

# Quality Improvement and Research: SickKids' Harmonized Review Process



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Marie Pinard  
Quality & Risk Management  
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**SickKids<sup>®</sup>**



# Overview

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- Background & Issues
- Review of Literature & Landscape
- SickKids QI Review Process
- Preliminary Results & Conclusions
- Next Steps



# Background & Issues

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# What Is Research?

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- Involves a systematic investigation to establish facts, principles or generalizable knowledge
- Uses scientific methods and standardized protocols
- May involve subjects through their physical participation and/or through collection or use of personal health information and tissues
- Research involving human subjects (including all human tissues and data) is required to undergo independent review



# What is Quality Improvement?

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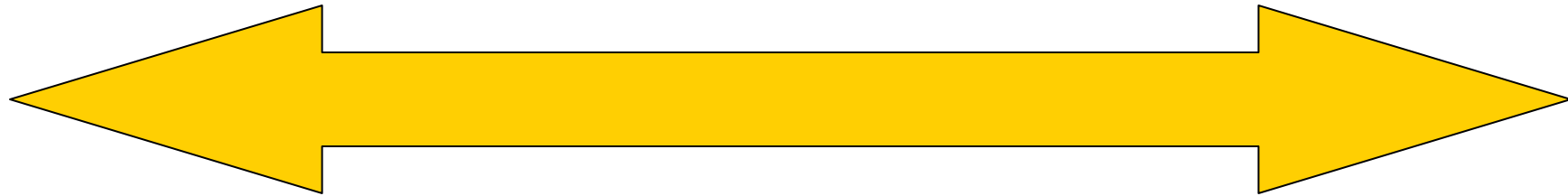
- Covers a broad range of activities
- Primary purpose is to monitor, evaluate or improve the quality of health care delivered
- Change carried out in operational context in which they are carried out
- Usually involve small tests of change for which rapid feedback is examined for trends prior to broader implementation in the local or organizational setting



# Research & QI

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Part of the continuum of change in healthcare



## Quality

### Improvement

### Clinical Practice

- Adaptation, innovation
- At the individual patient level

- Systematic experiential learning
- Operational context
- Rapid feedback of trends that shapes changes

### Clinical Research

- Distinct from clinical care
- Designed to contribute to scientific knowledge



# Background

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- Research has a comprehensive and well-established oversight mechanism
- Recent advances have contributed to “blurring” of the lines between QI and research
  - Greater rigor, QI methodology borrowed from other industries
  - Dissemination & publication
  - Requirements (for e.g. Accreditation)



# Issues

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- Lack of clarity of what distinguishes research from QI projects
  - Intimidated by REB process
  - Completing REB forms when not necessary
- REBs resource intensive process
- Minimal oversight for QI projects, but is there potential for harm?
  - Over-surveying of same population
  - Poorly designed or executed QI projects
  - Privacy, confidentiality issues



# Ethical Requirements

Research	QI
Social or scientific value	QI project is of benefit & justify resources/risks
Scientific validity	QI project uses sound principles/methodology
Fair subject selection	Fair distribution of burdens of QI project



# Ethical Requirements (cont'd)

Favourable risk/benefit ratio	QI participants are not subject to undue risks
Informed consent	Permission of participants when appropriate
Respect for participants	Privacy and confidentiality principles are maintained
Independent review	Appropriate ethical review and supervision



# Literature & Landscape

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# SickKids REB (before Nov/06)

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## REB FAQ

- “If we anticipate **publishing** the results of changes in our delivery of clinical care i.e., program improvements, do we need REB approval?  
- Yes”

## REB Expedited Review Criteria

- “The study involves non-invasive product testing, Phase IV drug or medical device testing, or **quality assurance activities and publication is planned.**”



# Tri-Counsel Statement

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- “Quality assurance studies, performance reviews or testing within normal educational requirements should also **not** be subject to REB review.”

Article 1.1 (d)



# Landscape

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- National Committee on Quality Assurance (US 2004)
  - QI needs oversight without hindering implementation
  - Develop structures that ensure QI best practices
  - A few “leading practice” US healthcare institutions



# Literature

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- Some attention (since late '90s)
- Mostly in the Quality field
- US case reprimanded by the Office for Human Research Protection
- Varying opinions, focusing largely on differentiating between QI and research



# Literature

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- National Health & Medical Research Council (Australia 2003)
  - Quality assurance activities are essential and integral to health care
  - Full review not required for most QA activities – develop efficient review mechanisms for low risk QA
  - Questions to guide participants when to consider full review



# Literature

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- Alberta Research Ethics Community Consensus Initiative (2005)
  - QI is different than research – it is part of the responsibility of healthcare providers
  - Some level of ethics review should be in place for all projects
  - Suggest varying levels of ethics review for both research and QI with multiple screening tools



# Literature

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- Hastings Center Special Report (2006)
  - Builds upon earlier AHRQ grant work
  - Move away from simply QI vs. Research
  - Professional responsibility for QI
  - QI should be implemented ethically
  - Cannot simply export IRB process to QI
  - QI review process according to risk



# Literature

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- Johnson et al. (2006) – survey of US academic medical centers
  - 50% have formal policies/guidelines related to the review and approval of QI projects
  - Responsibility for distinguishing QI from research: 41% IRB, 41% individuals proposing the project
  - Suggest criteria



# Research & QI - Similarities

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- Systematic
- Guided by data
- Varying degrees of complexity and methodological / statistical rigor
- Produces “generalizable” knowledge

# Research & QI - Differences



## Research

- Distinct and separate from care delivery
- Participation is optional
- Independent review

## QI

- Expected part of healthcare
- Implemented in the care delivery context in which it is carried out
- Participation not completely optional
- Frequently no review mechanism



# Research & QI – “Grey Zone”

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- **Designed** to be generalized
- Whether outcomes or processes are the targets
- Risk of harm to participants
- [Intent to publish]



# Publication as criteria

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- “Publication is not a definitive feature of research. There is research done that is never published and there's lots of publications out there that have nothing to do with research.”

Dr. M. Carome, Office for Human Research Protection – Secretary's Advisory Committee on Human Research Protection, 2004

- “The intention to publish does not by itself determine the primary purpose of a project.”

Alberta Research Ethics Community Consensus Initiative, 2005

# SickKids QI Review Process



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# QI Oversight - Goals

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- Protect QI participants from harm
- Help distinguish QI from Research
- Improve organizational awareness of QI projects across the hospital
- Improve effectiveness of QI projects
- Ensure process is not a barrier to QI
- Integrate with REB process



# Project Plan

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1. Establish Working Group
2. Review of Literature / Benchmarking
3. Develop Project Principles & Framework
4. Develop QI Project Review Process
5. Determine Criteria Requiring REB Review
6. Develop QI Projects Policy & Procedure / QI Form
7. Obtain Approval of QI Projects Policy & Procedure
8. Pilot QI Oversight Process
9. Implement QI Oversight Process
10. Evaluate QI Oversight Process



# QI Oversight Working Group - 2005

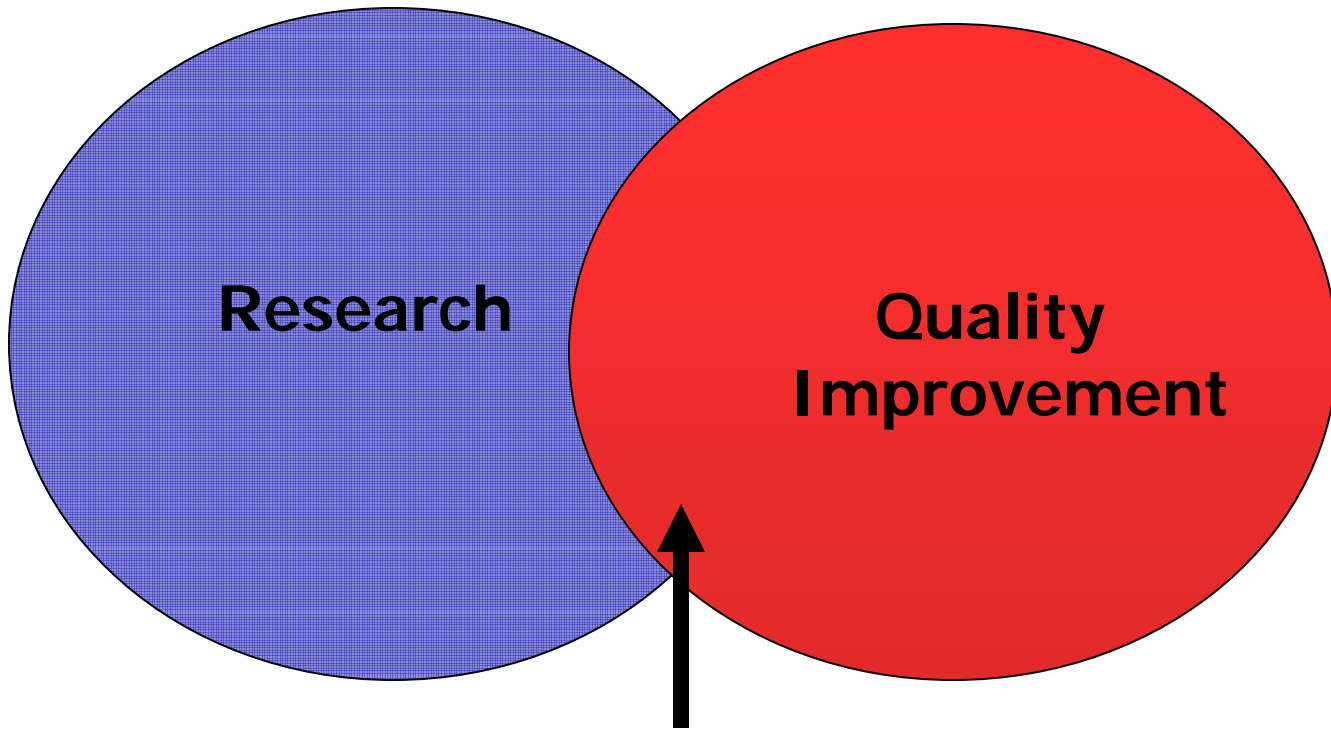
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- Marie Pinard, Quality & Risk Management
- Dr. Melvin Freedman, Chair, Research Ethics Board
- Polly Stevens, Director, Quality & Risk Management
- Dr. Ronald Laxer, Vice-President, Education and Quality
- Margo Farren, Manager, Research Ethics Board



# Grey Zone

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Require REB Review

# Process

Research Projects

REB process

QI Projects

"higher risk" QI project?

Yes

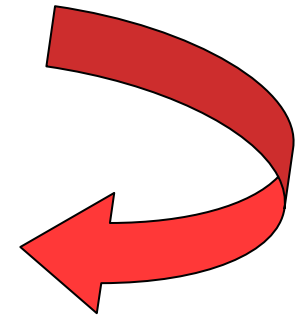
No

Review of QI Projects form

QRM guidance as required

Accountability via QM Committee structure & reporting

Determine high-risk criteria





# Criteria for REB Review

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- The **primary** audience of the QI project is the external scientific community
- The QI project involves interventions that are untested or different than the current standard
- The QI project could pose risks to the participant
- The QI project involves additional burdens which are beyond what would be considered reasonable and outside what is required for the normal delivery of care

# Hospital-Wide Document

Welcome Marie Pinard - All Documents Marie Pinard - Calendar Policies & Procedures - Approve... Quality Improvement Projects

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Hospital-wide Administration  
Policy, Procedure & Guideline

Valid only on date printed: 2007-01-30 14:59. Discard immediately after use!

## Quality Improvement Projects

SickKids

Document | Approvers

<b>Issuing Department:</b>	Quality & Risk Management	<b>Category:</b>	Quality & Risk Management
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<b>Written By:</b>	Marie Pinard - Quality & Risk Management	<b>Review Committee Name:</b>	Quality & Utilization Steering Committee



# Document Highlights

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- Policy, guideline and procedure – launched November 2006
- All QI projects involving surveys and all clinical QI projects will undergo review
- Strongly recommended for non-clinical projects
- Projects externally funded should consult first with the Chair of the REB



# Document Highlights

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- Consent and privacy
- Accountability lies with Department or appropriate hospital-wide body
- Procedure outlined
- 10 business day turnaround time
- Links to other relevant policies (research, privacy, consent, innovation)



# QI Projects Review Form



## Review of Quality Improvement Projects

This form must be completed for all "lower risk" QI projects\*. Submit completed forms to the Quality & Risk Management Department via email, internal mail or in person.

Note: Cells will expand to fit text

Attachments included: Yes  No

a) Cluster / Department:

Hospital-wide QI project Y  N

b) QI project contact name:

Phone:

c) Supervisor/Director sponsoring or involved with QI project:

d) Why are you undertaking this QI project (background)? What is the change intended to achieve?

e) Brief description of QI project (alternatively other documents that contain this information may be submitted):

f) List of key stakeholders involved with QI project (who will be affected?):

g) How will the QI project be evaluated? What type of data will you be collecting? Please attach any data collection tools developed (including surveys).



# QI Review Form Highlights

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- Relatively short
- Structured to reflect QI principles
- Uses simple language, terms familiar to the frontline
- Other documents also accepted in lieu



# QI Project Review Process

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- Completed forms submitted to Quality & Risk Management (QRM)
- Each project reviewed by two Quality Analysts
- Questions and concerns are discussed with the Chair of the REB as they arise
- Individuals are asked to report final results of project to QRM



# Evaluation Plan (6-12 months)

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- Number of projects submitted and breakdown of actions taken
  - Additional information / clarification required
  - Approvals
  - Approvals with recommendations
  - Referrals to REB for review
  - Refusals (with reasons)
- Feedback from users and key stakeholders
- Projects not submitted appearing on QM reports
- Feedback from QRM staff

# Preliminary Results & Conclusions



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# Pilot Results

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- Process tested with 7 project proposals
  - 6 “lower risk” QI project
  - 1 “higher risk” QI project → REB
- Minor changes to form
- Minor clarifications to policy
- One project deferred, rest remain in progress



# Early Results (3 months)

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- 10 QI projects submitted
  - 1 approved
  - 8 approved with recommendations
  - only 1 referred to REB for review (10%)
- 5 additional “consults” for which a submission has not yet been received
- 1 project known to be completed
- Mostly questionnaires; also utilization & compliance measures



# “Lower Risk” QI Projects

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- Average of 6.13 recommendations per project (range 0-14)
  - Reinforcing privacy principles
  - Reinforcing project endorsement
  - Consider timing of project (questionnaires)
  - Changes to data collection tools, construction of questionnaires



# Examples

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- Parent handbook (population specific)
- Policy development notification process
- Implementation of a staff distance orientation/education program
- Implementation of a pain management algorithm
- Double-gloving practice in IGT



# Criteria for REB Review

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# Conclusions Thus Far

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- Earlier consultation with QRM staff
- Staff still want to discuss project prior to submission
  - Measurement of referrals and recommendations more challenging
- Anecdotally, the form is easy to complete
- Publication as research criteria is entrenched



# Next Steps

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# Next Steps

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- Complete evaluation
- Follow up with projects completed
- Changes to form / process
- Further clarification of criteria
- Continue to monitor the landscape
- Assess workload
- Involve local QM Leaders in reviews

# Questions & Comments



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