Health Research Council

Guidelines on Ethics in Health Research

May 2002
(Revised 2005)

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1 Introduction to Ethics Committees

1.1 Introduction

The Treaty of Waitangi is the founding document of New Zealand. The principles of partnership and sharing implicit in the Treaty should be respected by all researchers and, where applicable, should be incorporated into all health research proposals.

The HRC Ethics Committee (HRCEC) requires that ethical approval from an accredited ethics committee must be obtained before HRC funding for any research proposal may commence.

Avenues for ethical assessment of applications for HRC funding have been established by the HRCEC through the adoption of the *Operational Standard for Ethics Committees* Ministry of Health, March 2002 and by delegating authority to accredited health and disability or institutional ethics committees to review research applications received by the HRC for funding. Copies of the *Operational Standard* are available from the HRCEC, the Ministry of Health or any accredited ethics committee.

The following HRCEC guidelines expand upon the guidelines established by the *Operational Standard* and will be revised from time to time.

1.2 Health Research Council Ethics Committee (HRCEC)

The HRCEC is an HRC statutory committee established under section 25 of the Health Research Council (HRC) Act 1990.

The functions of the HRCEC are set out in section 25 of the HRC Act and include the following:

- provide independent comment and recommendations on ethical issues that arise in any aspect of health research, especially those emerging through the development of new areas of health research;
- review and update guidelines for the Council;
- provide second opinions on research involving human participants and the introduction of innovative practices;
- accredit ethics committees;
- maintain standards of accredited ethics committees by review of annual reports;
- provide advice to ethics committees established by other bodies on membership and procedures to be adopted and standards observed, and
- ensure that, where appropriate, the investigator meets the obligations under the Animal Welfare Act 1999 in the circumstances where animals are involved.

Additional responsibilities may be undertaken after discussion and agreement with the National Advisory Committee on Health and Disability Support Services Ethics (NEAC).

1.3 HRCEC Membership

Members of the HRCEC are appointed by the Board of the HRC.

Membership is set out in section 26 of the HRC Act and must include the Chairperson of the Board and one other member of the Board with qualifications in science. Five other persons, who are not members of the Board, are appointed having regard to the need to have a diversity of knowledge and experience in relation to science, ethics, philosophy, law, theology, nursing, women's health, patient advocacy and tkianga Maori.

The Chair of the HRCEC is appointed by the members of the HRCEC.

During 1992, Council resolved that the maximum term of membership for HRCEC members will be three years plus possible renewal for up to a further three years.

1.4 Ethics Committee in New Zealand

The national system of ethics review is comprised of a number of committees with various responsibilities for human ethics and animal ethics.

For human ethics, the following ethics committees are established under statute:

- The Health Research Council Ethics Committee, **see 1.2 HRCEC;**
- The National Advisory Committee on Health and Disability Support Services Ethics, **See 1.5 NEAC;**
- The Ethics Committee on Assisted Reproductive Technology, **see 1.6 ECART**, and
- Six Regional Health and Disability Ethics Committees and the Multi-region Ethics Committee, **see 1.7 Health and Disability Ethics Committees.**

In addition, ethics committees are also set up by organisations and accredited by the HRCEC:

- Institutional Ethics Committees, and
- Private sector Ethics Committees.

see 1.10 Institutional and Other Human Ethics Committee

The framework for animal ethics is set out in the Animal Welfare Act 1999.

1.5 National Advisory Committee on Health and Disability Support Services Ethics (NEAC)

NEAC is established under the NZ Public Health and Disability Act 2000 by the Minister of Health for the purpose of obtaining advice on ethical issues of national significance in respect of any health and disability matters. NEAC must also determine nationally consistent ethical standards across the health sector and provide scrutiny for national health research and health services.

NEAC is made up of twelve representatives from a broad range of disciplines, professions and interests. Expertise in ethics, public health and healthcare, Maori health, health and disability research, and law, are brought to bear on all matters considered by the Committee.

Sub-Committee on Appeals

In 2005, NEAC convened a Sub-Committee on Appeals (SCA) to review appeals from decisions of Health and Disability Ethics Committees.

The SCA is made up of at least 12 members who are selected, primarily, to have the most appropriate expertise, skills, knowledge and perspectives to hear appeals form the decisions of the Health and Disability Ethics Committees. For information on the appeals process **see 2.7 Appeals**

See the following website for more information on NEAC:
www.newhealth.govt.nz/neac.htm

1.6 Ethics Committee on Assisted Reproductive Technology (ECART)

ECART is established under section 27 of the Human Assisted Reproductive Technology (HART) Act 2004 to consider and determine applications for assisted reproductive procedures or human reproductive research (which is research that uses or creates a human gamete, human embryo or a hybrid embryo).

ECART must follow policy and guidelines developed by the Advisory Committee on Assisted Reproductive Technology (ACART), also established under the HART Act.

The committees replace the former ministerial committee, the National Ethics Committee on Human Assisted Reproduction (NECHAR) in 2005.

1.7 Health and Disability Ethics Committees

Health and Disability Ethics Committees are established under section 11 of the New Zealand Public Health and Disability Act 2000. The Committees are accredited by the HRCEC and administered by the Ministry of Health. There are six Regional Health and Disability Ethics Committees and a single Multi-region Ethics Committee.

The committees' functions are to review health and disability research proposals in accordance with the *Operational Standard* and provide general ethical guidance.

Regional Health and Disability Ethics Committees review research that is to be carried out entirely in their designated region of authority (**the Health and Disability Ethics Committees Region Map is available at** www.hrc.govt.nz**)**. The Multi-region Ethics Committee considers research that is to be carried out in more than one of the four regions.

For a list of the committees and their administrators **see 1.9 Accredited Ethics Committees: Regional and Multi-region Ethics Committee**.

See the following website for more information on Health and Disability Ethics Committees: **www.newhealth.govt.nz/ ethicscommittees/**

1.8 Accreditation by HRCEC

It is the responsibility of the HRCEC to ensure that an independent ethical assessment of any proposed health research submitted for a HRC grant has been carried out either by the HRCEC itself, or an ethics committee approved by the HRC (see s25 of the HRC Act 1990). The HRCEC accredits ethics committees to carry out this function **see 1.9 Accredited Ethics Committees**.

Accredited ethics committees also meet the conditions required to conduct ethical review for the following purposes:

- to provide coverage of participants in a clinical trial who sustain injury, under the Injury Prevention, Rehabilitation, and Compensation Act 2001;
- to allow disclosure of health information for research where it is either not desirable or not practicable to obtain authorisation from the individual concerned under the Health Information Privacy Code, and
- to allow access to data held by the New Zealand Health Information Service database in accordance with the *Guide to NZHIS National Collections*.

The approval of ethics committees by the HRCEC is a formal process. The HRCEC requires every accredited ethics committee to provide an annual report plus any other relevant information required as stated in the *HRC Guidelines for Ethics Committee Accreditation*– available from www.hrc.govt.nz. Annual reports are due within three months of the reporting year end.

1.9 Accredited Ethics Committees

Institutional and Other Human Ethics Committees

Auckland University of Technology Ethics Committee	madeline.banda@aut.ac.nz
Lincoln University Human Subjects Ethics Committee	Davidsm2@lincoln.ac.nz
Massey University Human Ethics Committee	P.L.Broad@massey.ac.nz

UNITEC Research Ethics Committee	ethics@unitec.ac.nz
University of Auckland Human Subjects Ethics Committee	m.rotondo@auckland.co.nz
University of Otago Human Ethics Committee	gary.witte@stonebow.otago.ac.nz
Victoria University of Wellington Human Ethics Committee	Katy.Miller@vuw.ac.nz
Wintec Human Ethics in Research Committee	Stephen.Cox@wintec.ac.nz
Zenith Technology Corporation Human Ethics Committee	Linda.Folland@zenithtechnology.co.nz

Regional and Multi-region Ethics Committees

Northern X	pat_chainey@moh.govt.nz
Northern Y	amrita_kuruvilla@moh.govt.nz
Central	claire_yendoll@moh.govt.nz
Upper South A	alieke_dierckx@moh.govt.nz
Upper South B	katherine_bell@moh.govt.nz
Lower South	rira_tautau-grant@moh.govt.nz
Multi-region Ethics Committee	sheryl_kirikiri@moh.govt.nz

1.10 Resource Documents Relevant to Research Ethics

New Zealand Acts of Parliament

- Animal Welfare Act 1999;
- Health And Disability Commissioner Act 1994;
- Health Research Council Act 1990;
- Human Assisted Reproductive Technology Act 2004;
- Human Tissues Act 1964;
- Injury Prevention, Rehabilitation, and Compensation Act 2001;
- Medicines Act 1981;
- New Zealand Public Health and Disability Act 2000, and
- Privacy Act 1993.

New Zealand Guidelines and Regulations

The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996.

Health Information Privacy Code 1994 (incorporating Amendment Nos.1-5).

Ethical Considerations Relating to Research in Human Genetics, Winship and Marbrook, Health Research Council of New Zealand (2000).

Guidelines – Compensation for injuries caused as a result of participation in a clinical trial and the role of ethics committees (December 1993), Ministry of Health and ACC.

HRC Guidelines for Ethics Committee Accreditation, Health Research Council of New Zealand.

Guidelines for Completion of Application Form (NAFG-2005-v1) Health Research Council (2005).

HRC Guidelines for an Accredited Institutional Ethics Committee to refer Research Studies to a Health and Disability Ethics Committee Health Research Council of New Zealand (August 2003).

Report and Guidelines on the Clinical and Research Use of Human Genes, Health Research Council of New Zealand (1995).

Operational Standard for Ethics Committees, Ministry of Health (2002).

Implementing Research. A guideline for health researchers, Health Research Council of New Zealand (2000).

Interim Good Clinical Research Practice Guidelines, Medsafe, Ministry of Health (1998).

International Guidelines, Regulations, and Documents

Common Rule, 45 Code of Federal Regulations 46, US Department of Health and Human Services and Other Federal Agencies (1991).

Declaration of Helsinki, Adopted by the 18th World Medical Association, Helsinki, Finland (1964 and as revised in 2000).

Ethical Conduct for Research Involving Humans, Tri-Council Working Group, Canada (1998).

Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries, US National Bioethics Advisory Commission (2001).

Ethics of Research related to Healthcare in Developing Countries, UK Nuffield Council on Bioethics (2002); A Follow-up Discussion Paper (2005).

Guideline for Good Clinical Practice, ICH Harmonised Tripartite Guideline (1996).

Guidelines on the Practice of Ethics Committees in Medical Research involving Human Subjects, The Royal College of Physicians of London (3rd ed., August 1996).

International Guidelines for Biomedical Research Involving Human Subjects, Council for International Organisations of Medical Sciences (CIOMS), Geneva (1993 and as revised in 2002).

International Guidelines for Epidemiological Research, Council for International Organisations of Medical Sciences (CIOMS), Geneva (1991).

National Statement on Ethical Conduct in Research Involving Humans, National Health and Medical Research Council, Australia (1999).

Operational Guidelines for Ethics Committees that review Biomedical Research, World Health Organisation (2000).

Research Involving Patients, A report of the Royal College of Physicians (1990).

Universal Declaration on the Human Genome and Human Rights, UNESCO (1997).

Unlinked anonymous Screening for the Public Health Surveillance of HIV Infections; Proposed International Guidelines, World Health Organisation Global Programme on AIDS, Geneva (1989).

See also 6.13 Privacy Resources

2 Procedures

The Council expects investigators to conduct and report their work with objectivity and scientific honesty.

As part of their obligation to research participants, the community concerned (if relevant), and the public, investigators should ensure that the results of their research and an account of the methods employed are adequately and appropriately disseminated in a manner accessible to the research participants and the public as well as to the scientific community.

Investigators should refrain from making claims or advancing conclusions that are not supported by evidence. Investigators should also recognise the boundaries of their professional competence and should not undertake research of a kind that they are not qualified to carry out.

2.1 Research requiring ethical approval

Applications for funding received by the HRC

Under the requirements of sections 25 and 31 of the Health Research Council Act 1990, every application for funding received by the HRC must be subjected to independent ethical assessment. Research using animal or human participants, animal or human materials, personal information, or involving clinical trials, or combinations of such studies, require special consideration.

The definition of research involving human materials is broad, covering any matter, living or dead, which has been taken from a human and including the use of genetic materials. The definition of an animal and the use of animals in research are set out in the Animal Welfare Act 1999.

Research using personal information

Ethical approval is required when research involves the use of personal information which falls into any of the following categories:

- information from medical or other private or confidential files;
- information which may personally identify a research participant;
- information for which the participant has not given consent for the purposes of the research which is proposed, and
- information which is considered by the participant to be sensitive or valuable in a personal, social, cultural or commercial sense.

2.2 Special Case HRC Contracts

Pilot study and seeding contracts

The HRCEC may permit a contract made for the purpose of a pilot study or research development to commence prior to receipt of ethical approval, if it is clear that the funding is to enable development of the research proposal to a state where it will be submitted for ethical approval, or for the training of personnel undertaking the study. Research may not commence until ethical approval is obtained and a fully signed ethical agreement from the principal investigator is received.

Programme contracts or ongoing studies

The HRCEC recognises that in the case of lengthy research studies, such as programme contracts, it may not be possible or feasible for the investigator to fully anticipate the ultimate direction the research will take when applying for the contract. In such situations the committee may allow the research to commence when ethical approval for the first portion of the research has been obtained. Ethical approval for ongoing research resulting from this earlier portion of the study must be subsequently obtained following appropriate review of the research proposed.

Fellowships and Scholarships

The HRCEC accepts that, in the case of some fellowships or scholarships, a significant portion of training may be undertaken by the fellow or scholar before commencement of the research itself. A part of this training in research may comprise a detailed development of the research proposal, and the submission of that proposal for ethical approval. In such situations, funding for the training portion of a HRC Fellowship or Scholarship may commence before ethical approval for the research proposal is received. However, the research may not commence until a copy of the ethical approval for the research has been received together with a fully signed ethical agreement page.

Fellows or scholars undertaking HRC-funded research overseas are required to provided evidence of appropriate ethical approval **see 4.8 International Collaborations**.

2.3 How to obtain ethical approval

The HRCEC considers that ethical approval is best sought before submitting an application to the HRC, but accepts that this may not always be possible. Every application for HRC funding must contain a fully signed ethical agreement page, which says that appropriate ethical approval for the research has been or will be obtained.

No application approved for funding by the HRC will have funds released until a copy of an ethical approval, from an accredited ethics committee, is received.

Application to an Accredited Ethics Committee

The first step in obtaining ethical approval for an application for HRC research funding is to submit an application for ethical review to an accredited ethics committee.

The *National Application Form for Ethical Review of a Research Project* (NAF-2005-v1) must be used. The form and helpful guidelines, *Guidelines for Completion of Application Form (NAFG-2005-v1)* Health Research Council (2005), are available from all accredited ethics committees, and may be downloaded from www.hrc.govt.nz.

Applications to Health and Disability Ethics Committees should be made to the appropriate committee in the region in which the research is to be carried out (**the Health and Disability Ethics Committees Region Map is available at www.hrc.govt.nz)**. Where research is to be carried out in more than one ethics-committee region, an application should be made to the Multi-region Ethics Committee.

As a general guide, research originating in a tertiary educational institution will be reviewed by an ethics committee of the institution, if that committee is accredited by the HRCEC to review HRC funding applications. However, particular types of research proposals received by an accredited Institutional Ethics Committee should be referred to a Health and Disability Ethics Committee: see *HRC Guidelines for an Accredited Institutional Ethics Committee to refer Research Studies to a Health and Disability Ethics Committee* (May 2002) – available from www.hrc.govt.nz.

A research proposal which involves both human and animal subjects will require separate approvals from both human and animal ethics committees.

Locality Assessment

In addition, an investigator is required to have a study checked by the Locality Organisation(s) to show that the locality is appropriate to carry out the research proposal.

A Locality Organisation is an organisation through which substantial study recruitment or conduct is to take place, for example a DHB. A study conducted in one region might be conducted in several different locality organisations within that region. Where there is no locality organisation, the locality assessment is the responsibility of the ethics committee that reviews the study.

Researchers are responsible for ensuring that the Locality Organisations sign off a locality assessment form, which is found in the *National Application Form for Ethical Review of a Research Project* (NAF-2005-v1), – available from www.hrc.govt.nz.

A Locality Organisation must check that:

- the investigator's local role in the study is appropriate;
- the resources (other than funding, which often depends on ethics committee approval) and/or facilities that the study requires locally have been identified, are appropriate, and are available;

- the investigator has identified and satisfactorily addressed any cultural or other issues specific to the locality, or to participants for who study recruitment or participation is primarily at the locality, and
- the investigator will include the key local contact details in the Information Sheet for the participants.

The process of ethics committee review and locality assessment can occur in tandem, however ethics committee approval is contingent on sign-off of the locality assessment form by all proposed locality organisations.

Locality organisations may withdraw a favourable locality assessment if significant concerns arise in relation to locality issues after sign off. This withdrawal would effectively also withdraw ethics committee approval for study conducted at that locality. If favourable locality assessment is withdrawn, the locality organisation must notify the ethics committee and the investigator.

Ethics Committee Decision

Following review by an ethics committee the investigator submitting the research proposal for approval will be informed of the outcome of the committees' deliberations. The HRC suggests that the reviewing ethics committee/s respond with one of the following decisions:

- ***Approved***, either with or without comments or questions addressed to the applicant; any replies to a committee's comments or questions to be forwarded in due course;
- ***Approved subject to conditions***, subject to recommended revisions of the proposal and/or satisfactory answers to questions asked of the applicant. The applicant's reply and/or revised proposal must be forwarded via the committee administrator to the chairperson and/or delegated committee members to consider the revisions that have been made and to provide final approval;
- ***Approval deferred***, pending substantial revisions of the proposal/study and/or satisfactory answers to questions asked of the applicant. The applicant's reply and/or revised proposal must be forwarded to the committee for reconsideration and final approval, and
- ***Approval declined***. Reasons for declining approval to be forwarded to the applicant, either with or without an invitation to submit a substantially revised protocol for reconsideration.

As well as giving reasons for declining the application, the ethics committee should provide suggestions for a restructuring of the research project along ethically acceptable lines.

Every decision, comment or direction of an ethics committee should be made in writing to the principal investigator.

When ethical approval for the research is received by the applicant, the host institution must be given a copy. The approval should be included with the funding application or forwarded to the HRCEC secretary as soon as it is received (normally by the host institution). Where a contract is awarded, copies of all

approvals will be required since the HRC does not release funding until copies of all approvals have been received.

The successful applicant must also inform the host institution about ethical approval of the research.

2.4 Retrospective Approval

No retrospective approval for any study shall be given by an accredited ethics committee.

2.5 Reviews of decisions by ethics committees

Reconsideration

The researcher, the funder, or where relevant, a participant, may seek a reconsideration of a decision made by an ethics committee from that committee itself.

Second Opinion

A second opinion may also be requested from the HRCEC see 2.6 Second Opinion

Appeal

The principal researcher may lodge an appeal to the National Ethics Advisory Committee's Sub-Committee on Appeals (SCA) on a decision of a Health and Disability Ethics Committee. Appeals may only be made where the second opinion process has been completed, see 2.9 Appeals.

Independent Comment

Independent comment may be sought from the HRCEC by any person, or may be provided at the HRCEC's own initiative **see 2.10 Independent Comment**

Complaints

Complaints about research involving human participants can be made, where appropriate, to an accredited ethics committee, the HRCEC, the relevant institution/organization involved in the research, the Health and Disability Commissioner, or the Privacy Commissioner.

2.6 Second Opinions

A second opinion can be requested from the HRCEC on a proposal that has been submitted for ethical review. It is important to understand the principle that in the circumstances where a second opinion is requested, the final decision remains with

the committee that had made a decision in the first instance, after studying and reflecting upon the comments of the committee that had provided the second opinion. The process is as follows. A second opinion relating to a proposal that has been submitted for ethical review, or on any matter of proper concern for ethics committees as set out in the *Operational Standard for Ethics Committees*, may be sought either by an ethics committee or by an applicant who disagrees with a decision made by an ethics committee.

Requests for a second opinion on a research proposal, including any proposal with a research element, should be referred to the HRCEC. The HRCEC can be contacted for further details before a second opinion is requested. For other proposals, eg. service or treatment proposals, the Director-General of Health will advise to whom they should be referred.

Principles of natural justice underlie the second opinion process. All relevant parties should be advised of the process that will be undertaken, should be given opportunity to comment and respond, and should be kept informed.

A second opinion request must be accompanied by all relevant and up-to-date information, including a copy of the original application, the written comments supporting the original decision, and a description of the specific issues which form the basis of the request for a second opinion.

The HRC Ethics Committee will take into account information from both the applicant and the original ethics committee and, where appropriate, further submissions made by relevant parties. Other information that was available at the time when the original decision was made, or new information that has come to light since, may be reviewed in order to determine whether that information is relevant to the decision that was made. In some circumstances, a draft second opinion for comment may be provided to the relevant parties.

A second opinion is not regarded as a higher judgment but rather as a review of the proposal by an independent committee. The second opinion is not binding and the HRCEC is not an appeal body in the strict legal sense.

The final decision rests with the original ethics committee which must take into account the second opinion. The original ethics committee must provide reasons for the final decision to both the applicant and the committee from which the second opinion was sought.

In its annual report, an ethics committee must report on any proposal for which a second opinion was sought.

Explanatory Note:

It may be appropriate, depending on the circumstances, to lodge a complaint or seek advice. Also, independent comment could be made by the HRC Ethics Committee under statutory authority: s.25(1)(g) of the HRC Act 1990.

2.7 Appeals

An appeal to NEAC's Sub-Committee on Appeals (SCA) (**see 1.5 NEAC**) may be lodged by the principal researcher (identified in the application in question) on a decision of a Health and Disability Ethics Committee. Third parties may not lodge appeals.

Appeals may only be lodged after the second opinion process has been completed.

The SCA will 're-hear' the application, focussing on specific alleged errors of judgement or reasoning in the original decision. It has the discretionary power to re-hear any part of the evidence that is relevant to the alleged errors and will be able to receive further evidence and call individuals involved in the reconsideration decision to give evidence in person.

The SCA will be bound by the presumption that the original decision was correct. In making its decision it will either affirm or reverse the original decision.

2.8 Independent Comment from the HRCEC

Besides giving second opinions and responding to complaints, the HRCEC can provide independent comment on ethical problems that may arise in any aspect of health research. Independent comment may be sought from the HRCEC by any person, or may be provided at the HRCEC's own initiative. Where appropriate, the HRCEC may advise relevant parties of the process that will be taken by the HRCEC, seek input from relevant parties, and provide the opportunity for relevant parties to comment.

3 Research involving Humans or Human Materials

Protection of the welfare of human participants is a basic principle of ethical review of research. There is a need to balance potential risk of harm to individuals with the possible benefits to society at large. On occasions when there are major issues, there should be broader discussion with the community.

When investigators are considering enrolment of persons in research studies, clinical trials or social surveys, the investigators should take into account any other research procedures involving the same individual which may already be in progress.

The HRCEC requires investigators to review the ethics of their research at least annually or, where appropriate, more frequently. As part of such a review, the investigator should consider the outcome or development of similar research conducted elsewhere – whether in NZ or overseas. If significant variations to the research proposal are to be made, or the interim results of the research indicate that it may not be ethical to continue, the principal investigator should approach the ethics committee which approved the research proposal for comment and further discussion before undertaking any continuation of the research.

3.1 Informed consent

Researchers should make themselves familiar with the provisions of the Code of Health and Disability Consumers' Rights—available at www.hdc.org.nz.

In most cases research constitutes a health care procedure and, as such, written informed consent will be required unless there are good reasons to the contrary. If consent is not obtained in writing the justification should be given to the reviewing ethics committee, and the circumstances under which consent was obtained should be recorded. Ethics committees will be required to consider if the circumstances are appropriate ones in which to waive written consent.

The essential elements of informed consent to participate in a health research investigation are detailed in the *Operational Standard For Ethics Committees*. Elements of informed consent include but are not limited to, the following basic criteria:

- the participants' legal competence and ability to understand;
- information about the proposed research being comprehensively, properly and appropriately given, including any likely outcomes of participation in the research;
- the participants' consent must be voluntary and not influenced by financial reward (see Payments for Participation in Research), or by duress in any manner, nor must dependent or vulnerable groups be used;
- participants must be able to withdraw from the investigation at any time without waiver of any rights and without giving reasons;
- in the case of those who are unable to give their own consent, for example the mentally incapacitated or the unconscious patient, proxy consent should be sought from a person with appropriate legal authority, and
- in the case of research participants who are children the signature of the parent or guardian should be obtained in addition to the child's assent.

3.2 Payments for participation in research

Any payment, koha or gift of money, goods or services to a research participant or to a body or organisation assisting in the recruitment of participants, which is an undue inducement to participate in the research, is unacceptable.

Reimbursement for participants' out-of-pocket expenses (eg. taxi fares, meals, parking fees) or in compensation for inconvenience caused through their participation in the research may be made. Payments for inconvenience would typically be a nominal amount in recognition of the effort of the participant to attend the research project.

3.3 Declaration of Helsinki - Principles of medical research on human participants

Applicants should consult the *Declaration of Helsinki* (revised 2000, World Medical Association) as a general statement of the principles applying to medical research on human participants.

Applicants should also consult other relevant international ethical guidelines.

3.4 Standing Committee on Therapeutic Trials (SCOTT) approvals

SCOTT is a committee of the Health Research Council and is responsible for the assessment of the scientific validity and safety of clinical trials under section 30 of the Medicines Act 1981. The majority of applications reviewed by SCOTT are for clinical trials sponsored by the pharmaceutical industry and there is a fee of $2,800 per application payable to the Ministry of Health.

Applications for clinical trials which are funded by the HRC or other public good health research funding agencies may seek an exemption from the fee. Application for the fee exemption will be reviewed by the HRC which will recommend to the Ministry of Health whether the fee should be waived.

The review conducted by SCOTT, if required, is an additional requirement to the ethical approval process for clinical trials. All correspondence relevant to the SCOTT should be forwarded to the Chairperson.

Contact details:

Chairperson: Dr Richard Robson

Contact: Secretary, Clinical Studies Trust
PO Box 2856, Christchurch
Email: admin@ccst.co.nz

3.5 Clinical trials

Randomised controlled therapeutic trials are powerful studies for determining the value of new treatments or reassessing established treatments. However the following conditions must be met:

- when the administration of effective treatment is important for the well-being of the patient, a controlled trial can only be undertaken where there is genuine uncertainty about whether the trial treatment is more effective (or has less risk) than the standard treatment with which it is being compared;
- in general, random allocation to treatments should be conducted after the patient has given consent to randomization, and
- arrangements for monitoring the results of the trial and for the occurrence of adverse effects should be made at the outset. Research protocols should include stopping rules. Premature termination of the trial should take place if one treatment has been demonstrated to be superior, or if serious adverse

effects occur. Monitoring should generally be undertaken by an independent person or committee.

Fully informed consent with comprehensive information being available to participants is essential **see 3.1 Informed Consent.**

Clinical trials in New Zealand should observe the *Interim Good Clinical Research Practice Guideline 1998* (Medsafe, NZ). The New Zealand Good Practice Guidelines are based on the *Guideline for Good Clinical Practice (ICH GCP Guideline) 1996* that was developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. The *ICH GCP Guideline* establishes the international ethical and scientific standard for designing, conducting, recording and reporting clinical trials that involve human participants. The *ICH GCP Guideline* provides a unified standard for the European Union, Japan, and the United States, and has been accepted by Australia, Canada, and the Nordic countries.

3.6 Social, community-based, public health or health services interventions

When the focus of a study is a whole community (for example, to test the use of an additive in a community's water supply, or a new form of health care delivery), the individual will not usually have the ability to "opt-out". However, individuals may refuse to submit to questionnaires or blood tests, or other instruments designed to obtain data to evaluate the intervention.

All reasonable means should be used by the investigators to inform the population under study of the aims and intent of the proposed research and all possible advantages or disadvantages which may arise from it. It is normal for the investigators to secure the agreement and co-operation of the national or local body responsible for public health in the population to be studied. Where collective decision making is customary it is also advisable to seek the agreement of the community, usually through its chosen representatives. Consent to participate in the research obtained in hui is covered under the Treaty of Waitangi section.

Although some community based interventions (eg. an anti-smoking campaign) that do not involve personal contact between the researcher and the study population may not require research ethical approval, the evaluation of such interventions which did involve personal contact with individuals or collection of data from them, will require ethical approval. The community to which the intervention and evaluation is targeted should be informed of the study findings, once the study has been completed.

3.7 Surveys of the general population

Some types of research require surveys to be undertaken on "total" populations or on samples of the population selected from public records such as the electoral roll. It is considered that direct approaches (for example, by telephone, postal questionnaire or visit interview) to persons in the general population selected in this way do not require approval by any local health or medical body or individual practitioner.

However, it may be appropriate to inform local health practitioners about the study. Investigators should consult with and, where appropriate, obtain ethical approval from an accredited ethics committee for the research to proceed. The right of any person to decline to take part in such a survey or to withdraw from the survey at any time must always be respected.

Where approaches involve visiting or telephoning research participants at their home, it is generally desirable that some advance notice be given and field staff must be provided with means of personal identification including a reference telephone number which the participant may call to establish the field worker's legitimacy. In some circumstances it may be appropriate to inform local police and other relevant authorities.

Surveys may on occasion involve the physical examination or laboratory investigation of participants. In these circumstances informed consent from each participant must always be obtained before any examination is undertaken, and each participant must be informed of their right to withdraw without explanation from the research at any time without effect to their current or future health care.

The research participant must be informed of any consequences to them due to their withdrawal from the research. Where clinical examination is involved, advance information about the survey for local practitioners and appropriate authorities is of special importance.

3.8 Collection and use of human materials

Human materials are any organ, tissue, secretion or excretion derived from a human source whether living or dead and including the human foetus, placenta and human gametes.

Legal and cultural aspects which need to be considered will differ, according to whether the body parts and tissues come from deceased or living persons, or whether they are body tissues which can be described as "surplus". Regulations and guidelines published in the *Operational Standard for Ethics Committees* and elsewhere governing collection, storage and use of human specimens must always be observed. Issues of informed consent and privacy of information will also need to be considered. As a general rule the collection of human materials and their use in research requires the informed consent of the donor, if living.

3.9 Use of body parts and tissues from deceased persons

The use of body parts from deceased persons is governed by the Human Tissues Act 1964. This legislation must be complied with. It permits the removal and use of human parts from deceased persons where the consent of the deceased has been given to such removal before death.

If the consent of the deceased has not been given before death then the person lawfully in possession of the body may authorise the removal of body parts or tissues, provided that either the deceased has not expressed an objection prior to

death, or there has been no objection expressed by the surviving spouse or any surviving relative of the deceased.

Cultural concerns should always be addressed before body parts and tissues are removed. For example, for Maori the brain has special spiritual significance. Failure to address these concerns may result in mental and emotional upset to relatives.

3.10 Use of body parts and tissues from living persons

It is important that the fully informed consent of the participant be obtained before any body parts or tissues are obtained from living participants. A person has the right to determine what is to be done with his or her body parts, particularly if there are commercial implications arising from their use.

If the course of the research changes in any way, or the use to which the human materials are to be applied changes, then normally the donor, or in the case of deceased persons the donor's relatives, should be informed in order to gain consent to the changes.

The legal and cultural issues in relation to use of surplus parts and tissues (eg. aborted foetuses, placentae, spare embryos) are complex. In respect of some parts and tissues cultural concerns may need to be considered. For example, for Maori the placenta has special spiritual significance. Researchers should ensure that the cultural concerns of participants are fully considered and addressed before any research is commenced. These concerns may relate to use, to storage and disposal.

There may be limited circumstances where it is ethically permissible to use human materials for purposes other than those for which they were originally collected, without specific consent being obtained. Right 7(10) of the Code of Health and Disability Services Consumers' Rights, provides that where body parts or tissue have been obtained in the course of a health care procedure they may be used for research without consent, where it has been approved by an accredited ethics committee.

Such limited circumstances must be ethically justifiable and must be approved by an accredited ethics committee. Examples are where materials collected for one research use are proposed to be used for a different research project; or where left-over materials collected for clinical purposes are proposed to be used for research.

If a researcher considers that it is impossible, impractical or excessively costly to obtain consent or that doing so would adversely affect the outcome of the research, application for use without specific consent must be made to an accredited ethics committee. In these cases material should be unlinked from all identifiers and thus made wholly anonymous before testing, unless there are valid reasons for not doing so.

In considering an application for use of human materials without specific consent the ethics committee must be satisfied that:

- there is no harm to the person or interests of the donor or the donor's extended family; and

- the research will be of significant potential public benefit, and
- the research is not being conducted principally for commercial gain.

Ethics Committees must be satisfied that it is not practicable to get consent, or that the potential public benefit in allowing the research to proceed outweighs the very strong need to protect an individual's right to consent.

The World Health Organisation has recommended additional safeguards for unlinked anonymous testing for human immunodeficiency virus (HIV, the causative virus of AIDS) using left-over blood collected for clinical purposes (see 1.11 Resource Documents). For further ethical guidelines on the collection, storage, use and disposal of human materials see the *Report of the Human Specimens Ethical Guidelines Committee* (December 1992).

4 Specific Issues of Concern

4.1 Research Involving Personal Health Information

Research which involves the use of personal health information is required to comply with the Health Information Privacy Code 1994. In order to guide researchers and ethics committees the HRC Ethics Committee (HRCEC) has developed special guidance notes on health research and privacy, **see 6. Health Research and Privacy – Guidance Notes for Health Researchers and Ethics Committees.**

4.2 Cultural Sensitivity

People of different cultures may hold differing basic beliefs, have different value systems and regard differing modes of behaviour as acceptable. Since health involves matters which are often deeply personal and private, procedures for health research can very easily cause offence both to individuals and to ethnic groups, even though none has been intended.

Not only must there be due recognition of the indigenous culture of Maori as the tangata whenua (indigenous people) but also due allowance must be made for the increasing diversity of culture and religious belief which is now appearing in New Zealand society.

Practices and beliefs of an ethnic and/or religious nature must be fully respected. Research must be undertaken in a culturally sensitive and appropriate manner, in full discussion and partnership with the research participants whatever their ethnicity or religious affiliation, and the results of any investigation should be appropriately disseminated in a full and frank manner.

4.3 Requirement for full understanding

Participants have the right to receive, in language that they will easily understand, information about proposed research in which they are being invited to participate. Where large numbers of participants from an ethnic group are being recruited, a translation of the participant information sheets and the consent form should be provided. In seeking informed consent the involvement of a trained interpreter is highly desirable. If the number of participants from any ethnic group is small the use of trained interpreters to read and discuss the information sheet with the participant may obviate the need for a printed translation. However, a translation of the consent form should be provided. In certain circumstances, a verbal consent is considered appropriate.

The use of staff members from the participant's ethnic group as translators or interpreters is seldom satisfactory and may be culturally unacceptable. Participants may desire the presence of supporters to assist in any discussion of potential involvement in research.

4.4 The Treaty of Waitangi and Maori Cultural and Ethical Values

Respect for the principles of partnership and sharing implicit in the Treaty of Waitangi will be observed by incorporating the following requirements into health research proposals. All issues relating to Maori cultural and ethical values should be resolved in discussion with the Whanau, hapu or Iwi concerned. The ownership rights of participants to personal data must be respected. The *HRC Guidelines for Researchers on Health Research Involving Maori* should be consulted.

4.5 Informed consent

Investigators who initiate research within a Whanau, hapu or Iwi, where the research investigators and research participants are members of that same group, may prefer to provide, via a kaumatua or other person of authority in the group, a statement in the research proposal that group consent for participation in the research was obtained from the representatives/participants in hui.

An individual's right to decline participation in the research, expressed in hui, should also be noted. The statement of group consent obtained in hui should allow for research participants to withdraw at any time from the investigation if they so wish.

Where research is initiated from outside the Whanau, hapu or Iwi or when the investigators do not have a representative from that group within their number, the usual procedures for informed consent to participate in the study will be expected. In addition, a system of accountability of the investigators to the Whanau, hapu or Iwi concerned should be instituted after full discussion with and agreement by the participants and investigators. The group's right to decline research to proceed within their Whanau, hapu or Iwi if the research is unacceptable to them, is paramount.

Not all Maori have contact with Whanau, hapu or Iwi and the usual requirements for fully informed consent to participate in a research proposal will be expected in such cases.

4.6 Ethical approval

In the case of research initiated within a Whanau, hapu or Iwi where the investigators and research participants are members of that group, it may be appropriate for a kaumatua or other person of authority in the group to provide a statement that, in their opinion, the proposed research conforms with Maori cultural and ethical values. The HRCEC must review such research proposals and confirm that this mechanism will constitute adequate ethical approval.

It may also be appropriate for the advice of the HRC Maori Health Committee and other appropriate expert groups to be sought by an ethics committee when reviewing a research proposal.

In the event of issues which cannot be reconciled in discussions between the parties involved, the matter may be referred to the HRC Ethics Committee and the HRC Maori Health Committee for joint comment.

4.7 The Code of Health and Disability Services Consumers' Rights

Researchers should make themselves familiar with the Code of Health and Disability Services Consumers' Rights and the consumer complaints procedure. Researchers are responsible for supplying participants with information on the Code and for budgeting for any expenditure this entails.

4.8 International Collaborations

Any investigator participating in international collaborative research whose project is funded in full or in part by the HRC will require ethical approval from an accredited New Zealand ethics committee for the research. Research conducted overseas having human or animal involvement will also require appropriate ethical approval from an ethics committee (or equivalent body) in the country concerned, where such a body exists.

Any international collaborative research project, whether or not funded by the HRC, which involves investigations in New Zealand or its territories, should be subject to ethical review by an accredited ethics committee within New Zealand.

For guidance on ethical research in developing countries, investigators should consult the following:

- *International Ethical Guidelines for Biomedical Research Involving Human Subjects,* CIOMS (as revised in 2002), particularly Guideline 10;
- *Ethics of Research related to Healthcare in Developing Countries,* UK Nuffield Council on Bioethics (2002); a follow-up discussion paper (2005)
- *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries,* US National Bioethics Advisory Commission (2001).

4.9 Research Undertaken at an Overseas Location

Investigators who undertake all or part of an HRC-funded fellowship, scholarship or contract overseas are required to provide evidence of appropriate ethical approval for their research.

4.10 Human gene therapy and research review processes

In 1994, a working party established by the HRC following a request from the Ministry for the Environment, submitted a report entitled *Report and Guidelines on the Clinical and Research Use of Human Genes*. The report and guidelines discussed genetic manipulation technology and scientific ethical and cultural issues arising from its use. It also proposed processes and regulatory mechanisms for scientific

ethical and cultural review of research or manipulations involving human genetic material.

In 2000, the Government appointed the Royal Commission on Genetic Modification to inquire into the following matters:

- the strategic options available to enable New Zealand to address, now and in the future, genetic modification, genetically modified organisms, and products; and

- any changes considered desirable to the current legislative, regulatory, policy, or institutional arrangements for addressing, in New Zealand, genetic modification, genetically modified organisms, and products.

The Royal Commission's report and recommendations in 2001 can be downloaded from http://www.gmcommission.govt.nz

4.11 Guidelines on in vivo human gene manipulation proposals for human ethics committees

All attempts to introduce DNA or RNA into human cells in vivo should be considered to be experimental and reviewed by an accredited ethics committee in accordance with the *Operational Standard for Ethics Committees*. Specifically, the requirements of the *Operational Standard* for obtaining informed consent must be satisfied.

Somatic cell gene therapy involves the introduction of fragments of DNA or RNA into human somatic (non-reproductive) cells. The aim is to improve the health of people with certain grave inherited diseases, or with certain forms of cancer, or some virus infections. DNA or RNA may also be introduced into somatic cells to mark their distribution and fate in particular forms of research on serious diseases.

There may also be other well justified non-therapeutic reasons for introducing DNA or RNA. The development of methods of introducing DNA or RNA into somatic cells is acceptable. The introduction of DNA or RNA into germ (reproductive) cells or fertilised ova is not acceptable at present, because there is insufficient knowledge about the possible consequences, hazards and effects on future generations.

The following particular matters need to be taken into account when protocols for somatic cell gene therapy or research are being considered by an ethics committee.

- The therapy should be attempted at present only in monogenic diseases where the cause is a defect in a single pair of genes, or in cancers. There should be good reason to believe that the therapy may improve clinical outcomes.

- Introduction of DNA or RNA for research reasons should have a sound basis in current knowledge of the biological system involved.

4.12 The choice of selecting diseases for clinical therapy or research

The choice of selecting diseases for clinical therapy or research is critical. For the present, evidence of hazards associated with the treatment can only be estimated and evaluated from experiments on animals. Initial trials in human participants therefore should be limited to -

- Diseases for which there is no effective cure, and which cause a severe burden of suffering. Diseases causing a lesser burden, when account is taken of currently available treatment, should become candidates for somatic cell gene therapy or research only after the risks associated with this therapy have been determined by experience in humans over some years.
- Diseases in which the effects of treatment or research can be measured; and
- Patients for whom long-term follow-up is available.

When considering an application for somatic cell gene therapy, or introduction of DNA or RNA for research reasons, an ethics committee should also be satisfied that the following criteria are met:

- That the research team has the necessary depth and breadth of knowledge of, and experience in, molecular genetics.
- That the purity of the DNA or RNA to be inserted and the methods of handling it during its preparation are in accord with current regulations and official guidelines, particularly if viral vectors are used.
- That the technique of insertion has been shown by experiments in animals or cell cultures to:
    - confirm the inserted DNA or RNA to the targeted somatic cells; and
    - achieve the intended function in a high proportion of attempts, and
    - rarely cause undesirable side effects.
- That the probability of entry of the DNA into germ cells has been evaluated.

In considering each protocol for somatic cell gene therapy or other uses of human genetic material the ethics committee must institute appropriate consultation with any relevant ethnic group affected by the application, paying particular attention to issues of cultural sensitivity. Specific advice on these aspects should be obtained from the HRC's Maori Health Committee.

In seeking to satisfy itself on (a), (b), and (c) above, and on all technical aspects of any application for research on gene therapy, or introduction of fragments of DNA or RNA for research reasons, the ethics committee shall consult the official national body concerned with monitoring the safety of innovative human genetic manipulation techniques. The relevant New Zealand body is the HRC's Genetic Technology Advisory Committee (see also the HRCEC's publication *Report and Guidelines on the Clinical and Research Use of Human Genes,* 1995.

4.13 Genetic Technology Advisory Committee

GTAC has responsibility to undertake scientific assessments in the circumstances where an exemption under Section 30 of the Medicines Act (1981) is sought, or as required by the HRC, any of its committees or an accredited ethics committee. The proposals reviewed by GTAC include:

- Proposals for clinical trials which include the introduction of nucleic acids (genetically manipulated or synthesised in the laboratory) or genetically manipulated micro-organisms, viruses or cells into human participants for the purpose of gene therapy or cell marking.
- Proposals for clinical trials in which the introduction of nucleic acids (genetically manipulated or synthesised in the laboratory), or genetically manipulated micro-organisms, viruses or cells is designed to stimulate an immune response against the participant's own cells, as in the treatment of certain cancers.
- Proposals for clinical trials in which nucleic acids either from or within cells from animal species are transferred into humans for the purpose of disease treatment ie. xenotransplantation.
- Proposals for clinical trials in which human nucleic acids have been introduced into the genome of an animal species, including genetically manipulated micro-organisms, for the purpose of developing products to be used for either disease prevention or treatment in human participants.
- Proposals for clinical trials involving vaccines in which nucleic acids (genetically manipulated or synthesised in the laboratory) or genetically manipulated micro-organisms, viruses or cells have been introduced to stimulate an immune response to antigenic determinants of an infectious agent.

GTAC operates in a similar way to SCOTT (Standing Committee on Therapeutic Trials) (**see 3.4 SCOTT**). The Ministry of Health has agreed that gene therapy and other protocols involving administration of nucleic acids should be regulated under the Medicines Act 1981.

The definition of medicine given in Section 3 of the Medicines Act 1981 is "any substance or article that is manufactured, imported, sold or supplied wholly or principally - for administering to one or more human beings for a therapeutic purpose". Section 4 defines a therapeutic purpose as:

(a) treating or preventing disease; or

(b) diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition, or

(c) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily and whether by reducing or postponing, or increasing or accelerating the operation of that function, or in any other way.

If the "medicine" is to be used for the sole purpose of obtaining clinical and scientific information, the investigator will be required to seek approval for its use; see Section 30 of the Medicines Act 1981, "Exemption for Clinical Trial". Approval

under Section 30 is given by the Director-General of Health on the HRC's recommendation.

For pharmaceuticals the recommendation to the Director-General of Health is made by SCOTT.

4.14 Application process for GTAC approval

Application to the Ministry of Health for GTAC approval is to be made in the approved format which is available from the HRC or the Ministry of Health. The investigator seeking approval under Section 30 will also be required to lodge a $2,800 fee which, in the case of public good research, may be waived by the Ministry of Health on the recommendation of the HRC.

The fee or a letter seeking an exemption from the fee should accompany the application which should be sent to the Director-General of Health, Ministry of Health, PO Box 5013, Wellington, attention - Manager, Therapeutics Section. The application will be reviewed by GTAC within 30 days. The investigator may be required to attend a meeting with the committee to discuss the application. GTAC will provide the Director-General of Health with its recommendation as to whether the trial be approved.

If a proposal involves materials which originate from the USA, the investigator will be required to meet the regulatory requirements of the FDA to obtain an export certificate. The Director-General of Health will not give approval for a Section 30 exemption until the appropriate documentation for exportation of the product from the USA has been received and has been approved by the Ministry of Health.

Approval from an accredited ethics committee cannot be sought until the Director-General of Health has received a recommendation from GTAC that the trial can be approved.

When the Director-General of Health has received recommendations for approval from GTAC and an accredited ethics committee, written approval for an exemption under Section 30 of the Medicines Act 1981 will be given. Only then can the investigator proceed with the trial. Investigators should also ensure that they meet all the requirements of their host institution with respect to approvals.

4.15 Criteria for GTAC approval

GTAC will review applications to establish whether:

- there is adequate scientific evidence from laboratory and experimental studies in animals to allow procedures to be carried out in humans;
- the proposal will allow clinically beneficial and scientifically useful information to be obtained;
- adequate risk assessment has been carried out and whether satisfactory management procedures are included;

- the proposal contains adequate information on the safety and toxicity of the materials that impinge on the human procedures;
- the investigators have the appropriate qualifications, experience and track record, and
- the proposal contains the names of collaborators and their appropriate skills.

Before applying for approval, investigators should contact the HRC secretariat for a detailed list of requirements.

GTAC will provide the Director-General of Health with a written report and a recommendation as to whether the proposed study should be approved, declined or deferred.

4.16 Research Involving Animals or Animal Materials

The HRC requires all research involving animals or animal materials to be submitted for approval by the animal ethics committee of the institution/organization with which the investigator is associated. Evidence of approval from an animal ethics committee must be documented before funding commences.

If the institution/organization has no animal ethics committee, guidance on how to set up one for accreditation can be obtained from the National Animal Ethics Advisory Committee (NAEAC). Alternatively, it is possible to obtain approval to conduct the study under the approval and supervision of an animal ethics committee in the vicinity of the institution/organization. Guidance for this, including the following matters, should be obtained from the Secretary of NAEAC:

- guidelines on how to establish an animal ethics committee;
- the responsibilities and procedures in conducting animal ethics review;
- the criteria that should be considered in approving protocols;
- welfare issues in maintaining animal colonies, etc
- monitoring and audit procedures.

The Animal Welfare Act 1999 (AWA) is very prescriptive in all these requirements and the Ministry of Agriculture and Forestry (MAF) has prepared a guide to Part 6 of the statute that covers issues relating to research and animal ethics committees.

Under AWA, it is unlawful to carry out any research involving the 'manipulation' of animals (as defined in the Act) unless the research is conducted according to a protocol that has been approved by an accredited animal ethics committee. The function of accrediting and monitoring all animal ethics committees is undertaken by NAEAC. As part of the HRC site visit programme and other review processes, the HRC may from time to time review contract holders' degree of compliance with protocols approved by animal ethics and the standards of animal husbandry.

Regular issues of newsletters from NAEAC and the Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART) are

circulated to all animal ethics committees. The Secretary for NAEAC can be contacted at the following address for relevant publications:

National Animal Ethics Advisory Committee
Ministry of Agriculture and Forestry
PO Box 2526
Wellington

The Secretary for NAEAC can also be contacted for a current list of accredited animal ethics committees.

Relevant Publications:

Animal Use Statistics: Instructions For Use, Ministry of Agriculture and Forestry (January 2001)

Code of Recommendations and Minimum Standards for the Care and Use of Animals for Scientific Purposes, Code of Animal Welfare No. 17, Animal Welfare Advisory Committee (August 1995)

Guidelines for Institutional Animal Ethics Committees, National Animal Ethics Advisory Committee, Ministry of Agriculture (1988)

NAEAC Guidelines for Drafting an Animal Ethics Committee Protocol Application (2001)

NAEAC Guidelines for Animal Ethics Committees on Adequate Monitoring (2001)

Use of Animals in Research, Testing and Teaching: Users Guide to Part 6 of the Animal Welfare Act 1999, MAF Policy Information Paper 33 (May 2000)

4.17 Research Involving Use of Placebos

Applicants should consult the *Declaration of Helsinki* (revised 2000, World Medical Association) on research involving use of placebos. Ethics committees should have regard to the *Note of Clarification on Placebo-Controlled Trials* and decide on the circumstances of each case, having regard to all relevant ethical considerations, as to whether approval is to be given for a placebo arm in a randomized control trial.

The World Medical Association affirmed that "extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:

- where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method, or
- where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm."

5 General Issues that may have Legal Relevance

The following sets out general issues that may have legal relevance. The information provided below is not to be taken as legal advice but as an indication of matters which should be taken into consideration.

5.1 Biological Materials

See 3.8 Collection and Use of Human Materials for information about the use of body parts and tissues from living and deceased people, and the use of surplus body parts and tissues.

5.2 Intellectual Property Rights and Commercial Considerations

See HRC Rules for the HRC policy on intellectual property—available at www.hrc.govt.nz.

5.3 Copyright

Copyright is automatic under New Zealand law without application to any particular body for the legal right to copyright original material. Copyright exists from the time of production of the original copyrighted material. Materials covered by copyright include but are not limited to: Written, typed or printed information on any medium, artworks, computer source code and object code, data or results of investigations.

The HRCEC expects that copyright will be respected by investigators and other persons and that New Zealand and international laws relating to copyright will be adhered to in all cases.

5.4 Conflict of Interest

To achieve impartiality, any member of an ethics committee who has a proposal before the committee or who has a conflict of interest whereby the impartiality of that member could be questioned, will withdraw from the committee's assessment of that proposal. The HRCEC considers that, where a member of an ethics committee has a conflict of interest in the review of a proposal before the committee, the member has an overriding ethical duty to absent him or herself from the meeting room during the discussion of that proposal.

Where an issue arises in relation to a research proposal such that an investigator may have a conflict of interest (whether perceived, potential, or actual), the issue must be referred to an ethics committee for appropriate comment. The primary ethical concern is that any conflict of interest, particularly a financial conflict of interest, may compromise the well-being of research participants. An investigator should disclose any relevant matters that could give rise to a conflict of interest and,

where appropriate in the circumstances, the conflict of interest must be avoided or managed. The disclosure and, where appropriate, management of any conflict of interest should be stated in information sheets provided to participants. A review and audit of compliance with policies and processes relating to conflict of interest should be undertaken to identify areas that could be improved.

5.5 Scientific Misconduct

Individual host institutions should ensure that there are appropriate guidelines for the conduct of research and procedures for dealing with allegations of misconduct in research.

5.6 Compensation for Injuries Suffered by Participants in Research

The Injury Prevention, Rehabilitation, and Compensation Act 2001 (IPRC Act), provides cover for treatment injuries caused as part of a clinical trial where an accredited ethics committee has approved the trial and is satisfied that the trial was not to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled.

Treatment injuries are adverse medical events that must be causally linked to the treatment (but do not require a finding of fault) and are not a necessary part or ordinary consequence of the treatment.

Guidelines provided by the Ministry of Health and ACC in *Compensation for injuries caused as a result of participation in a clinical trial and the role of ethics committees* (December 1993) state that:

> "A clinical trial is defined as any research on human participants conducted to gain new knowledge into mental and physical health and disease. It would exclude research based on the analysis of secondary sources of health information. Clinical trials involve a wide range of health professionals with different qualifications, skills and expertise and would usually be conducted in hospitals, other health care settings, the community and academic host institutions."

In order to ensure that there is cover under the IPRC Act it is important that the trial is submitted to an accredited ethics committee for approval, and that the researcher makes a statutory declaration to the effect that the trial is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item (A declaration form can be found in the *National Application Form for Ethical Review of a Research Project* (NAF-2005-v1). If approval is not granted by an accredited ethics committee, the trial may not commence or proceed.

Any agreement in writing from a person who will participate in a trial should include all the requirements necessary to enable that person to give his or her fully informed consent, including information on compensation cover.

A claim for cover under the IPRC Act is a matter for decision by ACC. In the circumstances where a claimant has cover and is eligible for the entitlement, the

claimant's entitlement will depend on a number of factors, such as whether the claimant is an earner or non-earner.

5.7 Civil Liability

Where personal injury results from negligence during a non-approved clinical trial, or a clinical trial conducted by a manufacturer or distributor principally for the purpose of testing or proving a product, the injured person will have a right to sue for common law damages.

In respect of a trial that is conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled, it will be necessary for the researcher to ensure that all parties (including the researcher, the manufacturer, the distributor and the host institution) are adequately insured to meet any potential liabilities. Failure to ensure that all parties have adequate insurance will make the research unethical and will be a breach of Guideline 13 of the CIOMS *International Guidelines for Biomedical Research Involving Human Subjects*.

For research that is not eligible for cover under the Injury Prevention, Rehabilitation, and Compensation Act 2001, researchers must ensure that participants and the approving ethics committee are provided with evidence of adequate insurance cover in the event of injury resulting from participation in the research study.

The Researched Medicines Industry Association of New Zealand (RMI) has published guidelines which provide information on the minimum level of cover to be provided by member companies of RMI. Researchers should note that insurance cover does not provide protection from civil liability unless the terms of the policy provide cover against such liability.

5.8 Practising Certificates for ethics committee members

The Health Practitioners Competence Assurance Act 2003 provides a framework for the regulation of health practice in order to protect the place where there is a risk of harm from the practice of the profession.

The Medical Council of New Zealand registers doctors to practices in New Zealand. The Council has indicated that any medically qualified person has to have an Annual Practising Certificate if they are to engage in any activities which potentially could impact on public health and safety. An exemption can be sought from the Council for medical professionals who have retired.

As medically qualified ethics committee members are appointed for the purpose of their professional knowledge and experience, it is the view of the HRCEC that a medical practitioner should hold a current Annual Practising Certificate or an exemption.

Health Research and Privacy - Guidance Notes for Health Researchers and Ethics Committees

Acknowledgements

These guidance notes were prepared by Charlotte Paul, Associate Professor of Epidemiology, Department of Preventive and Social Medicine, University of Otago; Grant Liddell, Senior Lecturer, Faculty of Law, University of Otago; and Peter Skegg, Professor of Law, University of Otago. These guidance notes are also available from (1995) 1 Human Rights Law and Practice 196.

Note: A review of these guidance notes will be undertaken in 2003.

5.9 Introduction

The Health Information Privacy Code 1994 (HIPC) is the starting point for any consideration of the privacy issues which arise in health research. These guidance notes are provided to assist health researchers and ethics committees, but they should not be relied upon as a substitute for the provisions of the HIPC.

The notes have three functions:

- to highlight matters in the HIPC which are especially relevant to health research;
- to provide guidance for health researchers, ethics committees and custodians of health information where the HIPC leaves them with a discretion. The guidance notes indicate matters which should be taken into account in making decisions in such cases, and
- to deal with matters beyond the provisions or framework of the HIPC. The notes recommend good practice, in the use of personal information for research, which goes beyond the requirements of the Code.

The guidance about the matters which should be taken into account when making decisions, and the recommendations about good practice, reflect the judgments reached by a broadly based working party which in 1993 produced a draft code of practice for health research.

The draft code did not proceed but some of its provisions were incorporated in the HIPC, and some passages from the notes to the draft code now appear in the commentary which accompanies the 1994 code. However, much has not yet been utilised. Many of the judgments made by the earlier working party have been re-expressed here, in terms appropriate for a set of guidance notes and recommendations concerning good practice.

The writers have taken account of the international and other guidelines for ethical conduct of health research (see 1.11 and 6.13).

After providing guidance on the application of the HIPC to health research, these notes deal separately with the collection, use and disclosure of health information in health research.

5.10 Application of the Health Information Privacy Code

The HIPC applies where a *health agency* deals with *health information*. If a researcher is not a health agency, or part of a health agency, then, even though he or she might be dealing with health information, the HIPC will not apply. (However, even if the researcher is not a health agency, the record-holder usually will be, and the HIPC will apply to it.) In such a case, the researcher will need to apply the provisions of the Privacy Act 1993 itself, which make different and in many cases lesser demands. (This paper does not deal with those provisions.) The Privacy Act is subject to other legislation. If a request for health information is made by a person who is not the subject of the information, the request must be considered under the Official Information Act.

Health Agencies

There are many bodies that fall within the definition of health agency:

- a health agency is a person or body which provides health or disability services. Usually a researcher will not be providing services. If, however, the researcher has a clinical or service providing role as well, then even though the information might be sought for research purposes, the researcher will fall within the definition of a health agency, and thus will be governed by the HIPC;
- as well, any purchaser of health services is declared to be a health agency. Any research carried out under its auspices will be subject to the HIPC;
- a "school, faculty, or department of a tertiary educational institution which provides the training or a component of the training necessary for the registration of a health professional" is a health agency. This definition encompasses teaching functions. It is not clear whether it incorporates all the research functions of tertiary educational facilities that provide training, and
- certain specified agencies are stated to be health agencies. These include the HRC.

Health Information

Health information has at the core of its definition the notion that information relates to an identifiable individual. If information cannot be linked to an identifiable individual it will not come within the scope of the HIPC, nor indeed within that of the Privacy Act itself. Health information is information about the health of an identifiable individual. This includes information concerning:

- the person's medical history;
- any disabilities the person has or has had;
- health or disability services provided to that individual;
- his or her donation of any body part or bodily substance, or information derived from the testing or examination of any body part or bodily substance of that individual, and
- information about the individual which is collected before, or in the course of, and incidental to, the provision of any health or disability service to the person.

Researchers should note that anonymised information which cannot be linked to any identifiable individual is not health information, and thus is outside the reach of the HIPC.

For the HIPC to apply in relation to health research the researcher must be a health agency, and the information must be health information. If the research falls outside either of these definitions, the HIPC will not apply, but the Privacy Act will if personal information is involved.

The rules in the HIPC mostly apply prospectively from the date the HIPC commenced. This means that individuals can make complaints about failure to comply with the HIPC in relation to actions taken concerning their health information from 30 July 1994. However, some of the rules in the HIPC expressly apply in relation to health information obtained before the commencement date. These rules are:

- Rule 5 (storage and security of health information);
- Rule 6 (access to personal health information);
- Rule 7 (correction of health information);
- Rule 8 (accuracy etc of health information to be checked before use);
- Rule 9 (retention of health information);
- Rule 10 (limits on use of health information) - does not apply to health information obtained before 1 July 1993, and
- Rule 11 (limits on disclosure of health information).

5.11 The Collection of Health Information

Rules 1 to 4, and 12 of the HIPC deal with the collection of health information.

Rule 1 - Purpose of collection of health information

The researcher should collect only information necessary for the research project: Rule 1(b).

Rule 2 - Source of health information

Health information may be collected for research purposes from sources other than the individual concerned, if approval by an ethics committee (if required) has been given, and so long as it will not be published in a form that could reasonably be expected to identify the individual concerned: Rule 2((2)(g)(iii).

Rule 3 - Collection of health information from individuals

Where a researcher is collecting information directly from the individual concerned, the researcher must take reasonable steps to ensure the individual knows that the information is being collected, why it is being collected, who will receive it, what consequences might follow if the information is not provided, and what are the individual's rights of access to and correction of the information: rule 3(1)(a) - (g). It

is not necessary to comply with this requirement if compliance would prejudice the interests of the individual concerned or the purpose of collection: Rule 3(4)(b)(i) - (ii).

Rule 4 - Manner of collection of health information [3(a)(iv)]

Researchers must not collect health information by means that are unfair or that intrude to an unreasonable extent upon the personal affairs of the individual concerned: Rule 4(b)(i)- (ii).

Rule 12 - Unique identifiers

Health agencies must not assign a unique identifier to an individual unless to do so is necessary to enable the health agency to carry out its functions efficiently: rule 12(1). A unique identifier is something (other than the person's name) that uniquely identifies that individual. This will usually be some sort of alpha-numeric code.

Note that the rule regulates assignment not use of unique identifiers. Thus where researchers have collected health information to which another agency has already assigned a unique identifier, the HIPC does not prevent the researcher's use of that same unique identifier.

Where there is no practical way for a unique identifier to be linked to an individual or where a unique identifier has been subject to an irreversible encryption process, the identifier may be regarded as anonymised information.

The use of unique identifiers can enhance individual privacy where the unique identifier replaces other identifying information, and thus diminishes the possibility of unauthorised persons breaching the individual's privacy. However, the HIPC contains safeguards against overuse or abuse.

5.12 Collection - Guidance on Discretionary Matters

Ethics committee approval is required in order to rely on the exception for research in Rule 2, relating to the collection of health information from sources other than the individual concerned. This may be either from another individual or from health records. These two situations are discussed separately below.

Collection of information from another individual

Where the researcher proposes to collect information from someone else, then this should be with the authority of the individual concerned, except in special circumstances. For instance if the researcher proposes to collect personal information from a relative or someone else, without the authority of the individual concerned, because that individual is deceased, untraceable, incapacitated, or for some other good reason, then this approach should be explained in the protocol for the ethics committee, and carried out in accordance with any conditions the committee specifies.

Collection of information from health records

The use of health records for research without the authorization of the individual concerned should only be undertaken subject to certain extra conditions:

Justification

The reasons for not seeking consent should be justified to the ethics committee. These reasons may be scientific, practical or ethical.

The main scientific reason for not seeking consent to use health records for research is that failing to locate individuals to seek their consent may lead to less complete ascertainment of cases for study, and therefore possibly a biased (and hence incorrect) result. This is because the people who are hard to locate may differ in their health problems or the outcome of their treatment from those who are easy to locate.

Another reason for not seeking consent is practical. Sometimes access to records is required in order to determine who will be potential participants in a study. The researcher must identify the names of individuals with a certain condition prior to approaching the individuals to seek their consent to take part in the study.

It is usually impracticable for the individual's own doctor to seek his or her patient's consent for the release of the name to the researcher, because the records will not usually be held by the individual's own doctor, but will be held by hospitals or disease registries. Other practical difficulties occur when there are very large numbers of records and many of the individuals may be untraceable or deceased.

In some situations the process of seeking consent may cause undue anxiety or distress to individuals. This might arise where researchers were investigating a tentative link between an exposure and a serious disease. An example is a study in New Zealand of the use of an asthma drug as a possible cause of sudden deaths from asthma. This study compared the medical records of individuals who had died from asthma with records of asthmatics who had been admitted to hospital but had not died. It would have been wrong to have sought the consent of the group who had not died, because informing these people of an untested hypothesis might have frightened and distressed them without good cause.

Benefits

The potential benefits of the research must be described to the ethics committee, which must weigh up these potential benefits against the loss of privacy.

The potential benefits of the research may include a contribution to the identification, prevention, or treatment of illness or injury, scientific understanding relating to health, the protection of the health of individuals or communities, or the improved delivery of health services. The loss of privacy may be regarded as more important for very sensitive information, for instance termination of pregnancy, or genetic information that might have implications for other individuals.

5.13 Collection - Recommended Good Practice

1. ***Protocols -*** should be developed prior to undertaking research, specifying the information to be collected, why this information is necessary for the research, and the use to which this information will be put.

2. ***Valuable Information -*** where the researcher collects information directly from individuals, and the information could in any way be considered by the person from whom the information is derived to be sensitive or valuable in a personal, social or cultural sense, the research protocol should be approved by an accredited ethics committee.

3. ***Explanation -*** where information is being collected by the researchers directly from any individual, the purpose of the research should be explained to the individual. This information should be as specific as possible without compromising the validity of the research.

   There are many situations where providing very specific information about the study in advance of seeking consent would prejudice the purposes of the collection by compromising the scientific validity of the research. For example, if a mother is to be interviewed to establish whether she has been exposed to a particular medicine which might have caused a congenital abnormality in her baby, it would be wrong, when asking her to consent to the study, to give the name of the drug in question. If the name of the drug were disclosed this would have at least one scientifically unacceptable consequence.

   If the mother in question had a baby with a birth defect, she would have both a reason and a longer period of time, in advance of the actual interview, to remember that she had been exposed to the drug. In contrast, a mother of a healthy baby would have less reason to remember past exposure, and would not reflect on possible past exposure during the period between the consent procedure and the actual interview. This effect could lead to a spurious association between birth defects and drug exposure in the mothers interviewed; thus if such an association were found, it could be scientifically invalid. In studies such as this, biased reporting can be minimised, and scientific validity assured, only by not disclosing in advance the complete details of the hypothesis under test.

   Where specific information cannot be provided at the outset, the researcher should offer to provide results to participants, unless there are practical reasons to the contrary.

4. ***Voluntary -*** where researchers collect information directly from individuals, they should inform them that the supply of information is voluntary and (if in a health care context) that refusal to provide all or any part of the requested information will not affect the provision of health care to the individual in any way.

   The supply of information by individuals for research purposes is voluntary. Hence there must be no adverse consequences for the individual, which are under the control of the investigator, of refusing to supply information. But in some research projects which are not undertaken by health care providers, it

will not be appropriate to inform individuals that their provision of health care will not be affected.

5. ***No inducements -*** which could be regarded as constituting undue influence should be offered to research participants to provide information. Any recompense for participation in health research (either monetary or in kind) should be approved by an accredited ethics committee.

   It may be hard to draw a line between exerting pressure (or offering improper inducements) and legitimate encouragement. Whether such inducements constitute undue influence must be assessed in the light of prevailing social norms.

6. ***Positions of Power -*** researchers who are in positions of power over individuals, as in teacher/student relationships, should not use their positions to unduly influence the decisions of individuals to provide personal information for research purposes.

7. ***Intrusion -*** where research intrudes upon the personal affairs of individuals, a judgement on whether it does so to an unreasonable extent should be made by an accredited ethics committee. (The ethics committee's approval of the research does not relieve the researcher of this obligation, but the decision may provide evidence that the action was permissible).

   Where health researchers seek to enquire into the personal affairs of individuals, for instance in studies of sexual behaviour in relation to sexually transmitted diseases, in deciding whether such questioning intrudes to an unreasonable extent, the ethics committee should take into account the purposes of the research and the potential benefits in terms of the health of individuals or communities.

8. ***Information Collection -*** the following are elements of good practice concerning the collection of health information:

   i) Interviewers should be properly trained, suitable and culturally sensitive and, where appropriate, carry identification.

   ii) If it is reasonably foreseeable that health problems previously unknown to the individual will be identified, then arrangements for referral, with the individual's consent, should be made.

   iii) Care should be taken not to interfere with health professional/patient relationships.

5.14 The Use of Health Information

Rules 5, 8, 9 and 10 of the HIPC deal with the use of health information.

Rule 5 - Storage and security of health information

Rule 5 requires researchers to whom the HIPC applies to take reasonable steps to protect health information against loss, unauthorised access, use, modification, or

disclosure, or other misuse. The HIPC provides details of what might be appropriate safeguards in particular circumstances. In health research, these include removing names or other identifying information from records or data while in use, and using an identifier to ensure that identification of individuals is only possible by reference to a master index which is kept securely.

Rule 8 - Accuracy etc of health information to be checked before use

Rule 8 requires researchers only to use information if they have taken reasonable steps to ensure that the information is accurate, up to date, complete, relevant and not misleading. This involves the researcher making a judgment. The HIPC requires that judgment to be made by considering the purpose for which the information is to be used. Whether steps taken to ensure accuracy etc are reasonable will be judged on the circumstances of the case.

Rule 9 - Retention of health information

Rule 9 requires health agencies to keep health information for no longer than they require it for purposes for which the information may lawfully be used. Note that this does not mean that the health agency may keep the information for only as long as it requires the information for the original purposes for which it acquired the information. The rule entitles the health agency to keep information for as long as is necessary for any lawful purpose.

Thus this rule does not prevent a health researcher who collects or uses health information for one research purpose from retaining the information for another research purpose. However, such reuse may breach rules 3, 10 or 11 if the researcher has not indicated the possibility of reuse to the ethics committee, the individual concerned, or the agency holding the information.

Note that regulations prescribing minimum periods for which information must be kept have been made by the Health (Retention of Health Information) Regulations 1996. Obligations for minimum retention only apply to health information about identifiable individuals, and only to health service providers.

Rule 10 - Limits on use of health information

Rule 10 limits the use of health information. Where an agency has obtained health information for one purpose, it may not use it for another purpose, unless it can show that it reasonably believes that its proposed new use is authorised.

There are several points to note about rule 10 where it concerns health research. Firstly the rule refers to information obtained. Thus it applies to health researchers who hold information which they themselves may not have collected, but have received through some other means.

Secondly, the rule concerns information obtained for a *purpose*. This word is not defined in the Privacy Act or the HIPC. An ordinary understanding would differentiate between health information obtained for treatment purposes from that obtained for research purposes. But is health information obtained for a particular research project entitled to be used for a different research project because the common purpose of research links the two projects?

The HIPC permits such use if the new use is for a purpose "directly related" to the original purpose. (Rule 10(1)(b)). If this is read widely, it could permit such new research uses. The Privacy Commissioner's commentary to the Code, however, suggests that this is not intended, and that researchers who propose to use information from one research project for another need to rely on a different exception to rule 10.

Thirdly, the health agency must, in any event, be able to show that it believes on reasonable grounds that it is entitled to use the information for a purpose different from that for which it obtained the information.

As well as the exception in rule 10(1)(b) noted above, rule 10 also permits new uses of health information for purposes different from the original purpose for which the information was obtained:

- where the individual concerned agrees (rule 10(1)(a));
- where the source of the information is a publicly available publication (rule 10(1)(c)); and importantly for present purposes, and
- where the information is used for research purposes, an ethics committee has, if required, given approval, and only if the information will not be published in a form which could reasonably be expected to identify the individual concerned (rule 10(1)(e)(iii). (This is known as the research exception.)

The HIPC does not specify when ethics committee approval is required.

5.15 Use - Guidance on Discretionary Matters

Ethics committee approval may be required in order to rely on the exception for research in Rule 10, relating to the limits on use of health information.

Research

Ethics committee approval is required for the use of health information collected for clinical purposes for research, and for the use of health information collected for one research purpose for another purpose not directly related to the original purpose. (If the new research purpose is directly related to the original research purpose then such use is in accordance with Rule 10(1)(b) and there is no need to rely on the research exception).

The considerations which should guide an ethics committee in deciding whether the use of health information for research without the authorization of the individual concerned is justified are specified under Collection of information from health records.

The use of medical records (including disease registries) to identify and approach individuals is another research purpose for which ethics committee approval is required. The research protocol and the method of approach should be reviewed by the ethics committee. It should determine whether the approach may be made directly, or by the participant's medical adviser. If the approach is to be made directly, the consent for the individual to be invited to take part should be sought from the participant's medical adviser. In this circumstance, the individual should

be informed of the name of the person who had given consent for them to be approached.

Certain types of research, for instance research into the causes of injury, may only be able to be undertaken if the individuals who have had a particular injury are identified, contacted, and interviewed (with their agreement) to obtain information on possible causative factors. For example, research on falls from playground equipment has been undertaken to determine the dangers of equipment height and ground surface. To obtain accurate information on the circumstances surrounding such falls it is necessary to interview children and parents identified through hospital attendance data.

The reason for seeking the consent of the person's medical adviser for an individual to be invited to take part in research is not to usurp the individual's right to make the final decision about whether to take part, but to minimize the possibility of harm or distress to any individual. The medical adviser should be aware of the person's situation and be able to forbid a direct approach in the unusual situation that the person could be unduly distressed. Where there is uncertainty, the medical adviser should check with the individual that an approach is acceptable.

Audit/Monitoring

Normally, ethics committee approval is not required for the use of health information for monitoring or internal audit undertaken by staff involved in the institution or service.

Health information may be used for monitoring in accordance with rule 10(1)(b) as monitoring may be regarded as directly related to the purpose in connection with which the information was originally obtained.

In addition the exception for research may also be a relevant consideration, because of the similarities of purpose between monitoring and research. This exception may be relied on without having to seek ethics committee approval, provided of course that the information will not be published in a form that could reasonably be expected to identify the individual concerned. See also Section 22(c) (2) of the Health Act 1956.

5.16 Use - Recommended Good Practice

Storage and security

1. The principal investigator of the research group is responsible for the security and control of health research records and information.

2. Anyone who is to have access to health research records and information should give a written undertaking to maintain confidentiality.

3. Appropriate arrangements should be made and enforced at all times for the adequate physical security for housing of confidential information both when in use and when in storage.

4. Measures should be taken to prevent unauthorised access to identifying data held on computer systems.

5. Wherever practicable personal identifiers should be removed from records so that personal linking can be achieved only through the use of a separate cross-index.

6. Consideration should be given to deleting links to records by the irreversible removal of all personal identifiers but this should only be done where the retention of personal identifiers is considered unnecessary.

Though the deletion of links to records from personal identifiers is desirable as a method of safeguarding the security of personal information, there are a number of situations where it would be wrong to delete them. For instance the names of persons in drug trials should be kept long term, because of the possibility of delayed effects of the drug.

An example of the importance of this practice occurred with the drug stilboestrol, which has been demonstrated to cause cancer and congenital anomalies in the daughters of women administered the drug in pregnancy. Several trials were conducted in the 1950s to test the effectiveness of the drug in preventing miscarriage. After the association with cancer was first shown, many years later, many of the participants in the trials were traced and warned and more information was gained on other adverse effects of stilboestrol.

Accuracy

If there are doubts about the accuracy of information to be used for research, the researcher should take reasonable steps to check the information before use.

A particular problem might arise in using special disease registries to identify persons and contact them for research purposes. The accuracy of the diagnosis should be checked before contact with the individual is made.

Retention and disposal

1. Researchers wishing to keep identifying information or identified specimens longer than required for the original research project should obtain the agreement of an accredited ethics committee.

   A special reason for keeping personal information linked to specimens (eg. blood or other tissue) may be the likelihood of developing a new test which might make these specimens valuable for research in the future. Another reason for keeping identifying information will arise in clinical trials of drugs or procedures. Unsuspected long-term effects may become apparent after many years, thus the period of time regarded as essential for the original purpose may be long. Records should often be kept past the end of the research project in case other long term effects are suggested from elsewhere. These records can then be used to test this hypothesis and, if applicable, to warn the research participants.

2. Intact records should not be disposed of other than by shredding or burning on the premises, or by supervised transfer to a shredder or incinerator elsewhere.

3. Where the principal investigator ceases to be responsible for the project, responsibility for the security or disposal of the information will pass to the principal investigator's successor if any, or else to the head of the department or institution.

4. For the disposal of records involving Maori health information, where a Kaitiaki group has been established to act as guardian of Maori information in the area or research, the Kaitiaki group should be consulted on provisions for taonga tuku iho.

5.17 The Disclosure of Health Information

Rules 6, 7 and 11 of the HIPC deal with the disclosure of health information.

The HIPC regulates disclosure of health information with two sets of rules designed to reflect the different situations of (1) the individual who requests access to his or her own information, and (2) other disclosures. These may be either to third parties, in response to a request or at the volition of the health agency, or to the individual concerned at the volition of the health agency (ie. not in response to a request from the individual).

Rules 6 and 7 - The individual's rights of access to and correction of his or her health information

Individuals have rights of access to their own health information. These rights entitle the individual under rule 6 to obtain from the health agency confirmation of whether the agency holds the information and to have access to it. As well, the individual must be told of his or her rights under rule 7 to request correction of the information.

Before the right can be triggered, the agency must hold the information in such a way that it can readily be retrieved.

With a few minor exceptions concerning the private sector only in the cases of copies of X-rays, CAT scans, or video recordings or for repeated requests for the same information, individuals are entitled to free access to their health information (HIPC, clause 6, and s 35, Privacy Act 1993).

The rights are not absolute. There are grounds for withholding information. Three circumstances are relevant to health research, but are not likely to be invoked often. The health agency can refuse to disclose where:

1. Disclosure would involve the unwarranted disclosure of the affairs of another individual (s 29(1)(a), Privacy Act 1993).

2. Disclosure of the information would be likely to prejudice the physical or mental health of the individual requesting the information (s 29(1)(c), Privacy Act 1993).

3. Disclosure would, in the case of an individual under 16, be contrary to that individual's interests (s 29(1)(d), Privacy Act 1993).

Note that prejudice to the conduct of a research project is not a ground for refusing a person access to their health information. If a person insists on access to their health information in the course of a research project, and if to grant access would prejudice the validity of the research design, the Privacy Commissioner's commentary to the HIPC suggests that the research participants should be made aware of this consequence at the time when their consent is sought to participate in the project. If the person still insists on access, access must be given, even if this has to be treated as a withdrawal from the project. This might apply in blind randomized trials.

The rights under rule 7 are to request correction of an individual's health information, and to request that there be attached to the information a statement of a correction sought but not made. Health agencies must take reasonable steps to ensure that the health information they hold is accurate, up to date, complete and not misleading. If an individual makes a request for correction, the agency must determine, by reference to these requirements for accuracy etc, whether to make the correction sought.

However, the Privacy Act does not set out reasons for not making corrections. Where the researcher chooses not to make a correction, the researcher must inform the individual what was done and why, and advise the person that he or she may complain to the Privacy Commissioner about the refusal. The researcher must also advise the person that he or she may have a statement attached to the information of the fact that he or she had wanted the researcher to make a correction.

Rule 11 - Limits on disclosure of health information

In all situations other than where an individual seeks access to his or her own health information, rule 11 applies. Thus where a health agency proposes to volunteer information to the individual or to a third party, or the third party has requested access to a person's health information, rule 11 applies.

The underlying premise of rule 11 is that health agencies must not disclose individuals' health information unless they have good reason in terms of the exceptions that the rule provides. For health research, the following exceptions are likely to be applicable:

1. The researcher might disclose the information to the individual: Rule 11(1)(a).

2. The individual concerned, or the individual's representative, may authorise disclosure: Rule 11(1)(b). This might be done at the time that the individual's consent to participate in the research is obtained, or at some other time.

3. The disclosure of the information is itself a purpose for which the information was obtained: rule 11(1)(c).

If these exceptions are not available, a health researcher may also rely on the following exceptions, but only if the researcher believes on reasonable grounds that it is not practicable or desirable to obtain the individual's authorisation to disclose the information.

The disclosure was directly related to one of the purposes for which the information was obtained: Rule 11(2)(a).

The information is to be used for research purposes (for which approval by an ethics committee, if required, has been given) and will not be published in a form which could reasonably be expected to identify the individual concerned: Rule 11(2)(c).

Where either of these exceptions is used, disclosure is permitted only to the extent necessary for the particular purpose: Rule 11(3).

Researchers should note again that the HIPC applies only to identifying health information. If they have obtained or are using health information which cannot lead to the identification of the individuals to which it relates, the researchers may use and publish the information free of the restrictions of the Code.

5.18 Disclosure - Guidance on Discretionary Matters

Ethics committee approval will be required in order to rely on the exceptions for research in Rule 11, relating to the limits on disclosure of health information. In order for this exception to be applicable the health agency must also have reasonable grounds to believe that it is either not desirable or not practicable to obtain authorization from the individual concerned.

The considerations which should guide an ethics committee in deciding whether the disclosure of health information for research should be permitted are specified under Collection of information from health records. The ethics committee should also consider whether obtaining the authorization of the individual(s) concerned is not desirable or practicable.

5.19 Disclosure - Recommended Good Practice

1. ***Authorisation -*** in general health information should not be disclosed without the authorisation of the individuals concerned. It may not always be possible or desirable to obtain individual consent, in which case the safeguards set out below are particularly important. The overriding consideration should always be that no harm or distress will ensue for the individual or for the family, and that professional relations (for example, doctor-patient) will not be impaired in any way.

2. ***Ethics Committee Approval -*** the disclosure of personal records which are not publicly available should be made only after the proposed research has been considered by an accredited ethics committee. Where the researcher is the custodian of the records, disclosure to anyone else should be made only with the approval of an accredited ethics committee. See Publication.

3. ***Custodian's consent -*** *t*he disclosure of any part of the health records of identifiable persons requires the consent of the custodian of the record. The custodian may be the person's own health care professional (or other clinician), or in the case of health care facilities such as hospitals the custodian of the records will be the medical practitioner or other person who is the designated holder of that responsibility.

4. ***Confidentiality -*** the disclosure of personal records should only be made to persons who have given a written undertaking to ensure confidentiality. A named investigator of the research group to whom the records are disclosed should accept responsibility to ensure the safety and confidentiality of the records.

5. ***Kaitiaki group -*** for records involving Maori health information, where a kaitiaki group has been established to act as guardian of Maori information in the area of research, the kaitiaki group should be consulted.

6. ***Publication -*** *n*o information used for health research purposes should be published in a form that could reasonably be expected to identify the individual concerned, unless the individual has consented to publication.

7. ***Awareness of research -*** reasonable steps should be taken by the custodians of health records to publicise (through notices or pamphlets) the fact that health records may be used, under conditions of strict confidence, for research purposes.

8. ***Test results -*** investigators should always seek permission of the research participant to send to the participant's medical practitioner any relevant test results or abnormal findings that may be detected. If these findings suggest serious disease, research participants who have not given permission for the transfer of the information to their medical adviser should be urged to seek further advice.

   Investigators should normally avoid expressing opinions about findings to the research participant, or appearing to commit a patient's doctor to any particular course of action, but the individual rights of the research participants must be respected, particularly their right to be made aware of any information obtained about them in the course of the research.

5.20 Complaints

The Privacy Act 1993 provides that individuals may complain to the Privacy Commissioner of "interferences with privacy". For an action to constitute an "interference with privacy" it must both breach an information privacy principle of the Act or a provision of a code of practice and have caused, or may cause, harm, loss, detriment, damage, injury, or otherwise adversely affect the individual's rights, benefits, privileges, obligations, or interests, or result in significant humiliation, loss of dignity, or injury to the feelings of the individual. Thus "technical" breaches which do not cause harm to the individual cannot lead to successful complaints (s 66(1), Privacy Act 1993).

As well, individuals may complain to the commissioner if an agency, in response to a request, refuses or fails within the statutory time period (ordinarily a maximum of 20 working days, but in any event as soon as reasonably practicable within that period) to make personal information available, or imposes charges or conditions on the use of personal information it discloses, or refuses to correct personal information.

The HIPC requires health agencies to designate a person to deal with complaints (clause 8) and the commentary encourages individuals to refer their complaints to the health agency first. It suggests that a satisfactory complaints procedure includes a clear entry point for complaints, independence, an opportunity for both sides to be heard, expertise in handling complaints, and prompt responses to complaints.

The Privacy Commissioner has a wide discretion not to investigate complaints that appear to be of no substance, or if the matter is stale, or if the complainant has some other adequate remedy available, or if the matter has been satisfactorily resolved. The Commissioner attempts to conciliate agreed outcomes between complainant and agency, and can, for example, call compulsory conferences for both parties to attempt to identify and resolve the issues at stake.

If the commissioner cannot obtain an agreed outcome between the parties, or if the commissioner does not consider that the complaint has substance and the aggrieved individual does not agree, the matter can be referred to the Complaints Review Tribunal. If the Tribunal finds the complaint has substance, it can order a wide range of remedies, including damages up to $200 000, declarations, restraining orders, orders compelling the agency to redress the loss or damage the complainant suffered, or any other relief that the Tribunal thinks fit. It can also order the unsuccessful party to pay costs.

5.21 Privacy Resources

New Zealand Guidelines

Health Research Council of New Zealand, *Guidelines on Ethics in Health Research: Guidelines and requirements for researchers,* Auckland: Health Research Council, 1993.

Ministry of Health, *Operational Standard for Ethics Committees,* Wellington: Ministry of Health, 2002.

Australian Guidelines

Privacy Commissioner, *National Health and Medical Research Council Guidelines for the protection of privacy in the conduct of medical research,* Human Rights Australia, 1991.

National Health and Medical Research Council, *Report on ethics in epidemiological research,* Canberra: Australian Government Publishing Service, 1985.

European Guidelines

UK Medical Research Council, *Responsibility in the use of personal medical information for research: principles and guide to practice,* British Medical Journal 1985; 290: 1120 - 4.

Knox E.G., *The confidentiality of medical records. The principles and practice in a research-dependent environment,* Commission of the European Communities, 1984.

Steering Group on Health Services Information: *The protection and maintenance of confidentiality of patient and employee data,* London: HMSO, 1984.

International Guidelines

Council for International Organizations of Medical Sciences, *International guidelines for ethical review of epidemiological studies,* Geneva: Council for International Organizations of Medical Sciences (CIOMS), 1991.

Council for International Organizations of Medical Sciences, *International ethical guidelines for biomedical research involving human subjects,* Geneva: CIOMS, 1993.