



UNIVERSITY OF
KWAZULU-NATALTM
INYUVESI
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Reciprocity in ethics review for minimal risk studies



EDGEWOOD CAMPUS

HOWARD COLLEGE CAMPUS

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PIETERMARITZBURG CAMPUS

WESTVILLE CAMPUS

UKZN INSPIRING GREATNESS

Purpose of the presentation

The review
process

Value of
reciprocity in
reviews

Process

Oversight
and
monitoring

The review process



Protection of
study
participants

Enhances
scientific
rigor

Legitimacy to
the research
process

Ethics reviews at the REC level

Time
consuming

Delays

Communication
challenges

Researcher
Frustration



Streamlining
the process

Does not
impede
research

No lapses in
participant
protection

Risk levels

- No risk = **no human participants**. Information/data is in the public domain
- Minimal risk
- Increase in minimal risk (**vulnerable populations + circumstances that render vulnerability**).

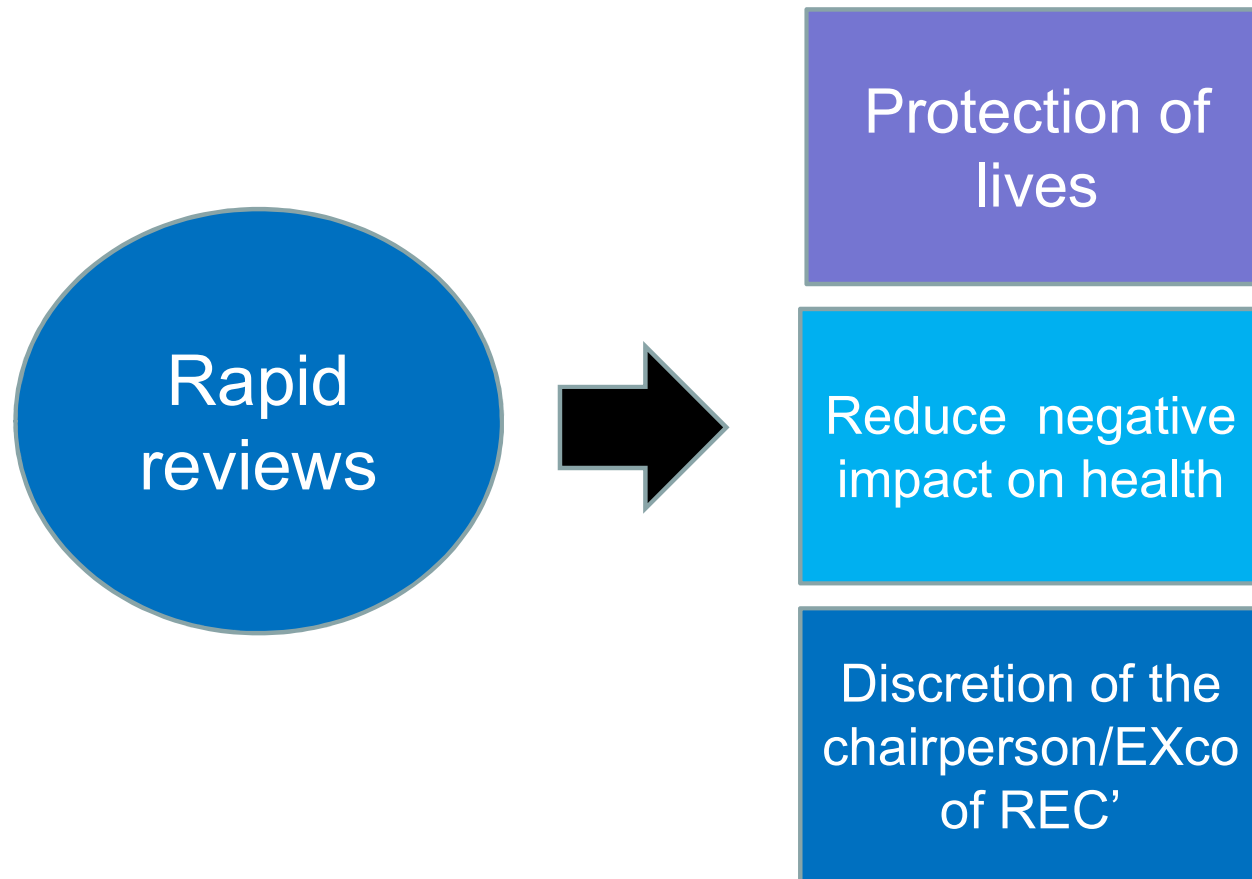
Minimal risk

Risk no greater than what one would experience in an every day setting

Expedited Review

- Studies involving minimal risk
- An expedited review procedure: review of research involving human participants:
one or more members of REC allocated to the study by the Chair.

Purpose of a rapid review



Defining reciprocal reviews

- i. RECs may, **at their own discretion**, recognize prior review and approval of a research proposal by **another registered REC** to avoid duplication of effort.
- ii. Reciprocal recognition means that two or more registered RECs decide to **recognize each other's prior review**.
- ii. RECs that recognize prior review in this manner must **determine the nature of the documents to be filed locally**, which must, at minimum, include a copy of the approval letter from the other REC

DoH (2015). Ethics in Health Research. Principles, Processes and Structures

Discussion

- What are the opportunities for reciprocal reviews?
- What could be the challenges?
- Who initiates/determines the reciprocal review?
- What steps should be considered for a REC SOP on reciprocal reviews?

Reference

DoH (2015). Ethics in Health Research. Principles, Processes and Structures

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- RECs wanting to engage with other RECs in reciprocal reviews for health research should take the following into account:
 - Is this a registered REC with the National Research Ethics Council of South Africa?
 - Is there a memorandum of agreement between the affected institutions or RECs to facilitate REC engagement in reciprocal reviews?

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- What are the stated terms and agreements for reciprocity related to ethics reviews? What are the implications in terms of impact on the affected REC's workload and oversight role for the proposed study?
 - Are there any REC operational challenges that could hinder the REC's oversight role?
 - Does the REC have the necessary discipline and expertise for the review of content and scope of the research area?

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- What are the context-specific risks that could be associated with the proposed study? How does these identified risks increase possible harms to the identified population?
 - Would a new REC oversight influence decisions such as access to care for research participants?
 - How would potential conflicts of interests be resolved? (Government of Canada 2018; Rachael *et al.* 2012)