



23 April 2012

Dear Heads of Department, Directors of Research Units, Chairpersons of DRCs and Researchers

RE: Notice from the Faculty of Health Sciences Human Research Ethics Committee (HREC) regarding amendment submissions

From the **01 June 2012**, the HREC will not accept any research amendments that do not have a local PI-constructed synopsis. The degree of detail in the amendment synopsis will depend on the nature and complexity of the proposed amendment. Any change in the risk-benefit of the study must be defended.

Background

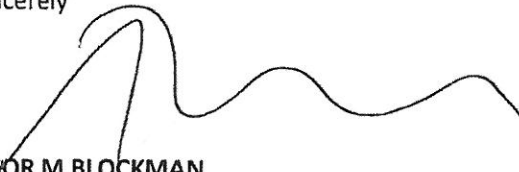
Researchers need to include sufficient information in the synopsis for Committee members to assess the amendment independently of any other protocol amendment documentation. Knowledge of and familiarity will make the principal investigator the best person to prepare a contextually-relevant and ethically-sensitive synopsis.

The amendment synopsis must:

- Be written in simple, non-technical and jargon-free language which is readily understood by Committee members who include non-scientists, non-experts in the PI's field and who represent the community. Acronyms must be spelt out when used for the first time.
- Specify how the amendment will advance health and scientific knowledge in this population.
- Succinctly identify the amendment purpose and objectives in the context of currently available and relevant knowledge.
- Provide a brief overview of inclusion and exclusion criteria if applicable.
- Describe, if applicable how participants will be recruited if different from the previously approved protocol. Specifically address how, when, where and by whom participants will be identified and approached.
- Describe the probability and severity of foreseeable harms: physical, psychological, social and economic.
- Describe any changes in site-specific measures to protect participants' privacy and the confidentiality of the collected data.
- Explain how risks will be minimised and how safety will be protected.
- Describe expected benefits to individual participants and potential societal benefits within the local setting.
- Indicate whether post-trial treatment access will be affected by the amendment..
- Explain how, when, where and by whom consent and assent will be obtained.
- Clarify special protections for vulnerable participants such as children, cognitively impaired, terminally or critically ill.
- Provide information on availability of compensation for research-related costs (e.g. travel) and inconvenience.
- Provide information on the on-going availability of insurance for research-related injuries.
- Where appropriate, briefly describe what measures and protections will be in place for collection, storage and exchange of biological specimens.

- Identify and justify any aspects of the amendment that could reasonably be considered morally controversial. Describe how ethical issues will be addressed and what extra protections, if any, will be put in place.
- Please make sure that all amendments are highlighted with appropriately coloured track changes.
- Please provide an updated informed consent document with appropriate track changes if applicable.

Yours sincerely

A handwritten signature in black ink, consisting of a series of loops and waves, positioned above the typed name.

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS