



Research Ethics at ACC

Guidelines for Staff

Prepared by the ACC Research Ethics Committee

August 2007

Contents

ACC RESEARCH ETHICS COMMITTEE MEMBERS	3
SUMMARY.....	4
1 INTRODUCTION.....	6
2 RESEARCH UNDERTAKEN AT ACC	6
3 THE ACC RESEARCH ETHICS COMMITTEE.....	6
4 ETHICAL REVIEW OF HEALTH AND DISABILITY INVESTIGATIONS.....	7
5 DEFINITIONS	9
6 ACC’S POLICY ON RESEARCH ETHICS	11
7 SCENARIOS	13
8 FAST – TRACKING OF APPROVALS.....	16
9 WHEN MUST YOU SEEK REVIEW FOR YOUR INVESTIGATION FROM THE ACC RESEARCH ETHICS COMMITTEE?	16
10 DECISIONS OF THE ACC RESEARCH ETHICS COMMITTEE.....	16
11 CONTACTING THE ACC RESEARCH ETHICS COMMITTEE	18
12 SUBMITTING A PROPOSAL FOR REVIEW	18
13 CLAIMANT SURVEYS – QUALITY STANDARDS AND RESTRICTIONS.....	18
14 REFERENCES.....	19
APPENDIX A, THE LEGAL FRAMEWORK.....	20
APPENDIX B, PROCESS FOR MANAGING REQUESTS FOR DATA FROM EXTERNAL RESEARCHERS.....	25
DATA REQUESTS FROM RESEARCHERS EXTERNAL TO ACC	26
APPENDIX C, CONFIDENTIALITY FORM	28

Caution. This document has been prepared in good faith according to the ACC Research Ethics Committee’s understanding of relevant Legislation, National Standards and ACC’s Code of Claimants’ Rights. Legislation, National Standards and ACC’s Code of Claimants’ Rights take precedence. The document will be amended and updated as required.

ACC Research Ethics Committee Members

The members of Committee are –

External Members

Sharron Cole Deputy Chief Commissioner, Families Commission (Co-Chair)

Alison Douglass, Barrister and Solicitor (Co-Chair)

Tere Scotney, Manager, Social Statistics Development, Statistics NZ

Dianne Wepa, Senior Lecturer and Co-ordinator, Eastern Institute of Technology,
Hawke's Bay

Bice Awan, Chief Executive, Skylight

ACC members

Katrina Ings, General Manager, Strategic Policy and Research

Paul Miller, ACC Privacy Officer

Kevin Morris, Director Clinical Services

Sandie Waddell, Customer Access Manager

Graeme Osborne, General Manager, Information Management

Summary

General

- The ACC Research Ethics Committee was established in 2004 to oversee the maintenance of research ethics
- the goal of the Guidelines for Staff is to lay an effective ethical foundation for research and promote high ethical standards consistent with legislation, national standards and codes of practice
- the Committee's role is to provide ethical review of research involving ACC, to protect the rights and interests of ACC claimants and stakeholders and to foster an awareness of ethical principles and practices in research within ACC. The Committee is not an accredited Health and Disability Ethics Committee and is not entitled to give ethics approval for any particular investigation. This is done by Ministry of Health Regional Committees and a Multi-regional Committee.
- the Committee is available to provide general advice on ethical matters.

Staff responsibilities

ACC staff are responsible to their managers:

- for ensuring that all investigations they are involved in are conducted to high ethical standards
- for informing the Committee of situations where a breach of standards occurs or may occur.

When must you contact the Committee about surveys and investigations?

Investigators (including ACC staff) should seek the Committee's opinion whenever they have any doubt about the ethical status of their studies. Enquires are welcome at anytime. ***Staff must seek advice from the Committee rather than make ethical decisions themselves.***

Proposals in the following categories must be reviewed by the Committee before referral to a Regional Health and Disability Ethics Committee (or Multiregional Committee) and/or the commencement of the study:

- Evaluations or claimant satisfaction surveys that would provide claimants' personal details or clinical information to third parties.
- Evaluations or claimant satisfaction surveys involving claimants who may in anyway be considered vulnerable (eg under 16, cognitively impaired, have a terminal illness, institutionalised, a sensitive claim).
- Research proposals (including preliminary investigations) where a claimant is to be contacted for additional information or additional tissue/fluid samples, treatments, observation or diagnostic tests etc.

- Research data requests from external researchers for data that requires personal details (names, addresses etc) which could lead to the identification of an individual.
- Pilots, programmes and innovative practice where the claimant's clinical treatment/rehabilitation is varied from their standard care, or where ACC will be requested to provide claimant data for evaluation.
- Changes to already approved projects must be submitted to the Committee for review.
- Studies that require Committee review in accordance with the Operational Standard for Ethics Committees 2006 or the National Ethics Advisory Committee's Ethical Guidelines for Observational Research.

About data requests and surveys of claimants

- Data requests from external researchers, other than for summary data, must be approved by the Committee before being actioned.
- All surveys that contact claimants (other than low risk satisfaction surveys) must be referred to Research Services who will review them for quality and process.

Obtaining copies of the complete Guideline

It is expected that the Guideline will be regularly updated. A full copy of the latest version may be obtained at- www.acc.co.nz/ethics.

Contacting the Research Ethics Committee

The Research Ethics Committee may be contacted at research@acc.co.nz

1 Introduction

The Research Ethics Committee has prepared these Guidelines as a reference for staff and external researchers with the intention of laying an effective ethical foundation for research and promoting high ethical standards consistent with legislation, national standards and codes of practice. It is intended to be a living document and for the latest version to be accessible on the intranet and the web (www.acc.co.nz/about-acc/research).

2 Research Undertaken at ACC

ACC is required by legislation to carry out its functions and deliver services in a manner that is cost effective and promotes administrative efficiency and may also seek to reduce the incidence and severity of injuries through research¹.

To this end the Corporation both undertakes and sponsors quantitative and qualitative investigations concerned with its functions of injury prevention, rehabilitation and compensation. The studies range from population-based epidemiological studies to claimant surveys where there is access to personal records and further contact with claimants.

3 The ACC Research Ethics Committee

General Comments

The ACC Research Committee established in 2004, a Research Ethics Committee for the purposes of overseeing the maintenance of ethical standards of research. This includes in certain situations, the screening of investigative proposals and requests for data (Section 8). The Committee is also available to give advice where staff would appreciate guidance (eg client vulnerability, service delivery issues, innovative practice).

The ACC Research Ethics Committee while supervising research ethics at ACC is not able to give ethical approval as such for any investigative project, as this right is reserved for National and Regional, Health and Disability Ethics Committees that are external to ACC and accredited in accordance with the Operational Standard for Ethics Committees².

Scope³

The Terms of Reference of the Committee describe the scope of its activities as –

- Ethical matters related to internal and external research commissioned by or involving ACC
- Advising staff on ethical issues related to research
- Maintaining links with other Ethics Committees
- Approving requests for research data including, requests for names and addresses, requests where staff or claimants are to be contacted and requests for data where linkage to data in other databases is planned.

Objectives of the Committee³.

The Committee is responsible for establishing and maintaining guidelines and processes for ACC in relation to research ethics and data requests for research purposes. In particular it will –

- Develop and maintain guidelines for research ethics at ACC
- Develop and maintain a policy to approve the release of data for researchers and manage requests for data from researchers
- Establish processes for handling data requests and develop any related forms to assist operational efficiency
- Approve the release of ACC data for research purposes
- Consider internally initiated research and, where necessary, refer it to an accredited Ethics Committee for its consideration prior to the research commencing
- Ensure all external research contracted by ACC where necessary, has approval from an accredited ethics committee
- Assess locality issues to ensure that proposed studies, researchers, facilities etc., are suitable to the claimant communities involved and considerate of their specific community issues.

4 Ethical Review of Health and Disability Investigations

In New Zealand there is currently no legislative framework for the provision of ethical review of Health and Disability Research in New Zealand. The requirements to submit proposals for ethical review by accredited ethics committees are derived from a variety of sources including international conventions, such as the Declaration of Helsinki, and domestic law including the Health and Disability Services Consumers' Code of Rights, The Health Information Privacy Code, and the Health Research Council Act 1990. In addition, the ACC Research Ethics Committee gives due emphasis to the Accident Compensation Act 2001 and the Code of ACC's Claimants Rights 2004.

Since the early 1990's Health and Disability Research has been subject to a requirement for ethical review. In 2002, the Ministry of Health released the 'Operational Standard for Ethics Committees'², that aimed amongst other goals, to achieve flexibility and consistency of ethical review throughout New Zealand. For example the Standard requires Health and Disability Research conducted by Government Departments to be submitted for ethical review unless they have statutory exclusion. This Standard, along with the Code of ACC's Claimant's Rights are the Committee's central references.

As a purchaser of research and an investigator, the Committee considers that ACC, is required to adhere to, and ensure its external contractors adhere to, the processes for ethical review of Health and Disability Research as set out in the Operational Standard for Ethics Committees. To this end, external researchers funded by ACC must enter into contractual relations with ACC that require them to obtain all necessary ethical approvals before the commencement of work.

The objectives of ethical review² are to:

- Safeguard the rights and interests of participants in research and innovative practice, and consumers of health and disability services
- Protect the cultural interests of Maori, Pacific Peoples and other ethnicities, promote their wellbeing and ensure mechanisms for participation in ethical review
- Foster awareness of ethical principles and practices within service providers, researchers and the wider community
- Consider any matters relevant to health and disability services
- Promote excellence in research for the wellbeing of society
- Give due consideration to both local and national community views and perspectives in ethical review
- Assure the public that the above is done.

These objectives are relevant to the ACC Research Ethics Committee developing ethical standards for all research with which ACC is involved.

The Operational Standard describes the following as ethical principles essential to ethical review:

- Respect for persons
- Informed consent
- Privacy and confidentiality
- Validity of the research proposal
- Minimisation of harm
- Justice [Equity]
- Cultural and social responsibility
- Compensation for research participants.

The Code of ACC Claimants' Rights are:

- The right to be treated with dignity and respect
- The right to be treated fairly, and to have your views considered
- The right to have your culture, values, and beliefs respected
- The right to effective communication
- The right to be fully informed
- The right to have your privacy respected
- The right to complain.

5 Definitions

Claimant Satisfaction Survey:

A survey conducted by mail, telephone and/or focus group to evaluate claimant's views on their experience and expectations of service delivery. The survey excludes questions about the claimant's clinical treatment, physical or mental state.

Audit:

Audit of claimant data is an activity distinct from case management and is essential to the delivery of quality health services. It is defined as -

- Existing information held about individuals is aggregated and analysed for the purposes of understanding the service and improving its quality. Typically the output of the analysis is a management report
- It may be conducted internally by ACC staff or externally for ACC by persons in a contractual relationship with ACC and who have signed the standard Confidentiality Form
- The collection of new information or additional information from claimants is specifically excluded⁴
- It does not include anything being done to or withheld from patients beyond their normal case management⁴
- Data other than that held on ACC's database may be included
- The report does not identify any individual either directly or indirectly.

Research:

Any systematic Health and Disability investigation undertaken for the purpose of discovering new knowledge or applying knowledge about preventing injuries or enhancing outcomes or services for ACC and its claimants, excluding audit and claimant satisfaction surveys.

Investigation:

The word is used in these Guidelines in a generic sense and includes research, audit and claimant satisfaction surveys.

Innovative Practice:

A planned deviation from the currently accepted practice of a New Zealand body of health professionals, involving an untested or unproven clinical intervention intended to be used on an ongoing basis. Innovative practice includes application of known procedures in new or novel circumstances in which they have not been previously tested. It may involve new delivery practices by health practitioners, new devices, new investigative procedures or clinical management options².

Health Information:

Health information² includes information –

- About the health of that individual including his or her medical history
- Any disabilities that the individual has or has had
- About any health services or disability services that are being provided, or have been provided to that individual

- About that individual which is collected before or in the course of, and incidental to, the provision of any health service or disability service of that individual.

6 ACC's Policy on Research Ethics

General

- ACC is committed to preventing injuries and improving services and outcomes for claimants through a considered programme of research: This includes the encouragement of external researchers to co-operate with ACC to realise this commitment
- ACC will seek to conduct such investigations according to New Zealand Legislation, the Operational Standard for Ethics Committees² and the Code of ACC Claimants' Rights

These sources form the basis for the decisions made the Research Ethics Committee. In addition the Committee emphasises the following policies -

- Researchers must consider the merits of including all relevant categories of ACC claimants (eg the elderly) in their investigative programmes
- While extra care may be required when investigating certain groups of claimants who may be considered more vulnerable, such claimants have a right to have their care researched for possible improvements
- Beneficial findings arising from research must be made available to all relevant claimants whether or not they were participants in the research programme
- The principal beneficiaries of any investigative programme must be ACC and/or ACC's claimants and potential claimants
- Investigations involving ACC's staff, levy payers and providers are to be conducted to the same ethical standards as that applied to claimants.

Cultural Issues

- Cultural issues are central to the ethical conduct of all investigations^{5 6}: ACC is committed to upholding the principles of the Treaty of Waitangi
- ACC's representatives and/or consultative committees of ethnic groupings (eg Te Roopu Manawa Mai, Pacific Consultancy Group) must be involved wherever investigations focus primarily on a particular ethnicity or where a particular ethnicity may be especially benefited by a more general investigation.

Responsibilities of ACC Staff

- Staff of ACC are individually responsible to their managers for ensuring that all investigations in which they are involved are conducted to high ethical standards and for informing the Research Ethics Committee of situations where a breach of standards occurs or may potentially occur
- In certain cases, proposals for investigations must be referred to the ACC Research Ethics Committee for review before the proposal is referred to a Regional Health and Disability Ethics Committee or before the investigation begins (Section 8).

ACC Data, Surveys and Data Requests

- For the purposes of research-like investigations, all ACC data is regarded as Health Information data
- Data requests from external researchers must be approved by the Committee before being actioned
- All surveys that contact claimants must be referred Research Services who will review their quality and process. Research Services will maintain a register of surveys and co-ordinate them with respect to frequency, content and purpose. Research Services will report regularly to the Research Committee on the status of claimant surveys
- External investigators requiring data must work with the sponsor within ACC and have the sponsor's approval to proceed. Research and Corporate Services may act as sponsor if no other appropriate contact within ACC is available
- External providers requesting data for audit purposes must have a direct responsibility for overseeing the safety and quality of the service for which the data is requested
- All reports using ACC data must not identify directly or indirectly, any claimant or service provider.

Operational Matters

- ACC reserves the right to decline investigative proposals and requests for data that are unreasonable from the perspective of its operational impact on Scheme Performance, the Network and staff
- Relevant Divisional Managers will be consulted before any operational decision is made
- Where claimants are to be contacted, ACC will contact the claimant first, seeking their approval to take part in the investigation, rather than divulge names and addresses to third parties before consent is given. Exceptions are only granted when the Committee is satisfied that the Health Information Privacy Code and Privacy Act are complied with.
- Investigations must be considerate of ACC staff sensitivities (eg contact with case managers)
- External researchers requesting data will usually be required to enter into copyright and confidentiality agreements with ACC
- The proposed investigation must not have significant potential to generate an unreasonable number of complaints or bring ACC into disrepute.

Requirement for Reporting

- External researchers funded by ACC, or using ACC data must provide a final report to ACC regardless of whether or not the outcome fulfils the original intentions of the investigator. It is expected that researchers will give careful consideration to publishing the results in a form that is accessible to the public and in a manner consistent with their contractual obligations to ACC.

7 Scenarios

The Research Ethics Committee has developed the following scenarios to illustrate links between general design features of investigations and ethical issues. The table is only meant to be a guide and individual cases are reviewed on their merits and in the light of relevant legislation.

	<i>Description</i>	<i>Scenario</i>	<i>Discussion Points</i>	<i>Study should be reviewed by ACC Ethics Committee</i>	<i>Ethical approval required from a Regional Ethics Committee</i>
1.	Patient Satisfaction Survey – Not collecting confidential or sensitive information.	The investigation is a questionnaire or survey that does not involve the collection or use of confidential or sensitive personal information (eg patient satisfaction survey). Vulnerable patients are not contacted.	Patient satisfaction surveys are permitted ² and in general do not require ethical approval. Such surveys must meet the quality standards and consider the suggested exclusions set out in section 12.	Not usually	No
2.	Claimant satisfaction survey. Vulnerable claimant contacted.	Claimant satisfaction survey but the claimant is considered vulnerable eg under 16, cognitively impaired, has a terminal illness, institutionalised, sensitive claims.	Special care is required to protect such claimants.	Yes	Yes
3.	Internal Audit/Management Reports.	The investigation is conducted internally by ACC staff for the purposes of audit or monitoring of quality of care and does not require the claimant to be contacted for additional health information.	Audit as defined in section 5 does not require ethical approval ² .	No	No
4.	Audit/Management reports done by an external contractor for ACC.	The investigation is conducted by an external agency contracted to ACC for the purposes of audit or monitoring of quality of care and does not require claimants to be contacted for additional health information. The contractor has a confidentiality agreement with ACC.	Audit done for ACC by external agencies does not require ethical approval providing that the agency has a contractual agreement with ACC and has signed the Confidentiality Form ² .	No	No
5.	Audit/Management Reports – For an external provider/ agency. Request is not covered by Statutory Authority	An external provider requests claimant data from ACC for the purposes of auditing/managing their service. The request is not covered by Statutory authority.	The request does not require ethical approval providing the data is at summary level. The rules governing these requests are:- <ul style="list-style-type: none"> • The provider is involved in the delivery of the service • The data requested must be 'injury -related' data¹ • No claimant can be identified by the data • The request is considered by Scheme Analysis to be reasonable from an operational perspective. 	No	No
6.	Audit/Management Reports – For an external provider/ agency. Request is covered by Statutory Authority	An external provider requests claimant data from ACC for the purposes of auditing/managing their service. The request is covered by Statutory authority.	<ul style="list-style-type: none"> • The request does not require ethical approval. 	No	No

	Description	Scenario	Discussion Points	Study should be reviewed by ACC Ethics Committee	Ethical approval required from a Regional Ethics Committee
7.	<p>Research, where the claimant is contacted for additional information</p> <p>Excludes claimant satisfaction survey.</p>	<p>The investigation is either conducted for purposes similar to that of audit for monitoring of quality of care but claimants are to be contacted for additional information. Alternatively the claimant is to be contacted for research purposes.</p> <ul style="list-style-type: none"> The information required may or may not be confidential or personally sensitive The information requested may or may not be about the medical condition, medical treatment or health of the individual The work may be done internally or externally by an agent of ACC. 	<ul style="list-style-type: none"> All ACC data is regarded as health data Contacting a claimant for additional information is regarded as research⁷ that requires ethical approval from the ACC Research Ethics Committee at the very least Usually, ACC will contact the claimant to verify their consent before providing names and addresses to the researcher In the case where the request for additional information only requires a mailout, ACC will usually mail out the survey on ACC letterhead, using ACC envelopes. A return envelope addressed to the researcher will be enclosed Where an investigator does not consider approval from a Regional Ethics Committee is necessary a case must be made and submitted to the ACC Research Ethics Committee. 	Yes	Usually
8.	<p>External Researcher Data request. No claimant ID provided.</p>	<ul style="list-style-type: none"> External researcher The research may or may not be initiated by ACC The researcher may or may not have a contract with ACC to do the research Claimants will not be contacted Data provided by ACC may contain health information but no claimant can be identified either directly or indirectly Results may be published only at summary level by the researcher. 	<ul style="list-style-type: none"> Health information held by a researcher is information that relates to an identifiable individual⁷ An operational rule is that where review of the data is likely to result in a report, a contract/ letter must be held by ACC guaranteeing a copy of the report be forwarded to ACC at the completion of the study. 	No	No
9.	<p>External Researcher. Data request. Claimant ID provided but claimant not contacted.</p>	<p>An investigation is conducted by an external research provider:</p> <ul style="list-style-type: none"> The researcher may or may not have a contract with ACC to do the research Claimants will not be contacted Data is provided by ACC that contains health information and personal identifiers (eg for the purposes of linkage of data to another data base) Results may be published at summary level by the researcher At the completion of the study the data is destroyed or returned to ACC. <p>(This is a special case and usually applies only to the Injury Prevention Research Unit, University of Otago).</p>	<ul style="list-style-type: none"> This is both personal information and health information relating to identifiable individuals even though those individuals are not contacted. Therefore ACC may not disclose such information to any third party unless disclosure is consistent with the Health Information Privacy Code If ACC considers that the request meets privacy considerations only information necessary to the immediate needs of the research project will be provided⁷. 	Yes	Yes

	Description	Scenario	Discussion Points	Study should be reviewed by ACC Ethics Committee	Ethical approval required from a Regional Ethics Committee
10	Injury Prevention Programme evaluation where programme participants are from the general population (e.g. parents, rugby coaches, snow boarders)	The investigation is a questionnaire or survey focussed on evaluating satisfaction/behaviour change as a result of the programme. It does not involve the collection or use of detailed health/injury information.	Programme participants are from the general population, not exclusively claimants. Consent to be involved in evaluation is confirmed prior.	Only if particular risky issues arise eg the programme investigates family violence	No
11	As above but detailed injury information is surveyed	A questionnaire or survey focussed on evaluating satisfaction/behaviour change as a result of the programme. Detailed health/injury information is collected.	<ul style="list-style-type: none"> • Programme participants are from the general population, not exclusively claimants • Consent to be involved in evaluation is confirmed prior • Health information is being collected from an identifiable person. 	Yes	Yes
12	Injury Prevention Programme evaluation where programme participants are claimants.	A secondary prevention programme where participants are recruited because they are claimants (e.g. a secondary falls pilot, suicide prevention brief intervention pilot) and programme evaluation involves recontacting these participants.	<ul style="list-style-type: none"> • Consent is obtained before evaluation begins • The evaluation would not usually require ethical review by the ACC Committee or from the Regional Committee if only the claimants satisfaction with the programme is surveyed (claimant satisfaction survey) • This case cannot be regarded as audit if the claimant is being contacted for significant new health information • If significant new health information is collected this must be regarded as Research and ethical approval would be required from the ACC Committee and a Regional/National Committee. 	Yes	Depends on the details of the case
13	Development of a new injury prevention programme and input from claimants is required	Research involving claimants in order to develop a programme (e.g. motorcycle claimants are surveyed to assist in development of the programme).	<ul style="list-style-type: none"> • If contact is confined to investigating non- health information, ethics approval need only come from the ACC Committee • If health information is to be collected then approval would normally be required from both the ACC and Regional/National Ethics Committees. 	Yes	Depends on the details of the case

8 Fast – Tracking of Approvals

The Committee may fast-track requests for approval when the proposal is considered to pose no or little ethical risk. Decisions about fast-tracking will be made by the Secretary of the Committee in conjunction with the Director of Clinical Services on request of the persons involved. Such decisions will be reviewed and if necessary revised by the full Committee at its next meeting.

9 When must you seek review for your investigation from the ACC Research Ethics Committee?

Investigators (including ACC staff) should seek the Committee's opinion whenever they have any doubt about the ethical status of their studies. Inquiries are welcome at any time. Proposals in the following categories must be reviewed by the Committee before referral to a Regional Health and Disability Ethics Committee and/or commencement of the study:

- ***Claimant satisfaction surveys*** that investigate confidential or personally sensitive information or survey claimants that may be considered vulnerable (eg under 16, cognitively impaired, have a terminal illness, institutionalised, sensitive claims.)
- ***Research proposals*** where the claimant is to be contacted for additional information or additional tissue/fluid samples, treatments, observation or diagnostic tests etc.
- ***Research data requests*** from external researchers for data that requires personal identifiers (names, addresses etc)
- ***Innovative practice:*** Claimants are to be requested to take part in a trial involving an innovative practice
- ***Changes to already approved projects:*** If an already approved investigation is changed during the course of the research the Committee must be advised and the changes submitted for review.

10 Decisions of the ACC Research Ethics Committee

The Committee will endeavour to respond in writing to a submitted investigative proposal within one month of the receipt of the proposal. After review, the Committee will classify a proposal according to one of the categories⁷ –

- Approved subject to review by an accredited Health and Disability Ethics Committee
- Approved (Approval from and accredited Health and Disability Ethics Committee not required)
- Provisionally approved subject to revision
- Approval deferred subject to substantial revision
- Approval declined.

The Committee will always provide reasons for its decisions and where appropriate provide suggestions for improving the proposal along ethically acceptable lines. The Committee welcomes comment on its decisions and will reconsider or seek a second opinion wherever this is warranted.

11 Contacting the ACC Research Ethics Committee

Those wishing to contact the Committee may do so by contacting in the first instance –

ACC Research Ethics Committee
Research and Corporate Services Division
PO Box 242
Wellington

Or

Programme Manager – Research
Phone 04, 9187656.
Email, research@acc.co.nz

12 Submitting a Proposal for Review

When submitting a proposal for review by the Research Ethics Committee the information provided should be commensurate with the scale of the project and the degree of ethical concern raised. Investigators requiring advice on the level of information required should contact the Programme Manager-Research (Section 10). The Committee expects investigators of complex proposals to attend the Review if this can be reasonably arranged. An electronic copy and one hard copy of each proposal is required.

(Investigators should note that if a proposal will eventually require ethical approval from a National or Regional Ethics Committee a form available from the Health Research Council must be completed (www.hrc.govt.nz). In such cases time may be saved if such applications are made on the National Application Form).

13 Claimant Surveys – Quality Standards and Restrictions

1. Surveys of claimants must be undertaken only for the purpose of obtaining information that will directly assist ACC fulfil its legislative mandate.
2. The potential benefit to ACC of a survey must be weighed against any potential negative impact or harm to the claimant.
3. The quality of the survey is of paramount importance; Methodology must be carefully considered eg sample selection, sample size, response rates and appropriateness of persons conducting interviews.
4. The survey must make it clear that –
 - Responding is completely voluntary
 - Whether or not a claimant takes part in the survey has no effect on their relationship with ACC
 - The approach to the claimant must be non-coercive.
5. Careful consideration needs to be given to inclusions and exclusions. Scheme Analysis endeavours to exclude the following cases from a survey unless specifically requested: -
 - Sensitive claims
 - Remote claims, dangerous claimants

- Medical Misadventure
 - Deceased or missing
 - Persons on ventilators
 - Fulltime attendant care
 - Currently being investigated for fraud
 - Moderate or serious head injury
 - Surveyed in the last 6 months (usually)
 - Claimants requesting exclusion.
6. Careful consideration needs to be given to surveying claimants who are under 16 or over 75.

14 References

1. Accident Compensation Act, 2001.
2. Operational Standard for Ethics Committee: Ministry of Health, 2002.
3. Terms of Reference, ACC Research Ethics Committee, 2004.
4. Review of current processes for the ethical review of health and disability research in New Zealand: National Advisory Committee on Health and Disability Support Services Ethics, 2003.
5. Guidelines on Pacific Health Research. (www.hrc.govt.nz), 2004.
6. Guidelines for researchers on health research involving Maori. (www.hrc.govt.nz), 1998.
7. Guidelines on Ethics in Health Research: Health Research Council of New Zealand, 2002.
8. Guidelines for processing information requests: Accident Compensation Corporation.

Appendix A, The Legal Framework

Accident *Compensation Act 2001*

ACC has a specific mandate to undertake research. A primary function of ACC as set out in the Accident Compensation Act 2001 is to promote measures to reduce the incidence and severity of personal injury. Research is one of several measures listed in the Act that ACC must undertake or fund provided certain fiscal requirements are met: Section 263(3). Specifically, s 263(4) provides:

The Corporation may in its discretion, conduct, participate in, commission, or subsidise research into the reduction of the incidence and severity of accidents and other causes of personal injury that is directed at reducing the cost of compensation and rehabilitation under this Act.

ACC undertakes both quantitative and qualitative investigations concerned with its injury prevention, rehabilitation and compensation functions ranging from epidemiological studies on a population basis to claimant surveys where there is access to personal records and further contact with claimants. Research is initiated both internally and externally. The Injury Prevention Units at both Otago and Auckland Universities undertake a significant amount of the contracted research.

In carrying out its functions ACC must deliver services to claimants and levy payers in a manner that is cost-effective and promotes administrative efficiency: s.262(3)(a). To this end ACC carries out auditing through extensive monitoring and evaluation in all aspects of its service delivery. ACC has statutory authority to collect personal information from individuals or organisations to carry out its functions. The broad range of purposes for which ACC may collect information set out in s 279 of the Act includes maintaining a claims database, facilitating the monitoring of the operation of the Act, injury prevention, and ascertaining appropriate levels of rehabilitation and compensation.

ACC also has statutory authority to disclose personal information about claimants for a variety of purposes to certain government agencies that have reciprocal statutory powers to access ACC information. This disclosure regime is not specifically for research purposes but for the interaction between ACC and various government agencies in carrying out their own duties and functions such as the disclosure of information for benefit purposes pursuant to the Social Security Act to the Department of Work and Income: s.281. Some disclosure of health information, however, may fall within the definition of an investigation, requiring ethical review to comply with the Guidelines. For example, disclosure of health information to the Ministry of Health and to district health boards to facilitate the auditing and monitoring of the provision of treatment under the Act where the personal information sought goes beyond the purposes identified in section 282.

The Act provides for the appointment of a statutory manager (the Information Manager), who reports to a Minister designated by the Prime Minister with responsibilities for the management of the extensive injury-related information held by ACC. The statutory manager resides at Statistics NZ. (*Injury related information' may be interpreted as 'health information' for the purposes of s.4(1) Health Information Privacy Code*). Not only must the Information Manager facilitate the development and maintenance of a research database on injury-related information (s.287(b))

but the Information Manager has statutory powers to disclose injury-related information to another government agency for research purposes. Section 289(4) provides:

(4) The manager may disclose injury-related information to any officer of another government agency solely for bona fide research or statistical purposes relevant to the functions and duties of that government agency, and bona fide private sector researchers, only if—

(a) the information is to be used in a form in which the individual concerned is not identified; or

(b) the information is to be used for statistical purposes and will not be published in a form that could reasonably be expected to identify the individual concerned; or

(c) 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 that could reasonably be expected to identify the individual concerned.

The Information Manager's functions include the development and maintenance of standards and compliance with the Health Information Privacy Code: s.289(6). This could be interpreted to include ethical standards and the requirements for ethical review of health and disability research. This function is consistent with ACC's obligation to ensure the correct ethical review procedures are followed regardless of whether the research is initiated by ACC or ACC receives an external request for injury-related information for research purposes.

Health and Disability Research – Requirements for Ethical Review

Currently in New Zealand there is no legislative framework for the provision of ethical review of health and disability research⁴. The requirements to submit proposals for ethical review by accredited ethics committees however are derived from a variety of sources including international conventions, such as the Declaration of Helsinki, and domestic law including the Health and Disability Services Consumers' Code of Rights, The Health Information Privacy Code and the Health Research Council Act 1990.

The standards required for ethical review of health and disability research are set out in the ***Operational Standards for Ethics Committees***, (Ministry of Health, March 2002). The objectives of ethical review and the ethics committees accredited in accordance with the Operational Standard are to:

Safeguard the rights and interests of participants in research and innovative practice, and consumers of health and disability services.

Protect Maori cultural interests, promote the wellbeing of Maori and ensure mechanisms for Maori participation in ethical review.

Foster awareness of ethical principles and practices within service providers, researchers and the wider community.

Consider any matters relevant to health and disability services.

Promote excellence in research for the wellbeing of society

Give due consideration to both local and national community views and perspectives in ethical review.

Assure the public that the above is done.

The Operational Standard sets out the kind of research investigations that are required to be submitted for review by an ethics committee. This includes research conducted by a government department unless they have a statutory exclusion (for example, Statistics New Zealand). As a purchaser and investigator of research, it is reasonable to conclude that ACC is required to adhere to, or ensure its external contractors adhere to, the processes for ethical review of health and disability research as set out in the Operational Standard for Ethics Committees.

Health Information Privacy Code

The Health Information Privacy Code 1994 (“the Code”) is the starting point for any consideration of privacy issues which arise in research and where ACC data is accessed by other government agencies and external organisations for monitoring and evaluation under provisions of the Act⁷. It applies specific rules to agencies in the health sector to better ensure the protection of individual privacy. With respect to “health information” collected, used, held and disclosed by “health agencies” the Code substitutes for the 12 information privacy principles in the Privacy Act 1993. To some extent ACC already has these rules embedded in the requirements for managing injury-related information under the Act but the Code has overall application to the operation of ACC and the health information held by it. This is further reinforced by ACC’s Code of Claimant Rights and in particular, Right 7, the right to privacy.

For the Code 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 Code will not apply, but the Privacy Act will if personal information is involved. The definition (Code,4(1)) of health information is wide and includes:

- 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 and disability service to the person.

As ACC collects, uses and discloses personal information about injured persons, their families, health related information (treatment and rehabilitation), accident details and earning information which would fall within this definition. However, not all information collected by ACC is health information, for example, income related information of a claimant, but may still be personal information to which the Privacy Act applies. If the non-health information is collected ***incidentally to*** the collection of health information it may still fall within the definition of health information.

ACC is a health agency for the purposes of the Code but there may be some instances where a researcher contracted by ACC is not. A researcher or their organisation may not be aligned to the provision of health services and will not therefore be a health agency. They will be regarded as a separate person and ACC must regard disclosure of health information to that researcher requiring compliance with the Code.

The rules in the Code that are particularly relevant to research are those concerned with the collection, use and disclosure of health information. In summary these are:

- Collection of health information : Rules 1-4, 12.
- Use of health information: Rules 5,8,9, and10.
- Disclosure of health information: Rules 6,7 and 11.

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). The reasons for not seeking consent should be justified to the ethics committee. These reasons may be scientific, practical or ethical. The potential benefits of the research should also be described to the ethics committee so that it can weigh up the potential benefits against the loss of privacy.

The manner of collection of health information from individuals is particularly relevant in the ACC context. 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, and what consequences might follow if the information is not provided : Rule 3(1)(a) – (g). It is important to distinguish between information that ACC requires from claimants in order to carry out its statutory functions and the collection of health information for research purposes which is voluntary. Refusal to provide all or part of the requested information will not affect the claimants relationship with ACC and their entitlements under the Act. Similarly, researchers must not collect 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).

Some ethical themes that underpin the Code include the following:

Purposive approach – Information collected for one purpose should not be used for another purpose without an individual's consent. The ethical basis is respect for autonomy and self-determination.

The “need to know” principle – only information essential to the investigation ought to be collected.

Guardianship/ Kaitiakitanga – researchers have a responsibility in safeguarding personal information and information about a community.

Official Information Act

ACC is subject to the Official Information Act 1982. “Official Information” is any information held by a government agency, such as ACC. It refers to information about the organisation’s management, operation, business practices, internal policies, rates, guidelines, forms and fact sheets. The basic principle of the Official Information Act is that all information held by government agencies should be made available to the public, unless a good reason exists for withholding it. The legislation specifies the reasons that are appropriate for an agency to withhold requested information⁸.

That most of all information held by ACC is official information, and is subject to the Official Information Act does not mean that information may, or should be disclosed. Mechanisms exist in the Act to protect information which, if disclosed would prejudice a particular interest such as an individual’s privacy, the commercial position of ACC or any other party. Information held by ACC regarding a research investigation would need to be considered under any request. This may include specifically, the research proposal, the final report and correspondence in relation to the investigation but is not likely to include the evaluative material of the investigation.

The Official Information Act is also concerned with requests for ***personal information***, defined as “any information held about an identifiable person” and therefore the Official Information Act and the Privacy Act (and the Code) overlap to some extent. Generally speaking, where requests are made by a person for personal information about themselves, the Privacy Act will apply whereas requests for personal information by organisations about themselves or requests by persons for personal information about another individual, are processed under the Official Information Act. In the research context, where ACC or a researcher for ACC holds information, either Act may apply depending on the precise nature of the information covered by the request and its relationship to the requester.

Appendix B, Process for managing requests for data from external researchers.

1. Investigators establish need for data.
2. External investigators requiring data must work with the sponsor within ACC and have the sponsor's approval to proceed. Investigators discuss the need for the data with the sponsor. Research and Corporate Services may act as sponsor if no other appropriate contact within ACC is available.
3. Investigators complete the ACC Data Request Form and send it to the Research Office, Research and Corporate Services, ACC.
4. Research Office checks form for completeness.
5. Research Office contacts Scheme Analysis, if required, to establish feasibility, numbers, possible restrictions on data to be applied (age of injury, seriousness of injury, dates defining data etc).
6. Research Office contacts members of the Research Ethics Committee for approval to proceed. (This includes the Privacy Officer). This may be done by email when required. The Research Office will advise Committee Members on the following matters as appropriate -
 - The nature of the request including the survey questions if these are to be used
 - The ethical review status of the request
 - The process by which the data request will be handled (eg ACC will do the mail out)
 - Restrictions to be applied to the data
 - Where a mail out is required, the probable numbers involved.
7. If ethics approval is required and not yet obtained it must be procured at this point by the researchers before further approval is given. A copy of the certificate must be sighted by ACC. The researcher is advised to obtain the ethics certificate.
8. Confidentiality Form developed (if necessary) and sent for signoff by the Investigators.
9. Confidentiality Form returned to ACC Research Office.
10. Data request processed.
11. If claimants are to be contacted, the Privacy Officer is advised of the timeframe and the Network advised.

Data Requests From Researchers External to ACC



Please complete this form.

- Researchers requesting access to ACC data should, before completing this form, consult first with their sponsor within ACC, or in the absence of a sponsor, Research Services at ACC, to discuss the reasonableness of the request from ACC's perspective. Establishing this test of reasonableness though, does not guarantee that the request will proceed
- Researchers who believe they may require ethics approval from an appropriate committee for the data request may complete and submit this form first, to ensure that ACC is willing to co-operate. Once preliminary approval is given the ethics certificate must be obtained and a copy sighted by ACC before the data request is completed
- If ethics approval has already been obtained please include a copy with this form.

Please complete the following details and sign -

1. Title of study:

2. Date of application:

3. Contact details:

3.1. Name of Principal Investigator:

3.2. Address of Principal Investigator including email:

3.3. Name of Institution:

3.4. Name of sponsor within ACC:

4. Contract details

4.1. Is the data request being done in partial fulfilment of a contract with ACC or other research organisation. Yes/No

If so -

4.2. Name of ACC Division with whom contract is held:

4.3. Name of contract:

5. Outline of study for which the data is required (not more than two pages). Alternatively, Researchers may attach the outline as a separate document. The outline may include -

5.1. Background

5.2. Aims

5.3. Methods

5.4. Relevance of the study to ACC

6. Ethics requirements

6.1. Has ethics approval been sought at any time for this study whether successful or not? Yes/No

6.2. Are personal identifiers required in the dataset? Yes/No

6.3. If personal identifiers are required will the clients of ACC be contacted at any time and if so by whom? Yes/No

Please list below the names of those responsible for claimant contact.

6.4 Briefly identify any relevant ethical issues in the space below.

7. Details of data requested. List of data fields required-

8. Declaration by Principal Investigator:

8.1 The information supplied in this application is, to the best of my knowledge and belief, accurate.

8.2 I have considered the ethical issues involved in this research and believe that they have or will be adequately addressed.

8.3 If the protocol for this research changes in any way I will immediately have the research programme stopped and advise ACC, and if appropriate, the relevant Ethics Committee. The programme will not be recommenced until approvals are given in writing by ACC and/or the relevant Ethics Committee.

Name :

Signature of Principal Investigator:

Appendix C, Confidentiality Form

ACC CONFIDENTIALITY FORM

Research Ethics Committee

***THIS CONFIDENTIALITY AGREEMENT is made the _____ day of 2007
BETWEEN ACCIDENT COMPENSATION CORPORATION (“ACC”) AND
 (“the Provider”)***

BACKGROUND:

- (A) The Provider has agreed to carry out, on certain terms agreed between the parties, ----- (“the Services”). The parties have agreed that the Provider will have access to ACC data to assist in the provision of the Services.
- (B) The ACC data contains personal identifiers which may identify individuals (“ACC Data”). This information is confidential. In order to protect the value and confidentiality of the ACC Data the parties have agreed to enter into this Agreement.

ACC AND THE PROVIDER AGREE as follows:

1. The Provider and its employees and agents shall keep confidential all ACC Data (whether in oral, written, visual or electronic form) provided by, under or during the Services, or produced as a result of the Services (including any reports), unless:
 - a) Required by law to disclose that information; or
 - b) That information is publicly available; or
 - c) ACC and the Provider mutually agree to disclose that information.
2. Breach of this Agreement will entitle, but not require, ACC to terminate the agreement for the Services. Any breach of this Agreement will be taken into account by ACC in considering any further data requests or research proposals from the Provider.
3. The Provider and its employees and agents will comply with the Privacy Act 1993 (including the Health and Information Privacy Code 1994) in respect of the ACC Data and, without limiting the generality of this clause, agrees that no ACC Data will be published in a form where individuals are identified.
4. The Provider and its employees and agents will store the ACC Data in compliance with Information Privacy Principle 5 of the Privacy Act 1993, to ensure the physical and operational security of all personal information in the ACC Data held by the Provider.
5. The Provider will only allow the following persons to have access to the ACC Data:
 - employees of the Provider who are directly involved in the Services;

- persons who are not employees of the Provider (“Associated Providers”) but who meet the requirements in clause 8 and who are directly involved in the Services.
6. The Provider shall only use the ACC Data for the purpose of the Services described above.
 7. The Provider will either destroy the ACC Data or return the ACC Data to ACC within 3 months of completion of the final report based on the Services. The Provider will not retain copies of the ACC Data after this date.
 8. The Provider shall ensure that every Associated Provider who has access to the ACC Data will enter into an agreement in a form and substance acceptable to ACC to maintain the confidentiality of the ACC Data. Breach of any such confidentiality agreement by the Associated Provider shall be deemed to be a breach by the Provider.

SIGNED by _____)
)
 [***name of signatory***]) Signature
)
 on behalf of the)
ACCIDENT COMPENSATION)
CORPORATION)

SIGNED by _____)
)
 [***name of signatory***]) Signature
)
 on behalf of the)
)