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Report of the Review of the Role and Functioning of Institutional Ethics Committees

**Report to the Minister for Health and Family Services
March 1996**

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Executive Summary

A Review of the Role and Functioning of Institutional Ethics Committees (IECs) was announced on 17 August 1994 by the Minister for Human Services and Health, the Hon. Dr Carmen Lawrence. The Review was established in response to concerns surrounding the clinical trials of the RU486 drug and with specific reference to recommendation 10 of The Inquiry into the use of Pituitary Derived Hormones in Australia and Creutzfeldt-Jakob Disease (The Allars Report).

The Review was charged with examining the way in which ethics committees operate, paying particular attention to reproductive technology and informed consent. The Review was asked also to consider existing arrangements for monitoring ethics committees and guidelines produced by the National Health and Medical Research Council (NHMRC). The Terms of Reference of the Review did not provide for the investigation of particular ethics committees.

It is important to observe that IECs are not the sole repository of ethical conscience in the institutions of this country. The Review Committee acknowledges that hospitals, universities, research institutions, government departments and professional associations have published codes of ethical practice and have introduced other initiatives to encourage, and better develop, the existing responsible attitude to research in this country.

The evidence presented to and considered by the Review Committee supports the fundamental role and operation of the current IEC system which is to protect the rights and interests of the subjects of research. The Review Committee does not recommend the introduction of any new structures to safeguard the rights and interests of research subjects. The Report does recommend the need for some improvement and reform of the current IEC system. In particular, the Report recommends alteration to the current membership of IEC's, that they are better resourced with improved record keeping, improved monitoring mechanisms and more defined accountability. The importance of fostering an ethical culture in research through education of ethics committee members (including ongoing training and skills development) and researchers is also emphasised.

Extensive public consultation was undertaken generating significant public interest and response. Public submissions have assisted greatly the Review Committee's work and report.

The Review Committee liaised with the Australian Health Ethics Committee (AHEC) of the NHMRC during its deliberations. A number of the matters under consideration by AHEC were directly relevant to the Review Committee particularly the monitoring of research by IECs and the conduct of multicentre research. As part of its consultations on these matters, AHEC held a series of National Workshops in May - June of this year in most State capital cities. Information and advice from these Workshops informed the recommendations of the Review Committee.

Summary of Recommendations

The Recommendations of the Review Committee are listed here according to the organisation to which they are directed.

To the National Health and Medical Research Council

- An IEC should be provided with proper resources to cover the development and publication costs of a Manual of Procedures for IECs. (Recommendation 11, section 5.4)
- The AHEC secretariat should be expanded to include a full-time IEC support officer. (Recommendation 18, section 8.2)

To the Australian Health Ethics Committee

- The *Statement on Human Experimentation* should be amended to reflect that the systematic use of an innovative treatment or therapy be considered to be research and subject to assessment and overview by an IEC.
 - a) Where a particular experimental treatment/intervention is expected to benefit an individual patient it may be considered to be innovative practice rather than research. Where this is the case, the treatment should be governed by doctor-patient ethical considerations.
 - b) Where any innovative therapy/intervention is trialed on more than one patient, or undergoes some other form of systematic investigation it should be presented for similar ethical assessment to any other research protocol. (Recommendation 1, section 4.2)
- AHEC should revise Supplementary Note 1 to the *Statement on Human Experimentation* and the additional guidelines on monitoring to recognise a tailored approach to monitoring. (Recommendation 4, section 4.9)
- The annual IEC compliance report to AHEC should require details of monitoring arrangements. (Recommendation 5, section 4.9)
- The meeting procedures listed in the current *Statement on Human Experimentation* should be re-drafted to provide a detailed statement consistent with section 5.1 of this Report. (Recommendation 6, section 5.1)
- The *Statement on Human Experimentation* should be amended to recognise the acceptability of expedited review. (Recommendation 9, section 5.3)
- AHEC should supervise the preparation of a Manual of Procedures for IECs following the re-drafting of the *Statement on Human Experimentation and Supplementary Notes*. (Recommendation 10, section 5.4)
- In the revision of the *Statement on Human Experimentation*, IEC membership requirements should be re-written in accordance with section 6.1 of this Report. (Recommendation 14, section 6.1)

- AHEC should develop a statement of core competencies for IEC members to assist in the development of courses for their in-service training. (Recommendation 15, chapter 7)
- AHEC should revise its current IEC Compliance Form and require annually the following information from IECs:
 - membership/membership changes;
 - number of meetings;
 - confirmation of full participation by minimum required members;
 - confirmation of due procedures
 - number of rejections and reasons for rejections
 - monitoring procedures in place and any problems encountered;
 - complaint procedures;
 - number of complaints handled.
 (Recommendation 2.1, section 9.3)
- AHEC should revise the *Statement on Human Experimentation*, under a new title to reflect all health research involving humans with due regard to relevant recommendations in this Report. (Recommendation 22, chapter 10)

To Institutional Ethics Committees

- The establishment of regional ethics committees is not recommended. (Recommendation 2, section 4.7)
- IECs should continue to develop mechanisms for improving the efficient consideration of multicentre research protocols; for example, through increased communication between IECs, by accepting a single technical assessment of research and through greater administrative consistency. (Recommendation 3, section 4.7)
- An IEC must not approve a research project unless it is satisfied that appropriate procedures providing for information to potential subjects and obtaining their voluntary consent are in place. (Recommendation 7, section 5.2)
- IECs with small workloads should consider the possibility of amalgamation with another, or other, IECs. (Recommendation 19, section 8.3)
- IECs should produce an annual report or contribute to the annual research report of their institution. This report should include the compliance information forwarded to AHEC and a listing of all research approved by the committee. (Recommendation 20, section 9.1)

To Institutions which have an established IEC

- All institutions with an IEC must nominate an independent complaints handling officer. (Recommendation 12, section 5.5)
- Institutions should make available sufficient (ongoing) funding to enable its IEC members to avail themselves of opportunities for relevant in-service training and development. (Recommendation 16, chapter 7)

- Institutions should ensure the provision of adequate resources for their IECs. A new IEC should not be established unless the institution can provide adequate means for resourcing the committee. (Recommendation 17, section 8. 1)

To Researchers

- All consent forms and information sheets provided to research subjects should be written in plain and accessible language. (Recommendation 8, section 5.2)
- The name and contact details of the complaints handling officer should be given to research subjects together with the procedures for raising concerns or obtaining additional information on the project. This should be provided when information on the research is first provided, should be in a form that the subjects can take away and should be additional to, and separate from, the consent and project information documentation. The *Statement on Human Experimentation* should be amended to provide for this. (Recommendation 13, section 5.5)

To the Minister

- That this report be published and disseminated broadly. (Recommendation 2-31, chapter 10)

Terms of Reference and Membership

This Independent Review of the Role and Functioning of Institutional Ethics Committees (IECs) in Australia was initiated by the Commonwealth Minister for Human Services and Health, the Hon. Dr Carmen Lawrence, in August 1994.

The Review was chaired by Professor Donald Chalmers, Professor of Law at the University of Tasmania and current Chair of the Australian Health Ethics Committee. Other members included Sister Regis Mary Dunne, former Director of the Queensland Bioethics Centre and currently ethics consultant to the Mater Research Institute; Professor Robert Finlay-Jones, Professor of Forensic Psychiatry at the University of New South Wales; and Ms Moira Rayner, former Victorian Human Rights and Equal Opportunity Commissioner and currently consultant to Dunhill Madden Butler Solicitors and Notaries of Melbourne. Secretariat support was provided by the Federal Department of Human Services and Health.

The Review Committee was requested by the Minister to:

- investigate the operation of existing arrangements for IECs, particularly in terms of their appropriateness for the discharge of IECs' responsibilities under the Clinical Trial Notification (CTN) scheme;
- consider the suitability of the existing arrangements for monitoring of IECs by the Australian Health Ethics Committee of the National Health and Medical Research Council;
- make recommendations on any changes which need to be made in the NHMRC Guidelines on Human Experimentation, in the operation of IECs and the level and degree of support required for IECs to operate effectively;
- have special regard to issues of concern to women, particularly in trials relating to reproductive technology; and
- examine and report on recommendation 10 of the Report of Inquiry into the Use of Pituitary Derived Hormones in Australia and Creutzfeldt-Jakob Disease (the Allars Report).

The Review Committee was not requested to investigate the functioning of individual Institutional Ethics Committees.

Review Procedures

The Review was conducted between August 1994 and November 1995. During this time the Review Committee met 9 times (4 by telephone conference). At its first meeting the Committee initiated the public consultation required by its terms of reference. An invitation to provide submissions to the Review appeared in 9 major State and Territory newspapers on Saturday 10 September 1994 (see Appendix 1) and was included as a flyer with the Australian Health Ethics Committee (AHEC) Newsletter which was sent in September 1994 to approximately 1770 subscribers. All institutional ethics committees (IECs) registered with AHEC were invited to make a submission as well as a number of community organisations, State Public Guardians and individuals identified as having an interest in the area. The Review Committee established a toll free telephone number to facilitate the receipt of submissions.

The closing date set for submissions was 15 December 1994, but submissions continued to be made throughout the Review and these have all been considered by the Committee. The consultation process generated interest from people and organisations encompassing a range of perspectives and 163 formal submissions were received as well as 25 confidential calls on the toll free number. The submissions raised a wide range of issues and have significantly assisted the Committee's work. Public submissions referred to experiences in the ethics committee system and additional literature (including guidelines of individual IECs and procedural manuals).

Information on the Review was also forwarded to the World Medical Association, the World Health Organisation and contacts in Canada, New Zealand and the UK with a request for information on similar reviews and/or other ethics review systems. Information was provided to the Review on the ethics committee systems in these countries.

The Australian Health Ethics Committee provided assistance and information to the Review Committee. In May-June 1995 AHEC (with funding from the Australian Health Ministers Advisory Council) conducted a series of National Workshops for members of IECs, researchers, research subjects and interested community groups. The Workshops were conducted in all State and Territory capitals except Darwin. The major topics discussed in all Workshops, monitoring of research and multicentre research, were the subject of specific reference to the Review Committee and a report of the Workshops was provided as a submission to the Review. In addition, AHEC invited the Review Committee to be involved in the Workshops and a presentation outlining the progress of the Review and major issues before it was made in each city. This prompted additional submissions to the Review from some delegates to the Workshops.

In addressing its Terms of Reference the Review Committee maintained contact with AHEC. A number of the matters AHEC is investigating are relevant to the Review and it was seen to be important to avoid duplication. The Research Ethics Standing-Committee (RES) of AHEC carries particular responsibility for the national system of IECs. Consequently the Chair of the RES, Dr Robert Loblay, was invited to attend selected Review Committee meetings. The Australian Health Ethics Committee provided relevant reports and information about the current operation of the IEC system including common and recurrent IEC concerns.

Advice from individuals on particular aspects of the report was obtained, for example, information on vulnerable populations from State Offices of the Public Guardian. A limited consultation was carried out which provided comments on exposure drafts of this Report.

The Review had access to a range of published literature, including articles and guidelines on international ethics committee arrangements (see bibliography).

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Acknowledgments

The Review Committee wishes to acknowledge the valued contribution of all those who provided submissions, additional information or comments on drafts of this report.

The Committee would also like to note their appreciation for contributions by the following international correspondents who provided information on other national systems of ethics:

Ms Melanie Gudsell, Ethics Committee Secretariat, Ministry of Health, Wellington;

Professor Grant Gillett, Bioethics Research Centre, University of Otago, and member of the National Committee;

Professor Ian Kennedy, Centre for Law and Medical Ethics, Kings College, London;

Dr Bessie Borwein, University of Western Ontario, Canada; and

Derek Jones, JD, Acting Director, National Council on Bioethics in Human Research, Canada.

Thanks is also extended to:

Dr Robert Loblay, Chairperson, Research Ethics Standing-Committee of AHEC; and

Ms Karen Hutchinson, Executive Secretary to the Review, for work on this report.

Abbreviations

AHEC	Australian Health Ethics Committee
AHMC	Australian Health Ministers Conference
ARC	Australian Research Council
ART	Assisted Reproductive Technologies
CIOMS	Council of International Organisations of Medical Science
CJD	Creutzfeldt-Jakob Disease
CTN	Clinical Trial Notification (Scheme)
CTX	Clinical Trial Exemption (Scheme)
FPV	Family Planning Victoria
IEC	Institutional Ethics Committee
IRB	Institutional Review Board (USA)
LREC	Local Research Ethics Committee (UK)
MRC	Medical Research Committee of NHMRC
MREC	Medical Research Ethics Committee
NCBHR	National Council of Bioethics and Human Research (Canada)
NHMRC	National Health and Medical Research Council
NBCC	National Bioethics Consultative Committee
REB	Research Ethics Board (Canada)
RES	Research Ethics Standing-Committee of AHEC
TGA	Therapeutic Goods Administration
WHO	World Health Organisation

Part A

1. Introduction

This Report is not intended as a definitive and comprehensive guide to the institutional ethics committee (IEC) system of this country. It is a report on the Terms of Reference issued by the Minister for Human Services and Health, the Hon. Dr Carmen Lawrence.¹

Ethical considerations are an inseparable component of decision making in health research and health care. The national system of IECs is one part of a broader system of ethical review. IEC review is the most visible form of ethical review for health research involving humans. All human research relating to health that is funded by the National Health and Medical Research Council (NHMRC); conducted by an institution which receives NHMRC funding; or approved under the Clinical Trial Notification Scheme has to be conducted in accordance with NHMRC Guidelines requiring review by a properly constituted IEC.

The NHMRC *Statement on Human Experimentation and Supplementary Notes (1992)* is a national standard for the conduct of ethical research in Australia. The Statement informs IECs on issues to be considered in assessing research protocols and specifies the composition and functions of IECs. Where research is conducted without appropriate IEC review, the NHMRC may withdraw funding from the researcher or the institution where the research is being conducted.

Importantly, the process of IEC approval of research projects is no longer restricted to those funded by the NHMRC. It is now wide-spread practice for bodies funding research to require the protocol be presented to an ethics committee for approval. The Australian Research Council (ARC) as well as other funding bodies require such approval. In addition major hospitals and universities generally require all research on humans conducted within or by members of their institution to be presented for IEC approval. In the case of universities this may include student projects.

A strength of the IEC system in Australia has been that the ethics committees have been established and resourced by the institutions (hospitals, universities etc) hosting research and their role has been to support ethically informed research. In Australia the IEC ethical review system promotes ethically responsible research by maintaining the co-operation of host institutions and researchers and by promoting discussion and education on ethical issues.

The core composition of IECs, their functions and their roles are set out in the *Statement on Human Experimentation and Supplementary Notes* issued by the NHMRC. In developing these guidelines AHEC recognised that individual IECs are best placed to approve and monitor individual research projects. They best understand the local factors that impact on research, the capacity of the institution to support the research and the social and cultural factors of relevance to research subjects. They are also well placed to interact with a research applicant and to perform an educative role within the institution.

The growing ethical culture has resulted in a progressive broadening of the scope and types of research that is submitted for ethics approval. Initially the focus was on human experimentation in a medical context but this has expanded to include population health

research and research undertaken in the social sciences. This trend continues. In recent years ethical review has broadened beyond research into health care towards consideration of the ethical issues involved in innovative therapy. Positive educative approaches to ethical review by IECs are as important in health care as in health research.

The IEC system in Australia continues to develop but it may benefit from review and improvement. It was observed in 1988 that, "I would be the last person to say that the Australian regulatory system based on IECs, and evolved over the last 10- 15 years, is perfect. But it does, ... cope with many problems and provide a secure base for future developments."² This comment from the former chair of the Medical Research Ethics Committee (MREC) remains pertinent to the operation of the IEC system.

Ethical Review in context

The Australian IEC system has not developed in isolation and does not exist in a vacuum. It should be considered as one part of an evolving international culture of ethical awareness which can be seen to be active on a number of levels including:

(i) International

A formal recognition by the international community of the ethical principles that should guide research involving humans can be traced to the development of the Nuremberg Code in 1946. This code formed the basis of the Declaration of Helsinki which was adopted by the World Medical Assembly in 1964 and has since been widely accepted throughout the world. Central to the philosophy of the Declaration is the statement that the interests of the individual research subject must always prevail over the interests of society and science.

The Declaration of Helsinki has also been adopted by the Council for International Organisations of Medical Science (CIOMS). The Council has an increasing influence in the international promotion of high ethical standards in research practice. Guidelines prepared by CIOMS have been widely promulgated and accepted by disciplines outside of medicine. Guidelines prepared by the Council include *International Ethical Guidelines for Biomedical Research Involving Human Subjects (1993)* and *International Guidelines for Ethical Review of Epidemiological Studies (1991)*.

(ii) National

Many countries have taken an active role in promoting an ethical culture of research by developing national guidelines and a system of review to ensure the conduct of ethical research. In Australia, AHEC, a principal committee of the NHMRC, is responsible for developing guidelines on ethical research practice involving humans and these guidelines are issued by the NHMRC. Bodies such as the ARC and the Committee of University Pro-Vice Chancellors for Research have contributed to the development of ethical standards in research.

Appendix 3 of this report includes some details of the systems that operate in the United States of America, Canada, the United Kingdom and New Zealand. All these countries have established committees to review the ethical aspects of research projects involving humans. In Canada there are proposals to merge small IECs while in New Zealand a new system of regional IECs has been established.

(iii) Professional Standards

The research culture has been progressively reinforced through the promulgation of codes of ethical conduct in research (by institutions, universities or national bodies such as the ARC), declarations of good professional practice, education and training, and codes of professional ethics. Good professional practice standards protect research subjects. Peer pressure and review, quality assurance mechanisms within an institution and good research standards all contribute to the protection of subjects in research and the promotion of an ethical culture in which to do research.

(iv) Local IECs

Australia has an established national system of IECs the primary function of which is to protect subjects in research by reviewing research proposals prior to their commencement. The system is dependent on the voluntary and unpaid contributions of the committee members. Institutions in Australia were not required by the NHMRC to have ethics committees prior to 1976. However, several larger institutions had what could loosely be termed ethics advisory committees in the late 1960s. In this sense, Australia has been proactive in addressing issues relating to the ethical conduct of research. By contrast, the United States developed a system of ethical review as a response to some scandals and poor research on humans publicised by a Harvard University professor. The larger Australian institutions have developed their own rigorous standards for the review of research and at the present time provide striking examples of best practice in the development of their procedures and in their sophisticated review of complex ethical issues.

Background to the Review: RU486 and the Allars Report

The establishment of this Review was effected in the context of the Family Planning Victoria (FPV) trials of RU486 in 1994 and the release, in the same year, of the *Report of the Inquiry into the use of Pituitary Derived Hormones in Australia and Creutzfeldt-Jakob Disease (CJD)*³ by Professor Margaret Allars (the Allars Report). Response to these, particularly in regard to ethical review and the operation of ethics committees in Australia, provided the impetus for this Review.

The FPV trials of RU486 formed part of an international multicentre study to determine the effectiveness of various doses of the drug and was sponsored by the World Health Organisation (WHO - Trial No 92092). Although much of the controversy surrounding the trials related to ideological differences and concerns as to the appropriateness of the drug importation procedures, issues regarding the adequacy of the ethics committee review process were also raised. It should be noted that an independent review of the specific RU486 trials was conducted and has reported⁴. Specific issues relating to the trials will not be addressed in this Review⁵. The Terms of Reference of the Review Committee do require consideration and comment on the more general issues relating to consent and the adequacy of IEC review procedures (including issues of membership and decision-making).

The Allars Report raises fundamental issues for consideration by the Review Committee relating to monitoring of ongoing research, the distinction between clinical treatment and research and the importance of consent by, and the duty to warn, research subjects. The importance of the Allars Report and the level of concern

regarding practice in reproductive technology are reflected in Terms of Reference which require the Review to have "special regard to issues of concern to women particularly in trials relating to reproductive technology". The Review was asked to "examine and report on recommendation 10 of the Allars Report' which states:

"10. That the NHMRC

- review the Statement on Human Experimentation to ensure that:
 - it provides guidance with regard to decisions as to whether treatment in a therapeutic setting constitutes an experiment;
 - a procedure is developed by which such decisions are scrutinised and not left entirely to the treating medical practitioner
- Issue a Supplementary Note on Reproductive Technology Procedures which ensures that new procedures, including the use of drugs in new treatment regimes, are:
 - registered with the Health Ethics Committee of the NHMRC; and
 - approved by the institutional ethics committee of the institution in which the procedure is carried out; and
 - consent is made on the basis of full information regarding risks and outcomes as defined in the Supplementary Note 2 on Research on Children, the Mentally Ill and Those in Dependent Relationships or Comparable Situations".

It is worth noting that the pituitary hormones program was initiated at a time before the establishment of the IEC system; the presence of a potentially infective agent could not reasonably have been anticipated before the commencement of the Program; the use of these hormones was considered to be a treatment that had already been adopted overseas; and many of the issues raised in the Allars Report relate to poor practice in relation to the collection and use of damaged pituitaries. These issues are beyond the scope of this Review.

The Review

The Review Committee had available to it a wide range of evidence from public submissions, the NHMRC and published literature. It is important to emphasise the limits of this Review. This Review was asked to examine the efficiency and adequacy of the current IEC system in Australia. The IEC system falls under the umbrella of the NHMRC but now relates to health research involving humans in the wider sense. Some institutions have established IECs which do not consider health research but other forms of research involving humans. Many of these IECs have been established in conformity with the NHMRC *Statement on Human Experimentation*. Submissions to the Review emphasised that independence was an essential characteristic of ethical review of research. In terms of the IEC system, submissions noted problems involving increasing workloads. It is apparent that there exists great diversity in IEC role and function. The NHMRC Statement has provided guiding principles but not specific procedural advice for IECs. As a result, many ethics committees appear to be unsure of aspects of their role and lack detailed procedures. For example, some submissions referred to instances of health care involving innovative therapy which need not be considered by an IEC.

The evidence presented to the Review supports broadly the continuation of the current IEC system but with modifications to further develop and improve the system. In particular, for IECs, there is a need for modification of current membership requirements, more appropriate resourcing and improved record keeping arrangements, improved monitoring mechanisms and more defined accountability.

Footnotes

¹ Issues which are not included under the Terms of reference of the Review or which are not subject to a specific recommendation in this report, such as privacy, are not extensively reviewed. For more detailed information the reader is directed to the bibliography for general references. The Report of the 1995 Ethics Workshops prepared by the Australian Health Ethics Committee (AHEC) is particularly helpful and general inquiries may be directed to the AHEC Secretariat at the NHMRC Office in Canberra.

² Professor R Lovell, "The Present Systems of Institutional research Ethics Committees in Australia", in Monash University Centre for Bioethics, conference proceedings: Can Ethics be Done by Committee, November 1988 at p27.

³ M. Allars, *Report of the Inquiry into the Use of Pituitary Derived Hormones in Australia and Cruetzfeld-Jakob Disease*, report to the Minister for Human Services and Health The Hon. Dr C.M. Lawrence, June 1994, AGPS, Canberra.

⁴ Q. Bryce, C, Clarke, J. Funder, *Report of the R U486 Consent Review Panel*, November 1994, Family Planning Victoria Inc.

⁵ Ibid., This Report concluded that the Review Panel "...is confident that clients who entered the trial did so of their own volition.." and that "...the processes and procedures adopted ... were clearly adequate in terms of client information as the basis for informed consent ... The operation of the FPV Ethics Committee was within NHMRC Guidelines, but suboptimal given the sensitivities regarding ... RU486 in the wider community: any operational deficiencies, however, did not compromise the adequacy of the client information or the informed consent" pp 19-20.

Part B

The Current System of Institutional Ethics Committees

2. Background to Ethics Review of Research in Australia

This section discusses the development of ethical review of research with particular reference to the IECs established in accordance with the NHMRC Guidelines⁶. These committees operate within institutions which are governed by Regional, State and Commonwealth rules and regulations.

2.1 Ethics Review of Research in Australia

Ethical review of research in Australia has been evolving since the ratification of the Declaration of Helsinki in 1965.⁷ The ethics committee system began its formal development in 1976 when the first NHMRC *Statement on Human Experimentation* was amended making it a condition of NHMRC funding that applicants for grants be given ethical approval by an institutional medical ethics review committee. The ethics review system was intended to ensure peer review. There was a stipulation in the 1976 version of the Statement that the composition of these committees was to include one person not connected with the institution. The Australian system was not established as a reaction to identified problems but as a precautionary move. At that time there had been no reports of serious breaches of ethics in research in Australia of the kind documented in the United States by Professor Beecher.⁸

The formal structure of IECs was revised again in 1982 when the NHMRC issued a new *Statement on Human Experimentation* which included four Supplementary Notes. Supplementary Note 1 provided an expanded statement of the membership and functions of IECs. It required that they be composed of men and women reflecting different age groups including a person not associated with the institution; a minister of religion; a lawyer; a medical graduate with research experience; and a laywoman and a layman. Supplementary Note 1 established the functions of the IECs which were, in summary, to:

- consider ethical aspects of all proposed research projects;
- maintain surveillance of approved research;
- maintain a register of projects;
- establish and maintain communication with the Medical Research Ethics Committee (of the NHMRC).

2.2 Medical Research Ethics Committee (MREC) 1982-1991

The MREC was established in 1982 as a standing advisory committee to the Medical Research Committee within the NHMRC. The MREC was commissioned to keep the IECs under review and make recommendations to the Council on ethical principles in relation to human experimentation and the work of IECs. During its term the MREC placed emphasis on consultation with IECs and conducted a number of workshops⁹ which provided an opportunity for communication between IECs and to review IEC composition and function. During its operation the MREC played a distinguished role in the development of a coherent national system of IECs and made a significant

contribution to the work of individual IECs. That the Australian IEC system is well established is in no small measure attributable to the efforts of the MREC.

2.3 National Bioethics Consultative Committee (NBCC) 1988-1991

The NBCC was formed in 1988 by the Australian Health Ministers' Conference (AHMC), which consists of both Federal and State Ministers, to address ethical, legal and social issues arising from reproductive technology and the provision and delivery of health services in the area of assisted reproductive technology (ART). The NBCC was a consultative committee and its powers were limited to the making of recommendations to State and Federal governments through the AHMC, the Standing Committee of Attorneys-General in Australia and the Council of Social Welfare Ministers¹⁰.

The NBCC had the specific function to provide advice and to undertake studies as requested by the AHMC on ethical legal and social issues arising from reproductive technology, including: embryo experimentation and the bearing of children, biomedical and health related research, the application of scientific and medical technology and the provision and delivery of health services. During its operation the NBCC produced a number of major reports¹¹. These reports did not have any significant influence on the development of the national IEC system but were relevant to the work of IECs within hospitals conducting reproductive technology programs.¹²

2.4 Australian Health Ethics Committee (AHEC) 1991- Present

Background To The Establishment Of AHEC

In 1991 a report¹³ to the Minister for Community Services and Health concluded that advice to government on health ethics matters should be concentrated within a principal committee of the NHMRC. It was agreed that the new committee would take up many of the responsibilities of the NBCC and the MREC as well as providing ethical advice on matters that could flow from the other principal committees of the NHMRC.

The Statutory Basis Of AHEC

The NHMRC was established by Order-in-Council in 1936. In 1992, the *National Health and Medical Research Council Act*¹⁴ gave the NHMRC a statutory existence. The Australian Health Ethics Committee is mentioned specifically. Section 35 requires the Minister to establish principal committees called the Medical Research Committee and the Australian Health Ethics Committee. The composition, functions and independence of the Australian Health Ethics Committee were established. The characteristics and functions of AHEC are as follows:

- there are 12 members and a Chair on AHEC and appointment is the subject of Section 36¹⁵. This section specifies a nomination system which must take place from amongst peak bodies in relation to areas of expertise.
- AHEC must not have more than one member of the Medical Research Committee (MRC) of the NHMRC and its Chair must be a person who is not a member of the MRC.¹⁶
- Matters can be referred to AHEC for consideration by the NHMRC other principal committees of the NHMRC or from Commonwealth and State ministers.

- AHEC has the function of developing guidelines for the conduct of medical research involving humans and these guidelines are to be issued unchanged by the NHMRC¹⁷.
- Community consultation is a requirement under the Act which specifies a 2 stage public consultation process for guidelines. The first stage seeks public views on whether guidelines should be published in an area. The second stage requires that, if guidelines are to be issued, the guidelines themselves are circulated for consultation and advice.
- AHEC receives annual compliance reports from all registered IECs.
- These compliance reports are consolidated into an annual report to the Medical Research Committee (MRC) of the NHMRC with subsequent presentation to the NHMRC.

Footnotes

⁶ For a history of the background development of ethical approval of research see particularly -PM McNeill, *The Ethics and Politics of Human Experimentation*, 1993 Cambridge UP, London, S Dodds, R Albury, C Thomson, *Ethical Research and Ethics Committee Review of Social and Behavioural Research Proposals* Report to the Department of Human Services and Health, June 1994

⁷ For a background on the development of research codes see R Gillespie "Research and Human Subjects: an Historical Overview" in Monash University Centre for Bioethics, conference proceedings: *Can Ethics be done by Committee?* November 1988 (3).

⁸ H Beecher "Ethical and Clinical Practice", 1966. *New England Journal of Medicine* 274 pp1354-1360.

⁹ In 1984 it was decided that the MREC should review the operation of IECs throughout Australia and in particular consider the performance and effectiveness of the supplementary notes in relation to IECs, their composition and function. During 1984 and 1985 a series of workshops were held in the major State capitals dealing with the constitution and functions of IECs. *Report on Workshops on the Constitution and Functions of Institutional Ethics Committees in Australia 1984-85* November 1985 NHMRC. Further workshops were held in 1993 and 1995 under the auspices of the new AHEC.

¹⁰ See Robyn Layton QC "The Work of National Bioethics Committees in Australia: A History *Reproductive Health Matters*, No 2, November 1993. Robyn Layton QC was Chair of the NBCC and first Chair of the Australian Health Ethics Committee.

¹¹

- *Donor Gametes, Record-keeping and Access to Information*, June 1988;
- *Access to Information: An Analogy Between Adoption and the use of Gamete Donation*, December 1988;
- *Surrogacy Report No. 1*, April 1990;
- *Discussion Paper on Surrogacy 2 - Implementation*, October 1990;
- *Human Embryo Experimentation: Background Paper and Select Bibliography*, November 1990; and
- *Reproductive Technology Counselling, Final Report*, March 1991.

¹² The Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia will not accredit an institution conducting ART unless, amongst other things, there is operating a properly constituted IEC.

¹³ Report by Professor Paul Finn (now Justice Finn of the Federal Court) of the Research School of Social Sciences. ANU.

¹⁴ No. 22.5 of 1992.

¹⁵ Section 36 establishes the following membership: The Chairperson; a person with knowledge of the ethics of medical research; a person who has expertise in law; a person who has expertise in philosophy; a person who has expertise in religion; a person who has experience in medical research; a person who has experience in public health research; a person who has experience in social science research; a person who has experience in clinical medical practice; a person who has experience in nursing or allied health practices; a person with knowledge of the regulation of the medical Profession; a person with understanding of health consumer issues; a person with understanding of the concerns of people with a disability; no more than two other persons with expertise relevant to the functions of the Committee.

¹⁶ Section 35 (6).

¹⁷ Compliance with these guidelines is not enforced by law but it is a condition of NHMRC grants and of approval under the Clinical Trial Notification Scheme that applications be approved by duly constituted IECs. Other granting bodies also require compliance.

3. The IEC System: Functions And Composition

3.1 Functions

IECs are concerned with the ethical assessment of research activities. An IEC may only approve a research project if it is satisfied that the project is acceptable on ethical grounds. A primary focus of an IEC is to ensure that research subjects give effective consent to participation in research. The ethical principle of respect for persons guides the deliberations of an IEC. It is the right of an individual to decide whether to be involved in the research project. Consent is the central aspect of the NHMRC *Statement on Human Experimentation*.¹⁸

The IEC reviews a written description of the research to be undertaken which includes information on how consent is to be obtained, the selection criteria for research subjects, the research method to be employed, the risks and benefits to subjects in the research program and the perceived benefits of the research.

The functions of IECs are defined in Supplementary Note 1 to the NHMRC *Statement on Human Experimentation and Supplementary Notes* which appears in full at Appendix 2. An IEC must ensure that research projects are acceptable on ethical grounds and must monitor the projects to ensure that they continue to conform to the approved protocols. In doing this IECs are required to maintain a record of all proposed research projects including approval details, any changes to the protocol and action taken by the IEC to monitor the conduct of the research.

The NHMRC is responsible for maintaining communication with, and auditing the activities of, IECs to ensure compliance with this supplementary note. In turn, IECs are obliged to provide information from their records to the NHRMC on request.

In carrying out these functions Supplementary Note 1 requires IECs to:

- (i) conform with the NHMRC *Statement on Human Experimentation and Supplementary Notes* as published from time to time;
- (ii) while promoting the advance of knowledge by research, ensure that the rights of the subjects of research take precedence over the expected benefits to human knowledge;
- (iii) ensure that, in all projects involving human subjects and relating to health, the free and informed consent of the subjects will be obtained;¹⁹
- (iv) ensure that no member of the committee adjudicates on projects in which they may be personally involved;
- (v) ensure that research projects take into consideration local cultural and social attitudes;
- (vi) give its own consideration to projects that involve research in more than one institution;²⁰

- (vii) require the principal investigator to disclose any previous decisions regarding the project made by another IEC and whether the protocol is presently before another IEC; and
- (viii) determine the method of monitoring appropriate to each project.

3.2 Composition

Supplementary Note 1 also establishes the following minimum membership for a properly constituted IEC in Australia:

- laywoman not associated with the institution
- layman not associated with the institution (a layperson is defined as one who is not closely involved in medical, scientific or legal work)
- minister of religion (of any faith)
- lawyer
- medical graduate with research experience.

It requires an IEC be composed of men and women of different age groups and that members be appointed as individuals for their expertise and not in a representative capacity. IECs may appoint more than the minimum membership and may appoint persons to stand in for members when necessary.

The survey of IECs conducted by AHEC in 1993 confirmed that very few IECs operate on a minimum membership. There is some variation in the size of IECs with the majority (55%) in the range of 10 - 15 members (5% had 16 or more members while 40% had 10 or less members).

3.3 Current IEC Details

There has been a dramatic expansion in the number of IECs over the last five years. This cannot be attributed solely to NHMRC grant requirements as many IECs have been created in institutions which do not receive NHMRC funding. There is a growing ethical culture which requires proof of compliance and commitment to the highest ethical standards in research.

In November 1995, there were 188 registered IECs in Australia with the following approximate proportional distribution:²¹

- Hospital - 42%
- University - 23%
- Health Departments/Government - 17%
- Research Institutions - 8%
- Agencies - 7%
- Professional Associations - 3%

In addition to these registered IECs, AHEC is aware that some private hospitals and government departments with IECs have not registered with AHEC and do not provide an Annual Compliance Report to AHEC.

3.4 Diversity in the IEC system

IECs have been established (some for many years) in universities, large and small hospitals, research institutes and government departments. Most of the long established, busy IECs have promulgated detailed procedures and documentation (including standard forms of application); have a history of providing advice to researchers and demonstrate efficient and accountable administrative practices in meetings and record keeping. The practices and procedures of these committees can serve as a valuable resource to be shared with newer IECs.

Diversity in IEC function results from the purpose of each institution and the nature of the research it supports, as well as the authority, power and responsibility given to, or accepted (or assumed) by the IEC. Some IECs have a broad role providing an advisory, policy and educational function relating to matters of clinical practice and management. Such committees may only rarely consider research proposals. Not all "policy and practice" ethics committees follow NHMRC guidelines. This is dependent on the particular function of the committee and their reliance on public funds to support research activities. Some do so in order to retain the option of seeking public funds for research, or participating in multicentre clinical trials. The NHMRC has reflected this diversity by providing only minimum standards to IECs.

Footnotes

¹⁸ Is Principle 8, NHMRC *Statement on Human Experimentation and Supplementary Notes, 1992* states that "Before research is undertaken the free consent of the subject should be obtained."

¹⁹ Except in accordance with section 7 of supplementary note 6 to the *Statement on Human Experimentation*.

²⁰ An IEC is free to discuss a project with other IECs if it chooses, with due regard to confidentiality.

²¹ Proportions based on figures in Annual Compliance Reports to AHEC 1993 and AHECs *Report of the 1993 Workshops for institutional ethics committees (IECs), consultation with researchers and forum on IECs* December 1993.

Part C

Outcomes of the Review

4. The Role and Functions of IECs

4.1 The Role and Functions Generally

The fundamental role of an IEC is to protect research subjects from unethical research, whether in formulation or conduct. The NHMRC *Statement on Human Experimentation* no longer applies narrowly to medical experimentation but applies more widely to health research. The role of IECs has altered accordingly. IECs no longer consider only the ethical validity of experimentation involving humans but also research "on" or "about" humans. Other IECs have been established to offer policy advice to the institution. This expanding jurisdiction has dramatically increased the workloads of most IECs.

The number of IECs registered with the NHMRC has multiplied over the last decade. In carrying out their approval role many IECs in Australia assume an educational role towards researchers by allowing the researcher to address and discuss any ethical problems which may be involved with their research project. Consultation between IECs and researchers in relation to projects which involve difficult ethical problems is a process which tends to lead to the modification or withdrawal of a research project rather than its rejection. For this reason IECs approve a high proportion of research projects presented. This high approval rating is attributable to these procedures. It has been argued that the value of the IEC is its existence rather than the exercise of its powers to reject research protocols.²² The IEC has an important role in contributing, to and fostering an ethically responsible culture within its institution.

Submissions to the Review supported the diversity in IEC roles, but many of the submissions to the Review were concerned at the apparent lack of consistency between individual IEC decisions and administrative procedures. Several submissions suggested the desirability of standardised procedures for IECs. These submissions argued that standardised procedures should concentrate on monitoring ethical practice (the ongoing consideration) rather than approval of the research protocol (a one off consideration) and should address the different responsibilities of researchers and the institution. While acknowledging that the primary role of an IEC is the protection of research subjects, these submissions suggested that care should be taken not to frustrate research as a result of ever-increasing numbers of ethics committees and the institutional fears of litigation. It was felt that current procedures sometimes alienate researchers and prevent the prompt consideration of research protocols. The submissions were not in agreement on appropriate solutions.

4.2 Research, Experimentation and Innovative Clinical Practice

The Review's Terms of Reference required specific advice as to when treatment in a therapeutic setting may constitute experimentation.²³

At the present time innovative therapy does not require IEC approval whereas experimentation does. Innovative therapy in some institutions is referred routinely to an IEC for assessment or to a clinical practice committee (in hospitals) for consideration.

The Human Pituitary Hormones program, the subject of the Allars Report, was considered to be an accepted therapeutic treatment for infertility and growth abnormalities. The treatment was not considered to be experimentation. As already noted, the IEC system did not exist when the program was in operation. Even under the current system, it is unlikely that the program would be referred for IEC scrutiny. If similar programs are to be scrutinised in the future an expanded definition of research, which includes some innovative clinical practice, is required. This would enable IECs to become involved in reviewing both the information which goes to the patient and the essential question of consent.

The distinction between research, innovative clinical practice, psychological assessment, clinical treatment, quality assurance programs, evaluation of new procedures and surgical therapies is often unclear. It is difficult to draw boundary lines between these activities. Research necessarily involves IEC scrutiny of a defined research task, its methodology and consent procedures. Innovative treatment is largely at the discretion of the treating practitioner (who is likely to consult with peers) and is regulated by codes of ethics governing doctor-patient relationships. Innovative therapy does not require IEC approval or other independent assessment. The US Federal regulations define research as "a systematic investigation designed to develop or contribute to generalizable knowledge."²⁴ The Review Committee considers that any distinction which can be drawn should be based upon the systematic nature of research.

The CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects²⁵ defines research as a class of activities either contributing to generalisable knowledge or relating to its development. The World Medical Association Declaration of Helsinki (which appears as an appendix to the CIOMS Guidelines) endorses the legitimacy of practitioners trying new or innovative therapies in the course of their work:

"(In) ... the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, re-establishing health or alleviating suffering. ... The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods"

The distinction between innovative therapy and research is drawn helpfully and most clearly by the United Kingdom Medical Research Council²⁶ which differentiates research from other apparently similar types of investigations by focusing on the intent of the intervention. The guidelines draw a distinction between " ... a novel medical intervention *per se*, done with a view to the benefit (if it works) of the individual patient, and the same intervention carried out systematically on more than one patient". The guidelines propose that the first be "regarded as treatment governed simply by the normal doctor-patient ethical considerations, and the second as research, and therefore governed by additional ethical considerations." Under this definition the pituitary hormones program (and innovative therapies of a similar nature) would have required ethics committee scrutiny (as the systematic use of an innovative therapy) and been subject to ongoing monitoring of outcomes and procedures.

The Review Committee endorses for adoption by AHEC the United Kingdom Medical Research Council's distinction between innovative therapy/treatment and research.

Recommendation 1

The *Statement on Human Experimentation* should be amended to reflect that the systematic use of an innovative treatment or therapy be considered as research and consequently be subject to assessment and overview by an IEC.

- a) Where a particular experimental treatment/intervention is expected to benefit an individual patient it may be considered to be innovative practice rather than research, Where this is the case, the treatment should be governed by doctor-patient ethical considerations.
- b) Where any innovative therapy/intervention is trialed on more than one patient, or undergoes some other form of systematic investigation it should be presented for similar ethical assessment to any other research protocol.

4.3 Issues of Concern to Women

The Review Terms of Reference require it to "have special regard to issues of concern to women particularly in trials relating to reproductive technology" and to "examine and report on Recommendation 10 of the Allars report" (relating to the application and definition of innovative therapy and reproductive technology).

AHEC has established two Working Parties which are addressing issues of relevance to women: the Reproductive Technology Working Party, which was established in 1994 to revise Supplementary Note 4 (on in vitro fertilisation and embryo transfer) to the *Statement on Human Experimentation* and the Women and Clinical Trials Working Party, established in 1995 to advise AHEC on any necessary changes to current NHMRC guidelines and further action as appropriate.

The Review Committee is satisfied that the matters of concern identified by the Allars Report are being addressed directly by AHEC through these two Working Parties. For this reason, the Review makes no recommendations particular to women or relating to reproductive technology.

4.4 Social Science Research

The Review Committee received submissions which raised concerns about the use of NHMRC guidelines in relation to the review of research protocols in the social and behavioural sciences. In particular, concerns were raised about the present minimum membership of an IEC which requires a medical graduate with research experience but not a graduate in social or behavioural sciences. In 1986 the NHMRC *Statement on Human Experimentation* was amended to require approval by an IEC for health research. There was no alteration in 1986 to the minimum membership required for an IEC. The concerns raised in the submissions to the Review Committee are consistent with comments made during the IEC Workshops conducted by AHEC during 1993 and again in 1995. In addition the Review Committee consulted a major report prepared for the Department of Human Services and Health entitled *Ethical Research and Ethics Committee Review of Social and Behavioural Research Proposals* which was presented in 1994.²⁸ This Report stated that "there was wide-spread concern expressed by social and behavioural researchers about the suitability of expertise of IECs, as presently constituted, for the review of social research. The medical model of a research practice and problems was seen as inadequate. Many expressed the need

for changed membership to reflect suitably the expertise employed in social research and for extensive information and education of IECs about social research methodology and the frequently more complex and sensitive ethical issues which arise".²⁹

The submissions to the Review Committee argued that the best method for ensuring the competence of an IEC to assess social and behavioural science research projects was to appoint a person with experience in research methods in the social sciences to an IEC. The Review Committee is aware that some institutions have appointed members to their IECs with knowledge and experience in social science research. This is consistent with the NHMRC guidelines being minimum requirements which do not prevent the appointment of other members with relevant knowledge or competencies. Other institutions, particularly some of the teaching hospitals and the universities, have appointed Social Science IECs (either as subcommittees to the IEC or as separately constituted IECs). These institutions have recognised the distinctive characteristics of social and behavioural research and responded appropriately by extending membership or establishing differently constituted committees to ensure that social and behavioural sciences research projects are reviewed adequately and competently.

The Review Committee has made a specific recommendation in relation to the membership of an IEC which will require amendment of the current *Statement on Human Experimentation* (see chapter 6).

4.5 Cultural Issues

A small number of submissions addressed the role and function of IECs in multicultural Australian society. These submissions focused on confidentiality and the capacity of research subjects to understand and interpret research information and consent forms.

The Review Committee had little evidence on which to assess the performance of IECs in relation to ethnic and Aboriginal and Torres Strait Islander research subjects. It is essential that 'local' IECs dealing with this research address the perspectives of these groups. IEC decision-making must pay appropriate regard to the diversity of our community. Similar precautions should be taken by an IEC in the consideration of research projects involving individuals or groups from non-English speaking backgrounds. It is essential that in considering such research projects, the IEC ensures that the values of the group to be studied are respected and not offended. Primary responsibility rests with the researcher in ensuring that ethnic issues have been appropriately addressed. It is the responsibility of the researcher to demonstrate to the IEC that appropriate advice has been sought and relevant ethical issues have been addressed.

The *Interim Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research* (NHMRC) are well accepted and referred to by researchers and IECs. IECs dealing with this research need to be aware that there are a variety of cultural perspectives within the Aboriginal and Torres Strait Islander Community and of the need for specific community consultation and special consideration when ensuring effective consent.

The Review Committee considers that the NHMRC *Statement on Human Experimentation* should be revised to incorporate principles in the *Interim Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research*. In particular, the guidelines should address the need for an IEC to:

- take additional care in ensuring that consent is voluntary and that the research project is clearly understood;
- ensure that special regard is being paid to research subject confidentiality and privacy and that specialist advice on the subject group has been obtained; and
- ensure that proper consultation has been conducted with the research subjects/community as appropriate. In some circumstances this may involve co-opting persons representative of subjects as ad hoc members of an IEC.

4.6 Scientific Assessment

A major issue for consideration by the Review Committee was whether an IEC should be involved with a scientific assessment of the research protocol presented to it. Submissions to the Review differed on whether the role of an IEC should include an assessment of the scientific validity (methodology, safety etc) of a research proposal. Some argued that the focus should be on ethics and not methodology and cited examples of ethics committees rejecting research proposals because of an apparent bias towards particular research methodologies (this concern was prevalent among social researchers). Other submissions argued that ethics and science are inseparable, bad science being unethical.

All submissions agreed that it is not appropriate for an ethics committee to approve research that is methodologically unsound. However, a distinction needs to be made between the poor or inappropriate use of an established methodology and the use of new research methods with which the IEC may not be familiar. In the first instance this may constitute "bad science"; in the second, "innovative research". In either case, the ethics committee's responsibility is to research subjects through an assessment of the ethical appropriateness of the project. Where methodological or safety issues are relevant to this assessment, additional information should be sought by the IEC.

Principle 1 of the *Statement on Human Experimentation* states that "...research must conform to generally accepted moral and scientific principles." However, this principle goes on to state that ethical aspects of projects should be submitted for approval by an ethics committee. Supplementary Note 1 in paragraph 3 confirms that an IEC must ensure that ethical standards are maintained in research. The Statement and Supplementary Notes do not require an IEC to consider the scientific aspects of research. IECs consider ethical aspects of research and vary in the way they establish scientific merit.

4.7 Multicentre Research

A significant number of research projects are carried out at more than one centre. This collaborative research is known as 'multicentre research' and includes clinical trials of drugs as well as social science, epidemiology, health services and public health studies. Currently, researchers must gain the separate approval of the IEC at each institution in which the project is proposed. This requirement caused a number of major concerns expressed both in submissions to the Review and by participants at the 1995 AHEC Workshops.

Supplementary Note 1 to the *NHMRC Statement on Human Experimentation* requires that "All research projects involving human subjects and relating to health must be considered and approved by a committee constituted in accordance with this supplementary note". A footnote states that projects under consideration can be discussed between IECs as long as due regard is paid to confidentiality. It is unclear whether this guideline allows research conducted in one institution to be considered and approved by the IEC of another. As a result, usual practice for the assessment of multicentre research protocols is that each IEC considers each protocol separately, usually in isolation from other IECs considering the same proposal.

The current system poses problems for both researchers and IECs. Researchers are subject to delays in gaining the separate approval of a number of IECs and are often required to present the same information to the various IECs in different formats. This can lead to inconsistencies in process and decisions, with different IECs having different requirements and requesting different modifications to the protocol. For IECs there can be unnecessary duplication of effort with IECs at the various institutions giving separate consideration to the same protocol. Resources are already strained as the workloads of many IECs continue to increase in scope and volume.

A particular advantage of the current institutional process of ethical review is that it provides for assessment by multi - disciplinary committees that are familiar with the culture and capacities of individual institutions or organisations. The ethical review can consider local cultural and ethnic issues; knowledge of qualifications and expertise of individual researchers within the institution; knowledge of facilities and resources available within the institution for research; and the ability to monitor research within the institution. The separate consideration of proposals by IECs increases independence in decision-making and ensures that the institution's legal duty of care to the research subjects is satisfied. Each IEC is responsible for monitoring, the research within its institution.

Improving the Assessment of Multicentre Research

These problems could be addressed in a number of ways within the scope of existing NHMRC guidelines. Approaches suggested in submissions to the Review and discussed at the 1995 AHEC Workshops included: improved communication and cooperative arrangements between IECs; the acceptance by IECs of a single assessment of the scientific and safety/privacy aspects of a proposal; and encouraging administrative consistency amongst IECs.

(i) Communication and cooperative arrangements

Improved information sharing between IECs might result in a more streamlined assessment process for multicentre research. The current duplication of effort and the time spent by each IEC in assessing a multicentre proposal could be greatly reduced if IECs were able to discuss aspects of their assessments with one another.

Participants at the 1995 AHEC Workshops supported better communication between IECs and with AHEC. Good communication could facilitate the approval of multicentre research; promotion of training and education programs; sharing knowledge and advice between IECs; and collaboration and cooperation between committees.

The Review Committee considers that AHEC should encourage and continue to support IEC communication networks.

(ii) Single technical assessment

In assessing a research proposal, IECs are concerned principally with ensuring that the rights of the research subject take precedence over expected benefits to knowledge. An understanding of the scientific and safety or privacy aspects of a protocol is an essential component of this review. From the submissions, many IECs do not believe they have the necessary expertise to assess science and safety issues. In some cases, (particularly drug trials) IECs refer this function to other committees/experts within their institution.

IECs at participating institutions could collaborate to arrange a single assessment of the scientific and safety aspects of a research protocol. One submission noted that "... a central review of scientific merit could improve efficiency, decrease approval time, and take some of the burden from ethics committees and many subsidiary committees that have been formed at institutions (e.g., Drug Committees, Scientific Review Committees)". This approach could streamline the review process, reduce duplication of effort by IECs and allow more efficient use of the available expert opinion (particularly in areas such as epidemiology or pharmacology). The assessment, adequately documented, could be accepted by the IECs at the participating institutions, which would then conduct their own review of the other ethical aspects of the proposal. The single technical assessment could be conducted in a number of ways including the development of a composite scientific committee/s; the use of a coordinating IEC; or the establishment of ad-hoc expert panels (for example, through the Medical Research Committee of the NHMRC).³⁰

(iii) Administrative Consistency

Greater consistency in the administrative processes of IECs is desirable. Transparency of decision making is essential for collaborative decision making or recognition of a single IEC approval. Greater consistency in processes would both facilitate and result from the development of such transparency. Researchers need to know in advance what the ethical review process will entail and what documentation they need to submit. This need could be met by the development of a standard checklist of the information required from researchers.

As is evident from the submissions to the Review, some IECs have taken steps towards developing a standard application form to assist the submission and assessment of multicentre projects. While it is unlikely that a single comprehensive application form would be universally acceptable to IECs (for example to both hospitals and universities), a standard application form would be a useful tool for IECs.

Regional Ethics Committees

Some submissions suggested that a form of centralised committee approval for research, particularly for multicentre research, may be desirable. Suggestions ranged from the establishment of a 'peak' national IEC to the establishment of regional IECs akin to the UK Local Research Ethics Committees or the New Zealand Regional Ethics Committees. These considerations were made frequently in the context of multicentre research.

There are three broad considerations in relation to the development of regional IECs including:

- (i) Different types of research pose different problems. For example, clinical drug trials may present particular concerns for IECs choosing to use the assessment of another IEC. Institutions may be less willing to accept another institution's ethical clearance of a clinical trial, due to legal liability concerns and the more 'invasive' nature of the research. Alternatively, survey based research may more appropriately be considered by a single ethics committee, or a central committee composed of representatives of the centres conducting the research.
- (ii) The Australian IEC system has developed within individual institutions. Institutions may not wish to have their IEC relinquish its decision-making autonomy in favour of another committee with different expertise.
- (iii) There are important local issues which may be best considered by a particular IEC. IECs have a high degree of local expertise in particular research fields. These local issues range from the policies of the institution, the capacity of institutions to support research and knowledge of the population served by the institution.

The Review Committee is not in favour of establishing regional ethics committees³¹. The submissions and the 1995 AHEC Workshops support the view that issues relating to multicentre trials are being addressed without the establishment of a regional authority.

Recommendation 2

The establishment of regional ethics committees is not recommended.

Recommendation 3

IECs should continue to develop mechanisms for improving the consideration of multicentre research protocols; for example, through increased communication between IECs, by accepting a single technical assessment of research and through greater administrative consistency.

4.8 Clinical Trial Notification Scheme ³²

The Terms of Reference of the Review Committee requested an assessment of the appropriateness of the discharge of IEC responsibilities under the CTN Scheme. In general, submissions to the Review supported the CTN Scheme. However, concerns were expressed at the increase in IEC responsibility and in particular the increased demand for monitoring and the strain on already limited IEC resources. The need for education of members of IECs on CTN/X Schemes was stressed. Concerns were also raised in relation to the lack of relevant expertise (particularly toxicology) within IECs. Some submissions suggested limiting the types of protocols that could be considered under the CTN Scheme, others suggested limiting the assessment of CTN applications to accredited institutions/committees. IECs would benefit from additional information regarding the types of protocols that are appropriate to CTN and CTX review. CTN review should only be undertaken by an IEC where mechanisms are in place for comprehensive technical/safety assessment of the protocol.

The concerns relating to the increased workload and monitoring role of IECs due to assessing CTN applications requires comment. Several submissions recommended a central review of the scientific merit of clinical trials as an effective and efficient means to reduce the time for approval of new products and to relieve the workload on individual IECs. The proposal for IECs to rely on an external technical or safety assessment of research protocols is a major issue before the national IEC system and has been discussed previously in this report in relation to the conduct of multicentre trials.

At its commencement, there were considerable concerns about the implementation of the CTN Scheme³³ particularly in relation to potential legal liability. However, the introduction of the Scheme has been cautious and deliberative. Not all IECs participate. By a process of self selection only some fifteen IECs in large hospitals are undertaking significant involvement in the CTN Scheme. There has been a major increase in the workload of those IECs which have undertaken this type of work.

The submission from the Royal Australasian College of Physicians concluded that " ... the College believes that most IECs have developed appropriate mechanisms for working in the CTN system".

The Review Committee considers that IECs are able to discharge adequately their responsibilities under the CTN Scheme provided that information is made available to IECs as to the types of protocols that are appropriate to the CTN and CTX Schemes and mechanisms are in place for appropriate technical assessment of research protocols.

Background to clinical trials

In Australia there are two ways of initiating a clinical trial of new drugs or new uses of existing drugs - the Clinical Trial Notification (CTN) Scheme and the Clinical Trial Exemption (CTX) Scheme. The choice of scheme lies firstly with the sponsor and then with the individual IEC. The difference between the two Schemes rests on an assessment of the safety of the drug. Under the CTX Scheme the sponsor is required to submit pharmaceutical, toxicity and safety information to the Therapeutic Goods Administration (TGA) for evaluation. If the sponsor does not receive notification from the TGA within 50 days, the trial may proceed subject to IEC approval. The CTN Scheme

offers an alternative in which the TGA need only be notified of the trial and is not involved in scrutinising the data. Under this Scheme, an IEC is responsible for assessing the information presented by the investigator but may seek assistance if required. When the trial is approved by the IEC the investigator must notify the TGA that IEC approval has been obtained.

Until 1983, sponsors of all clinical trials involving imported products were required to obtain Federal approval prior to the initiation of the trial. Pharmaceutical chemistry, preclinical and clinical data were required in the same detail as that required to support applications to market a new chemical entity.³⁴ In February 1983, a degree of deregulation was introduced in that sponsors were permitted to undertake additional trials without Federal review of the subsequent protocols, provided that the trial was within the approved dosage range and duration of treatment. Each trial required approval by the IEC of the host institution and sponsors were required to notify the Federal agency at the time of approval by an IEC.

CTX Scheme - In August 1987, revised procedures for review of clinical trials were introduced incorporating the concepts of a Clinical Trial Exemption (CTX) Scheme,³⁵ under which the trial was permitted to proceed if no objection was raised by the Therapeutic Goods Administration within a given time frame. Under these arrangements, consideration of the essential safety aspects of a product proposed for use in a clinical trial remained a Federal responsibility and consideration of the related protocol was the responsibility of the IEC at the institution(s) at which the trial was to be conducted. The scientific validity of the study and the ability of the researcher and institution to carry out effectively the particular study were to be included in the IEC's consideration of ethical aspects of the trial.

CTN Scheme - In July 1991 following the publication of the Baume Report³⁶ links between clinical trials in Australia and marketing applications were severed. This allows clinical trials to be conducted whilst an application for registration for marketing is under review and vice versa. The introduction of the CTN Scheme³⁷ at the same time allows for drugs to be released for clinical trial purposes, provided authorities are notified of the trial beforehand and the trial is approved by the IEC of the hospital or university where it is to be conducted. Only IECs complying with NHMRC guidelines are able to participate in these arrangements.

The main impact of the deregulation of clinical trials, from the point of view of IECs, has been an expansion of their tasks and responsibilities to include the assessment of toxicological and safety data for trials submitted under the CTN Scheme³⁸. The Scheme was the subject of a review, the *Report to the National Manager of the Therapeutic Goods Administration on the Clinical Trials Notification Scheme*³⁹, which was completed in 1993. The implementation of recommendations from that review is being monitored by AHEC and being reported to the NHMRC. In response to the review recommendations, the Therapeutic Goods Regulations were amended. The regulations now specify that approval for the conduct of the trial must be given by the body or organisation conducting the trial, rather than by the Chairperson of the IEC. It is now clear that legal responsibility for the trial lies with the body or organisation conducting the trial.

Development of a clinical trials register

The development of a clinical trials register is important for facilitating long-term follow-up on clinical trials. One submission invited the Review Committee to consider the possibility of "... creating a data-bank of research subjects in major clinical trials of novel treatments, for long term reference ..."

A national register of statistics and data would enable the effectiveness of particular interventions to be monitored over time. Another submission stated the "development of a register of clinical trials and publication of findings emanating from such trials would facilitate the effective monitoring of clinical trial operations". The register should assess the performance of all clinical trials.

The NHMRC has recently agreed to the establishment of a clinical trials register and discussion is continuing as to where the register should be located. There are particular problems in relation to retaining clinical trials data for the ongoing monitoring of trials. Specific problems in terms of privacy need to be addressed.⁴⁰

The Review Committee endorses the moves by the NHMRC to implement a clinical trials register in Australia noting that the effectiveness of the register will depend on researchers forwarding data to it.

4.9 Monitoring of Research

The Terms of Reference of the Review Committee requested advice on arrangements for monitoring research approved by an IEC. Currently, the primary responsibility for monitoring research rests with the principal investigator. The approving IEC is responsible for ensuring that the research is monitored and the interests of the research subjects are adequately protected.

The Allars Report raised a major concern over adequate monitoring in relation to the conduct of the Pituitary Hormones Program. Concerns over the adequacy of monitoring have also been expressed as a result of a number of highly publicised cases, mostly overseas, in relation to research.

Monitoring by an IEC is only one of a number of mechanisms that currently exist for overseeing research undertaken within institutions. Many institutions have a range of committees reviewing different aspects of research, for example, scientific review, research, PhD, scholarship, medical advisory, drug advisory, biohazard, management, clinical and faculty/education committees.

It is usual for a pharmaceutical company sponsoring clinical drug, trials to have its own system of monitoring. "Monitors" may make regular visits to trial sites to check that investigators are following the research protocol and keeping accurate records. Their functions are to detect any side effects of the trial drug, to ensure the scientific validity of the research results and to prevent fraud or falsification of data.

The current NHMRC guidelines require IECs to "ensure that there is appropriate monitoring of research projects until their completion."⁴¹ To achieve this it specifies that the IEC shall:

"(i) at regular periods, and not less frequently than annually, require principal

investigators to provide reports on matters including:

- security of records
- compliance with approved consent procedures and documentation
- compliance with other special conditions;

(iii) as a condition of approval of the protocol, require that investigators report immediately anything which might affect ethical acceptance of the protocol, including:

- adverse effects on subjects
 - proposed changes in the protocol
 - unforeseen events that might affect continued ethical acceptability of the project;
- and

(iv) establish confidential mechanisms for receiving complaints or reports on the conduct of the project.

The direct responsibility for monitoring has always been and will remain with the principal investigator. The Review Committee does not recommend any change to this responsibility.

The NHMRC Monitoring Guidelines⁴² set minimum requirements for IECs. Those minimum requirements are as follows:

- The provision of reports to the IEC on the progress and conduct of the research project.

The responsibility for reporting back to the IEC lies with the principal investigator. As a minimum requirement, reporting may be in the form of a written reply to a questionnaire. Such reports must be provided at least annually and/or upon the completion of the project, although provision is made for an IEC to require more frequent reporting on a case by case basis. The Monitoring Guidelines also specify the information required to be provided. That is, the status of the project, compliance generally with the NHMRC Guidelines and any other conditions imposed by the IEC in granting approval to the project, and the security of the information collected and conditions governing access to such information. Provision is made for an IEC to require other forms of reporting where this is considered necessary. This may be by way of an interview with the principal investigator or others directly involved with the research project, examination of consent forms and other documentation, as well as site inspections.

- Immediate notification to the IEC of any matter affecting the ethical acceptability of the research project, including adverse effects on research subjects and steps taken to deal with this, substantial changes to the research protocol and any other unforeseen events.

Again, the responsibility for this important notification is placed on the principal investigator,

- The establishment of mechanisms for the confidential handling of complaints from research subjects or others involved in the conduct of the research project.

Current monitoring practice

The NHMRC Monitoring Guidelines establish "minimum requirements". An IEC may introduce "further procedures" where considered necessary.⁴³ In practice, most IECs comply with the minimum requirements of the guidelines by relying upon written reports from the principal investigator and notification by the principal investigator of any adverse or unforeseen consequences of the project.⁴⁴

Additional monitoring mechanisms are used by some IECs and include the following:

- auditing documentation and records relating to a random selection of research projects;
- appointing a member of the IEC or other member of staff within the institution to act as a 'monitor' for a specific research project and oversee the conduct of the project;
- establishing a subcommittee of the IEC, delegated the task of reviewing progress reports from the researchers;
- circulating the research project register within the institution every three months so as to familiarise and inform staff of research projects being conducted within the institution and encourage feedback to the IEC on any problems that may have been encountered;
- imposing, as a condition of initial ethical approval, a requirement on researchers to sign a statement to the effect that research is conducted in compliance with the NHMRC Guidelines and any other conditions imposed by the IEC in granting ethical approval;
- imposing, as a condition of initial ethical approval, a requirement that research results be produced to the IEC every six months for examination and review;
- imposing, as a condition of initial ethical approval, a requirement that researcher submit to or inform the IEC of all publications arising from the research;
- imposing, as a condition of initial ethical approval, a requirement that all research results be published;
- giving initial ethical approval to research projects for a set period of time, (usually one year), necessitating renewal of approval by the IEC at the beginning of each year that the project continues to be conducted;
- developing and circulating discussion papers on monitoring, to facilitate greater understanding and awareness of the relevant issues;
- conducting ad hoc site audits; and
- receiving informal feedback from other staff within the institution, or as a result of "informal outreach" by the Chair of the IEC.

1995 AHEC Workshops

Monitoring of approved research by IECs was a key theme of the 1995 AHEC Workshops. Many IECs felt that their monitoring procedures were superficial, relying predominantly on written compliance reports from researchers, and were inhibited by resourcing inadequacies. One of the aims of the Workshops was for AHEC to receive feedback on its proposed strategies for addressing these concerns. AHEC's proposal of a "tailored"⁴⁵ approach to monitoring research was broadly endorsed by participants at the Workshops.

Evidence to the Review Committee (public submissions, 1995 AHEC Workshops and information from AHEC in Annual IEC Compliance Reports) does not support the development of a separate administrative system of monitoring or the introduction of

paid public officials as was recommended in the United Kingdom.⁴⁶ The Review Committee endorses the proposal from the 1995 AHEC Workshops that a system of tailored monitoring be implemented.

This approach recognises that monitoring by an IEC is only one aspect of the overall strategy for the protection of the interests of research subjects. Peer review, institutional supervision, professional ethical standards of researchers and effective information and complaints mechanisms are all integral to the protection of research subjects from potential harm.

Recommendation 4

AHEC should revise Supplementary Note 1 to the *Statement on Human Experimentation* and the additional guidelines on monitoring to recognise a tailored approach to monitoring.

Recommendation 5

The annual IEC compliance report to AHEC should require details of monitoring arrangements.

4.10 Privacy

Breaches of confidentiality and threats to privacy can harm research subjects. A small number of submissions identified confidentiality and privacy as areas of concern. Issues raised related to the conduct of epidemiological research, the use of medical records for purposes other than those for which they are collected, storage and destruction of confidential information (including trial protocols) and the special concerns of minority groups (including people with a disability).

The storage of data (comprising personal information) raises considerable problems. Codes of good scientific practice⁴⁷ require that data collected for a research project be retained for a period of time to enable response to possible allegations of fraud. In the case of health research it is common practice for data to be retained for use in follow up studies. The principal researcher must ensure that data is retained under conditions of security and with due regard to the legal and ethical obligations of confidentiality to the research subjects.

The legal and professional ethical duties of confidentiality and the statutory standards of privacy are not to be regarded as absolute principles. Section 95 of the Privacy Act (Cwth) makes it clear that the protection of privacy is not absolute in law. The application of the Information Privacy Principles (see Appendix 4) tolerates intrusions to privacy on limited grounds particularly where there is a public interest. AHEC has recently released an Information Paper (*Aspects of privacy in the Conduct of Medical Research, 1995*⁴⁸) outlining circumstances in which privacy may be breached legitimately in research. Supplementary Note 6 (Epidemiological Research) to the *Statement on Human Experimentation* and the draft information paper *Ethical Aspects of Qualitative Methods in Health Research* (circulated for comment by AHEC in 1994) draw attention to the particular privacy implications of some research methods.

The Review Committee is aware that AHEC has a Privacy Working Party addressing questions of privacy. The Review Committee therefore makes no recommendations in

respect of these issues. It may be appropriate for AHEC's Working Party to consider the benefits to IECs and researchers of a checklist information sheet that details the requirements for the collection, use and storage of research data and results. The Working Party may also wish to consider the various existing privacy guidelines and suggest mechanisms for reconciling the contradictions between these guidelines.

Footnotes

²² Pettit, P "Instituting a Research Ethic: Chilling and Cautionary. Tales", 1992, *Bioethics* 6(2).

²³ See recommendation 10 of the Allars Report.

²⁴ 45 Code of Federal Regulations s.46.102(e).... see Furrow, B, *Health Law*, West Publishing 1995 at p842.

²⁵ Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organisation (WHO). Geneva 1993. See in particular definition on p 11.

²⁶ *Ibid*,p49

²⁷ See *Responsibility in Investigations on Human Participants and Material and on Personal Information*, Medical Research Council. UK.

²⁸ Dodds, Albury, & Thompson, 1994.

²⁹ *Ibid*, at para A 7.7.1 pp 4-5.

³⁰ For more information on these options see AHEC's *Report of the 1995 Ethics Workshops*.

³¹ This recommendation does not extend to area health service IECs or IECs who review research on behalf of more than one institution.

³² Supplementary Note 3 to the *Statement on Human Experimentation* (see Appendix 2) provides guidance to IECs on clinical trials. The NHMRC has also issued interim guidelines for IECs on the CTN Scheme *The Clinical Trial Notification Scheme: Interim guidelines for institutional ethics committees*, 1992.

³³ Professor R Day (Chair) *Report to the National Manager of the Therapeutic Goods Administration on the Review of the Clinical Trials Notification (CTN) Scheme*, May 1993.

³⁴ In addition, the trial protocol and names and qualifications of investigators, institutions and laboratories involved in the trial were required. Any variation in these required separate approval. A review period of 60 working days was set, at the end of which there was a formal meeting between sponsors, investigators and reviewers.

³⁵ The submitted toxicological and safety data were still evaluated. The main features of the scheme were: an exemption period of 60 working days for full applications and 30 working days for applications consisting of pharmaceutical data only; with the exemption of biologicals, the introduction of a pharmaceutical check list as an alternative to a full review of pharmaceutical data; the provision of safety data only, in relation to clinical experience (efficacy data were not required); the preparation of a set of core documents, including usage guidelines, to assist IECs in their

consideration of clinical trial protocols; and the introduction of a *Voluntary Code of Conduct of Clinical Trials*.

³⁶ P Baume, *A Question of Balance Report on the Future of Drug Evaluation in Australia*, Commissioned for the Minister for Aged, Family and Health Services, Hon. Peter Staples, July 1991, AGPS, Canberra.

³⁷ See *Clinical Trials of Drugs in Australia DEB 1 Therapeutic Goods Administration (199 1)*; Clinical trials were further deregulated on 1 October 1992 through changes to the CTX Scheme. Under this revised CTX Scheme, only summary data is required for review by the Drug Evaluation Branch of the TGA. Chemical and pharmaceutical summary documentation may be more extensive than the check list provided previously but overall the pharmacological, toxicological and clinical safety data provided for review are far less extensive. The period allowed for full evaluation under the CTX Scheme was also reduced from 60 to 50 working days.

³⁸ IECs had expressed concern over possible legal liability in administering this scheme and the need for appropriate indemnity. See NHMRC *Report on Compensation, Insurance and Indemnity Arrangements for Institutional Ethics Committees*, November 1994.

³⁹ Professor R Day (Chair). 1993.

⁴⁰ AHEC has commenced work on the revision of Supplementary Note 6 to the *Statement on Human Experimentation* (on epidemiological research), as it pre-dates the Commonwealth *Privacy Act*.

⁴¹ Paragraph 8, Supplementary Note 1, *Statement on Human Experimentation*.

⁴² *Guidelines for the Monitoring of Research by Institutional Ethics Committees*, NHMRC, 1992.

⁴³ *Ibid*, Preamble.

⁴¹ IEC Annual Reports for the period 1 July 1993 to 30 June 1994. The information generated was based upon responses to Question 2 in the Annual Report which asked: "What procedures does your IEC have in place to monitor research projects approved by your IEC to their completion?"; See also AHEC *Report of the 1993 workshops for institutional ethics committees (IECs), consultation with researchers and forum on IECs*, December 1993.

⁴⁵ See S Linden-Laufer, *Monitoring approved research protocols -a question of balance*. Unpublished discussion paper prepared for the 1995 AHEC Workshops.

⁴⁶ See J Neuberger, *Ethics and Health Care: The Role of Research Ethics in the UK*, Research Report 13, Kings Fund Institute, 1992 at p 47 "... the REC is well placed to take a view, on what it has approved and amended. It should therefore be responsible for the monitoring, but a paid official of the DHA would need to be responsible for carrying it out".

⁴⁷ Including those promulgated by the Australian Vice Chancellors Committee, the Therapeutic Goods Administration, and the NHMRC's *Statement on Scientific Practice, 1990*.

⁴⁸ This paper has been developed by the AHEC Working Party on Privacy which includes in its membership the Federal Privacy Commissioner, Kevin O'Connor.

5. PROCEDURES FOR IECs

Supplementary Note 1 to the *Statement on Human Experimentation* provides the following guidance on decision making by IECs.

- (i) Wherever possible, a decision by an IEC shall be made after a person from each of the categories listed in section 4 (i) of this supplementary note has had an opportunity to contribute their views during the decision making process;
- (ii) An IEC should seek to reach decisions by general agreement which need not involve unanimity;
- (iii) In the absence of general agreement that a project is ethically acceptable, an IEC shall either establish a procedure to arrive at a decision, for example a simple majority, or inform the principal investigator of necessary amendments to the protocol;
- (iv) An IEC may the investigator(s) to be present for discussions of the project; and
- (v) an IEC may seek advice and assistance from experts to assist with consideration of a proposal."

Many of the long-standing IECs in major institutions have detailed, refined and published procedures operating for their IECs. Submissions to the Review Committee identified IEC administrative procedures and decision-making processes as of concern. Submissions addressed the need for IECs to follow consistent and comprehensive administrative procedures and noted the need for appropriate mechanisms to receive comment, feedback and complaints (as appropriate) on the conduct of research and/or the approval process. One submission stated that "... operating procedures and communication vary between IECs. Standardisation of all would help towards establishing an equitable and more professional IEC system". These matters are not of concern in relation to all IECs.

5.1 Proposed IEC Procedures

From their inception, IECs have operated under NHMRC Guidelines. These guidelines were expressed in broad terms and provided a skeleton of procedures and variations have developed. The submissions supported overwhelmingly the adoption of common administrative procedures between IECs. The Review Committee notes the importance of IECs conducting their business in accordance with proper working procedures. In particular, IECs should formalise working procedures concerning.

- frequency of meetings;
- what constitutes a quorum;
- preparation of agenda and minutes;
- distribution of papers prior to meetings;
- expedited review (determine the scope of Chairperson's action and the delegation of tasks to sub-committees and the consequent relationship between the Committee and such sub-committees);
- a determination about the class of research projects which may receive expedited approval procedure;
- confidentiality;
- conflict of interest of a member with regard to an application;
- the maintenance of a register of research proposals and action taken regarding them;

- the basis of decision-making, that is, bare majority, 2/3 majority etc and any special rules on decisions concerning particular types of research project, for example, research on children;
- the recording in writing of decisions made by the Committee and reasons for decisions;
- notification and review of decisions;
- the monitoring of an approved research project;
- the reporting of adverse occurrences;
- access to ethics committees by researchers and research subjects; and
- fees, if any, charged.⁴⁹

The evidence presented to the Review Committee indicates that many of the major IECs in Australia already have in place and follow formal published procedures.

The Royal College of Physicians in the United Kingdom has developed a commendable set of working procedures for ethics committees.⁵⁰ These working procedures include details about required quorums, adverse decisions, confidentiality, declaration of interest and other relevant matters. The Review Committee is aware that some IECs require guidance in the development of adequate working procedures and suggests that in providing this guidance AHEC refer to the above mentioned document.

The UK guidelines do not address the difficulties which arise when committees cannot reach a unanimous decision. On this issue the Review Committee supports the advice of AHEC that it is desirable and the usual case that a unanimous decision is reached. A majority decision should only be taken after all reasonable efforts have been made to debate the concerns of the minority members.

Recommendation 6

The meeting procedures listed in the current *Statement on Human Experimentation* should be re-drafted to provide a detailed statement consistent with section 5.1 of this report.

5.2 Consent and the Protection of Research Subjects

The role of an IEC is to ensure the effective consent of research subjects to participation in a project and that any risk which may be involved is acceptable. In providing directions to IECs, the NHMRC *Statement on Human Experimentation* is explicit and unequivocal. An IEC shall, "while promoting the advance of knowledge by research, ensure that the rights of the subjects of research take precedence over the expected benefits to human knowledge".⁵¹

The current NHMRC *Statement on Human Experimentation* does not include a detailed list of the matters which must be disclosed to potential research subjects and states only that the investigator "is responsible for providing the subject at his or her level of comprehension with sufficient information about the purpose, methods, demands, risks, inconveniences and discomforts of the study. Consent should be obtained in writing unless there are good reasons to the contrary".⁵² Other national guidelines, for example, the United States regulations made under their National Research Act, 1994, are more prescriptive of the matters to be disclosed to research subjects.⁵³

Supplementary Note 2 to the *Statement on Human Experimentation*⁵⁴ addresses the special care required when considering research projects involving vulnerable groups such as children,⁵⁵ the mentally ill, unconscious and critically ill patients or others in dependent relationships or comparable situations (specifically elderly persons, wards of state, those in doctor-patient and teacher-student relationships, prisoners, members of the services, hospital and laboratory staff). In summary, this Supplementary Note requires substituted consent to be obtained from others, special attention to be paid to research involving these people and the rights and welfare of the individuals to be protected. Submissions to the Review Committee were particularly concerned with the adequacy of protection for vulnerable groups. Where vulnerable populations are involved in research, consent should be ongoing.

The process of consent

Emphasis should not be on the consent form alone but on the process by and the circumstances under which consent is obtained. An IEC should ensure that the provision of appropriate and adequate information to research subjects forms part of the consent process.

There are particular characteristics of the process of consent when applied to social and behavioural research. This is recognised and well expressed in the report to the Department of Human Services and Health entitled *Ethical Research and Ethics Committee Review of Social and Behavioural Research Proposals*.⁵⁶

Participation in research entitles the research subject to all relevant information relating to the project, including the objectives and consequences of involvement and details of any identifiable (known or potential) risks and inconvenience. Potential research subjects, having received this information, are then entitled to decide whether they wish to participate in the research. For a research subject to give a valid, informed and voluntary consent, it is essential that the information is given in a comprehensible form and that there is an absence of any form of coercion during the process. This process will be accompanied by the distribution of an Information Sheet, written in plain and accessible language, to the potential research subjects. Time should be made available to the research subject to consider participation in the project and there should be an opportunity to obtain further advice or counselling in relation to involvement.

It is appropriate for consent requirements to be tailored to the type of research involved. One way of considering this process may be by establishing a matrix of matters for consideration for IECs.

Key matters in the matrix may be:

- (i) Level of research - Whether the research involves access to personal records, body tissue or blood, or directly involves the person.
- (ii) Research process - Whether the research involves observation, collection or use of information or experimentation.
- (iii) Degree of unknown risk or magnitude of potential harm

Minimum standards procedures for consent for each category should be developed. In some research projects a cooling-off period may be required for research subjects. An

IEC should assess the consent process outlined in the research protocol taking into consideration the following factors:

- status of the subject population (for example, children, mentally ill);
- confidentiality and privacy (including level of reporting); and
- outcomes (benefits for research subject).

Concerns were raised about the difficulty research subjects may have in understanding consent forms, especially for research involving subjects from non-English speaking backgrounds and Aboriginal and Torres Strait Islander communities. The Canadian Report on Research Ethics Boards⁵⁷ found that there was a need to improve the consent forms used in medical research in Canada. The National Council on Bioethics in Human Research recommended that consent forms be written so that they can be clearly understood by a subject with an eighth-grade education. The Canadian National Council also suggested that Research Ethics Boards should be stricter when considering consent forms and ought to withhold approval until acceptable forms had been received.⁵⁸ The provision of information to research subjects in plain and accessible language was fully supported by the submissions to the Review.

Recommendation 7

An IEC must not approve a research project unless it is satisfied that appropriate procedures for providing information to potential subjects and obtaining their voluntary consent are in place.

Recommendation 8

All consent forms and information sheets provided to research subjects should be written in plain and accessible language.

5.3 Expedited Review

The desirability of establishing a system of expedited review has been recognised by overseas organisations.⁵⁹ A submission to this Review noted that the functioning of IECs "could be improved and expedited by developing schedules of research: those that do not need ethics clearance and those which need only minimal ethics clearance". Most projects should be submitted for review by a full IEC meeting, however, investigations that do not pose foreseeable ethical problems to the research subjects may not require review by a full meeting.

Some Australian IECs have already established procedures for expediting review. These vary with the institution and the nature of its work. In some institutions an appropriately constituted sub-committee⁶⁰ reviews the research, in others the chair or the deputy chair assesses the research with subsequent ratification of their decisions by the full IEC meeting. In these latter cases, the expedited review is not complete until consideration by the IEC.

Full IEC review should remain the norm and expedited review the exception. Expedited review may take the form of sub-committee or chair-only consideration. Formal procedures for expedited review will relieve some of the work load problems allowing concentration on more ethically complex protocols.

To institute a system of expedited review, each institution will need to decide which research projects can be expedited and which should be referred for assessment by the full ethics committee. Because expedited review procedures will vary between institutions (for example, a university ethics committee may delegate consideration of student research proposals to a sub-committee located in the relevant faculty), guidelines should be developed to establish the minimum conditions for operating such a system.

Expedited review must not be treated as approval "fast-tracking" nor an encouragement to researchers to be less efficient and prompt in preparing their research documentation for presentation to the IEC.

Features of an expedited review model might include:

- all research proposals should be assessed according to the level of potential harm with minimal risk studies referred to a person/subcommittee/chair/faculty for consideration;
- full IEC review is still required for research involving significant actual or potential risks to research subjects;
- IEC has power to delegate consideration of low risk proposals to nominated persons or sub-committees;⁶¹
- sub-committees need not consist of IEC members (for example, faculty sub-committee for consideration of student proposals) and may consist of the Chair alone; and
- delegated sub-committees are responsible for approving the protocols before them but all decisions will be reported to the IEC for information.

Recommendation 9

The Statement on Human Experimentation should be amended to recognise the acceptability of expedited review.

5.4 Manual of Procedures

Appended to some of the submissions presented to the Review Committee were copies of procedural manuals from a number of established IECs. In addition, manuals of procedures for research ethics committees have been developed overseas, such as the United Kingdom Department of Health's framework for ethical review.⁶² Standard operating procedures for UK Local Research Ethics Committees have also been published.⁶³

The Review Committee is confident that, with the permission and agreement of those institutions with detailed and published procedures, a standard manual of procedures could and should be developed for Australian IECs based on best practice and existing precedents available in this country. The development of a manual of procedures for IECs in Australia would not preclude IECs developing their own manual or varying any published national standard manual. Such a manual for procedures would not be mandatory but intended to assist the decision-making process of an IEC. An acceptable national standard manual could contribute significantly to promoting consistency and

predictability in the operation of the IEC system. The development of a national standard manual for IECs should include the following:

- standard terms of reference;
- standard format for applications to IECs;
- standard operating procedures for assessment of protocols;
- standard operating procedures for approval/refusal of protocols;
- summary guidance on general principles of consent, confidentiality, vulnerable research subjects etc; and
- consolidation of the many guidelines prepared by NHMRC, TGA and other bodies, organised thematically.

Recommendation 10

AHEC should supervise the preparation of a Manual of procedures for IECs following the redrafting of the *Statement on Human experimentation and Supplementary Notes*.

Recommendation 11

AHEC should be provided with proper resources to cover the development and publication costs of a Manual of procedures for IECs.

5.5 Independent Complaints Mechanisms

In addition to the obligation to monitor approved research projects, paragraph 8 (iii) of Supplementary Note 1 recommends that an IEC "establishes confidential mechanisms for receiving complaints or reports on the conduct of the project". In conjunction with other forms of monitoring, an independent complaints mechanism provides an important independent procedure for quality assurance of the IEC system and any research approved by the IEC.

There are many institutions which have formal mechanisms whereby concerns about the conduct of research projects can be raised. Some institutions have developed their own local complaint handling mechanisms, with the appointment of a complaints officer or patient advocate, acting as the "listening ear" of the institution. Apart from institutional mechanisms, complaints procedures have been adopted by some IECs including:

- providing a contact number on all consent forms or patient information sheets of a person appointed to investigate complaints or concerns or receive comments about the project;
- and making it a condition of initial ethical approval that the researcher forward all complaints or expressions of concern to the Chair of the IEC.

Most States and Territories in Australia have established, or are in the process of establishing formal, independent health complaint handling procedures on a statutory base. The focus of such Health Complaints bodies is on the redress of health consumer grievances concerning the provision of health services. Access to these Health Complaints Commissions provides research subjects with an additional avenue for raising concerns regarding the conduct of any research in which they are involved.

Submissions to the Review did not support the establishment of formal, legalist appeals processes. At the 1995 AHEC Workshops a number of delegates pointed out that, provided there is an independent avenue for access to information, a large number of

research subject concerns can be resolved satisfactorily without the need for a formal grievance procedure. Any mechanism for dispute resolution is most likely to be effective where it is based on open communication and mutual respect.

The NHMRC *Statement on Scientific Practice* (1990) requires that an institution conducting research has in place procedures for the receipt of complaints or allegations of misconduct in research. The institution must designate a person to whom complaints are to be made. Procedures are outlined for the investigation of any concerns raised.

The Review Committee considers that this process model should also be used for receiving complaints, expressions of concern or request for additional information from research subjects. The name and contact details of the complaints handling officer should be given to research subjects when information on the research is first provided. This should be in a form that the subjects can take away and be separate from, and additional to, the consent and project information documentation. The information should outline the procedures to be followed for raising concerns or obtaining additional information on the project.

Recommendation 12

All institutions with an IEC must nominate an independent complaints handling officer.

Recommendation 13

The name and contact details of the complaints handling officer should: be given to research subjects together with the procedures for raising concerns or obtaining additional information on the project. This should be provided when information on the research is first provided, should be in a form that the subjects can take away and should be additional to, and separate from the consent and project information documentation. The *Statement on Human Experimentation* should be amended to provide for this.

Footnotes

⁴⁹ List of procedures adapted from Ian Kennedy, "Research Ethics Committees and the Law", *Manual for Research Ethics Committees* 2nd ed., 1995, Centre for Medical Law & Ethics, Kings College, London.

⁵⁰ Report of the Royal College of Physicians, *Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects*, 2nd ed. 1990, s7 "Method of Working".

⁵¹ Supplementary Note 1, paragraph 6 (ii) *Statement on Human Experimentation*.

⁵² Principle 8 *Statement on Human Experimentation*.

⁵³ These matters are:

- a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- a description of any reasonably foreseeable risks or discomforts to the subject;
- a description of any benefits to the subject or to others which may reasonably be expected from the research;
- a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

- a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- an explanation of whom to contact for answers to pertinent questions about the research and the research subject's rights, and whom to contact in the event of a research-related injury to the subject;
- a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

Also when appropriate:

- a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or foetus, if the subject is or may become pregnant) which are currently unforeseeable;
- anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- any additional costs to the subject that may result from participation in the research;
- the consequences of a subject's decision to withdraw from the research and the procedures for orderly termination of participation by the subject;
- a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
- the approximate number of subjects involved in the study. (Federal Regulations).

⁵⁴ See Appendix 2.

⁵⁵ See also British Pediatric Association Ethics Advisory Committee Report, "Guidelines for the Ethical Conduct of Medical Research Involving Children", Professor C Normand (Chair), published in *Bulletin Medical Ethics*, August 1992, pp 13 -20.

⁵⁶ Dodds, Albury & Thomson, 1994 at para F14 p25.

⁵⁷ National Council on Bioethics in Human Research, Protecting and Promoting the Human Research Subject: A Review of the Function of Research Ethics Boards in Canadian Faculties of Medicine", 1995, in *NCBHR Communiqué 6(1)* pp3-32.

⁵⁸ *Ibid*, recommendation 11.

⁵⁹ NCBHR, 1995 recommendation 4. See also, Royal College of Physicians (*UK*) *Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects*, 2nd ed. 1990, s4.3, 4.8; In the USA, regulations specifically exclude some categories of low risk research from IRB coverage. 45 Code of Federal Regulations s.46. 10 1 (b), see Furrow, *B.*, *Health Law*, West Publishing, 1995 at p843.

⁶⁰ Frequently these sub-committees mirror the composition prescribed in Supplementary Note 1 (see Appendix 2) and can be considered as properly constituted IECs.

⁶¹ For example, simple questionnaires, routine extensions of existing projects, student research. In New Zealand, matters not requiring ethical appraisal include internal clinical audit; access to personal health information for the purposes of monitoring the quality of care, and questionnaires and surveys which do not use confidential personal or medical information - see *National Standard for Ethics Committees (Interim)*, Ministry of Health, NZ, May 1994.

⁶² See Department of Health, *UK Standards for Local Research Ethics Committees: A Framework for Ethical Review*, NHS Training Division, 1994.

⁶³ See C Bendall, *Standard Operating Procedures for Local Research Ethics Committees*, April 1994, McKennan & Co.

RESEARCH
MEDICINE

6. COMPOSITION

Supplementary Note 1 to the *Statement on Human Experimentation* identifies the current membership requirements for IECs. It requires that IECs be composed of men and women reflecting different age groups including a minister of religion (of any faith); a lawyer; a medical graduate with research experience; and a lay woman and man not associated with the institution. These are minimum requirements and in fact most IEC operate with approximately 10-15 members.⁶⁴ Persons may be appointed to stand-in for members when necessary and all members are appointed as individuals for their expertise and not in a representative or advocacy capacity. Subjecting research to the scrutiny of IEC members serves the important function of bringing an outside perspective into a relatively closed institutional culture where ethical dilemmas in traditional practices can sometimes remain unrecognised and unchallenged.

The current voluntary and unpaid contribution of IEC members should not be underestimated. The entire national IEC system operates on a shoestring budget and achieves commendable levels of operational efficiency and quality through the voluntary dedication of the approximately 2,000 members of the various IECs. One submission noted "volunteers provide extraordinary service by reviewing projects and attending meetings considering there is no allegiance to the institution beyond public interest and the devotion to assist others". As Professor Lovell, the early architect of the IEC system, has said "... [IEC] members are the key decision-makers. IECs are the linchpins of the system. The whole thing depends on their conscientiously performing their functions".⁶⁵

Many of the submissions commented upon membership of IECs. These submissions particularly raised questions ' about the appropriate categories of minimum membership, whether members act as individuals or in a representative capacity, the internal ratios of members (institutional to non-institutional; male: female; science to non-science). Particular concerns were also raised about power differentials between the members of the IEC particularly whether the biomedically trained members may dominate the lay members. This concern was raised in a number of submissions and was particularly well expressed in one submission which stated that " ... the failure of the [Supplementary] Note to specify a maximum number of members for an IEC, combined with conscientious efforts ... to obtain sufficient medical and clinical expertise on an IEC inevitably leads to the lay/religious/legal members being in a significant numerical minority". A number of submissions raised the need for guidelines to help an institution in the critical process of IEC member selection. Finally, some submissions addressed issues of the use of expert advice from persons outside the IEC and the payment of members of an IEC.

6.1 Membership

The Review Committee, accepting the critical role played by IEC members, considered membership issues at length. It is imperative that an IEC be composed of members who have the competence and judgment to be able to make ethical assessments about research projects and the consequences of participation in the project by the research subjects. All members must look primarily to the welfare of the research subjects and have adequate understanding to be able to consider research proposals. Most importantly, members must be impartial and must not see themselves as representative advocates for a particular group. The member's obligation is to the

interests of the research subject. Members should endeavour to facilitate the decision-making processes of the IEC without adversarial debate.

Membership generally

The following are the Review Committee's resolutions regarding IEC membership generally.

The selection of members - The selection of members should be subject to an open selection process with nominations sought for any vacancy. The selection process may vary between institutions, however, the institution should record details of the process.

Attributes of members - In addition to their particular knowledge/skills, all members should have good judgment, the ability to function in a committee and a commitment to the research subject. They should possess both the qualities of integrity and curiosity or an enquiring mind.

Independence of the IEC from the institution - The committee must be capable of acting independently. The ethics committee should be considered a part of, but independent within, the institution, performing an advisory function for the institution.

Minimum required membership - The Review Committee considered that the minimum required membership of an IEC should be increased from 5 to 7 members and 8 members in the case of a hospital IEC. The minimum membership should be as follows:

- Chairperson
 - Person with knowledge of and experience in research involving humans (medical, social, epidemiological as appropriate)
 - Person with knowledge of and experience in the professional care, counselling or treatment of humans (medical practitioner, clinical psychologist, social worker)
 - Minister of religion or equivalent (for example Aboriginal elder)
 - Layman
 - Laywoman
 - Lawyer,
- and, in the case of a hospital IEC
- Nurse

Comments on minimum membership

Chairperson - The important attributes of this position are those of any Chairperson particularly, an ability to guide the meeting and to mediate between the IEC and researchers where required (a non-adversarial approach). As with other members, the Chairperson should not have any apparent or actual conflict of interest and the capacity for independence is paramount. The Chairperson must have no involvement in the conduct or supervision of research considered by the committee. It is desirable that the Chairperson not be employed or otherwise directly connected with the institution. If this is not possible independence should be ensured in other, structural ways.

Knowledge of and Experience in Research Involving Humans - Person with formal training and experience in an appropriate science/social science/health related area.

The essential attributes of this person are an ability to understand and comment on issues of scientific merit and a firm grounding in research methods.

In 1986 the Statement on Human Experimentation was amended to require IEC approval for "health" research. Comments were made during the 1993 and 1995 IEC workshops (conducted by AHEC) and the Review Committee received submissions which pointed out that IECs, as currently constituted, do not have the knowledge or competence to properly assess social science research in the health area. These submissions generally argue that the best way to ensure that an IEC is competent to assess social science research projects is to appoint a person with experience in research methods in the social sciences. Some submissions stated that the requirement for a medical graduate to sit on an IEC is inappropriate in the case of institutions which are involved principally in social science health related research.

Person with knowledge of and experience in the professional care, counselling or treatment of humans - In the case of a hospital ethics committee, this position would normally be filled by a Medical Practitioner. Where an IEC considers predominantly social (or non-medical) research the inclusion of a person such as clinical psychologist or social worker may be more appropriate. This category of membership is proposed because such a person has contact with potential subjects in research and insight into the possible impact of research on research subjects.

Minister of Religion or equivalent - Religious person of any faith with moral training and experience in pastoral care. A minister of religion is included among the required membership of an IEC as a person who holds the importance of humanity and human life above all else. Experience in pastoral care is not an attribute that can readily be filled by another category of membership (for example, ethicist, moral philosopher). However, it is recognised that there are cultural equivalents (for example, Aboriginal elders) and that the category should not be so narrowly defined as to only include ordained people.

Layman and Laywoman - Laymembers should hold a non-institutional view point and a research subject focus. They should be respected by the community, articulate, curious and able to advance an argument. The qualities important in laymembers include the ability to represent the community (with current or recent community involvement) and to mirror community standards. There should also be an emphasis on the term local in the selection of lay members (that is, lay persons should be aware of relevant local conditions and represent community interests). In the case of the locality comprising ethnic or Aboriginal populations, the institution may select lay members from amongst those populations especially in circumstances where the research considered by the IEC is principally carried out amongst those groups.

Lawyer - A number of submissions to the Review supported the value of retaining a lawyer among the core committee membership. The lawyer should be able to advise the committee on legal implications of research considered or decisions taken and whether formal legal advice is necessary. The attributes important in this position include training in critical thinking and experience in the clarification of issues. Attributes of the lawyer should include good judgment and experience in dealing with people.

Nurse - Where the committee is a hospital ethics committee or patient care is involved a nurse is to be included in the minimum required membership. Nurses should be included on these committees because of their training and experience in patient care leading to a patient-focused approach and their monitoring capacity.⁶⁶

Additional requirements in relation to membership

The Review Committee considers that the following additional requirements should ensure the balance and independence of IEC membership.

- The 1993 AHEC survey of IECs and submissions to this Review recorded that laymembers were often significantly out-numbered by institutional and medical committee members. This has significant implications for the contributions of laymembers to the committee's functioning and decisions. Where additional members are appointed an appropriate balance between institutional/non-institutional and medical/non-medical must be maintained. Specifically, not less than half the committee should consist of non-medical members from outside the institution.
- Persons may be appointed to stand-in for members when necessary.
- Due regard should be paid to age and genuine efforts to provide a gender balance in committee representation.
- When appointing laymembers, due regard should be paid to the ethnic backgrounds of the research subjects dealt with by the researchers.
- A member may not fill more than one of the minimum categories.
- The responsible institution (university, hospital) will formally appoint members of the IEC after receiving appropriate advice. The members should receive a formal notice of appointment which includes a guarantee that the institution will provide reasonable legal protection for the member.
- The duration of membership should be determined by the relevant institution. It is desirable that the members are appointed for an appropriate period to allow the members to acquire and apply new ethical knowledge and decision-making skills. A period of between three and five years is suggested and members should be eligible for reappointment.
- The 7 required members must participate in all decisions (**Note** it is not necessary for all required members to be present at every meeting but all should participate in the decision making process.)

With regard to research subject representation it is the view of the Committee that no one person could be representative of all research subject groups. All IEC members are appointed to represent subjects in research. Consequently, it is the objective of all committee members to use their particular knowledge/skills to anticipate the rights, needs and expectations of research subjects. As a result there should be no need for a separate patient advocate or research subject representative on the committee.

Recommendation 14

In the revision of the *Statement on Human experimentation*, IEC membership requirements should be re-written in accordance with section 6.1 of this Report.

6.2 Payment of IEC Members

Serving on an ethics committee involves a considerable investment in time and dedication. Payment of committee members has the potential to alter the nature of the committee, for example, serious conflicts of interest may arise if payment were to be made to IEC members from any person or organisation with a financial interest in the approval of its research project by an IEC. Very few of the public submissions raised the issue of payment to IEC members. There was no call by IEC members for payment although the Review Committee is aware that some IECs now receive sitting fees. The majority of submissions on this issue expressed the view that there is a public responsibility aspect to service on an IEC. Other reasons given for undertaking the onerous, important and time consuming membership on an IEC were the degree of interest, the importance of the work and the public need for voluntary work. On the other hand, many submissions noted that resourcing of IECs (in particular secretariat support) was inadequate.

The Review Committee considers that the appropriateness of payment to IEC members is an issue to be determined by individual institutions. In any case, members of an IEC should be reimbursed for expenses incurred in the conduct of their duty (for example, parking, additional child care expenses). Where a sitting fee is paid care should be taken to ensure that this does not result in an apparent or actual conflict of interest for the member(s) concerned.

Footnotes

⁶⁴ *Report of the 1993 Survey of Institutional Ethics Committees* NHMRC, December 1993. A leading international text in this area is that of PM McNeill, 1993, *The Ethics and Politics of Human Experimentation*. Cambridge University Press; see also PM McNeill, CA Bergland, IW Webster, "Reviewing the Reviewers: a survey of *institutional ethics committees in Australia*", 1990 *MedJ of Australia* 152 (6) pp 289-296.

⁶⁵ Per Emeritus Professor R. Lovell Valedictory Comment: *MREC Newsletter* 1(4), December 1988 p2.

⁶⁶ Several submissions felt that the failure to specify nursing representation on IECs has been a major oversight given that nurses are the primary carers for most potential subjects.

7. EDUCATION AND TRAINING OF IEC MEMBERS

Many submissions recognised the need for ethics education for members of IECs, researchers and others in the institution. As one submission stated, there is a "need for an education strategy within an institution regarding ethics and the role of [an] IEC". It was argued that, for members of IECs, education should involve: the facilitation and coordination of an IEC network; the provision of seminars, workshops, newsletters and educational material including a set of consolidated guidelines and/or a handbook; the training of new members on the role of IECs and ethical decision making; and information on consumer rights issues.

Some submissions drew the attention of the Review Committee to training programs conducted in the United States (*Educating Health Care Ethics Committees*) which are supported by the Federal Department of Education Fund for the Improvement of Post Secondary Education. Courses are also run in the United Kingdom for members of Local Research Ethics Committees⁶⁷. Such official training programs were recommended. One submission stated that they would more " ... effectively reach the membership of the IECs, than the current system of voluntary participation in AHEC mini-conferences".

Education for researchers and institutions should improve their awareness of the IEC process and consumer rights issues. The current lack of funding and resources within AHEC to sustain or establish a strong education component was also noted. It was felt that a major step in the education process is the provision of accurate and comprehensive information to IECs followed by ongoing forums for communication and discussion both between IECs and with AHEC. Education, stated one submission, " ... does not happen by pious wishes or recommendations ... there must be some set policy, some definite program ... quality of IECs could be improved if adequate funding was available... ".

The Review Committee is aware of a number of ethics courses which are offered by Universities and Ethics Centres in Australia, some of which are directly aimed at IEC members. Consequently, the Review Committee does not recommend that specific funds be allocated to AHEC for preparing, establishing and presenting specific courses-for the in-service training of IEC members. However, the Review Committee recognises that AHEC has the statutory responsibility for overseeing the IEC system in Australia and it is appropriate that AHEC plays a significant role in the in-service training of IEC members.

Recommendation 15

AHEC should develop a statement of core competencies for IEC members to assist the development of courses for their in-service training.

Recommendation 16

Institutions should make available sufficient (ongoing) funding to enable its IEC members to avail themselves of opportunities for relevant in-service training and development.

Footnotes

⁶⁷ The Review Committee notes that the Centre for Law and Medical Ethics at King's College, London, runs three day courses specifically for members of Local Research Ethics Committees. These three day courses cover a number of topics including law, ethics and science (research methods, statistics, methods of scientific validity).

RESEARCH
INDICATED

8. RESOURCES

The resources available to an IEC are provided by the relevant institution. With the increasing workload of many IECs there is a need for substantial administrative support and secretarial assistance from the institution. Submissions recognised the need for increased resources in order to enable IECs to function effectively. Many submissions drew attention to the need for ongoing in-service training for IEC members, an activity requiring the allocation of adequate resources. Those IECs which participate in the CTN Scheme submitted that the Scheme is particularly labour intensive. These IECs draw attention to the question of resources available to make proper assessments of the research protocol and to conduct adequate monitoring. IECs which are considering participation in the CTN Scheme also expressed concern about the resources required to fulfill their role.

8.1 IEC Resources

The submissions called for further resources to IECs. The varied responsibilities of government, institution and researcher were discussed and some submissions suggested that AHEC (NHMRC) identify the minimum resource level required to service an IEC. The submissions also proposed that the IEC Annual Compliance Report to AHEC include a section which audits the resourcing of an IEC to ensure that resources provided are adequate. Other submissions suggested that a standard user-pays levy on research protocols be set by AHEC.

Ethics committees require ongoing and coordinated secretarial support. In many instances only ad hoc secretarial support is available for IECs making it difficult for the IEC to do even its primary approval function. Most IECs are not resourced sufficiently to enable them to become involved in network and educational initiatives. Some committees, because of an absence of secretarial support, also suffer from a lack of accumulated "corporate knowledge" in the committee.

Another aspect of resourcing of IECs is the issue of a fee for service to the institution. It is apparent that a number of institutions charge an administrative fee for ethical approval of clinical trials. Comments in the submissions and at the 1995 AHEC Workshops note that these fees vary substantially between institutions. The Review believes that an administration fee may be appropriate where it constitutes an actual reimbursement for costs incurred and not an inducement to approve research or to "fast-track" particular research protocols. Further discussion regarding the level of such a fee and safeguards to ensure the independence of the IEC (that no conflict of interest is created) should be undertaken by AHEC.

Recommendation 17

Institutions should ensure the provision of adequate resources for their IECs. A new IEC should not be established unless the institution can provide adequate means for resourcing the committee.

8.2 AHEC Resources

The submissions also raised the question of resources available to AHEC. Currently the Research Ethics Standing Committee of AHEC has responsibility for overseeing and handling issues relating to IECs. Several submissions pointed to the need for AHEC to

be properly resourced in order to fulfil its support and advisory functions in relation to IECs.

The Review Committee considers that there is a need for the secretariat of AHEC to be expanded to include the services of an officer dedicated to IEC support. This position would be responsible for the ongoing support of IECs and IEC networks.

Recommendation 18

The AHEC secretariat should be expanded to include a full-time IEC support officer.

8.3 Amalgamation of IECs

The National Council on Bioethics and Human Research in Canada has recently published a report entitled *Protecting and Promoting the Human Research Subject: A Review of the Function of Research Ethics Boards in Canadian Faculties of Medicine*.⁶⁸ This report invites research ethics committees considering fewer than 50 research protocols annually to consider amalgamation with another or other IECs.

Some IECs meet infrequently, or review only a small number of research protocols on an annual basis. In these cases considerations must arise about the time spent serving on these committees and the breadth and depth of experience needed by committee members to maintain an adequate level of review. Of course, there may be specific and special institutional reasons to preserve the IEC. However, with the substantial increase in the number of IECs over the last decade it is likely that some of these newly established IECs may assess few research proposals. Some submissions to the Review raised concerns that particular IECs might have been established with the interests of researchers in mind, rather than those of the research subjects, calling into question the independence of the review process. The Canadian proposal for amalgamation where a committee is considering less than 50 protocols annually is worthy of consideration.

Recommendation 19

IECs with small workloads should consider the possibility of amalgamation with another or other, IECs.

Footnotes

⁶⁸ See NGBHR *Communique 6(1) pp3-32*.

9. ACCOUNTABILITY IN THE IEC SYSTEM

The Review Committee was specifically asked to "consider the suitability of the existing arrangements for monitoring of IECs by the Australian Health Ethics Committee of the National Health and Medical Research Council".

9.1 Accountability in Research Generally

Most research in Australia is publicly funded and conducted within public institutions. Institutions conducting research should have in place transparent systems of accountability to enable public scrutiny of their activities. One submission stated that the community is entitled to be informed about the work of IECs, and specifically about their approval, or disapproval, of research and related matters. Ultimately, the ethical conduct of research projects and the integrity of the researchers involved is the responsibility of the institution. This responsibility is also clearly shared by the researcher who is subject to quality assurance standards through training, publication, seniority structures and peer review. Those public institutions conducting research are committed to quality assurance programs to ensure that all their activities meet with best practice standards. IECs are, in effect and practice, another quality assurance mechanism within an institution.

Several submissions argued that there should be improved opportunities for public scrutiny of the ethics process including IEC functioning and decision making. One submission summed up a quite general view that the "result of this lack of specific guidelines, monitoring or supervision functions is that IECs are not accountable to government, public or subjects. There is need for greater transparency, monitoring and supervision." It was suggested that all approved research should be submitted for publication (peer review journals, institution's annual report). It was also suggested in some submissions that current AHEC procedures for gathering information on IECs' compliance with NHMRC guidelines were not sufficient and should be reviewed. Several submissions felt that a more intensive monitoring of the IEC process and decisions was required.

The Review Committee has no persuasive evidence of unsatisfactory or poor conduct in the current operation of IECs to justify the introduction of more stringent inspection (for example, external independent audits) of IECs. Independent audits and the like should not be routinely introduced and should be a "last-choice" option used when there is evidence of misconduct. There was little support in the submissions for the conduct of random audits.

It is appropriate, at this stage, to retain the current position with regard to AHEC's role in overseeing IECs. Compliance reports should remain the primary source of information collected by AHEC. However, accountability could be improved. The records of IECs must be sufficiently detailed to provide a comprehensive statement of activities. The reports to AHEC should be more detailed. Publication is a way by which IECs can be more accountable publicly. AHEC presents annually to the NHMRC a report on IECs. If improved this has the potential to be an effective method for ensuring the accountability of the IEC system.

Recommendation 20

IECs should produce an annual report or contribute to the annual research report of their institution. This report should include the compliance information forwarded to AHEC and a listing of all research approved by the committee.

9.2 Sanctions

The IEC system has not required the imposition of sanctions for its successful operation. The success of the system has depended on voluntary compliance with the NHMRC guidelines by the IEC members and researchers. There are sanctions available to an IEC in the event of a failure by the principal investigator to comply with the reporting and notification requirements. Firstly, an IEC can withdraw ethical approval for the research project resulting in withdrawal of funding by the funding body. Where an IEC withdraws its ethical approval, the Guidelines indicate that it should notify the parent institution who should then notify the relevant funding body. Secondly, there is the possibility of disciplinary action by the governing body of the institution against the researcher(s). Such action is recommended only in extreme cases, such as repeated and continued failure on the part of the researcher(s) to comply with the reporting, notification or other monitoring requirements imposed by the IEC.⁶⁹

9.3 The Role of the Australian Health Ethics Committee

Institutions are responsible for their IECs. This institutional accountability is supplemented by the legal requirements of the NHMRC Act, 1992. Under this Act, it is a statutory condition of the payment of grants that IECs report to AHEC which in turn presents a report to the NHMRC. AHEC presents an annual report of IECs' compliance with NHMRC guidelines to the Council meeting. The primary function of this compliance report is to certify to the NHMRC that research funded by the NHMRC has been assessed by an IEC operating in accordance with NHMRC guidelines. Currently, compliance information required by AHEC is relatively scant and of a level able to be extracted from the minutes of committee meetings. This information includes confirmation of the continued membership and effective participation of core members in the decision-making process. The Review Committee considers that this reporting procedure needs to be improved if it is to represent a genuine accountability procedure.

The submissions received by the Review Committee displayed a significant lack of understanding of the current role and responsibilities of AHEC. They argued for the need for a strong advising and education role and the importance of AHEC maintaining a coordination function for IEC networks as well as the collection and dissemination of information. A number of submissions felt that AHEC should be a reference point for IECs in problem situations. For example, the submission of a university ethics committee highlighted that "in the past it has been somewhat frustrating that AHEC, which is in a position to oversee and direct IECs and make judgments as to the suitability of their policies and mechanisms for operation, has been reluctant to provide written advice or approval for specific local practices". Others felt that AHEC should be responsible for developing procedural standards and terms of reference for IECs (including standard application and consent forms).

AHEC has continued the work, initiated by the former MREC, of supporting IECs (188 at November 1995) through activities such as workshops, providing a newsletter and advice and speakers on request.

Importantly, AHEC also has the specific statutory responsibility to:

- advise the NHMRC on ethical issues relating to health;
- develop and give the NHMRC guidelines for ethical conduct in the health field, medical research involving humans and for the purposes of the Privacy Act 1988;
- promote community debate and consult with individuals, community organisations, health professions and government on health ethical issues;
- monitor and advise on the workings of institutional ethics committees;
- monitor international developments in relation to health ethical issues and liaise with relevant international organisations and individuals.

AHEC maintains a clearing house function for IECs and is responsible for coordinating, collecting and disseminating information as well as monitoring IECs in line with its statutory requirements. AHEC receives Annual Compliance Reports from all IECs operating in Australia. These reports provide details relating to the IECs' membership and procedures during the reporting period and are collated to form an Annual Report to the NHMRC on the operation of the IEC system. This reporting procedure provides an important, though minimal, source of public accountability for the national system. More comprehensive information should be obtained from IECs through this mechanism.

It is apparent that the IEC support/advice role of AHEC needs additional resourcing as there is a uniform demand for this assistance. Resources should be made available to further develop the support function between the Research Ethics Standing Committee of AHEC and IECs. Recommendations relating to the resourcing of this function are made elsewhere in this report (see section 8.2 - AHEC Resources).

The role of AHEC should remain one which facilitates and assists the work of IECs whilst maintaining an appropriate reporting structure aimed at ensuring proper public accountability. One means of facilitating improved communication between IECs and with AHEC may be for AHEC to prepare, and distribute to IECs, a directory of names and contact addresses for the Chairs and secretaries of all Australian IECs.

Recommendation 21

AHEC should revise its current Compliance Form and require annually the following information from IECs:

- Membership/membership changes;
- number of meetings;
- confirmation of full participation by minimum required members;
- confirmation of due procedures
 - number of rejections and reasons for rejections
 - monitoring procedures in place and any problems encountered;
- complaint procedures;
- number of complaints handled.

Footnotes

⁶⁹ AHEC names IECs which are not in compliance when it provides its annual report to the NHMRC.

RESCINDED

10. NHMRC Statement on Human Experimentation

The NHMRC *Statement on Human Experimentation* has a distinguished record in promoting ethical conduct in research in this country. The influence of the Statement has gone beyond medical researchers and IECs. Submissions to the Review raised objections about matters of detail rather than the core ethos of the Statement. Objections have arisen about the biomedical research focus of the Statement and it has been criticised as being too concerned with risk of physical harm rather than risks to privacy, reputation or other social harm.

The Statement has been adopted by universities because it is a comprehensive statement and one which has been based closely on the Declaration of Helsinki and its subsequent amendments. As was highlighted in one of the submissions, many universities have adopted the Statement and interpreted and applied it broadly to:

- protect the rights and welfare of human subjects and minimise the risk of physical and mental discomfort, harm and danger from research procedures;
- protect the rights of the researcher to carry out legitimate investigation, as well as the university's reputation for the research conducted and sponsored by it;
- minimise the potential for claims of negligence made against the researcher and the university.

A number of concerns about the Statement were raised by submissions to the Review. In general it was felt that the guidelines were too general, lacking detail and specificity. The need to clarify the scope of the guidelines and to recognise their applicability to non-medical research was also raised. Other submissions noted the potential benefits in consolidating the various NHMRC guidelines into one comprehensive manual, and the need for periodic review of all guidelines.

The Review Committee recommends that the NHMRC *Statement on Human Experimentation* undergo a substantial revision and be given a more appropriate title. At various points in this Report specific views of the Review Committee are expressed on matters to be addressed in this revision⁷⁰. Under the NHMRC Act, 1992, there are statutory requirements for a two-stage consultation process for such guidelines. It is therefore not within the competence of the Review Committee to re-draft the guidelines. It must remain the role of AHEC to re-draft and submit the document for the required two-stage consultation procedure.

Revised guidelines must reflect changing health research practice and should embrace all types of health research including research in relevant areas of social science. In revising the document AHEC should make it more broadly applicable, targeting the concerns of researchers, IECs and research subjects and should include specific reference to Aboriginal and Torres Strait Islander communities and minority cultural groups.

The guidelines should also address issues of concern to IECs relating to the collection, use and storage of information in research. This would involve taking account of good practice codes (for example, those promulgated by the Australian Vice Chancellors Committee and the Therapeutic Goods Administration) and the current Commonwealth Information Privacy Principles and should result in the development of a checklist for

researchers detailing the requirements for the collection, use and storage of research data and results.

Recommendation 22

AHEC should revise the *Statement on Human Experimentation* under a new title, to reflect all health research involving humans, and with due regard to relevant recommendations in this Report.

Recommendation 23

That this report be published and disseminated broadly.

Footnotes

⁷⁰ See in particular recommendations: 1 (section 4.2), 4 (section 4.9), 6 (section 5.1), 9 (section 5.3), 13 (section 5.5) and 14 (section 6.1) and section 4.3 (Cultural Issues).

APPENDIX 1

Invitation to provide submissions and list of submissions received

LIST OF SUBMISSIONS

Professor Henry Brodaty	Ms AM Pickhaver
Academic Department of Psychogeriatrics	Lecturer
Prince Henry Hospital	School of Medicine
	Palliative Care Unit
Mr Keith Harrison	The Flinders University of South Australia
Scientific Director	
The Queensland Fertility Group	Sir Raymond Hoffenberg
	Professor of Medical Ethics
Dr Paul Dugdale	Royal Brisbane Hospital
AINSLIE ACT	and
	Chairman
Ms Jane R Howard	Research Ethics Committee
Medical Director	Royal Women's Hospital
Family Planning Queensland	Brisbane
Mr Len Wakeman	Associate Professor TM Adamson
MAYLANDS WA	& Dr RG King
	Standing Committee on Ethics in Research
Professor R.R.H. Lovell	on Humans
Executive Secretary	Research Services Division
Victorian Cooperative Oncology Group	Monash University
Anti-Cancer Council of Victoria	
	Professor TJ Martin
Mr Keith Rex	Chairman
PADDINGTON NSW	Human Research Ethics Committee
	St Vincent's Hospital
Mr N Schultz-Lorentzen	
Executive Director	Chris Borthwick
The Danish Council of Ethics	BRUNSWICK VIC
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APPENDIX 2

NHMRC Statement on Human Experimentation and Supplementary Notes 1-3

NHMRC STATEMENT ON HUMAN EXPERIMENTATION

The collection of data from planned experimentation on human beings is necessary for the improvement of human health. Experiments range from those undertaken as part of patient care to those undertaken either on patients or on healthy subjects for the purpose of contributing to knowledge, and include investigations on human behaviour. Investigators have ethical and legal responsibilities toward their subjects and should therefore observe the following principles:

1. The research must conform to generally accepted moral and scientific principles. To this end institutions in which human experimentation is undertaken should have a committee concerned with ethical aspects and all projects involving human experimentation should be submitted for approval by such a committee ¹ (see supplementary note 1 on institutional ethics committees).
2. Protocols of proposed projects should contain a statement by the investigator of the ethical considerations involved.
3. The investigator after careful consideration and appropriate consultation must be satisfied that the possible advantage to be gained from the work justifies any discomfort or risks involved.
4. The research protocol should demonstrate knowledge of the relevant literature and wherever possible be based on prior laboratory and animal experiments.
5. In the conduct of research, the investigator must at all times respect the personality, rights, wishes, beliefs, consent and freedom of the individual subject.
6. Research should be conducted only by suitably qualified persons with appropriate competence, having facilities for the proper conduct of the work; clinical research requires not only clinical competence but also facilities for dealing with any contingencies that may arise.
7. New therapeutic or experimental procedures which are at the stage of early evaluation and which may have long-term effects should not be undertaken unless appropriate provision has been made for long-term care, observation and maintenance of records.
8. Before research is undertaken the free consent of the subject should be obtained. To this end the investigator is responsible for providing the subject at his or her level of comprehension with sufficient information about the purpose, methods, demands, risks, inconveniences and discomforts of the study. Consent should be obtained in writing unless there are good reasons to the contrary. If consent is not obtained in writing, the circumstances under which it is obtained should be recorded.
9. The subject must be free at any time to withdraw consent to further participation.

10. Special care must be taken in relation to consent, and to safeguarding individual rights and welfare where the research involves children, the mentally ill and those in dependant relationships or comparable situations (see supplementary note 2 on research on children, the mentally ill and those in dependant relationships or comparable situations, including unconscious patients).

11. The investigator must stop or modify the research program or experiment if it becomes apparent during the course of it that continuation may be harmful.

12. Subject to maintenance of confidentiality in respect of individual patients, all members of research groups should be fully informed about projects on which they are working.

13. Volunteers may be paid for inconvenience and time spent, but such payment should not be so large as to be an inducement to participate.

Supplementary Note 1 (1992) - Institutional Ethics Committees

Supplementary Note 1
adopted by the Council at its 113th
Session June 1992

1. All research projects involving human subjects and relating to health must be considered and approved by a committee constituted in accordance with this supplementary note.
2. Institutions in which such research is undertaken should establish and maintain an institutional ethics committee (IEC) composed and functioning in accordance with this supplementary note.

Where an institution cannot maintain a properly constituted IEC, approval of research proposals should be sought from an IEC established and maintained by another institution.

3. An IEC must ensure that ethical standards are maintained in research projects to protect the interests of the research subjects, the investigator and the institution.

4. Composition

(i) An IEC shall be composed of men and women of different age groups, and include at least one member from each of the following categories:

- laywoman not associated with the institution
- layman not associated with the institution
- minister of religion
- lawyer
- medical graduate with research experience

(ii) Persons may be appointed to stand-in for members when necessary.

(iii) An institution may appoint more persons than those specified in 4 (i) as members of an IEC.

(iv) Members and stand-in members shall be appointed by an institution on such terms and conditions as the institution determines and in such manner as to ensure that the committee will fulfil its responsibilities.

(v) Members shall be appointed as individuals for their expertise and not in a representative capacity.

(vi) A layperson is one who is not closely involved in medical, scientific or legal work.

(vii) A minister of religion may be of any faith.

5. Functions

(i) A research project may be approved and may continue only if an IEC is satisfied that:

- the project as set out in the protocol is acceptable on ethical grounds; and
- the project continues to conform to the approved protocol.

(ii) An IEC shall maintain a record of all proposed research projects including:

- name of responsible institution;
- project identification number;
- principal investigator(s);
- short title of project;
- ethical approval or non-approval with date;
- the relevance of the Privacy Guidelines, which address the use of data from Commonwealth agencies;
- approval or non-approval of any changes to the protocol; and
- action taken by the IEC to monitor the conduct of the research.

The protocols of research projects shall be preserved in the form in which they are approved.

(iii) The NHMRC accepts the responsibility to communicate with and audit the activities of IECs to ensure compliance with this supplementary note.

An IEC shall accept an obligation to provide information from its records to the NHMRC on request.

6. Application of functions

In carrying out these functions, an IEC shall:

(i) conform with the *NHMRC Statement on Human Experimentation and Supplementary Notes* as published from time to time;

(ii) while promoting the advance of knowledge by research, ensure that the rights of the subjects of research take precedence over the expected benefits to human knowledge;

(iii) ensure that, in all projects involving human subjects and relating to health, the free and informed consent of the subjects will be obtained;²

(iv) ensure that no member of the committee adjudicates on projects in which they may be personally involved;

(v) ensure that research projects take into consideration local cultural and social attitudes;

(vi) give its own consideration to projects that involve research in more than one institution;³

(vii) require the principal investigator to disclose any previous decisions regarding the project made by another IEC and whether the protocol is presently before another IEC; and

(viii) determine the method of monitoring appropriate to each project.

7. Meeting procedures

(i) Wherever possible, a decision by an IEC shall be made after a person from each of the categories listed in section 4 (i) of this supplementary note has had an opportunity to contribute their views during the decision making process;⁴

(ii) An IEC should seek to reach decisions by general agreement which need not involve unanimity;

(iii) In the absence of general agreement that a project is ethically acceptable, an IEC shall either establish a procedure to arrive at a decision, for example a simple majority, or inform the principal investigator of necessary amendments to the protocol;

(iv) An IEC may invite the investigator(s) to be present for discussions of the project; and

(v) An IEC may seek advice and assistance from experts to assist with consideration of a proposal.

8. Monitoring

An IEC shall ensure that there is appropriate monitoring of research projects until their completion. To achieve this a committee shall:

(i) at regular periods, and not less frequently than annually, require principal investigators to provide reports on matters including:

- security of records
- compliance with approved consent procedures and documentation
- compliance with other special conditions;

(ii) as a condition of approval of the protocol, require that investigators report immediately anything which might affect ethical acceptance of the protocol, including:

- adverse effects on subjects
 - proposed changes in the protocol
 - unforeseen events that might affect continued ethical acceptability of the project.
- and

(iii) establish confidential mechanisms for receiving complaints or reports on the conduct of the project.

Supplementary Note 2 - Research on children, the mentally ill, those in dependent relationships or comparable situations (including unconscious patients)

Revised supplementary note 2
adopted by the Council at its 113th Session
June 1992

Ethics of research on children⁵

In these notes the principles and guidelines that are set out largely reflect the "Report on Ethics of Research in Children" prepared by the Council of the Australian College of Paediatrics and published in the *Australian Paediatric Journal* 17:162, 1981.

1. Scientific research is essential to advance knowledge of all aspects of childhood disease. Such research, however, may be performed only when the information sought cannot in practice be obtained by other means.

2. All research must be based on sound scientific concepts and must be planned and conducted in such a fashion as will reasonably ensure that definite conclusions will be reached. Some programs may offer direct benefit to the individual child, while others may have a broader community purpose. In appropriate circumstances both may be ethical.

3. In all centres undertaking research in children, the following special responsibilities of the institutional ethics committee are emphasised:

- (i) protecting the rights and welfare of children involved in research procedures;
- (ii) determining the acceptability of the risk/benefit relationship of any research study conducted;
- (iii) ensuring that informed consent from parents/guardian and where appropriate the child, is obtained in a manner appropriate to the study;
- (iv) encouraging the performance of necessary and appropriate research; and
- (v) preventing unscientific or unethical research.

4. Consent to research should be obtained from:

- (i) the parents/guardian in all but exceptional circumstances (e.g. emergencies); and
- (ii) the child where he or she is of sufficient maturity and intelligence to make this practicable.

In this context "consent" means consent following a full and clear explanation of the research planned, its objectives and any risks involved.

5. Risks of research may be considered in terms of:

- (i) therapeutic research (where the procedure may be of some benefit to the child).

In determining whether there is an acceptable relationship between potential benefit and the risk involved, it is essential to weigh the risk of the proposed research against customary therapeutic measures and the natural hazards of the disease or condition.

(ii) non-therapeutic research (where the procedure is of no direct benefit to the child).

The risk to the child should be so minimal as to be little more than the risks run in everyday life.

Risks of research in this context include the risk of causing physical disturbance, discomfort, anxiety, pain or psychological disturbance to the child or the parents rather than the risk of serious harm, which would be unacceptable.

The mentally ill

It is always desirable to obtain informed consent from a person who has the intelligence or capacity to make this practicable. In the case of those who lack legal capacity due to mental illness, consent should also be obtained from the person who stand legally in the position of guardian, next friend, or the like.

Those in dependant relationships or comparable situation

Some people merit special attention before inclusion in a project in order to ensure that consent is both informed and free. It is not possible to define them exhaustively, but in addition to children and the mentally ill they may include the following:

- elderly persons who may have legal capacity but may nonetheless be in a position where they are unable to give a free or comprehending consent;
- wards of the state;
- those in doctor and patient, and teacher and student relationships;
- prisoners;
- member of the Services; and
- hospital and laboratory staff.

Unconscious and critically ill patients

Unconscious, semi-conscious or critically ill patients from whom or on behalf of whom consent cannot be obtained for treatment or other intervention, because of the urgency of their condition, also merit special attention.

A person might be in such a situation, for example, following a drug overdose or a cardiac arrest. Two kinds of experimental intervention may be envisaged. The first is intended or expected to benefit the person. The second is intended or expected to yield important scientific information but is not intended or expected to benefit the person. (The taking of a sample of blood for studies not directly relevant to the diagnosis or treatment of the patient would be an example of the latter.)

1. Experimental intervention intended or expected to benefit the patient.

Before approving a research protocol an institutional ethics committee should satisfy itself

(i) that the guidelines, other than those bearing on consent, in the statement on human experimentation are followed; and

(ii) that in the light of available knowledge it is reasonable to adopt the experimental intervention as being in the interests of the patient.

2. Experimental intervention is neither intended nor expected to benefit a patient.

Before approving a research protocol, an institutional ethics committee should satisfy itself:

(i) that the guidelines, other than those bearing on consent, in the statement on human experimentation are followed;

(ii) that there are good reasons why the experimental intervention cannot be limited to persons from whom, or on behalf of whom, consent can be obtained;

(iii) that the experimental intervention will be one which will involve no material risks beyond those associated with procedures that are clinically indicated for the patient;

(iv) that the requirements of the research do not influence the procedures that are clinically indicated; and

(v) that the confidentiality of information identifying the patient will be preserved.

Supplementary note 3 - Clinical trials

Revised supplementary note 3
adopted by the Council at its 104th Session
November 1987

A clinical trial is a study done in humans to find out if a treatment or diagnostic procedure, which it is believed may benefit a patient, actually does so. A clinical trial can involve testing a drug, a surgical or other procedure, or a therapeutic or diagnostic device.

The drug procedure or device may be a new or an old one. It may be under trial in new clinical circumstances, or its conventional use may be under review. It is not always possible to make a clear distinction between ordinary diffusion of clinical knowledge and the medical and surgical circumstances that warrant a formal clinical trial. Clinicians should be aware of the benefits that come from (a) designing and conducting clinical trials, and (b) sharing ethical responsibility for innovation in medical practice.

The *NHMRC Statement on Human Experimentation and Supplementary Notes* are applicable to all clinical trials.

Following are some particular matters concerning the design and conduct of clinical trials that need to be taken into account when ethical aspects are being considered. Clinical trials involving DNA (gene) therapy are subject to additional requirements (see supplementary note 7).

1. Trials should be conducted according to written protocols, which should be approved by institutional ethics committees.
2. When an institutional ethics committee is reviewing a proposal for a clinical trial involving a drug it should be assured:
 - (i) that a pharmacologist or clinical pharmacologist has been involved in preparing the protocol;
 - (ii) that for trials involving new drugs the protocol includes a full investigational profile⁶ of the drug or drugs to be used;
 - (iii) that the protocol contains precise information on dosage, formulation, frequency of administration and methods of assessing safety; and
 - (iii) that all suspected adverse drug effects observed in the course of a trial will be reported to the Commonwealth Department of Health, Housing and Community Services.
3. When an institutional ethics committee is reviewing a proposal for a clinical trial involving a therapeutic or diagnostic device it should be assured:
 - (i) that persons suitably qualified to assess the technical and clinical aspects of the device have been involved in preparing the protocol;
 - (ii) that the protocol contains adequate information on methods of use, risks and benefits expected; and

- (i) that the guidelines for investigational use of therapeutic devices prepared by the Commonwealth Department of Health, Housing and Community Services are taken into account⁷.

4. The aims of every trial should be precisely stated and important enough to be worth achieving, having in mind the time, effort, cost and possible discomfort that may be involved.

5. The experimental design should be such as to ensure that it will be possible to answer the question asked. In particular institutional ethics committees should be assured of the statistical validity of the design of a proposed trial.

6. Some trials involve the use of control groups for purposes of comparison. Patients in control groups should receive what is considered to be the best treatment currently available; in some cases this may be simply observation or administration of placebo.

7. When informed consent is being sought, costs which may be incurred by subjects as a result of participation in the trial should be discussed with them.

8. There should be a reasonable expectation that the objectives of a clinical trial will be achieved within a defined period of time. In some circumstances it may be unethical to continue a trial for the full period that was planned. For example, it would be wrong to continue if there were substantial deviations from the trial protocol, or if side effects of unexpected type or frequency were encountered. It would also be wrong to continue if one of several treatments or procedures being compared proved, as the trial progressed, to be so much better, or worse, than other(s) that continued adherence to the trial would disadvantage some of the subjects enrolled.

The progress of a trial should generally, therefore, be monitored. Monitoring should be done by an independent person or small committee. Independence is necessary because it is often important, in order to minimise observer and patient bias, for those conducting a trial to remain unaware of trends in the results during the study; it may also be hard for them to take a detached view of the merits of continuing a trial already under way. Those conducting the trial should give the monitoring body such information as it may request to enable it to be satisfied that the trial protocol is being followed and that the outcome of treatment, including side effects, is not such as to warrant premature termination of the study.

APPENDIX 3

International ethics systems

INTERNATIONAL ETHICS SYSTEMS

Australia has followed contemporary international developments in the ethical review of research. Internationally, the same broad conclusion has been reached that the assurance of ethical conduct in research is to be achieved by a cross-disciplinary committee with a degree of independence from the institution in which the research is conducted. In an endeavour to set international standards, the Council for International Organisations of Medical Science (CIOMS) has developed standards for the conduct of biomedical research. The CIOMS guidelines have become an essential reference point for any discussion on ethics and biomedical research.

Council for International Organisations of Medical Sciences (CIOMS)

CIOMS has an increasing influence in the international promotion of high ethical standards in research practice. Its guidelines⁸ state that the objectives of research are to be directed to justifiable advancement in biomedical knowledge that is consistent with prevailing community interests and priorities. The research should also only be conducted where the information cannot be obtained from animal studies and where the study has been designed with a view to obtaining information from as few subjects as possible. Before any research project is undertaken, the risks should have been defined following literature searches and experimental studies. Research is also required to be carried out by a responsible and appropriately qualified and experienced researcher. The researchers must make every effort to inform research subjects of the objectives and consequences of involvement in the project and must particularly raise with them identifiable risks and inconvenience.

CIOMS has become more active in recent years in publishing declarations in relation to medical and bioethical issues. For example, in 1994 CIOMS held its XXVIII conference on "Poverty, Vulnerability, the Value of Human Life and the Emergence of Bioethics". At the end of this conference, CIOMS published the Declaration of Ixtapa entitled "A Global Agenda for Bioethics" which reasserted guiding principles in relation to bioethics and the health sector.

United States Of America

Ethics Committees

American Ethics Committees have a variety of roles including:

- advising doctors and family on decisions about withdrawing life support treatment;
- provision of advice on withholding treatment from newborn infants with birth defects;
- policy making through the drafting of guidelines for hospital personnel on controversial areas of medical practice;
- education through the organisation of seminars on areas of controversy; and
- provision of advice on specific ethical dilemmas in the treatment of specific patients.

These committees are also evolving to become general consultative bodies allowing doctors and health care providers an opportunity to discuss and explore ethical issues involving general practice.

In effect American Ethics Committees are "patient care committees" and are often called such. Caution must be exercised in drawing comparisons between these committees and IECs in Australia. The role and functions of Australian IECs are closer to those of American Institutional Review Boards.

Institutional Review Boards

As well as the infamous Tuskegee Study⁹, a number of questionable human experiments were disclosed before the United States Congress in the early 1970s. Much of this research was conducted in prisons and mental hospitals and on human fetuses. Following these events the *National Research Act* 1974 was introduced which requires that each institution conducting federally supported research involving human subjects establish its own institutional Review Board (IRB). These IRBs¹⁰ are required to review the ethical aspects of all research protocols within the institution. By 1975 almost all universities, medical schools and research hospitals had established IRBs. The Code of Federal Regulations was revised in 1981 to allow low risk research to be considered by an IRB.¹¹

In order to fulfil the requirements of the Federal Regulations, each IRB is required to follow written procedures for the conduct of initial and continuing review of research and for reporting findings and actions to the investigator and the institution. An IRB determines which projects require review more often than annually and which projects need verification from sources other than the investigator.

Changes in approved research may not be initiated without IRB review and approval (except where necessary to eliminate apparent immediate hazards to the human subjects). In addition to reporting to the IRB, appropriate institutional officials and the Food and Drug Administration must be told of any unanticipated problems involving risks to human subjects or others, any instance of serious or continuing non-compliance with Federal regulations or the decisions of the IRB, or any suspension or termination of IRB approval. Except when an expedited review procedure is used, research must be reviewed by a majority of the members of the IRB, at least one of those members is required to be one whose primary concerns are in non scientific areas and the proposal needs to receive the approval of a majority of those members present at the meeting.

United Kingdom

Local Research Ethics Committees (LRECs) in the UK are locally established and formally constituted as subcommittees within the health authority system. They began to develop in the 1960's and in 1967 the Royal College of Physicians formally recommended that clinical research investigations be subject to ethical review.

LRECs are diverse in function and do not directly relate to Australian IECs in that they operate within the National Health Service. A UK Department of Health circular of 1989 (HSC (IS) 15-31) requires that each district health authority appoint a "...properly constituted Local Research Ethics Committee (LREC), which meets regularly, to register, review and approve (or not approve) the research conducted by its staff, or

using its premises or facilities, including access to personal health information held by the authority (and research undertaken by general practitioners within its boundaries)." The LREC's follow guidelines from the Royal College of Physicians and the Department of Health.

The growth of ethics committees has followed diverse paths and a number of "informal" ethics committees have been established beyond the terms of the Department of Health Circular Guidelines. Brazier¹² particularly notes that a number of fertility units have established advisory committees to assist practitioners in making decisions about the admission of individual patients to the program.

National Health Department Guidelines recommend that LREC membership be between 10-12 members consisting of both sexes and drawn from a wide range of age-groups. Membership should include hospital medical staff, nursing staff, general practitioners and two or more laypersons. At least one lay member should not be professionally connected with health care and be neither an employee nor an adviser of any National Health System body. Either the chair or the deputy chair should be a lay member. The membership of LRECs varies considerably in size, frequently above the suggested maximum of twelve¹³.

A Report¹⁴ prepared on the operation of Research Ethics Committees discovered that these ethics committees were "chronically under staffed" and that there was room for considerable improvement at a constitutional level as well as in terms of organisation. This Report made a number of recommendations aimed at strengthening ethics committees in their work, providing the members with training and support, ensuring greater standardisation of practice and giving research subjects greater protection and further information. Significantly, the major recommendation of this Report was that there should be legislation to strengthen LRECs' role, and to empower them to carry out their genuine tasks properly.

New Zealand¹⁵

New Zealand began to establish ethics committees in hospitals in the early 1970s. A Department of Health Circular in 1972 recommended that these review committees include experienced members of the institutions' professional staff. In 1975, the Medical Research Council required that applicants for the Council's grants have the consent of a local review committee. At this time most ethics committees consisted of 3-6 members and generally only included medical members.

The 1988 Cervical Cancer Inquiry conducted by Judge Cartwright¹⁶ focused attention on the role of the ethics committee in the protection of the welfare of the patient who is the subject of research, and in ensuring that sufficient information is supplied to the patient so that informed free consent be obtained. All recommendations made by the inquiry were adopted by the Minister of Health and their implementation has substantially altered the system of ethics review in New Zealand.

National Standard for Ethics Committees

An Interim National Standard for Ethics Committees has been issued by the Ministry of Health. The Standard guides the establishment and operation of ethics committees setting out: the role of ethics committees; requirements for composition and membership of committees; and procedures for ethical review. The Standard also includes guidelines for compensation for injuries caused as a result of participation in a clinical trial. The Standard is currently being reviewed and it is anticipated that the revised edition will include standard application forms for ethical review.

The National Standard requires that the chairperson of an ethics committee be a lay member and that approximately 50% of the committee's membership consist of laymembers. In the selection of members, attention should be paid to cultural diversity, gender balance, and inclusion of people with a disability. At least three members of the committee are to be Maori and the minimum number of committee members is specified as seven.

An appendix to the Standard outlines 'procedures for fast-tracking' committee decisions. Recognising that some proposals do not require referral for full ethics committee review the Standard includes instructions to ethics committees on developing procedures to 'fast-track' review where appropriate.

Regional Ethics Committees

The four Regional Health Authorities (RHAs) are required, through their funding agreement with the Crown, to purchase regional ethical review services. There are currently 14 regional ethics committees. RHAs are required to ensure that regional ethics committees are established and operate in accordance with the National Standard for Ethics Committees. Each regional ethics committee has a defined geographical area of interest and all research and innovative treatment protocols carried out in that geographical area is referred to that committee.

Under the Health Research Council Act 1990, the Health Research Council Ethics Committee is required to approve ethics committees reviewing research and a system of accreditation has been developed by the Health Research Council. Universities, tertiary institutions and professional bodies also have ethics committees. There are moves to bring these committees under the National Standard and the accreditation process.

National Ethics Committees

National Ethics Committee on Assisted Human Reproduction - this committee was established in May 1995. It is a ministerial committee responsible for reviewing new or innovative assisted human reproductive proposals of national importance.

National Advisory Committee on Health and Disability Service Ethics - this committee was established in December 1994. It is responsible for advising the Minister on ethical issues, drafting and reviewing the National Standard for Ethics Committees, accrediting and monitoring regional ethics committees and providing second opinions as requested. It is also responsible for the networking of regional ethics committees and co-ordination of national meetings of the Chairs of regional committees.

Canada

Review of Medical Research

Since 1966, the Medical Research Council of Canada has required research using human subjects to be reviewed by local ethics review committees. In 1987 guidelines promulgated by the Council adopted the name Research Ethics Boards for these committees. There are over one hundred REBs in Canada. These boards are institutionally based, principally in universities and hospitals. The majority of REBs apply the Medical Research Council guidelines to their operations, however, where a research project is funded by the United States National Institutes of Health or other US funding body, US Guidelines may also be followed. There are no centralised or regional ethics committees. However, there are a number of models of collaboration with REBs serving a number of institutions. For example, the University of Western Ontario Review Board for Health Sciences Research considers research projects from the University of Western Ontario, the three major teaching hospitals and the three research institutes in the area.¹⁷ The workload of Canadian REBs has increased markedly in recent years. No minimum membership is mandated, rather categories of expertise are indicated.

The REBs in Canadian Faculties of Medicine were the subject of a three year study by a working group of the "National Council on Bioethics in Human Research (NCBHR). The aims of the study were: (a) to assist Canadian REBs in reviewing the strengths and weaknesses of their current system of ethics review; (b) to foster dialogue and understanding on the utility and limits of national ethical guidelines in the institutional setting; and (c) for the benefit of the national research ethics community, to compile a national data base on REB practices.

The report of the evaluation has since been published.¹⁸ Its recommendations are intended to reform and promote the further development of Canadian REBs. Key recommendations included that expedited review could be used for projects which entailed negligible or minimal risk (Rec 4); that educational and training materials be prepared (Recs 6, 8); that REBS considering less than fifty proposals should amalgamate with another REB (Recs 10, 12); that monitoring mechanisms should be thoroughly reviewed (Recs 16-18); and, that consequences of non-compliance with guidelines be clarified and compliance site visits to be continued (Recs 19,20).

Review of Social Science Research

The Social Science and Humanities Research Council (SSHRC) of Canada administers guidelines for the review of social and behavioural research. The guidelines were initially developed by the Canada Council in 1977. The SSHRC recommends that the ethics committee be an institutional review committee set up as a standing committee within the institution. Only general guidance as to the memberships of these committees is provided. It is suggested that the committee be broadly based with representatives from inside and outside the department or discipline.

¹ (a) An application to the NHMRC for a research grant involving human experimentation is required to be certified by the ethics committee of the applicant's institution as complying with the *NHMRC Statement on Human Experimentation and Supplementary Notes* before the application will be considered for funding.

(a) Persons undertaking human experimentation who are not associated with an institution should ensure that comments on their protocols are sought from an established ethics committee e.g. in a university or hospital.

² Except in accordance with section 7 of supplementary note 6 of the *NHMRC Statement on Human Experimentation and Supplementary Notes*.

³ An IEC is *free to* discuss a project with other IECs if it chooses, with due regard to confidentiality.

⁴ This does not necessarily require the presence of a person from each of the categories at every meeting of an IEC. There are a number of options available to deal with situations where all members cannot be present and these are at the discretion of each IEC. For example, if a member cannot be present at a meeting, their opinion could be communicated in writing or orally and recorded at the meeting.

⁵ In this supplementary note the word "child" extends to a person from birth until the legal age of majority. Some States and Territories in Australia have special laws applying to the medical treatment of minors.

⁶ The data on formulation would normally be that contained in the National Drug Information Service drug profiles.

⁷ Guidelines for the General Marketing or Clinical Investigational use of Designated Therapeutic Devices are available from the Department of Health, Housing and Community Services, Medical Devices and Dental Products Branch GPO Box 9848, Canberra ACT 2601.

⁸ See for example CIOMS *International Guidelines for Biomedical Research Involving Human Subjects*, 1993, Geneva.

⁹ See Furrow, B., 1995, *Health Law*, West Publishing, at pp 839-84 1.

¹⁰ The general standards for the composition, operation and responsibility of IRBs are contained in Federal Regulations (Code of Federal Regulations, 21, Food and Drugs, Part 56, revised at 1 April, 1992).

¹¹ For an excellent coverage of regulation of research on human subjects in the USA see Furrow, B., 1995 chapter-23.

¹² Brazier, M., 1990, "Liability of Ethics Committees and their Members" *Professional Negligence* 186.

¹³ Gilbert Foster, C., Marshall, I., & Moodie, R., 1995, "The annual reports of Local Research Ethics Committees" *Journal of Medical Ethics* 2 1, pp 214-219.

¹⁴ See Neuberger, J. 1992, *Ethics and Health Care: The Role of Research Ethics Committees in the United Kingdom*, Research Report 13, Kings Fund Institute.

¹⁵ Information provided by Melanie Gudsell, Ministry of Health, Wellington NZ.

¹⁶ S.R., Cartwright, 1988, *The Report of the Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and into Other Related Matters*, Government Printing Office, Auckland NZ.

¹⁷ Information provided by Dr B Borwein, Chair University of Western Ontario Review Board for Health Sciences Research Involving Human Subjects.

¹⁸ Published in NHMRC *Communique*, 1995, 6(1) pp 3-32.

RESEARCH
INDICATED

APPENDIX 4

Information Privacy Principles

INFORMATION PRIVACY PRINCIPLES

Principle 1 Manner and purpose of collection of personal information

1. Personal information shall not be collected by a collector for inclusion in a record or in a generally available publication unless:

(a) the information is collected for a purpose that is a lawful purpose directly related to a function or activity of the collector; and

(b) the collection of the information is necessary for or directly related to that purpose.

2. Personal information shall not be collected by a collector by unlawful or unfair means.

Principle 2 Solicitation of personal information from individual concerned

Where:

(a) a collector collects personal information for inclusion in a record or in a generally available publication; and

(b) the information is solicited by the collector from the individual concerned;

the collector shall take such steps (if any) as are, in the circumstances, reasonable to ensure that, before the information is collected or, if that is not practicable, as soon as practicable after the information is collected, the individual concerned is generally aware of.

(c) the purpose for which the information is being collected;

(d) if the collection of the information is authorised or required by or under law the fact that the collection of the information is so authorised or required; and

(e) any person to whom, or any body or agency to which, it is the collector's usual practice to disclose personal information of the kind so collected, and (if known by the collector) any person to whom, or any body or agency to which, it is the usual practice of that first-mentioned person, body or agency to pass on that information.

Principle 3 Solicitation of personal information generally

Where:

(a) a collector collects personal information for inclusion in a record or in a generally available publication. and

(b) the information is solicited by the collector.

the collector shall take such steps (if any) as are, in the circumstances, reasonable to ensure that, having regard to the purpose for which the information is collected:

(c) the information collected is relevant to that purpose and is up to date and complete; and

(d) the collection of the information does not intrude to an unreasonable extent upon the personal affairs of the individual concerned.

Principle 4 Storage and security of personal information

A record-keeper who has possession or control of a record that contains personal information shall ensure:

(a) that the record is protected, by such security safeguards as it is reasonable in the circumstances to take, against loss, against unauthorised access, use, modification or disclosure, and against other misuse; and

(b) that if it is necessary for the record to be given to a person in connection with the provision of a service to the record-keeper, everything reasonably within the power of the record-keeper is done to prevent unauthorised use or disclosure of information contained in the record.

Principle 5 Information relating to records kept by the record-keeper

A record-keeper who has possession or control of records that contain personal information shall, subject to clause 2 of this Principle, take such steps as are, in the circumstances, reasonable to enable any person to ascertain:

(a) whether the record-keeper has possession or control of any records that contain personal information; and

(b) if the record-keeper has possession or control of a record that contains such information:

(i) the nature of that information;

(ii) the main purposes for which that information is used; and

(iii) the steps that the person should take if the person wishes to obtain access to the record.

2. A record-keeper is not required under clause 1 of this Principle to give a person information if the record-keeper is required or authorised to refuse to give that information to the person under the applicable provisions of any law of the Commonwealth that provides for access by persons to documents.

3. A record-keeper shall maintain a record setting out:

(b) the nature of the records of personal information kept by or on behalf of the record-keeper;

(b) the purpose for which each type of record is kept;

(c) the classes of individuals about whom records are kept;

- (d) the period for which each type of record is kept;
- (e) the persons who are entitled to have access to personal information contained in the records and the conditions under which they are entitled to have that access; and
- (f) the steps that should be taken by persons wishing to obtain access to that information.

4. A record-keeper shall:

- (a) make the record maintained under clause 3 of this Principle available for inspection by members of the public; and
- (b) give the Commissioner, in the month of June in each year, a copy of the record so maintained.

Principle 6 Access to records containing personal information

Where a record-keeper has possession or control of a record that contains personal information, the individual concerned shall be entitled to have access to that record, except to the extent that the record-keeper is required or authorised to refuse to provide the individual with access to that record under the applicable provisions of any law of the Commonwealth that provides for access by persons to documents.

Principle 7 Alteration of records containing personal information

1. A record-keeper who has possession or control of a record that contains personal information shall take such steps (if any), by way of making appropriate corrections, deletions and additions as are, in the circumstances, reasonable to ensure that the record:

- (a) is accurate; and
- (b) is, having regard to the purpose for which the information was collected or is to be used and to any purpose that is directly related to that purpose, relevant, up to date, complete and not misleading.

2. The obligation imposed on a record-keeper by clause 1 is subject to any applicable limitation in a law of the Commonwealth that provides a right to require the correction or amendment of documents. Where:

- (a) the record-keeper or a record containing personal information is not willing to amend that record, by making a correction, deletion or addition, in accordance with a request by the individual concerned; and
- (b) no decision or recommendation to the effect that the record should be amended wholly or partly in accordance with that request has been made under the applicable provisions of a law of the Commonwealth;

the record-keeper shall, if so requested by the individual concerned, take such steps (if any) as are reasonable in the circumstances to attach to the record any statement provided by that individual of the correction, deletion or addition sought.

Principle 8 Record-keeper to check accuracy of personal information before use

A record-keeper who has possession or control of a record that contains personal information shall not use that information without taking such steps (if any) as are, in the circumstances, reasonable to ensure that, having regard to the purpose for which the information is proposed to be used, the information is accurate, up to date and complete.

Principle 9 Personal information to be used only for relevant purposes

A record-keeper who has possession or control of a record that contains personal information shall not use the information except for a purpose to which the information is relevant.

Principle 10 Limits on use of personal information

1. A record-keeper who has possession or control of a record that contains personal information that was obtained for a particular purpose shall not use the information for any other purpose unless:

(a) the individual concerned has consented to use of the information for that other purpose;

(b) the record-keeper believes on reasonable grounds that use of the information for that other purpose is necessary to prevent or lessen a serious and imminent threat to the life or health of the individual concerned or another person;

(c) use of the information for that other purpose is required or authorised by or under law;

(d) use of the information for that other purpose is reasonably necessary for enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the protection of the public revenue; or

(e) the purpose for which the information is used is directly related to the purpose for which the information was obtained.

2. Where personal information is used for enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the protection of the public revenue, the record-keeper shall include in the record containing that information a note of that use.

Principle 11 Limits on disclosure of personal information

1. A record-keeper who has possession or control of a record that contains personal information shall not disclose the information to a person, body or agency (other than the individual concerned) unless:

(a) the individual concerned is reasonably like to have been aware, or made aware under Principle 2, that information of that kind is usually passed to that person, body or agency;

(b) the individual concerned has consented to the disclosure;

(c) the record-keeper believes on reasonable grounds that the disclosure is necessary to prevent or lessen a serious and imminent threat to the life or health of the individual concerned or of another person;

(d) the disclosure is required or authorised by or under law; or

(e) the disclosure is reasonably necessary for the enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the protection of the public revenue.

2. Where personal information is disclosed for the purposes of enforcement of the criminal law or of a law imposing a pecuniary penalty, or for the purpose of the protection of the public revenue, the record-keeper shall include in the record containing that information a note of the disclosure.

3. A person, body or agency to whom personal information is disclosed under clause 1 of this Principle shall not use or disclose the information for a purpose other than the purpose for which the information was given to the person, body or agency.

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