Think outside of the ERC

A reflection on how to move towards better research ethics systems

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Ethics Review Committee = ERC

- One element –of many— of research ethics systems
- Current systems imply a particular arrangement of ERCs:

  Repeated ethics review processes by different independent ERCs dictated by institutional and national rules

Current arrangements

- Are they the best way to ensure the protection of research participants and overall that research is ethical?
- Can the goals of ensuring that research is conducted ethically and promoting ethical research be accomplished differently, more effectively or more efficiently?

Research has changed but the way we take care of research ethics remains unchanged

- Are the current arrangements the best way to ensure ethical research? Or are they the result of inertia? Can they be improved?
- From “collaborative research” to “collaborative research ethics”?

It's not true that "the more the merrier"

- There is no ethical reason to require more than one ethics review.
- One thorough, knowledgeable of specific contexts, and genuinely independent ethics review is what is justified on ethical grounds.

Current arrangements are mostly an attempt to address weaknesses of ethics review systems

Repeated ERC reviews:

"Safety mechanism" to compensate for other problems

Lack of: standards, capacity of ERCs, regulations, oversight, adherence to rules, etc.

Current arrangements may be justified based on current situation

- They *might* well be the best way to proceed now.
- But we should
  - reflect whether they are the best arrangement to catalyze ethical research,
  - address other problems of research ethics systems.

Two other justifications for current (multi-institutional, multi-site, multi-country multi-challenging) arrangements

1. Conflation of purely ethical and institutional / legal goals

2. Necessary context-specificity of ethics review

Conflation of ethical and institutional / legal goals

Ethics review aims at:

- Ensuring (better?) protection of research participants
- "Protecting the institution"

Nothing wrong with that, but clarity about double goals is important to rethink current arrangements

2. Necessary context-specificity

Ethical principles are universal, but what they dictate in specific circumstances is context-specific.

Ethics review must be context-specific.

But: With current technologies aren't there other ways to ensure context-specific review?

Three interrelated systemic issues should be addressed to move to more efficient ethics review arrangements

- Weak **standards**
- Lack of **trust**
- Poor **accountability**

Standards

- Good ethics review –what is that?
  - Trained ERC members
  - Independent and accredited ERCs
  - Not univocal decisions: “Scope of reasonability”
- **We should**:
  - conceptualize (substantive and procedural) standards
  - develop indicators

Standards for each element of research ethics system

- Normative and regulatory framework
  - Adherence
- National body with responsibility
  - Governance of ERCs
  - Including RCR
- Ethics training for all researchers?

Trust

- To have standards ➔ to know we have standards
- Trust: inter-institutional, inter-governmental, intra-national, international, and society overall
- [Is goal of institutional protection hampering trust? “Don’t expose your weakness”]

Further challenge

- Distrust in research overall

  different from lack of trust in research ethics systems / ethics review

- **We should** clarify the value of research and disseminate the standards of research ethics systems
  - Outside the research ethics community

Accountability

[Subset of standards? Performance vs accountability?]

- Responsibility ("consequences")
- Transparency
- Oversight
- "Procedural strength"

We should establish / facilitate mechanisms for accountability (not just of ethics review /approval)

We should also

- Strengthen global, regional… forums
  - To strengthen current systems (e.g. global/regional ethics consult services?)
  - To discuss ways to change them to catalyze ethical research
    - Consensus (incremental change?)
- Study positive experiences
  - Pilot proposals?

Research ethics systems projects

- (Study on reasons why proposals aren't approved by PAHOERC)
- Software for ethics review developed by PAHO with PUCPR (Brazil)
  - Accountability, transparency, some standards, some capacity building, possible network review…
- Indicators for research ethics systems (WHO, Toronto, PAHO, etc)

Stay in touch

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