Guidance for researchers requesting Urgent/Rapid HREC Review

Introduction

HREC acknowledges that there could be extenuating circumstances that necessitate a researcher/s requesting ethics review outside the scheduled review and meeting cycle. *This applies to both new submissions and requests for amendments.*

The first responsibility of the researcher is to inform external parties of the scheduled review cycles as these are planned a year ahead to ensure that ethics submissions receive due consideration in line with national regulations. Furthermore, it is vital to acknowledge that HREC members serve in a voluntary capacity and thus requests for urgent review places further strain on members which HREC needs to make in an ethical and professional manner.

HREC acknowledges, however, the need to support SU researchers and or research units to facilitate access to research funding. To manage such extra-ordinary requests, the researcher should follow the steps as outlined below:

1. For **new submissions**: Direct an email to the Head: Health Research Ethics Office, via the ethics inbox ethics@sun.ac.za with a cover letter attached outlining the request and the circumstances necessitating the request.
   The researcher is requested to provide full details of the timeframes involved and any information that will allow the Head to assess and manage the request in consultation with the relevant HREC Chairperson. **Kindly note:** *HREC will assess the request based on the cover letter and reserves the right to enter into discussion with external parties should this be deemed necessary.*

   If the request pertains to use of data from existing or past studies, please attach the approved protocol(s) and informed consent forms, and DTA/MTA pertaining to the previous studies as well as the HREC reference numbers.

   In the case of **amendments**: The practice by HREC is to assign requests for amendments to the original reviewer/s. It is thus important to communicate with the HREC Office as soon as possible when urgent/rapid review of a protocol amendment is requested.

2. The researcher/research team would also need to devote time to develop a research protocol (based on the funding application and or funding agreement) outlining the interface with human participants, or in the case of reuse of data from a previously approved study or studies, provide the originally approved protocol and informed consent documentation. In cases where amendments have subsequently approved, the most recently approved documentation should also be appended.

3. Ensure that there is parallel interaction with the Research Contracts Office to ensure any contractual agreements (DTA/MTAs or research contracts) can be developed simultaneously. A standing agreement exists between HREC and Research Contracts for the parties to raise or consult regarding any specific ethico-legal considerations to facilitate finalisation of ethics and contracts approval.

4. Set up a consultation to determine the feasibility and timeliness of the urgent review request in discussion with the HREC Chairpersons and the Head: Health Research Ethics Office. Such a consultative meeting also serves the purpose of surfacing any additional ethical considerations that may need reflection by the researcher/research team during the ethics submission process.

5. *Kindly note: in line with the HREC Standard Operating Procedures, reviews of studies categorised as 'more than minimal risk' or involve vulnerable populations (DoH, 2015), require full committee review. As such an urgent review cannot be finalised (that is, final approval issued) without HREC ratification.*

6. Submit the application online via the EthicsRM submission system ***as soon as possible***. Please ensure that full documentation is uploaded to prevent the submission being returned because it is administratively incomplete. For example, if the submission is linked to a grant funding application, please ensure that the research protocol and the supporting recruitment materials, informed consent documents, data collection instruments and so forth are available for HREC review.

7. Inform the Head: HREO and copy to Ms Elvira Rohland at elr@sun.ac.za once the application has been completed to enable allocation to a committee and to enable HREC co-ordinator to assign reviewers.

Urgent review request HREO/HREC Flow-chart:

(a) Written request to Head: HREO who discusses with the HREC Chairpersons to determine optimal path for assigning to HREC 1 or 2. Such consideration will be based on, amongst others: the timing of the request vis-à-vis the scheduled meeting cycle, review expertise required and availability, the feasibility of the urgent/rapid review within the required timeframe, and so forth.

(b) Discuss with the Chairpersons, assess the request for urgent/rapid review, assess risk category, and assign reviewers accordingly.

(c) Assignment by Senior Health Ethics Administrator to the relevant committee HREC1 or 2 based on discussion with the Chairpersons.

(d) Table request at the closest meeting if more than minimal risk study and requires meeting deliberation and recommendation (e.g., CT, and vulnerable participants)
    i. Ad hoc meeting: at the Chairperson's discretion, where required to deliberate any challenges identified before feedback is provided to the applicant, an ad hoc meeting can be considered. Members of the ad hoc meeting shall include the Chairperson, Vice-Chairpersons, reviewers, Head: HREO and HREC co-ordinator. The Chairperson shall also have recourse to invite additional members or experts as provided for in the HREC SOP.

ii. The feedback from the ad hoc meeting and reviews will be shared with the researcher/research team to ensure that any modifications requested by HREC can be attended to.
iii. The decision of the ad hoc committee is ratified at the next scheduled meeting and final approval issued or approval with stipulations (to ensure administrative requirements (e.g., institutional permissions, DTA/MTA finalisation etc.) are met by the researcher/research team.

(e) To ensure the integrity of the ethics review process, a turnaround of 7-10 working days can be expected, in line with rapid review processes as outlined in the Research in Emergencies SOP (kindly refer to section 24 of HREC SOP).