



Standard Operating Procedures
Research Ethics Committee (Human) (REC-H)

- Research in the context of a major incident

1 RESEARCH IN THE CONTEXT OF A MAJOR INCIDENT

1.1 BROADENING THE THEORETICAL FRAMEWORK FOR RECS DURING A MAJOR INCIDENT

1. Research in a major incident e.g., natural, or man-made disasters such as floods, earthquakes, outbreaks of deadly disease or political violence and armed conflict, is important for advancing emergency health care interventions and treatments and refining resource allocation, policymaking and implementation. This led to additional guidelines being published in 3.4.1 of the Department of Health Guidelines 2015 ²⁶
2. Major incidents such as a COVID-19 pandemic can result in challenges (for example, forced isolation) which have significant effects on clinical trials and community-based research.
3. *Public health emergencies require a public health ethics approach. This will necessitate a broadening of the theoretical framework used by RECs to consider public health principles, focusing on solidarity, mutuality, and reciprocity, among others.* ²⁶
4. For specific guidance on conducting clinical trials during a pandemic, refer to section 10.11 of SA Good Clinical Practice: Clinical Trial Guidelines 2020.⁸
5. The research must still be conducted in a manner that complies with acceptable principles that underpin the scientific and ethical integrity of research with human participants. Thus, careful ethical review is essential, albeit the urgency.
6. Expedited ethics review procedures will apply to low-risk research, however expedited processing does not equate to curtailing deliberation time. The expedited processes therefore are specific to the administrative processing of the ethics application.
7. In the context of a major incident a rapid ethics review may be conducted. In this case fewer REC members may be required to review the proposal. The time for deliberation by the REC will be reduced to five days. Rapid review is important, but not relevant for all research in such circumstances, as not all research is urgent.