UNIVERSITY OF CAPE TOWN
iYunivesithi YaseKapa
Universiteit van Kaapstad

Dr Max Price: Vice- Chancellor

Private Bag X3, Rondebosch, 7701, South Africa
Room 101, Brenner Building, Lower Campus, Lovers’ Walk, Rondebosch, Cape Town, 7700
Tel: +27 (0) 21 650-2105/6 Fax: +27 (0) 21 650-5100
E-mail: vc@uct.ac.za Website: www.uct.ac.za

Statement from the Vice-Chancellor of the University of Cape Town
about
Research involving humans and s 71 of the National Health Act

On 1 March 2012 section 71 of the National Health Act came into effect. This information was made known only on the 23 March. Subsequently, a letter from the National Health Research Ethics Council (NHREC) dated 3 April 2012 explained that the section was promulgated without its accompanying regulations. This means that, in a technical sense, the section is effective, but that it cannot be implemented for lack of its regulations.

Section 71 has a drastic and material effect on the logistics of doing research with human participants, especially with minors. Specifically, s71 introduces new requirements for health research, including that there must be written consent; consent from a parent or guardian for research with minors; that ‘therapeutic research’ must be in a minor’s best interest, and that consent from the Minister must be obtained for ‘non-therapeutic’ research with minors. These requirements mean that the previously acceptable manner and methods of obtaining informed consent from potential human participants, especially minors, are changed by this provision. However, it is not possible for researchers to change to the new methods because there are no regulations to guide one to know e.g. how to get ministerial consent now required for ‘non-therapeutic’ research on minors.

The letter from the NHREC indicates that it is trying to obtain clarity on how researchers are to meet the new requirements, especially that regarding ministerial consent. It indicates also that the NHREC is aware of the consequent conflict between the newly promulgated legal requirements and the current national research ethics guidelines.

Necessarily, therefore, this state of affairs presents a logistical conundrum for researchers at UCT regarding how to go forward in the immediate future. One option is to halt all affected research until the technical problem is cleared up. Quite clearly this option is to be avoided if at all possible because the detrimental effects would be considerable.

Another option is to continue to follow the procedures and decision-making patterns of the immediate past i.e. in use prior to 1 March 2012, on the basis that these patterns are ethically acceptable and comply with the prevailing research ethics guidelines. In light of the letter from the NHREC, it is our view that the second option is preferable for the immediate future at UCT.

Consequently, we hereby indicate our support for the continuation of procedures and decision-making patterns as they were implemented immediately before 1 March 2012 until such time as the conundrum is removed. It is important that all researchers, especially those who use minors as research participants, must ensure that informed consent processes are carefully carried out in accordance with current (2004) Department of Health Research Ethics Guidelines. It is important also to note the imminent likelihood of the drastic change and to make contingency plans for the medium term. The ORI, EiRC and Faculty-level RECs will keep researchers informed as matters change.

Dr Max Price
Vice – Chancellor
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