

Appendix 4

Australian Health Ethics Committee Bulletins

REVOKED

HREC Bulletin of The Australian Health Ethics Committee

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The HREC Bulletin is published by the Australian Health Ethics Committee (AHEC) as part of its support for Human Research Ethics Committees (HRECs). The primary purpose of the Bulletin is to inform HREC members of the work carried out by AHEC and to provide information about emerging issues. This Bulletin and previous issues are available online at <http://www.nhmrc.gov.au/issues/committeehumansupport.htm>.

Message from the Chair of AHEC

New Appointment to AHEC - Welcome Ms Bebe Loff

Following the resignation of Mr Robert Griew, Ms Bebe Loff was appointed to AHEC in November 2001 in the category of a person with understanding of health consumer issues. Ms Loff is a lawyer who currently holds a teaching position in the Department of Epidemiology and Preventive Medicine at Monash University in Melbourne. She has taught aspects of law and medicine in both the law and medical faculties for a number of years, including a postgraduate course entitled "Health, Ethics and Human Rights".

Bebe was a temporary United Nations adviser assisting in the development of what became the UNAIDS guidance document entitled "Ethical considerations in HIV preventive vaccine research" (Geneva 2000). She is currently working on a project for the Department of Health and Ageing to devise ethical guidelines for preventive HIV vaccine trials conducted by Australian researchers. She has been a participant in the Global Forum on Bioethics in Research. During the late 1980s to early 90s Bebe was the Manager of the Policy and Legislation Review Unit of what was then the Health Department, Victoria, responsible for the legislative programs of Ministers of Health. She has been a member of numerous community-based organisations including Fitzroy Legal Service, the

Health Issues Centre, Women Against Rape, Feminist Lawyers and the Prostitutes Collective of Victoria. She has been a member of two hospital ethics committees and is a correspondent for the medical journal "The Lancet".

News for HREC's

HRECs and Public Accountability

HRECs and their institutions will have received and considered AHEC's proposed policy on public access to information about HRECs. The development of that draft policy reflects a recognition that openness and transparency in the ethical review of research involving humans contributes to public confidence in that process.

AHEC believes that HRECs have an important role in fostering a culture of public awareness of such research, its goals and methods and the reasons for and focus of ethical review. HRECs may choose to consider sympathetically requests for people to attend their meetings as observers or to speak to community groups about the ethical review of research.

AHEC is aware that some HRECs publish their own annual reports, contribute to their institution's annual report, and/or have information on a website. This transparency is applauded and AHEC encourages all HRECs to consider these avenues for providing information to the Australian community.

AHEC would value receiving copies of HREC annual reports and advice of examples of websites containing HREC information.

Blood / tissue samples for research

AHEC is aware that, with increasing frequency, research participants are being asked to consent to the taking of samples of human tissue or blood for present and future research use without being fully informed of the nature of that future use. Consent forms that seek approval for a future use, without adequately specifying that future use, raise a number of questions:

- Can consent conform to the requirements of paragraphs 1.7 – 1.9 of the National Statement if the participant does not know fully the future intended use?
- Could requiring consent to unspecified future uses, as a condition of participation, be coercive contrary to paragraph 1.10 of the National Statement?
- What control will the participant and researcher have over the sample(s) in the future?
- Will samples be de-identified and is this in the best interests of the participant?

Further, paragraph 15.8 of the National Statement authorises HRECs to decide to waive the requirement for consent to research with human tissue in certain circumstances. These include the need to decide when a research project is an extension of, or closely related to, a previously approved research project.

Other issues that may need consideration are:

- The basis on which tissue banks are established, the rules of their operation and how commercial interests are addressed.
- Costs associated with obtaining sample(s).
- Potential for identifying non-paternity that participants may unwittingly discover.
- The global nature of information transfer and the potential for breach of privacy.

Responses to these questions need to be considered carefully by each HREC and their institutions. It is for them to decide what conditions need to be satisfied before proposals for collection of tissue for research are approved.

Where consent is to be sought for such research, an HREC needs to be satisfied that sufficient information is provided to meet the requirements of paragraphs 15.4 -15.7 and, where there will be genetic research, paragraphs 16.9 – 16.11, of the National Statement. Examples of the matters that an HREC might consider relevant include:

- Whether the sample will be destroyed on completion of the research;
- Whether the use of the sample could reveal non-paternity or non-maternity;
- Whether the sample will be used and stored in an identifiable, potentially identifiable or de-identified form;
- Whether the consent will permit the sample to be used for future research related to the initial study and/or future unrelated research;
- Whether participants will be advised if further research is conducted;
- Whether participants will receive results of the research, with or without counselling;
- Whether participants' medical advisors are to be informed of the study results that relate to participants' families;
- Whether identifying genetic information will be released to a third party, including family members with or without consent.

The use of a separate information sheet and consent form for the tissue study where it is associated with other research, such as a pharmaceutical drug study, can be an effective response to concerns about coercion.

Where consent is to be waived, HRECs need to be satisfied that all of the elements of paragraphs 15.8 and, where applicable 16.13, are satisfied.

House of Representatives Standing Committee on Legal and Constitutional Affairs review of AHEC's report "Scientific, ethical and regulatory considerations relevant to cloning of human beings".

Dr Wooldridge referred AHEC's report *Scientific, ethical and regulatory considerations relevant to cloning of human beings*, to a Parliamentary committee of inquiry in August 1999. The terms of reference for the review were simply to review AHEC's report. The Standing Committee on Legal and Constitutional Affairs (the "Andrews Committee") took written and oral submissions from interested parties over a two-year period. The final report was tabled in September 2001, some two years after commencement of the review.

The Report contains 15 recommendations. Of these, 12 involve the Commonwealth legislating to: regulate human cloning and stem cell research; ban the cloning of humans for reproductive purposes; and establish a national licensing body to regulate any research involving the isolation, creation and use of embryonic stem cells. The remaining recommendations: seek AHEC involvement in monitoring scientific developments in this area; call for an independent review of the human research ethics committee system; and require all Commonwealth departments to seek advice from the licensing body on any issue relating to the use of human reproductive material, embryonic stem cell research or cloning research.

AHEC is preparing a response to this report, which will become part of the response of the NHMRC.

The report of the Andrews Committee is available on the web at:
<http://www.aph.gov.au/house/committee/laca/previnq.htm>

Contact: Ian Denley 02 6289 9802

Recent AHEC Progress

Guidelines approved under Section 95A of the Privacy Act 1988

The NHMRC *Guidelines approved under Section 95A of the Privacy Act 1988* (s95A Guidelines) will come

into effect from 21 December 2001, in line with the implementation of the Commonwealth *Privacy Amendment (Private Sector) Act 2000*.

Guidelines issued by the Office of the Federal Privacy Commissioner (OFPC) will also be important for ensuring privacy is protected in the conduct of research generally. OFPC Guidelines are available from www.privacy.gov.au.

The s95A Guidelines will need to be applied by HRECs when reviewing research, statistical or health service management proposals that involve the collection, use or disclosure of identifying health information where consent is not sought from the individual concerned. HRECs should note that the review of health service management proposals is only required where it is proposed to undertake an initial collection of health information without consent.

From 19th December 2001, the Guidelines will be on the NHMRC web site at **www.nhmrc.gov.au**. AHEC will send all HRECs a copy of the guidelines in January 2002. AHEC will also provide information on the details to be recorded by HRECs when reviewing proposals using the s95A Guidelines. This information will be important for annual compliance reporting purposes and will feed into the larger evaluation of the Commonwealth privacy legislation, which is to be undertaken in two years.

Given the complexity of the new private sector privacy legislation and the added responsibilities of HRECs under the s95A Guidelines, it will be essential that AHEC properly monitors and evaluates the operation of the s95A Guidelines.

The AHEC Privacy Working Group is currently developing a brief plain-English document on privacy regulation in Australia. This document will outline the critical factors for researchers and HRECs to consider in deciding when and how to apply the Commonwealth privacy legislation and associated guidelines when preparing and reviewing research proposals. The document will also briefly highlight relevant State/Territory legislation.

AHEC is also proposing to hold a series of national workshops in the first half of 2002 focussing on privacy.

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Australian Health Ethics Committee review of the NHMRC Ethical guidelines on assisted reproductive technology (1996)

In September 2001 AHEC established a working party to review the 1996 *Ethical guidelines on assisted reproductive technology*. The review is to be completed in the current triennium. A round of public consultation has been completed and the working party is considering a range of issues including:

- the strengths and weaknesses of the guidelines;
- emerging issues in assisted reproductive technology including research on embryos and the development and use of stem cells derived from embryos;
- practices currently prohibited which should be either no longer prohibited or should remain prohibited;
- practices that have emerged since the 1996 guidelines and which should be either prohibited or authorised;
- whether guidance on clinical practice and on research should be separate or combined in one set of guidelines; and
- the role of HRECs in reviewing proposals for clinical practice and/or research.

Contact: Ian Denley 02 6289 9802

2002 National Workshop Series

AHEC has commenced work on the next series of workshops with privacy as the focus. Information will be sent to HRECs and posted on the website as it comes to hand.

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Protection of Human Genetic Information Inquiry

In the last Bulletin, it was reported that AHEC is conducting an inquiry jointly with the Australian Law Reform Commission into the protection of human

genetic information. The issues paper for this inquiry has been released and can be downloaded from www.alrc.gov.au. Printed copies are available at no charge from the ALRC, 131 York Street, Sydney or (02) 9284 6333.

Public consultations have been held in Melbourne, Hobart, Perth, Adelaide and Brisbane. Further consultations in other capital cities and regional centres will be conducted early in the New Year. Information about consultation venues and dates can be obtained from www.alrc.gov.au.

AHEC encourages HRECs to examine the issues paper and to consider making submissions to this important inquiry.

Other useful information

The NHMRC Gene and Related Therapies Research Advisory Panel

The Research Committee, a principal committee of the NHMRC, established the Gene Therapy Committee in June 1993. This committee was renamed the Gene Therapy Research Advisory Panel in 1997 and has recently been renamed the Gene and Related Therapies Research Advisory Panel (GTRAP).

Part of GTRAP's role is to assist HRECs in their assessment of research proposals involving human somatic cell gene therapy and related issues, including xenotransplantation. HRECs give the final approval and monitor gene therapy studies under their jurisdiction.

HRECs have been advised not to approve studies involving xenotransplantation without GTRAP input. National guidelines for xenotransplantation are presently being formulated by the NHMRC, however, GTRAP will continue to advise HRECs on xenotransplantation research proposals until those guidelines are developed.

Further information about GTRAP's membership and work program can be found at <http://www.nhmrc.gov.au/research/gtrap.htm>.

Contact: Helen Willimott 02 6289 9806

2001 National Workshop Series Questions & Answers

Continuing our series of questions and answers from the 2001 workshops.

Question: If a patient withdraws from a clinical trial, is it ethical to continue to collect information from the patient medical record for the purposes of the trial?

Answer: It should be made clear to the patient, at the commencement of a trial, what information regarding the patient will be collected. It should also be made clear to the patient what "withdrawing" from the trial means. Hence, the ongoing collection of information after the patient has withdrawn from a trial will be determined by the consent given by the patient at the commencement of the trial or at the time of withdrawal. In some circumstances it is legally permissible to use patient information without consent for the purposes of research if approval for this activity is given by the HREC. However, this situation can be easily avoided, and the welfare of the patient fully protected, by providing the patient with full information at the commencement of the trial and obtaining appropriate consent.

Question: Will the National Statement be updated in compliance with the new privacy legislation? Is there a possibility the Statement will exempt medical research from the legislation?

Answer: The National Statement will not be specifically updated to accommodate the Commonwealth *Privacy Amendment (Private Sector) Act 2000* which will come into effect on the 21 December 2001, nor will it exempt medical research from the legislation.

Chapter 18 of the National Statement will continue to be the source of general guidance on the protection of personal information in the conduct of research. However, the NHMRC *Guidelines under Section 95 of the Privacy Act 1988* (s95 Guidelines) and the new *Guidelines approved under Section 95A of the Privacy Act 1988*

(s95A Guidelines) are designed to protect the privacy of personal information in prescribed circumstances (essentially, where access to or use of information is proposed without consent) and form part of the *Privacy Act 1988*. The s95 Guidelines apply to medical research (involving Commonwealth held data). The s95A Guidelines apply to research, statistical and health service management activities (involving data held by the private sector organisations).

For further information about the new NHMRC *Guidelines approved under Section 95A of the Privacy Act 1988* (s95A Guidelines), which will also come into effect on 21 December 2001, please refer to the article in this Bulletin under 'Recent AHEC Progress'.

The National Statement will be reviewed and revised in accordance with NHMRC policy on the review of guidelines ie. after five years.

Question: Recognising that HREC members spend many hours before and during a committee meeting, what are the issues relating to compensation, reimbursement or payment of HREC members?

Answer: HRECs members are appointed by, and act on behalf of, institutions. In accordance with paragraph 2.2 of the National Statement, "The institution or organisation must, when establishing an HREC, set out its terms of reference including its scope of responsibilities, relationship to non-affiliated researchers, accountability, mechanisms of reporting, and remuneration, if any, for members."

Consequently, it is the decision of individual institutions as to whether HREC members are remunerated for their contribution, for example, by payment of a sitting fee. It is recommended that, as a minimum, HREC members be reimbursed for expenses such as travel and parking. Anecdotal evidence suggests that currently a small number of Australian institutions pay a sitting fee to HREC members.

When deciding whether to provide payment that is more than reimbursement to HREC members, institutions would need to consider the respective status of employee and non-employee members and any potential for such payments to affect public perceptions of the integrity and independence of the ethical review of research.

Future AHEC meetings for 2002

The meeting dates for 2002 are as follows:

- 27-28 February
- 8-9 May
- 4-5 September
- 10-11 December

Reference materials for HRECs

The Australian and New Zealand Journal of Public Health recently published an article written by Dr Sandy Webb for AHEC "*Consent for the linkage of data for public health research: Is it (or should it be) an absolute pre-requisite?*" (2001 Vol. 25 No. 5). The abstract for the article is reproduced below.

Data linkage research is being conducted in an evolving and complex environment. The National Health and Medical Research Council's *Guidelines Under Section 95 of the Privacy Act 1988* and *National Statement on Ethical Conduct of Research Involving Humans* allow scope for such research to be legally and ethically acceptable, although conducted without consent. Although the *Privacy Amendment (Private Sector) Act 2000* will extend privacy requirements into the private sector and into the areas of health statistics and health service management, it is vital that valid and useful public health research will be allowed to continue in a broadly similar framework.

New HREC members may find useful references to current NHMRC and ethical issues including past issues of this bulletin at our <http://www.nhmrc.gov.au/> web-site.

Letters to the Editor

If there are issues that you would like to see discussed in future bulletins, please write or email to the AHEC secretariat. We would be happy to receive your questions, ideas or comments for consideration for publication.

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