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RESEARCH IN EMERGENCIES (RiEM)
GUIDELINES FOR PROTOCOL SUBMISSION AND REVIEW OF NEW STUDIES

1. INTRODUCTION

Research in Emergencies (RiEM) refers to studies that relate to and take place before, during and after major incidents. Within this context, the interface of clinical care provision, research and public health interest and surveillance comes to the fore.

Such research studies often relate to the development, utilization and monitoring of prophylactic and/or therapeutic biomedical and care interventions and ways of mitigating the risk and effect of the major incident. The psycho-social realities of such a major incident are often severe, and front-line staff and first responders are at high risk.

Research ethicists acknowledge the moral obligation to undertake research in such times and wish to support well-designed studies that foster respect, community engagement, fairness, equitable access and trust. The risk-benefit relationship, participant protection, and informed consent remain paramount in considering protocols.

1.1. These studies are time-sensitive and require a flexible and fast-track mode of review in the interest of participants and health care and should not compromise safety of participants and staff.
1.2. Such studies will receive urgent attention by the activation of a rapid review process "which means that the time for deliberation is curtailed" (DoH, 2015:33).
1.3. The HREC however, needs to maintain quality of review and rigour, and function autonomously in such reviews.
1.4. It is accepted that the full palette of research foci and methodologies will be considered over time (Example: Figure 1).
1.5. HREC will apply online/ virtual methods to review and meet as agreed, for example via MS Teams. It is however noted that discourse/dialogue between committee members may be negatively affected to some extent.
1.6. The HREC Chair needs to carefully navigate review processes, recommendations, decisions and outcomes. Where necessary, remedial or directive decisional steps may need to be taken by the Chair in co-operation with the Vice-Chairs.
1.7. The HREC will make the final decision on whether a study qualifies for rapid expedited or rapid full review, however investigators might make recommendations and motivate accordingly (as in a normal application).

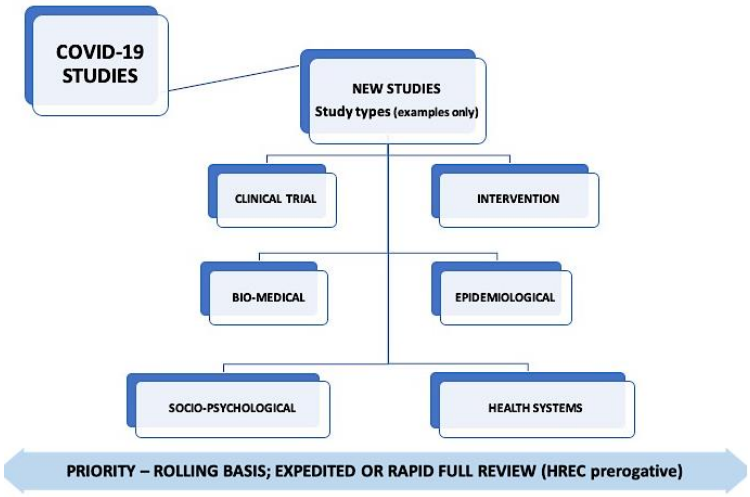

Figure 1: EXAMPLE: COVID-19 NEW STUDY TYPES

2. GUIDELINES FOR RESEARCHER(S) – NEW STUDIES

2.1. Introduction

The requirements for a protocol submission remain the same, what needs careful attention is the unpacking of the study as research in the time of an emergency. Secondly, detailed attention to participant and researcher protection from harm is critical. Lastly, there is an important need to fast-track such submissions due to the importance for the communities we serve and the common good.

HREC members will be available for consultation or to provide guidance ahead of submission to ensure that applications to be submitted, meet required criteria and that turnaround time is as short as possible. Such a discussion between researchers and the HREC members as agreed, may aid in accelerating the reviewing process by obviating omissions and or amendments.

2.2. Procedural guidelines

2.2.1. Submit a complete protocol with all the relevant additional documentation at any time on the Infonetica system:

2.2.2. Ensure the focus of the emergency research (for example COVID-19) is mentioned in the title of the project.

2.2.3. Provide a clear rationale for the study to be conducted and the significance thereof.

2.2.4. Carefully describe all the measures that will be put in place to limit exposure to the major incident (for example the COVID-19 virus), to protect all participants and researchers. The standard precautions could be described in an annexure and referred to in the protocol text.

2.2.5. Indicate how health care workers and participating members will be protected and supported where relevant.

2.2.6. Within the COVID-19 major incident, an “in the time of COVID-19” register that will contain personal identifiable information need to be included in the submission. Please describe how such data will be collected, stored and protected in respecting the confidentiality of participant data.

2.2.7. Highlight how findings and data will be rapidly shared, where reasonable and necessary. A data collection and data sharing plan to be included.

2.2.8. Outline carefully the benefit-risk relationship, and how risk for the participant and the researcher will be prevented, limited and managed. This to include the reporting of Adverse Events.

2.2.9. Give careful attention to informed consent, and where applicable, assent. Where a waiver of or delayed/ deferred consent is required, such need to be carefully motivated and the process unpacked.

2.2.10. Where research will be conducted using biological samples, the researcher needs to be very clear in defining and operationalizing informed consent (or variations thereof), and the conditions and precautions put in place in which biological samples will be collected, stored, shared and used. This will include for example MTAs where appropriate.

2.2.11. Immediately contact the HREO and/or HREC Chairs in the case of any uncertainty or clarification to limit resubmissions and/or fallouts.

2.2.12. Flag the submitted study to the HREO – email Elvira Rohland at elr@sun.ac.za to facilitate urgent action.

2.2.13. Additionally, all research that is potentially hazardous to humans, animals or the environment, involving recombinant DNA, pathogens and infectious agents, or biological toxins requires REC: BEE[1] approval prior to commencement.

3. GUIDELINES FOR HREC - NEW STUDIES: RESEARCH IN EMERGENCIES

3.1. Introduction

3.1.1. Allow for the flexible submission of new protocols related to Research in Emergencies on a rolling basis outside of the normal schedule of HREC meetings.

3.1.2. Prioritize Research in Emergencies studies in terms of review and of communicating review outcomes.

3.1.3. Make time available for consultations prior to submission, with researchers, reflecting on possible pitfalls and recommendations to facilitate the upcoming approval process.

3.1.4. Collaborate in the review of standard protocols as submitted – whether local, national (multi-centre) or international – this includes communication with national regulatory authorities, between Health Research Ethics committees, REC: BEE, REC SBE[2] and other relevant stakeholders.

3.1.5. Provide access to relevant and useful documents such as guidelines, generic protocols and statements via the HREC website.

3.2. Procedural steps: Rapid reviews

3.2.1. Protocols for new Research in Emergencies studies will be assigned to either HREC 1 or 2 co-ordinator by the HREO (alternating between the two committees to balance workload)

3.2.2. The relevant HREC chairperson will determine the perceived risk level of the study and categorize it as either an

a. **Rapid expedited review**: The risk is perceived to be minimal in context and requires one reviewer according to current HREC practices who acts in cooperation with the Chairperson. The study will be assigned to a reviewer in co-operation with

[1] REC: BEE – SU Research Ethics Committee: Biosafety and Environmental Ethics
[2] REC: SBE – SU Research Ethics Committee: Social, Behavioural and Education Research

the co-ordinator of the Committee. The outcome of the review will be followed up and provided to the researcher as soon as available.

b. **Rapid full rapid review**: The study carriers a higher or significant risk and thus requires the protocol will be assigned to at least two expert reviewers (either from the relevant HREC or from a wider pool of experts) in co-operation with the Chair and the co-ordinator.
    i. In the case of a Clinical Trial, the input of a legal expert will be pursued.
    ii. When the completed reviews are submitted, an urgent Quorate meeting of at least five HREC members (online, preferably MS Teams) will be organised by the coordinator.
    iii. The inclusion of a community member will be pursued. However, this requirement may need to be waived if a community member cannot join the Quorate meeting.

3.2.3. It is important to note, that any and all outcomes and decisions related to rapid reviews (both expedited and full) will be included in the agenda of the next HREC meeting, where members will reflect on the outcomes and ratify the decisions. Where members identify any concern, such concern will be communicated to the researcher in a follow-up letter for action, if any.

3.3. Suggested time frame for Full Rapid Reviews

3.2.1. May be adjusted due to progress and unanticipated events

3.2.2. Submission: Workday 1.
3.2.3. Allocation: Same day or next working day.
3.2.4. Review: Two working days.
3.2.5. Circulation and review by quorate group members of the HREC: Two working days.
3.2.6. Quorate meeting of at least five HREC members (online, preferably MS Teams) following these two working days (to be calendared by coordinator in advance).

OPERATIONAL DEFINITIONS

Major incident

The DoH (2015:33) states that "major incidents include any sudden event that occurs where local resources are constrained, so that responding urgently and appropriately is difficult. Major incidents include acute disasters – natural or man-made – such as floods, tornados, earthquakes, outbreaks of deadly disease, or political violence and armed conflict with resultant injuries to humans. They may also take the form of an unusual and sudden demand on local resources or other emergency with consequent ethical implications for patient care. Research in these contexts is important for advancing emergency health care interventions and treatments, and for refining resource allocation policies. The potential benefits of major incident research include improved triage methods and procedures, effective treatment for life-threatening conditions and improving therapies for survival and quality of life".

Rapid review

Time sensitive, fast-tracking review of research protocols - ensuring a significantly decreased turnaround time for research focussing on or related to serious sudden-onset emergency situations, such as epidemics, pandemics, natural disasters and so forth. Rapid review studies are considered on a rolling basis in times of research related to and during emergency situations. The HREC may classify such protocols as either a rapid expedited or a rapid full review.

a) Rapid expedited review

Within HREC nomenclature, an expedited review refers to a study with minimal risk that usually only requires one reviewer in cooperation with the Chair of the relevant HREC. A

study is considered limited risk reviewer (usually quick, a day or two as you do not wait for the second reviewer's report) a rapid review within a week

b) Rapid full review

Such a study holds more than minimal risk and requires two reviewers (higher risk requiring a broader opinion, slightly longer have to first wait for both reviews and possible 3-5 committee member further discussion if deemed necessary by the reviewers), but still a rapid review process try to complete within a week if possible

REFERENCE

Department of Health (2015). **Ethics in Health Research: principles, processes and structures** (2nd Edition). Department of Health: Pretoria, South Africa.

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