Research ethics reviewing during COVID-19: adaptation, responsiveness, support

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Introduction

- Human Sciences Research Council's REC
  - formal ethical review of research with human participants
- National legislative framework
- REC's review framework
- HSRC's REC experience with pandemics
- Uniqueness of the COVID-19 pandemic (rapidly evolving, scientific knowledge limited, uncertainty, direct impact on vulnerability including of potential study participants)

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Characterising the REC environment

- Creativity of researchers from early career to established specialists
- Flexible REC – including the mainstreaming of emergency reviews of COVID-19 studies that require rapid implementation
- Support and understanding on the part of the HSRC senior management
- Overall collegiality and consultations
- Emphasis on learning opportunities

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REC's review framework

- In reviewing research protocols, the HSRC REC is guided by **eight requirements for ethical research** (Emanuel et al., 2004)
  - Focused on clinical research in developing countries
  - Adapted for social sciences by Wassenaar, 2006; Wassenaar & Mamotte, 2012)

Based on the 4 key principles in research ethics

- Non-maleficence, Beneficence, Respect for autonomy and Justice: Fair balance of risks and benefits

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Emanuel et al. (2004) 8 requirements for ethical research

- **Principle 1: Collaborative partnership**
  - *Community representatives*
  - *Responsibility sharing*
- **Principle 2: Social value**
  - Research beneficiaries
  - Impact on health systems

- **Principle 3: Scientific validity**
  - Appropriate design and methods
  - Applicability of results
  - Impact on provision of health care services
  - Study design feasibility
- **Principle 4: Fair selection**
  - Suitable study population
  - Risk minimisation
  - Benefits to participants
  - Vulnerability

- **Principle 5: Informed consent**
  - Recruitment and incentives applicability to local context
  - Appropriate disclosure documents and processes
  - Presentation and accuracy of information
  - Legally authorised representatives
  - Gatekeeper's permission
  - Context of consent process

- **Principle 6: Favourable risk-benefit ratio**
  - Risk identification and minimisation
- **Principle 7: Independent review**
  - Regulatory compliance
  - Minimisation and reconciliation of multiple reviews
- **Principle 8: Respect for participants**
  - Monitoring health and well-being
  - Confidentiality and privacy
  - Voluntariness

Responsiveness to Stakeholders' needs

Not business as usual for the REC and its clientele

- **Consultative approach** buy-in from HSRC senior management
- Protecting the committee's key stakeholders
  - Researchers and fieldworkers,
- Protecting communities and participants
  - Encouraging researchers to play their part: create awareness, educate, engage with "communities" so they benefit from participating in research

COVID-19 related studies

- The need for rapid studies – evidence base for policy responses
- **Designs:** social surveys, epidemiological studies, qualitative designs
- **Data collection methods**: online/digital, social media, photovoice, focus group discussion
- **Populations/samples/units of analysis**: Adults, youth (KAB), children, employees (impact, w.f.h)/ households, individuals

Proactive measures to facilitate reviews

- How were different studies affected?

  In-the-field studies

  Provisionally approved studies

  New studies

- REC's approach to protecting lives – guided by the **national response** and the calibration of risk levels from 5 to 1.
- **New standard operating procedures**
  - **10th March meeting – REC/MGNT**

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COVID-19 specific ethics review issues

- **Need to reorganise the committee's business**
- **Expedited reviews –** in between meeting reviews by sub-committee members
- Study protocols: COVID-19-related research and non-COVID related topics
- **Commonalities and differences**
- Overall need to adapt methodologies to the **new** safety requirements, harm minimisation
- Protocol amendments…

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Critical assessment of some of data collection methods that researchers propose

- Feasibility? E.g. Focus group discussions – social distancing? (safety)?
- Legality? – E.g. Photovoice during Level 5 lockdown
- Science and ethics? – uncertainty with testing procedures and science **not immediately** benefiting study participants
- The tacit sense that one's study is important – less careful risk-benefit ratio assessment
- Reimbursements online data collection – **data costs**

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Thank you

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