

## Quality Assurance and Education Program (QAEP)

Promoting a culture of ethical practice in  
human research

CAREB/ACCER 2010 National Conference

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1

### Outline

- Why a QAEP?
- Authority for oversight
- QAEP's goal
- QAEP's mission
- Basic assumptions
- Educational approach
- QAEP components
- Educational activities
- Quality Improvement (QI) Visits
- QI Visit findings
- Summary
- Conclusions

2

### Why a QAEP?

- Scope of oversight at the MUHC
  - 9 Research Ethics Boards (REBs)
  - McGill Faculty of Medicine IRB
- Approved studies at the MUHC
  - Over 1400 ongoing
  - Over 400 approved each year
- Need for a systematic method of review to comply with laws and policies
- REB meetings inefficient for educating investigators
- REB members (volunteers) and Ethics Coordinators lack time and/or expertise

3

### Authority for oversight

- MUHC Board of Directors delegate responsibility for oversight to the REBs
- Two types of oversight:
  - Passive (mandatory)
  - Active (optional)
- REBs Delegate responsibility for active oversight to QAEP staff

(Gazette Officielle du Québec, 29 août 1998, 130<sup>e</sup> année, n° 35, art. 1<sup>er</sup> and 4<sup>er</sup>)

4

### QAEP's role

To support the REBs in their  
mandate of oversight of ongoing  
research

5

### QAEP's Mission

The Quality Assurance and Education Program strives to promote a *culture of ethical practice* among all members of the research community.

6

## Basic assumptions

Investigators and study team members are:

- Qualified
- Dedicated professionals
- Responsible
- Committed

Education promotes:  
Understanding

- Learning

7

## Educational approach

- MUHC policy highlights that ongoing education is essential (The Regulatory Framework in Health Research at the McGill University Health Centre, Art. 2.5.3)
- An educative approach is expected to be most effective in reducing violations and promoting best practices because it:
  - Encourages a supportive environment
  - Reduces fear that mistakes are revealed and reprimands become public

8

## Educational approach (Cont'd)

- Generates more satisfaction because research community members receive explanations and clarifications about why certain practices are required and/or recommended
  - Fosters openness
  - Enhances the likelihood of learning transfer
  - Increases motivation
  - Promotes peer support and mentoring
  - Diminishes the potential for serious breaches in ethical conduct
  - Fulfills expectations for changes in practice

9

## Educational approach (Cont'd)

Ultimately, an educational approach encourages learning about research ethics, which, in turn, can contribute to QAEP's mission to promote a culture of ethical practice

10

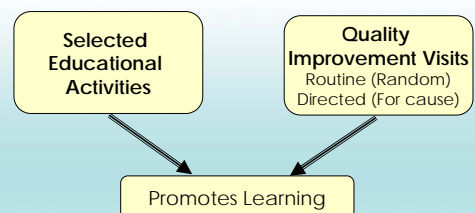
## QAEP Components

Conduct both retrospective and prospective oversight activities by:

1. Systematically reviewing ongoing approved REB studies
2. Educating members of the research community about research ethics

11

## QAEP components (Cont'd)



12

## Educational activities

Address both specific and general needs of the research community (e.g. REB members, investigators, trainees, study coordinators, other research staff and members of the general public)

- Educational materials (e.g. brochures, publications)
- Web pages and links to online training modules
- Group sessions and workshops
- Conferences, lectures
- One-on-one consultations
- Professional development initiative
- Outreach

13

## Educational activities (Cont'd)

Topics for educational sessions and workshops:

- Ethical core principles (e.g. respect for privacy and confidentiality) and their practical applications
- Review of commonly found violations
- Particular areas of research (e.g., international research, informed consent, qualitative research, vulnerable populations, etc.)

14

## Educational activities (Cont'd)

### Conference and workshop feedback

- Were well received
- Expressed need for peer support and mentoring
- Call for sessions to address specific needs and to target specific groups
- Desire more sessions on a diversity of topics

15

## QI Visits

The purpose of QI Visits is to ensure that research is conducted according to the highest ethical standard.

Accomplished through a two prong approach:

1. Identifies strengths and weaknesses
  1. Reports findings and makes recommendations to the REB
2. Providing educational support to research teams
  - Reinforces strengths and providing guidance on best practices

Therefore, QI Visits comprise both Quality Assurance and Education

16

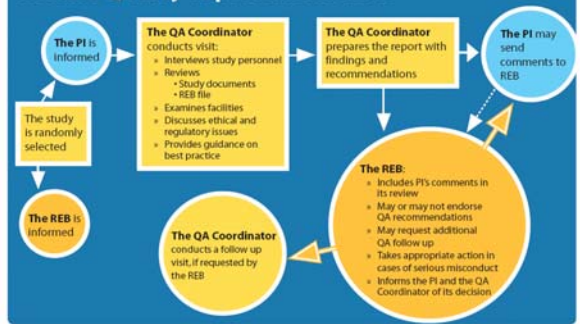
## QI Visits (Cont'd)

### Routine QI Visits

- Selected randomly by a statistician outside the Research Ethics Office
- Identifies suboptimal practices while supporting and educating investigators and research team members

17

## Quality Assurance (QA) and Education Program Routine Quality Improvement Visits



## QI Visits (Cont'd)

### Directed QI Visits

- Mandated by 2 authorities designated by QAEP policy and justified by an allegation or reasonable suspicion of misconduct or a serious deficiency
- Conducted as specified (mandate can be large or narrow) while supporting and educating investigators and research team members

19

## Quality Assurance (QA) and Education Program Directed Quality Improvement Visits

**The QA Officer** is mandated to conduct the visit by two authorities designated by policy.

The visit is prompted by a suspicion or an allegation of misconduct.

**The PI is informed**

**The QA Officer:**

- Conducts the visit as specified
- Prepares two reports

**The REB:**

- Receives the report with the findings **including** the recommendations
- Includes the PI's comments in its review
- Takes appropriate action, if necessary, according to laws, regulations, policies and procedures
- Informs the PI and the QA

**The QA Officer** conducts a follow-up visit, if requested by the REB

**The PI:**

- Receives the report with the findings but **without** the recommendations
- Responds to any questions or comments from the REB

## QI Visits (Cont'd)

### 1) SAMPLE OF THE VERSION SENT TO THE INVESTIGATOR AND THE REB AFTER THE QI VISIT

Centre universitaire de santé McGill  
McGill University Health Centre  
Research Ethics Office - Quality Assurance and Education Program  
QI Visit Report

Study Title: A Randomized Controlled Trial of Drug X for Condition Y  
REB Study Code: REB-00-000  
Date of On-Site Visit: 25-Sep-2008  
Study Personnel Interviewed: Dr. Zed  
Current Study Status: Active

Findings	Applicable Regulations and	QA Recommendations	Investigator's Comments to REB
1) Most consent forms were signed and dated by the participant and the designated member of the study team. However, the name and signature of participant AA were missing from the consent form on file in the data base.	Article 31 of the Access to Information Act (ATIA) "Prior to a subject's participation in the trial, the written participant consent forms should be signed and dated by the participant, by the investigator, and by the participant's designated member of the study team."	The participant should sign the consent form at his last seen study visit, as well as a statement indicating that the study was fully explained to him/her before he/she participated.	

Additional comments from the QA coordinator: None  
Additional investigator comments:

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- Page 1 of 1 -

## QI findings

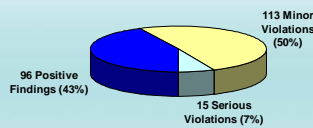
QI Visit conducted in 2008-2009:

- 3 Pilot QI Visits
- 2 Directed QI Visits
- 26 Routine QI Visits
- **31 Total**

22

## QI findings (Cont'd)

Summary of QI Visit Findings  
(Serious / Minor / Administrative / Human Protection)  
n = 224



23

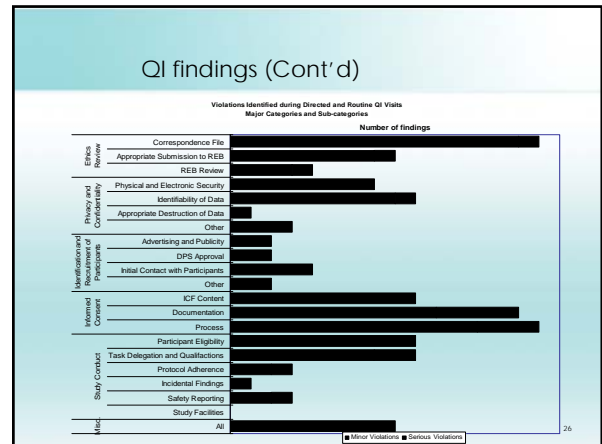
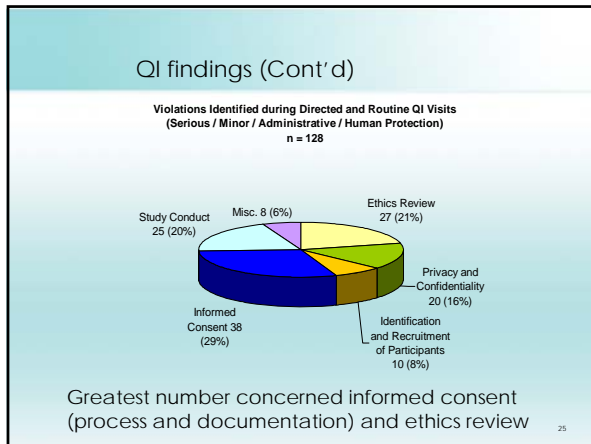
## QI findings (Cont'd)

Findings are categorized:

Major categories

1. Ethics review
2. Privacy and confidentiality
3. Identification and recruitment of participants
4. Informed Consent
5. Study conduct
6. Miscellaneous

24



- ### QI findings (Cont'd)
- #### QI Visit Finding categories and sub-categories
- Ethics Review
    - Correspondence file
    - Appropriate submission to REB
  - Privacy and Confidentiality
    - Physical and electronic security
    - Identifiability of data
    - Appropriate destruction of data
    - Other
  - Identification and Recruitment of Participants
    - Advertising and publicity
    - Appropriate approvals for accessing medical records
    - Initial contact with participants
    - Other
- 27

- ### QI findings (Cont'd)
- #### QI Visit Finding Categories (Cont'd)
- Informed consent
    - ICF content
    - Documentation
    - Process
  - Study Conduct
    - Participant eligibility
    - Task delegation and qualifications
    - Protocol adherence
    - Incidental findings
    - Safety reporting
    - Study facilities
  - Miscellaneous
- 28

- ### QI findings (Cont'd)
- Research teams are committed to good ethical practice
- Violations found:
- Serious
    - Very rarely
  - Minor
    - Majority
  - Wide ranging
  - Primarily due to insufficient knowledge about research ethics
- 29

- ### Summary
- Policing or punitive measures are undesirable and ineffective to address most violations because:
- Punitive measures do not provide information on best practices or their purpose
  - Illogical to punish for lack of knowledge without a prior attempt at teaching
- 30

## Summary (Cont'd)

- To avoid blaming and shaming research staff when violations occur
  - Investigators are encouraged to:
    - Keep copies of QI Report findings separate from the study file (i.e., should not share them with Study Sponsors or monitors)
    - Study Sponsors are to be:
      - Absent during QI visits
      - Denied routine access to findings
    - Share findings with colleagues and research staff

**The QAEP staff have a legal obligation to report cases of serious ethical misconduct**

31

## Summary (Cont'd)

The QAEP attempts to:

- Avoid a "policing" as in "caught in the act" attitude



- Conduct QI Visits in a collaborative and collegial atmosphere while reviewing studies.



32

## Conclusions (Cont'd)

How to evaluate and improve learning in research ethics?

Need:

- To develop evidence-based methods to assess whether learning is occurring and ethical practice is improving
- Better ways to create outreach and develop educational strategies that meet the specific needs of a diverse research community

33

## Conclusions (Cont'd)

The QAEP's educational approach is an effective tool:

- Promotes learning about emergent ethical issues, rules and policies, roles and responsibilities, rights of research participants, etc.
- Encourages dialogue and communication about ethical issues and challenges
- Diminishes attributions of blame and shame
- Identifies positive and suboptimal ethical practices
- Serves to correct/prevent serious ethical violations
- Lends itself to research on ways to create better educational strategies, increase professional development and provide evidence of improvements in ethical practice

34

## Conclusion (Cont'd)

In essence, the QAEP fulfills its mission to protect human participants by promoting a culture of Ethical practice through education, though we need better means to assess effectiveness and impact

Such a program should be considered a fundamental part of any institution conducting human research

35