

ETHICAL APPROVAL OF SPECIAL STUDY MODULE PROJECTS

The Human Research Ethics Committee (HREC) has a growing concern regarding research ethics review of undergraduate student research in the Faculty of Health Sciences. This relates particularly to the devolved ethics approval process for undergraduate student research projects. The specific concerns include: 1) the quality of the undergraduate research protocols; 2) the volume of undergraduate protocols presenting too large a burden to the UCT patient base; and 3) a lack of confidence in the uniformity and appropriateness of devolved review standards among department research committees and individual mentors responsible for devolved ethics supervision.

To address these concerns, the HREC will no longer devolve ethical approval of undergraduate student research protocols to department research committees or individual supervisors. From 2014, Special Study Module (SSM) undergraduate research projects are required to be submitted to the HREC for expedited review and approval.

The HREC require that all undergraduate student research projects must be restricted to minimal risk research. Risk is considered to be minimal if the probability or magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life.

Undergraduate student research projects should also not engage vulnerable populations. In research, “vulnerable” generally means that a potential participant may be open to some form of coercion or undue influence in considering whether or not to take part in research. Vulnerability may arise from a lack capacity to give individual consent (e.g., children, individuals with intellectual disabilities); limited language proficiency in which the study is being conducted; significant pain or terminal illness; emergency room situations; where no effective treatment is available; socioeconomic inequalities; or cultural values or beliefs.

Due to the nature of conducting research in a South African context, the HREC accept that it may be necessary to perform undergraduate research in populations with limited language proficiency, in groups with diverse cultural values and beliefs, and where socioeconomic inequalities exist. Supervisors will be required to justify the scientific value of the research; and to explain measures that will be in place to minimise potential vulnerability of participants (for example, translation of informed consent documents; or how coercion or undue influence will be avoided).

Formal ethical approval must be obtained from the HREC prior to the commencement of any research activities. Research activities include advertising a research study; validating measurement instruments; pilot studies; screening and recruitment of participants, data collection; and data analysis.

The HREC are aware of the short timelines and practical limitations of the SSM research projects. To facilitate the review and approval of research projects within the available time, the HREC have committed to conduct an expedited review of SSM research projects between the allocation of SSM projects (approximately 12 to 13 June 2014) and the commencement of SSM projects on 14 July 2014.

To facilitate this process supervisors are requested to submit SSM protocols for HREC review between Monday 16 June 2014 and Tuesday 1 July 2014. SSM protocols should only be submitted for ethics review once students have been assigned to projects for 2014. Please note that to ensure that supervisors have adequate time to address feedback from the HREC so that formal ethics approval may be granted by Monday 14 July 2014, no SSM protocols will be accepted for review after 1 July 2014.

An undergraduate ethics application form (FHS021 form) must be completed for each undergraduate student research project. The supervisor must be listed as the principal investigator (PI). All students involved in the project must be listed as co-investigators. The ethics application form must be signed by the supervisor as PI, the students, and the Head of Department.

Once the research has been completed, a copy of final report must be submitted to the HREC together with a study closure form (FHS010 form).

Please also refer to the HREC website for guidance regarding preparing the protocol and the undergraduate student research protocol application form (FHS021 form) (<http://www.health.uct.ac.za/research/humanethics/forms/>), and informed consent documents (<http://www.health.uct.ac.za/research/humanethics/sop/>). There are also other useful SOPs, resources and links to external sites. The ethics review process will be greatly facilitated if the FHS021 form is completed in full, and if the protocol and informed consent documents adhere to HREC guidelines.