**FHS014: Preparing a Synopsis: Section B –**

**Pointers for Researchers**

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| Instructions |
| * Forms to be downloaded from the HREC website:   <http://www.health.uct.ac.za/fhs/research/humanethics/forms>   * The HREC will not accept any research proposal that does not have a local PI-generated synopsis. The degree of detail in a synopsis will depend on the nature and complexity of the study. * The synopsis should not be more than four pages. |

Introduction

With the exception of the two or three primary reviewers, remaining Committee members rely on the synopsis and supporting materials such as the informed consent forms to evaluate a proposal. Therefore, researchers need to include sufficient information in the synopsis for Committee members to assess the proposal independently of any other protocol documentation. Knowledge of and familiarity with the local setting in which a study will take place make the principal investigator the best person to prepare a contextually-relevant and ethically-sensitive synopsis. In general, sponsor-produced synopses do not contain enough site-specific detail to permit proper ethical review.

The 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 research will be conducted in this setting; for example, what is the socio-demographic and educational background of participants at the local site, how will the study advance health and scientific knowledge in this population.
* Succinctly identify the study’s purpose and objectives in the context of currently available and relevant knowledge.
* Explain the design of the study. In the case of clinical research, carefully distinguish experimental interventions from the standard of care.
* Provide a brief overview of inclusion and exclusion criteria.
* Describe how participants will be recruited. 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 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 will be available for local participants and if not, why not.
* 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 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 study that could reasonably be considered morally controversial such as the use of a placebo, withholding standard of care, deception, commercial drug or device trials where interventions are unlikely to be affordable in the local setting, and any restrictions on publication. Describe how ethical issues will be addressed and what extra protections, if any, will be put in place.