THE UNIVERSITY OF NEW SOUTH WALES
SYDNEY • AUSTRALIA

HUMAN RESEARCH ETHICS COMMITTEE (HREC)

29 August 2011

Professor Maree Teesson
National Drug and Alcohol Research Centre

Dear Professor Teesson,

A Comprehensive universal and targeted intervention to prevent substance use and related harms in Australian adolescents: The CAP study
HREC 11274

Thank you for the letter to Mrs Margaret Wright dated 12 August 2011.

The Executive of the Human Research Ethics Committee considered the above protocol at its meeting held on 16 August 2011 and is pleased to advise it is satisfied that this protocol meets the requirements as set out in the National Statement on Ethical Conduct in Human Research*.

The University of New South Wales declared that this research proposal has been quality checked. It is of sound design, has an adequately specified methodology appropriate to the goals of the project and conforms to the criteria for quality research provided in the SERAP guidelines.

Having taken into account the advice of the Committee, the Deputy Vice-Chancellor (Research) has approved the project to proceed.

Would you please note -:

- approval is valid for five years (from the date of the executive meeting i.e. 16 August 2011);
- you will be required to provide annual reports on the study's progress to the HREC, as recommended by the National Statement;
- you are required to immediately report to the Ethics Secretariat anything which might warrant review of ethical approval of the protocol (National Statement 3.3.22, 5.5.7) including:
    a) serious or unexpected outcomes experienced by research participants (using the Serious Adverse Event proforma on the University website at http://www.gmo.unsw.edu.au/Ethics/HumanEthics/InformationForApplicants/ProformasTemplates/C13_SAE%20Proforma.rtf) ;

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(HREC 11274 cont'd)

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b) proposed changes in the protocol; and
c) unforeseen events or new information (eg from other studies) that might affect continued ethical acceptability of the project or may indicate the need for amendments to the protocol;

- any modifications to the project must have prior written approval and be ratified by any other relevant Human Research Ethics Committee, as appropriate;

- if there are implantable devices, the researcher must establish a system for tracking the participants with implantable devices for the lifetime of the device (with consent) and report any device incidents to the TGA;

- if the research project is discontinued before the expected date of completion, the researcher is required to inform the HREC and other relevant institutions (and where possible, research participants), giving reasons. For multi-site research, or where there has been multiple ethical review, the researcher must advise how this will be communicated before the research begins (National Statement 3.3.23 and 5.5.6);

- consent forms are to be retained within the archives of the Centre and made available to the Committee upon request.

Yours sincerely,

Professor Michael Grimm
Presiding Member
HREC

*http://www.nhmrc.gov.au

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