2 February 2012

Research Ethics and Governance eBulletin

UPDATE: MOU for Single Ethical Review of Clinical Trials between New South Wales Health, Queensland Health & Victoria Department of Health

Memorandum of Understanding

The NSW, Queensland and Victorian Departments of Health signed a Memorandum of Understanding to introduce mutual acceptance of ethical and scientific review of multi-centre interstate clinical trials undertaken by Public Health Organisations (PHO). The aim is to reduce duplication of ethical review and to inform the development of a national system of single ethical review.

Each proposal for a multi-centre clinical trial conducted across the participating states will be ethically and scientifically reviewed once by a Public Health Organisation (PHO) HREC that has been certified by the National Health and Medical Research Council (NHMRC) in clinical trials.

PHOs will continue to undertake a site-specific assessment (SSA) of all research studies that are to be conducted at institutions under its control, in compliance with the relevant jurisdictional standard operating procedures. An SSA must be completed for all research projects to be conducted at sites under the control of NSW, Queensland and Victorian Public Health Organisations.

The commencement date for the introduction of the MOU between QH and Victoria was Monday 24 October 2011. The NSW Department of Health will now commence mutual acceptance for multi-centre clinical trials in public health organisation from 1 February 2012.

The MOU will not apply to retrospective approvals.

Scope of Mutual Acceptance Research

Clinical trials Excluded from the MOU

Certain research projects are excluded from Mutual Acceptance because of State specific requirements. The following clinical trials are excluded:

- Clinical trials involving persons in custody or staff of the jurisdictional Justice Health departments
- Clinical trials specifically affecting the health and wellbeing of Aboriginal people and communities
- Clinical trials requiring access to statewide data collections
- Clinical trials involving persons unable to provide consent and
- Clinical trials involving access to coronial material.

The above studies will continue to be reviewed under the current State arrangements. Researchers should contact their local jurisdiction if unsure of the process or require further detail.
Application information

Checklist for Coordinating Principal Investigators to submit with HREC applications

CPI PI Ethics Checklist 2012

Privacy forms

If consent is not being sought from participants and there is a request for the reviewing HREC to waive the need for informed consent for a research project in Victoria and New South Wales then the following must be completed:

☑ Victorian Specific Module - Section 3 must be completed if Victorian sites participate

☑ The NSW Privacy Form must be completed when NSW sites are participating: NSW Privacy Addition to National Ethics Application Form

☑ In QLD the Public Health Act (PHA) application is made after HREC approval using http://www.health.qld.gov.au/ohmr/documents/pha_info_app_form.doc

Read more from the REGU October 2011 e-bulletin.

Model for single ethical review of clinical trials (NSW Health, Qld Health & Victorian Department of Health)

Terms of Reference

Victorian Specific Module

NSW Privacy Addition to National Ethics Application Form

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