics of Using QI Methods to Improve Health care Quality and Safety – Hastings Center Report (July-August 2006)"

QI vs. Research

Figure 1 –

- **Research** – systematic investigations *designed to develop or contribute to generalizable knowledge*
 - Examples
 - Basic and applied medical research
 - Research w/ a potential impact on health care quality, i.e. epidemiological
 - Health services research
 - Management research
 - Educational research

QI vs. Research

Figure 1 (cont) –

- **Quality Improvement & Research** – systematic, data-guided activities designed to bring about local change and its an investigation designed to develop or contribute to generalizable knowledge
- **Research on QI** - systematic investigation designed to produce generalizable knowledge relevant to the design and implementation of QI activities. E.g. evidence-based medicine – a) generation of new knowledge on behavior of systems and b) research on QI contributes to this knowledge by helping to answer questions such as “what are the principles of change?” “How do the principles work within different organizational contexts”

QI vs. Research

Figure 1 (cont) –

- **QI/Research on QI** – research on QI can be independent of the QI activities it studies.
 - E.g. a PI could do a retrospective study of QI activities carried out in different organizations w/ the aim of testing a hypothesis about the effects of organizational characteristics on results.
 - Single activity designed to produce both immediate local change and generalizable knowledge about the process of change. E.g. HCO w/ multiple delivery sites could conduct an activity in which the sites are divided into 2 groups to introduce a practice; each w/ a different strategy. Goal is to facilitate the knowledge of the results to the other organization

QI vs. Research

Figure 1 (cont) –

- **Clinical and Managerial Innovation and Adaptation** – activities designed to bring about immediate local improvements in clinical and managerial practice.

QI/QA – IRB Approval (Y/N)

YES

- Quality assurance or quality improvement projects conducted, at least in part, for research purposes. Design may feature comparison or control groups.

NO

- Practice of evidence-based medicine; quality assurance or quality improvement projects designed to improve clinical care, patient safety, health care operations, etc. The design does not include comparison or control groups but may include measuring outcomes of the initiative. Secondary publication of project results is permissible.
- Practice of program evaluation, self-assessment of programs or business practices, and other quality improvement projects where methods rather than humans are the subject of the study. Publication of project results is permissible.