REBs - How would we know if we are doing it right? The need for meaningful performance indicators

Professor Michael McDonald, PhD, CGA (hon.)
W. Maurice Young
Centre for Applied Ethics
University of British Columbia

Overview

1. My perspective
2. Doing it right
3. Evidence-based ethics review
4. Meaningful indicators

1. My perspective

- Involvement in research ethics policy
- Research Ethics scholarship
  - Centring the human subject project
  - Law Commission of Canada Report
  - Canadian Network for the Governance of Ethical Health Research Involving Humans: Evidence, Accountability and Practice
- REB involvement
  - Canadian Blood Services, OCREB Governance
- Accounting ethics: CGA Canada

Centring the human subject in health research:

- Understanding the meaning and experience of research participation
  - Susan Cox, Michael McDonald, Joe Kaufert, Patricia Kaufert, & Anne Townsend
  - CIHR operating grant
- 3-phase project
  - Individual interviews with participants, REB members, researchers, research workers, policy-makers, & scholars
  - In depth case studies
  - Knowledge translation and exchange

Goals of research

- Explore the meanings and experiences of being a research subject from the standpoint of subjects.
- Compare and contrast the perspectives of research subjects with the perspectives and practices of researcher professionals, REB members, scholars, and policymakers.
- Assess the ethical and other implications of recent and emerging changes in the context and design of health research.
- Pilot methods for implementing new understandings of the experience of being a research subject in research design, the process of ethical review and the governance of research ethics.

Research Participants' experiences

- Diversity of experiences, perspectives & motivations, e.g., altruism/egoism
- Still common themes – examples:
  - Importance and fragility of trust
  - Concern with the quality of research
  - Wanting to know research results
  - Practical costs often trump more abstract ideals
  - Acute insights into researcher behaviour
  - Impact of research on their lives

2. Doing it right

- REBs invented to address actual & perceived abuses of research participants
  - Failure of individual self-regulation
  - Need for standards & processes
- Standards
  - Range of authorities with different degrees of prescriptivity, concern, & oversight
- Process
  - Basically peer review
  - Supplemented by some external oversight

Ethics review

- The main line of institutional protection
- Prospective review mainly to assess if protocols will likely meet standards
- Supplemented by varying degrees of
  - Self-reporting by researchers
  - Monitoring, auditing and quality assurance

Doing it right

- Challenges of predicting the direction of research, impacts on participants and appropriate safeguards
- Doing it right: project by project & system wide
- Across diverse & specialised areas of research

Big questions

What on earth, is "doing it right"?

- **Is there a single "it" (task) or multiple "its" (tasks)?**
- **Can we find and effectively use meaningful indicators of success for diverse levels?**
  - REBs
  - Institutions
  - Systemic: specific research areas (e.g., oncology trials) and jurisdictions (e.g., provincial & federal)

Broad answers (1)

- Doing it right has 2 main aspects
  - Research-centred – advancement of knowledge
  - Participant-centred – protection from harm; assurance of respect
  - Often tensions within and between 2 aspects
    - Commercialisation vs. public knowledge
    - Autonomy vs. protectionism
- Doing it right involves more than standard-setting; it means getting things right "on the ground"

Broad answers (2)

- Diverse parties involved in participant protection have
  - Overlapping but only partially congruent interests and agendas, e.g., REBs and researchers
  - Different levels of institutional and financial power, e.g., big pharma and a local REB
  - Different roles to play, e.g., ethics review vs. quality assurance
- Participants & various publics also have diverse interests and concerns

3. Evidence-based ethics review

- "There is an urgent need for empirically informed and ethically sensitive research on the effects of research on human subjects as well as on the effectiveness of governance procedures. There is little point in experimentation … without careful research-based assessments of processes and results."
  - McDonald (2000) Law Commission of Canada

Performance & outcomes

- "The current system does not systematically assess performance or outcomes"
  - the Consortium to Examine Clinical Research Ethics, Emmanuel et al. Annals 2004

Evidence-based ethics

- "The time is ripe for evidence-based ethics. Similar to evidence-based medicine, an evidence-based ethics would emphasize the importance of data in informing discussions and decision-making about the ethical issues inherent to clinical medicine and research."
  - Sugarman JAMA 2004

We noted that …

- "It is paradoxical that those in the health professions base their practice on evidence-based standards *except* in the case of ethical review."
  - Beagan & McDonald HLR 2005

Ethics Argument

1. It is **not enough** to simply say that we (countries, research institutions, research sponsors) have protection for human subjects in research in the form of policies and regulations, ethics review and consent forms.
2. We must provide to subjects and the populations from which subjects are drawn **reasonable assurance** that they are protected in research.
3. We cannot provide a reasonable assurance of protection unless we have **good evidence** for it.
4. In most cases, there is almost no solid evidence of protection.
5. Hence, it is **ethically essential to seek evidence and act upon it** in maintaining and reforming local, regional, national, and international systems of human research protection.

Objectives

- Evidence-based feedback loops
- That is, “virtuous learning loops”
  - Learning from successes and failures
- Providing verified systemic protection
- With accountability to principal stakeholders – particularly research participants

FIGURE 1

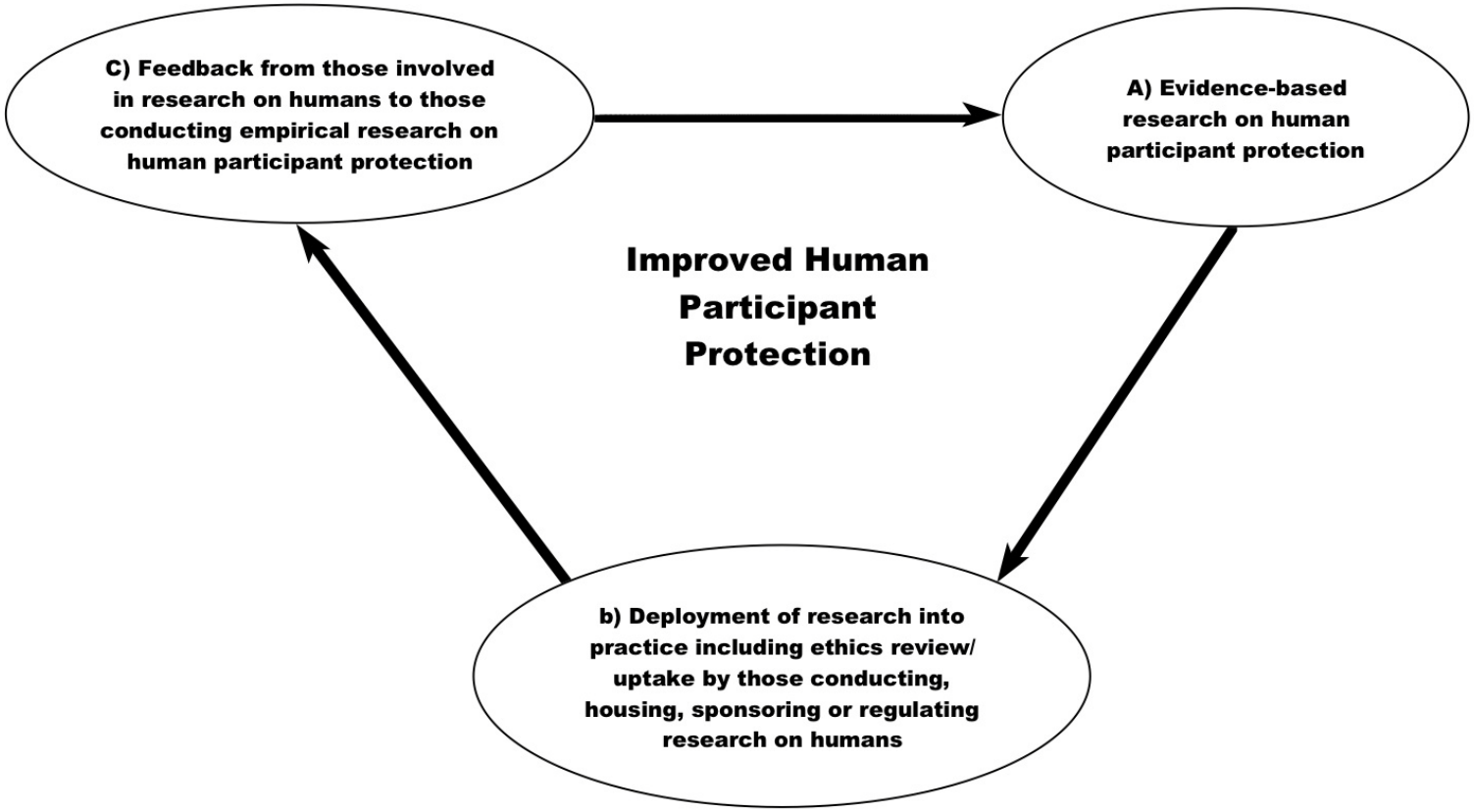
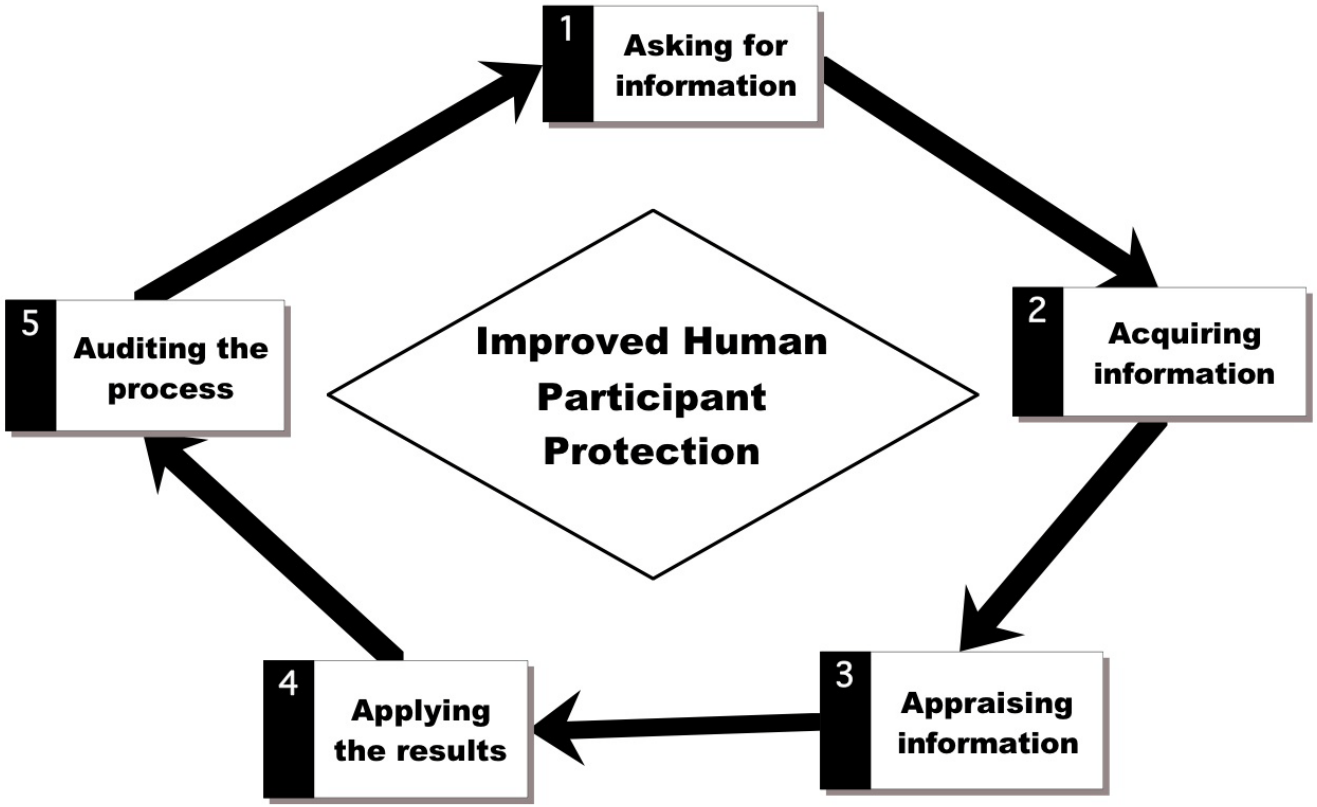

C) Feedback from those involved in research on humans to those conducting empirical research on human participant protection
A) Evidence-based research on human participant protection
Improved Human Participant Protection
b) Deployment of research into practice including ethics review/ uptake by those conducting, housing, sponsoring or regulating research on humans

FIGURE 2


1
Asking for information
2
Acquiring information
3
Appraising information
4
Applying the results
5
Auditing the process
Improved Human Participant Protection

Evidence

- Should centre on
  1. Research participants
  2. Research output – was the game worth the candle?
  3. Mechanisms to achieve (1) & (2): ethics review, monitoring, auditing, QA/QI
- And address information/control needs of key stakeholders, particularly participants

For example

- From a participant perspective
  - Does participation in research align with my goals and my sense of responsibility?
  - Are potential gains worth the opportunity costs?
  - Are the researchers, the research institution & sponsor trustworthy?
  - Will I know that I have made a meaningful contribution to science?

Lessons from Accounting Theory

1. Measures should track what is important to information users.
2. Not all information users are alike: users have different needs, roles and capacities.
3. There is a trade-off between accuracy/comprehensiveness and timeliness.
4. It is essential to recognize the strengths and weaknesses of specific measurements.
5. Measuring has its costs.

Information Users: needs, roles, capacities

- Those with a stake in participant protection
  - Actual & potential participants
  - REBs, HPP staff/admin, institutional officials
    - Regulatory compliance, institutional reputation, acting responsibly
  - Researchers, research workers, coordinators, & sponsors
    - Speed/costs of review; effects of research quality/productivity; reputation
  - Regulators
    - Oversight effectiveness and cost; political & social accountability; reputation
  - Various "publics" – citizens, taxpayers, health consumers, etc.

Level-specific needs

- Macro – policy formation and oversight
  - Numbers & kinds of research & participants
  - Comparison with animal research
- Meso – institutional management and oversight; education; quality assurance
- Micro – project and participant specific issues
  - REB review level
  - DSMB, monitors
  - Research team

Thoughts about indicators

- Likely to be easier to develop & apply process indicators than substantive indicators, yet substantive indicators are crucial
  - **Process** indicators: participant numbers, length of review, signed consent forms, etc.
  - **Substantive** indicators: harm levels, consent comprehension, participant satisfaction

The way ahead

- Moving to evidence-based ethics review will require a coordinated effort on evidence & indicators by
  - Research ethics scholars
  - REBs, research administrators & research institutions
  - Research sponsors and regulators
- Need for experimentation & refinement of measurement methods & tools
- Reorientation in research ethics review practices and research ethics scholarship

Concluding thoughts

- Ethics review is a means to an end/ends
- Evidence is needed that ends have been achieved
- Evidence gathering is ethically essential
- Developing good tools and indicators is challenging, but essential
- To be effective evidence has to actually be used to guide practice and provide accountability

Thanks/Merci

- Centring the Human Subject Research Team
- Canadian Blood Services
- Canadian Institutes for Health Research
- CAREB, MUHC, and McGill Bioethics
- Certified General Accountants of Canada