

# Research Ethics Committee



PREVENTION. CARE. RECOVERY.

Te Kaporehanga Āwhina Hunga Whara

## Minutes of the ACC Research Ethics Committee, 3 March 2010

### Members Present



In attendance:



#### 1 Apologies

Apologies were received from [redacted] and [redacted].

#### 2. Confirmation of Minutes

Minutes of the meeting held on 2 December 2009 were confirmed as a correct record.

#### 3 Matters arising

##### 3.1 Goals and self-regulation skills in brain injury rehabilitation: an RCT, [redacted] [redacted], Auckland University. # 151

Expansion of the recruitment process for this study was granted by the Regional Ethics committee for the use of a recruitment pamphlet and poster to be distributed to ACC Branch Managers in the Auckland and Hamilton offices.

This amendment to the protocol was approved by the Chair on 15 December.

##### 3.2 The mechanisms and types of non-motor vehicle injuries to pedestrians in the transport system and indicated infrastructural implications, [redacted], Opus International Consultants. #147

The Ethic Data Monitoring form was viewed at the last meeting by the committee. It was noted that there had been a complaint about one of the interviewers. The committee requested further information regarding the nature and management of the complaint.

There were two issues:

- (1) A GP who was contacted by [redacted]'s team had not received a letter from ACC asking for permission to pass her details to the researchers. Her main concern was that the same could happen to patients. The action taken was that researchers modified their approach by checking that people had received a letter from ACC before proceeding.
- (2) Another complaint was received from the mother of a 14 year old boy whose details had been passed to Opus without her consent. It turned out that the father (the parents were separated) had already given consent and the matter was resolved.

##### 3.3 A Study into why ACC clients have not completed their dental implants with crowns, [redacted], ACC. # 174

This study was approved at the last meeting subject to changes to the letter to potential participants. The amended letter was viewed by the Chair and approved.

3.4 Unintentional or Accidental Strangulation or Hanging, [REDACTED]  
[REDACTED], Auckland DHB. #175

[REDACTED] The committee also noted that a number of other causes of strangulation, for example, cot bars or being caught up in a buggy were not represented in the ACC data. After discussion with the researchers a revised search strategy was identified and this produced over 150 results. Given the increased number of cases and reassurance about how the data will be used and approval from the Chair the report was released to the researchers.

3.5 Adult outcomes of TBI, [REDACTED], University of Canterbury. # 171

At the December meeting the committee noted that some potential participants may not have had contact with ACC for some time or may not know that they had a head injury as a child. Therefore any letter from ACC to potential participants would need to clearly explain the research. The committee wanted to see the draft letter to potential participants and approval from the Regional Ethics Committee. The Upper South Ethics Committee has provisionally approved the proposal with the ACC letter being sent out with the information sheet attached. The Committee noted that ACC has an obligation to its clients to protect them from being over researched and therefore those clients with a serious injury may only be approached and asked to participate in research once during a year. Consequently the data received from ACC will have TBI clients already withheld for ACC research purposes and therefore the data received by the researcher will be a subset of the total pool of TBI clients

The information sheet was approved subject to:

- The sheet should start by informing clients why they have been approached and that they may have had a head injury previously.
- The information sheet should inform clients that their ACC entitlements will not be affected by participation in the study.
- The researchers should consult with Research Services regarding the available pool of ACC TBI clients and how this may effect the study.

#### 4 Conflict of interest declarations

None.

#### 5 Approval of research and data requests – for approval

5.1 Assessment of pituitary function in children who sustained traumatic brain injury (TBI) in infancy [REDACTED], University of Auckland. #177

The Committee considered this to be a worthwhile project, but raised the following issues:

- Is there a treatment available for this condition? Outcomes of the research need to address expectations
- The second letter needs to be in lay person's language.
- The Committee would also like to see the initial letter that was sent out.
- The 'opt in' letter needs to contain a contact point for researchers.
- There is a need to look at the \$20 for costs. This may not be sufficient for people out of town.
- Amend the Information Sheet under the heading 'What are the potential benefits and risks?' last paragraph to read ".....appropriate treatment which will improve their health *at the Starship*" to avoid any confusion.

- Information on application of the numbing cream on the appointment letter is inconsistent with that on the information sheet for the child as to who applies it.

**5.2 Anatomical based errors in clinical practice, [REDACTED], University of Otago. #178**

The committee considered that access to all the information held in the treatment injury database was too wide a field of personal information without obtaining individual consent from claimants. The provision of ACC data is restricted to information required for the research purpose only.

The Committee fully supported the utility of the research and supported an alternative way forward. The definition of anatomical error may need to be more closely defined to help narrow down the data required. Would summarisation of the files be appropriate?

The Committee recommended that [REDACTED] work further with [REDACTED], Team Manager, and [REDACTED], Clinical Analyst, Treatment Injury Centre, to refine the data search and resubmit a further application to the committee.

**5.3 Brain Injury outcomes New Zealand In the Community (BIONIC), [REDACTED] University of Auckland. #179**

The committee discussed issues regarding ACC's obligation to its clients to protect them from being over researched and therefore those clients with a serious injury may only be approached to participate in research once during a year. As a consequence, the data received from ACC will have TBI clients already withheld for ACC research purposes and therefore the data received will be a subset of the total pool of TBI clients.

The number of READ codes suggested to identify potentially eligible cases of TBI for the study was extensive and will result in an extremely large number of cases being identified.

It recommended that the researchers liaise with Research Services regarding these two matters and then report back to the committee on the implications to their research, before final approval can be given.

**5.4 School of Dentistry Research Project, [REDACTED], University of Otago. #180**

This proposal uses the same data that has been used in the past. There is no individual consent required. [REDACTED] is to be thanked for his paper published in respect to previous work.  
Proposal approved.

**5.5 Research into the Maori experience of ACC, Researcher to be confirmed, Department of Labour. #181**

[REDACTED] attended the meeting and apologised for the incomplete documentation. The committee considered that it would be useful for the research proposal to include a literature review and review of previous research to inform the methodology chosen.

While acknowledging the need for the stocktake to be independent of ACC, the committee suggested that data already held by ACC could be utilised and if these data

sources were sufficient further research would not be required. It was suggested that further discussion with [REDACTED] Research Manager, would be useful to identify available data.

If appropriate data was unavailable the committee would require a resubmission providing further information regarding the investigator, information sheets, information about the recruitment process, community consultation and engagement plans.

The Committee acknowledged the tight timescale for the project and expressed agreement in doing its utmost to assist in a timely manner to view any further submission.

**6 Other Business**

**6.1 Review of the ACC Research Ethics Committee update**

The review of SP&R included looking at the function of various committees to see that they align with the strategic directions of ACC. A review team consisting of [REDACTED] [REDACTED], and two senior evaluators, was asked by [REDACTED] to look at how the Ethics Committee is operating, the process for applications, privacy, data and Research Group support and also its relationship to the R&D Committee. They are also looking at other organisations' structures against the ACC model. The Review Committee has now reached the point of doing qualitative interviews and [REDACTED] [REDACTED] enquired, on behalf of the Review Committee, how the Ethics Committee members would like to be interviewed. The majority of the Ethics Committee opted for face-to-face interviews and also requested that [REDACTED] send them out a copy of the current Terms of Reference.

**6.2 The Chair suggested that a letter of thanks should be sent to [REDACTED] for her work on behalf of the Committee.**

**Next meeting: Wednesday 7 April .**

# Research Ethics Committee



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## Minutes of the ACC Research Ethics Committee, 7 April 2010

### Members Present



In attendance: [REDACTED]

#### 1 Apologies

Apologies were received from [REDACTED] and [REDACTED].

#### 2. Confirmation of Minutes

Minutes of the meeting held on 3 March 2010 were confirmed as a correct record.



#### 3 Matters arising

##### 3.1 Adult outcomes of TBI [REDACTED], University of Canterbury # 171

[REDACTED] has acknowledged that the remaining small sub-set of the sample left after ACC has removed its own requirements, may not be enough for a true representative sample. The information sheet has been amended and the Committee gave final approval to the research proposal

##### 3.2 Assessment of Pituitary Function following Traumatic brain Injury in Early Childhood [REDACTED], Liggins Institute #177

The researchers have decided to use ADHB sources to try and contact potential study participants but have requested that their request remain open should they need to return to ACC.

##### 3.3 Traumatic Brain Injury Burden in New Zealand: a population based incidence and outcomes study (BIONIC) [REDACTED], AUT. #179

[REDACTED] originally requested an extensive number of read codes which would have resulted in ACC having to send out 12,000 letters. However, after discussions with [REDACTED], he expressed an intention of re-submitting a request for a smaller number. ACC is awaiting her formal reply.

##### 3.4 Letter of thanks was sent to [REDACTED].

#### 4 Conflict of interest declarations

[REDACTED] declared a conflict of interest regarding the Treatment Injury Market research application.

#### 5 Approval of research and data requests – for approval

##### 5.1 Supported Activities Service Evaluation [REDACTED] st, PS Services. #183

[REDACTED] joined the meeting.

This is a qualitative study and is part of a larger evaluation programme and information collected will be used in conjunction with that collected by other people.

- The Committee expressed concern over whether twelve case studies would be enough to evaluate the service. However the case studies also include, as well as the client, providers, family, carers, providers and other involved organisations which should increase the number of interviews to 50-60 people which should be enough to draw out common themes. The Committee also expressed concern that with the limited number of case studies, care would have to be taken to ensure that participants were not able to be identified and also that Maori and Pacific island people are included in the study. The regions chosen do contain a high proportion of Maori and Pacific island people.
- Timeline is very tight.
- It was suggested that the language used in the information sheet should be simplified because it is being sent to clients with moderate to severe brain injuries and these people may have difficulties with the language. The modified information sheet should be sent to the Chair for approval.
- Extreme care should be exercised when disseminating the outcome reports to protect the privacy of the participants as the sample is so small. Released reports should be at executive summary level or top line reports, not case study level. Participants should be provided with feedback or an executive summary of the findings of the evaluation.

The proposal was approved subject to these matters being addressed and the information sheet being viewed by the Chair.

5.2 **Feasibility of a national study of workers' exposures to health and safety risks** [REDACTED], IPRU, University of Otago. #184

The Committee noted that consent was initially obtained from participants up to 2005, with no time constraint placed on the duration of the consent. It is unclear what the clients' understanding was at that time. However, because the study intends to use the data for the same purposes as it was collected, the consent obtained at that time is still valid.

Also, given that they are still using the same data obtained when the original consent was given, and that there was an undertaking given at that time to destroy the data after 5 years, the Committee would still expect this undertaking to be honoured which now imposes a considerable time limitation.

The Committee noted that the Multi-region Ethics Committee approval was given in October 2009 for the project to start in October and would therefore have expected to see an application to the ACC Research Ethics Committee sooner.

The Committee approved the research proposal.

5.3 **Treatment Injury Service Delivery Monitoring** [REDACTED], Research New Zealand. #182

This is part of the Customer Satisfaction suite of surveys that ACC has undertaken over a number of years. This application seeks approval for this survey to be done every year for the next three years. The survey is needed to meet KPI measures. The committee approved the proposal and suggested that the FAQ Sheet needs to include information on the purpose of the survey and also should note, for the client's benefit, that ACC will not know that the client has participated in the survey.

5.4 **Re-submission – Anatomical based errors in clinical practice** [REDACTED] [REDACTED], University of Otago. #178

The method of data collection has now been modified to provide a de-identified dataset for initial analysis and then ACC will provide the relevant claim records (e.g. operation notes, relevant clinic letters, etc) for those claims specifically requested. The committee approved the revised application.

**6 Other Business**

- 6.1** Review of the ACC Research Ethics Committee update by [REDACTED]. The Committee was thanked for participating in the interviews which are now coming to an end. Other government departments have also been consulted (Justice, Police etc) as well as people external to ACC. Focus groups are now being held with staff. Currently there is a strong consensus of opinion around the value that the Ethics Committee provides in terms of risk management. The results of the consultation will be discussed with the CEO in approximately three weeks time and then a paper will be prepared for ELT with a recommendation scheduled for the end of May.

**Next meeting:** Wednesday 5 May 2010.

# Research Ethics Committee



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## Minutes of the ACC Research Ethics Committee, 5 May 2010

### Members Present



In attendance:



### 1 Apologies

Apologies were received from and

### 2. Confirmation of Minutes

Minutes of the meeting held on 7 April 2010 were confirmed with two minor amendments.

### 3 Matters arising

#### 3.1 Adult outcomes of TBI, , University of Canterbury # 171

The information sheet was approved by the Chair.

#### 3.2 Brain Injury outcomes New Zealand In the Community (BIONIC), University of Auckland. #179

The researchers are still working alongside ACC Senior Research Advisors, on prioritising and refining the number of codes to be requested.

### 4 Conflict of interest declarations

is the sponsor for the application from for advice and approval to develop comprehensive business rules and protocols for the regular on-going ACC-MOH data linkage for research and service design purposes.

### 5 Approval of research and data requests

#### 5.1 Advice and approval to develop comprehensive business rules and protocols for the regular ongoing ACC – MOH data linkage for Research and Service Design purposes, , ACC, #185

attended the meeting. The Ethics Committee raised the following issues for clarification and further development:

- The need for a clear diagrammatic explanation of the process whereby Acc client information moves from being identifiable data to being non-identifiable



information through the data linkage process. The diagram should included delineation of responsibility at each stage of the process.

- The proposal needs to be set within a legal framework to include the ACC Act, section 289 and the Privacy Act to provide a mandate for the data linkage and explain how the administrative data could be utilised. Examples would be helpful. Both ACC and MOH collect information for a purpose but the joint purpose needs to be clarified. [REDACTED] to supply a set of protocol examples on how the data will be used.
- There is a need for further clarification of the dichotomy between privacy, which is legally governed, as opposed to confidentiality, which is a relationship based concept. The meaning of confidentiality in statistical terms could be further explained.
- It was unclear what consent clients currently give for the use of their health information on the ACC 45 form and a need to be certain that information is used in accordance with the purpose for which it was collected and that the individual's data is protected.
- It was suggested that the development of the business rules be a separate step after the establishment of principles and protocols.
- It was noted that there may be concerns raised by the Consumer Outlook Group (COG) around who will have access to the database, and it was suggested that this proposal should also be presented to COG for comment.
- Early involvement of the Office of the Privacy Commission was recommended.

## 5.2 Integrated Rehabilitation service – Traumatic Brain Injury (IRS-TBI) Service Trial Evaluation: Client Experiences, [REDACTED], UMR Research Limited, #186

The meeting was attended by [REDACTED] (UMR) and [REDACTED] (ACC Research Services).

It was explained to the Committee that the proposal was part of a suite of research being done by ACC and the proposal was the only part that involving direct contact with the clients.

The Committee noted a lack of consistency in some of the documentation, for example, some documents mentioned that the client's employer may be contacted but in others this information was absent. The use of the phrase, "From this list of clients you have been identified as a potential participant in the study", appeared impersonal and it was suggested this could be rephrased in a softer manner. The Committee wanted the information sheets to state that withdrawal from the research at any stage would result in any information that had been collected being destroyed immediately.

The proposal was approved by the Committee.

## 6 Other Business

### 6.1 Review of the ACC Research Ethics Committee update by [REDACTED] and [REDACTED].

The Committee was thanked for participating in the interviews.

The next steps after completion of the analysis would be discussion with [REDACTED], General Manager of Policy & Governance, and [REDACTED], Chief Executive Officer. A paper will go to ELT by 27 May 2010.

**Next meeting:** Wednesday 2 June 2010.

# Research Ethics Committee



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## Minutes of the ACC Research Ethics Committee, 7 July 2010

### Members Present



In attendance: 

#### 1 Apologies

Apologies were received from 

#### 2. Confirmation of Minutes

Minutes of the meeting held on 5 May 2010 were confirmed.

#### 3 Matters arising

##### 3.1 Brain Injury outcomes New Zealand In the Community (BIONIC), , University of Auckland. #179

The researchers have now reduced the number of read codes to be used which will lessen the impact on ACC, but will still yield approx 6,000 clients for the research.

Fiona was requested to circulate the letter sent to the client to the committee for information.

#### 4 Conflict of interest declarations

None.

#### 5 Approval of research and data requests

##### 5.1 Integrated Rehabilitation service – Traumatic Brain Injury (IRS-TBI) Service Trial Evaluation: Client Experiences, , UMR Research Limited, #186 – Amendment to research protocol

Approval was sought for a modification to the proposal approved by the Committee at the June meeting.

In order to be able to interpret the research findings in a meaningful way, it was felt necessary to expand the sample group to better understand the experience of clients receiving rehabilitation under the *Active Rehabilitation* service. It is proposed to interview 16 *Active Rehabilitation* clients, taking the total sample for the client experience part of this evaluation from 18 to 34. The goal is not to directly compare the two services, but rather to have a clearer understanding of the client experience in each service.

The Committee agreed that the information sheet and consent forms should be amended to inform the business-as-usual clients in Canterbury/Otago that the research was part of a wider study being undertaken in Auckland.

Approved on condition that the amended information sheet and letters be forwarded to the Chairs for approval.

5.2 **Anatomical-based errors in clinical practice, [REDACTED], University of Otago, #178 – Amendment to research protocol**

[REDACTED], Clinical Analyst, Treatment Injury, attended the meeting.

Approval was sought to extend the research to include data for a period of six months, that is, the last six months of 2009. The focus of the project is now specifically on iatrogenic nerve injury. 113 nerve injuries were noted in the first six months of data and it is expected that an additional six months data will add greater statistical power to the research. [REDACTED] is aiming to publish the results in international medical journals.

Approved.

6 **Other Business**

6.1 **Monitoring Forms**

Only 50% of the monitoring forms that were sent out have been returned. [REDACTED] to send out reminder emails, with a copy to the researcher's institutional office, reminding them that monitoring was a condition of the original approval being granted.

The monitoring form received from [REDACTED] included a request for an extension in time for final data analysis. The Committee requested that [REDACTED] submit a formal request for this extension to include clarification its intended use its utility to ACC.

6.1 **Review of the ACC Research Ethics Committee**

[REDACTED] gave an account of ELT's reaction to the review findings as circulated to the Committee. The ELT response to the report acknowledged the importance of an independent Chair and external membership in mitigating organisational risk and that the external committee members played an important role for ACC. The ELT resolved the following:

- (a) **Agree** that the Research Ethics Committee be a standing committee of the Leadership Group with a reporting line via the General Manager Governance Policy and Research.
- (b) **Agree** the number of external appointees may be reduced to 2-3
- (c) **Agree** that the chair of the committee will be an external appointee
- (d) **Agree** that an external member will represent the requirements of Maori
- (e) **Note** that the terms of reference and supporting processes will be amended to ensure flexibility and streamline the committees operations.

The Committee discussed the findings and recommendations from the review.

The next meeting for August 2010 was planned to be conducted with the Committee as it currently exists.

**Next meeting:** Wednesday 4 August 2010.

# Research Ethics Committee



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## Minutes of the ACC Research Ethics Committee, 4 August 2010

### Members Present



In attendance: 

### 1 Apologies

Apologies were received from 

### 2. Confirmation of Minutes

Minutes of the meeting held on 7 July 2010 were confirmed.

### 3 Matters arising

#### 3.1 Brain Injury outcomes New Zealand In the Community (BIONIC), , University of Auckland. #179


The letter was received and viewed by the committee

### 4 Conflict of interest declarations

None.

### 5 Approval of research and data requests

#### 5.1 Exploring relationships between self-reported Physical Activity Level, fatigue and Return to work following Mild Traumatic Brain Injury, , University of Auckland, #172 – amendment to methodology

The Committee appreciated the researcher coming back to the committee for advice about a proposed change and for taking the issue seriously. This also reflected good supervision by 

Approved.

#### 5.2 Factors affecting artificial eye wear , University of Auckland, #188

An enquiry to the ACC data warehouse confirmed that there is no definitive way of coding a loss of an eye. Although there were a few READ codes that came close, the best method of identifying loss of an eye was to use those claims that have had a payment of a prosthetic eye, of which there were 346 claims. They could also be identified from the accident description but this would be a time consuming process. In going back to 1974 there was a risk of attempting to contact a deceased person

The Committee queried whether the nine national prosthetic eye centres might be a better source of research subjects.

It was decided that in respect of deceased persons, they should be removed from the data as far as possible on the 346 claims.

Approved by the co-Chairs subject to the following to be viewed by them:

- The information sheet should make provision for those who may be vision impaired or have 2 artificial eyes
- Where people are invited to participate they should have the option of having a friend/support person present. Further information should be provided about the physical examination and if any discomfort is to be expected.
- "characteristics" on the first page of the information sheet should be changed to "demographics"
- The initial letter and information sheet to be sent from ACC should explain ACC's role in the identification of potential subjects.
- A standard statement regarding a person's right to complain under the Code of Health and Disability Consumers' Rights should be included should any harm occur. The intended physical testing of participants means this research is a clinical trial and as such requires approval by an accredited ethics committee.
- There should be a standard statement on the information sheet to inform potential participants that their coverage and entitlement of ACC will not be affected whether or not they choose to participate in the study

**5.3 Study of 750 clients who have attended rehabilitation clinics over the past 3 years with chronic low back pain, [REDACTED] TBI Health, #187**

The committee discussed the data matching of TBI Health with ACC data and expressed concern that the consent form

- did not actually extend to consenting to data matching of ACC and TBI health data
- stated that health information would be used "ONLY to the extent necessary for the services we provide". While this consent would cover treatment it did not cover research

It was unclear how the results would be disseminated to the public domain and the proposal did not guarantee publication. The results could be used solely for business promotion.

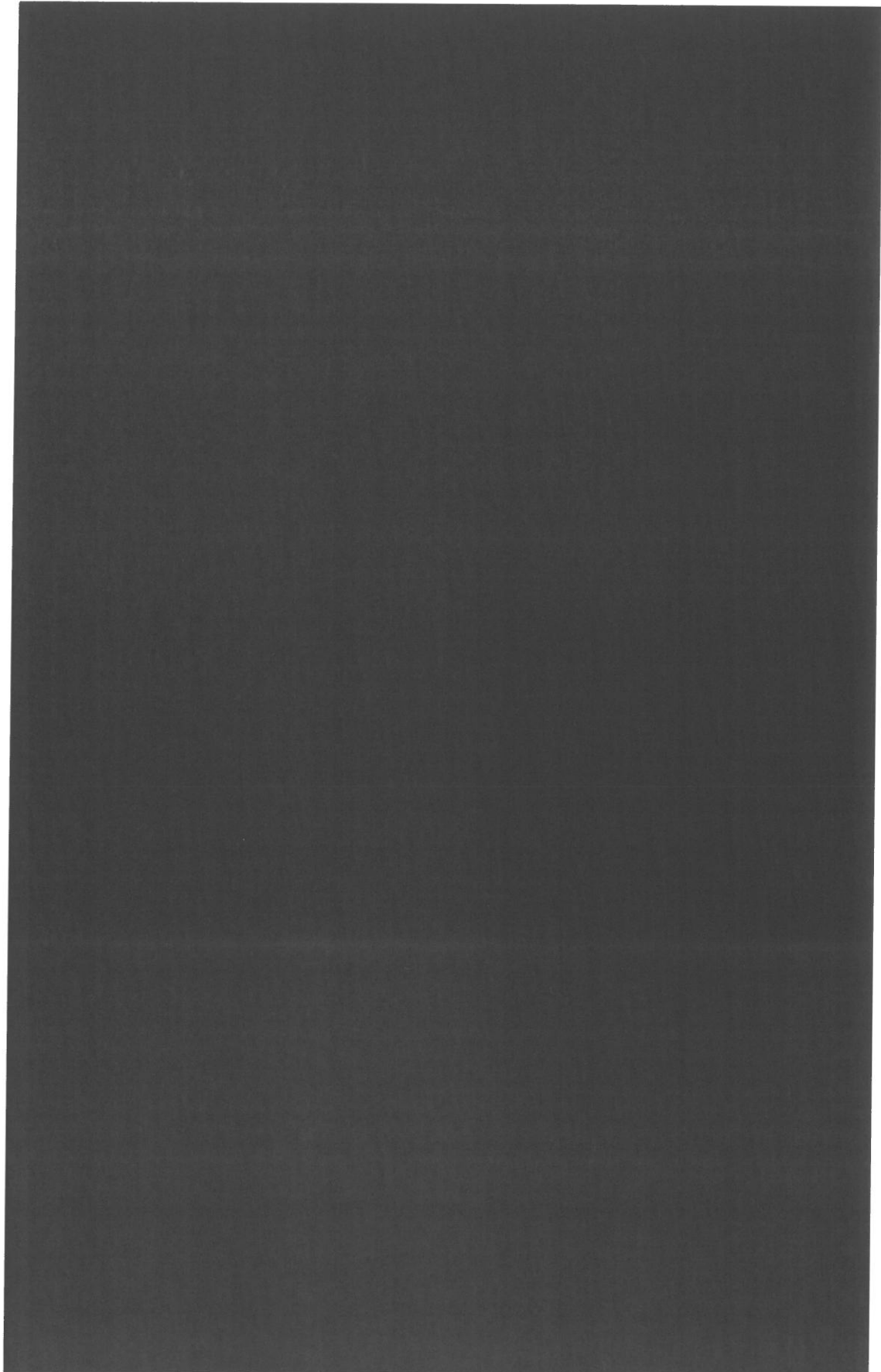
This application was declined but the researchers were invited to resubmit the application with the decision of the Central Division of the National Ethics Committee.

**5.4 Testing a new measure of workability, [REDACTED], University of Auckland, #154 – request for project extension**

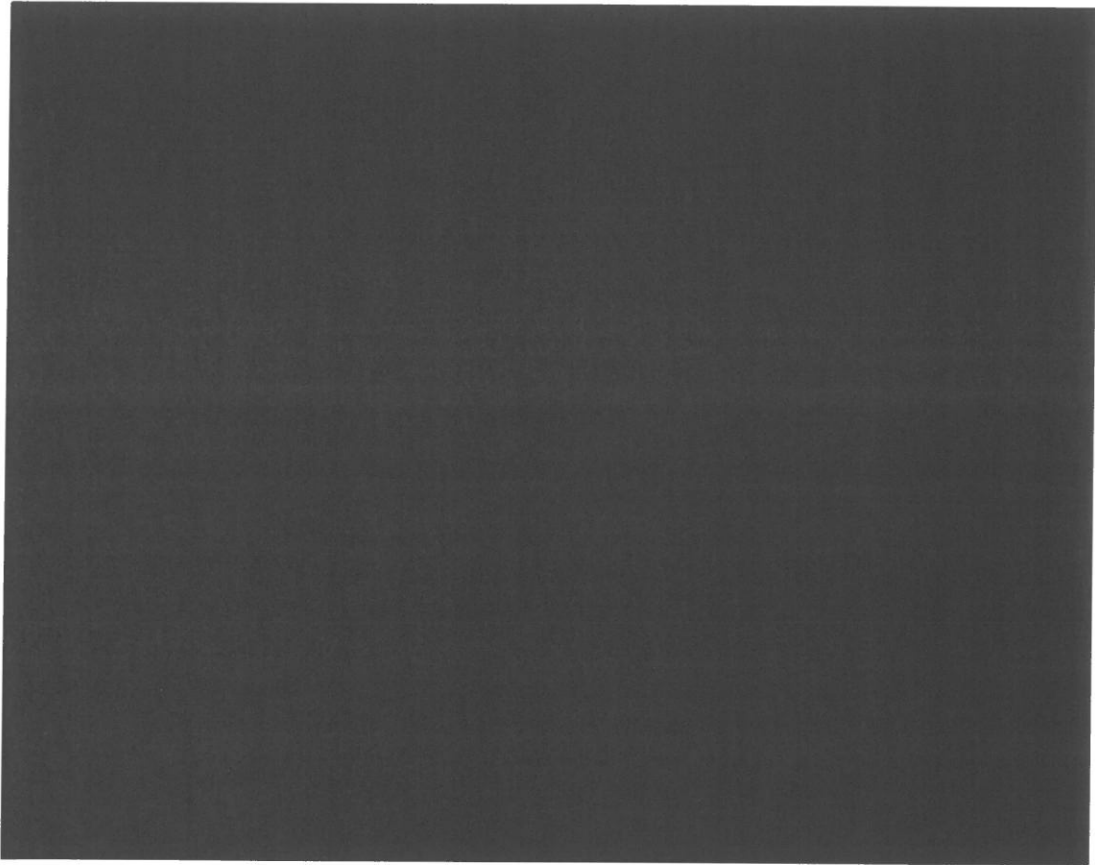
The Committee appreciated the full response from the research about the reasons for the request for the extension.

Approved.

5.5







**6 Other Business**

- 6.1 Review of the ACC Research Ethics Committee update

**Next meeting:** Wednesday 1 September 2010.

# Research Ethics Committee



PREVENTION. CARE. RECOVERY.

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## Minutes of the ACC Research Ethics Committee, 1 September 2010

### Members Present



In attendance:



#### 1 Apologies

Apologies were received from

#### 2. Confirmation of Minutes

Minutes of the meeting held on 4 August were amended and confirmed.

### 3. Matters arising

#### 3.1 Factors affecting artificial eye wear, , University of Auckland, #188

It was confirmed that the Health and Disabilities Multi Regional Ethics Committee had approved this project but a copy of the approval has not been viewed by the Committee. Therefore it was not clear whether the Health and Disability Ethics Committee had considered the research to be a clinical trial. If it was deemed a clinical trial with the possibility of physical harm, the information sheet would need to have an appropriate statement regarding cover from ACC in the event of injury.

The Committee required changes to the information form to change the statement about the Health and Disability consumer's rights to state that participants had a right to complain under the Code. Under 'Complications the Committee required "incidental findings" to be changed to "such findings". The information sheet and letter should include a statement about the ACC Research Ethics Committee and Health and Disabilities Multi Regional ethics Committee approval for the research

#### 4 Conflict of interest declarations

declared his involvement in 5.3 Advice and approval to develop comprehensive business rules and protocols for the regular ongoing ACC-MOH data linkage for research and service design purposes.

#### 5 Approval of research and data requests

##### 5.1 Home Injury Prevention Intervention Study , Health Research Council, University of Otago. #190

The Committee noted the importance of the research about home injuries. However they also noted the confusing nature of the application and requested further clarification on the following:

1. The present research study needs to be linked to the previous research to explain the context further and provision of the outcomes from the research thus far would be helpful.
2. The Committee noted that an application had been sent to the Central Ethics Committee and that the Committee had requested changes to the protocol. The Committee noted the researcher response to the Central Committee dated 17 June 2009 but wanted to view what the Central Committee had said and how the researchers had altered their protocol in response to that Committee's decision. The ACC Committee requested to see a copy of all the correspondence between the researchers and the Central Ethics Committee.
3. The Committee noted that given the identifiable nature of the data there would need to be informed consent for the release of this information and requested further information around the process and documentation for this.
4. The Committee requested that information sheets, consent forms and letters to be used in the research be provided to the Committee.

It was suggested that these matters be clarified and the researcher invited to attend at the next Committee meeting to address these matters.

**5.2 Brain Injury outcomes New Zealand In the Community (BIONIC), [REDACTED], University of Auckland. #179**

[REDACTED], Senior Research Advisor attended the meeting. Thus far 949 out of the planned 5,888 letters had been sent out to potential participants of the study. Twelve complaints to the researchers had been received from the parents or guardians of children, concerned that ACC had asked the researchers to investigate them as possible perpetrators of child abuse. The complainants had refused to participate in the research.

The Committee appreciated that this matter was brought before them and requested that a memo be sent to the Committee addressing the following:

- The background to the research and the complaints
- The potential harm to parents or children from the letter
- The reasoning for not contacting the 949 potential participants further
- The changes to the letter to address the complaint and how the letter will be trialed.
- If the research uncovers child abuse how will the researchers deal with this – a clear process needs to be put in place.

The memo is to be sent to all members of the Committee for comment before the next scheduled meeting.

**5.3 Advice and approval to develop comprehensive business rules and protocols for the regular ongoing ACC-MOH data linkage for research and service design purposes [REDACTED], ACC, #185**

[REDACTED] attended the meeting to provide an update of the research proposal progress and in response to the Committee's recommendations provided in June.

The Committee discussed the adequacy of the ACC 45 and ACC 167 consent forms currently used by ACC when individual data is used for this type of research. The Privacy Impact Assessment Report is planned to address this matter.

It was noted by the Committee that it is useful to have examples to assist in illustrating concepts particularly in understanding the identification and anonymising of data throughout the linkage process. This will be provided in the Privacy Impact Assessment Report and [REDACTED] intends to keep the Ethics Committee informed of progress with this project.

**6 Other Business**

**6.1 ACC Research Ethics Committee Terms of Reference**

In light of the conversation regarding the management of complaints about research, it was agreed that this issue should be addressed in the Terms of Reference. [REDACTED] agreed to make some amendments to the TOR and distribute these to the Committee prior to the next meeting.

**6.2 Acknowledgement of members leaving the Committee**

The Committee wished to acknowledge the valuable contributions of [REDACTED], [REDACTED] and [REDACTED] and agreed that a letter expressing appreciation and thanks from the Committee should be sent to them.

**6.3 Appointment of new member to the Committee**

[REDACTED] announced the appointment of [REDACTED], from the Ministry of Health, to the Committee as the representative for Maori interests

**Next meeting:** Wednesday 6 October 2010.

# Research Ethics Committee



Te Kaporeihana Awhina Hunga Whara

## Minutes of the ACC Research Ethics Committee, 6 October 2010

### Members Present

[REDACTED] [REDACTED]

In attendance: [REDACTED] and [REDACTED]

### 1 Apologies

Apologies were received from [REDACTED] and [REDACTED].

### 2. Confirmation of Minutes

Minutes of the meeting held on 1 September were amended and confirmed.

### 3. Matters arising

3.1 Brain Injury Outcomes New Zealand in the Community (BIONIC), [REDACTED] #179 – amendments to letters to potential participants following complaints. The researchers submitted a revised letter and plan to manage the issue. This was viewed by the committee and approved by the Co-Chair [REDACTED]. The researchers will provide a brief interim report after they have trialled the first revised 50 letters to parents. The decision was ratified by the Committee

3.2 Appointment of new member to the Committee – [REDACTED] from MOH will not now be joining the committee as representative for Maori interests and the position is yet to be filled. [REDACTED] suggested contacting [REDACTED] from Te Pūmanawa Hauora about a possible representative for the Committee.

### 4 Conflict of interest declarations

None declared.

### 5 Approval of research and data requests

5.1 Home Injury Prevention Intervention Study, [REDACTED], Health Research Council, University of Otago. #190

[REDACTED] attended the meeting.

The Committee raised two issues:

It was queried whether there would be interim analysis planned and what would happen if causation of injury from hazards in the home became obvious. It was queried as to whether there were any stopping mechanisms in place so that people in the control group would not continue to be exposed to risk for an indeterminate period. [REDACTED] confirmed that there would be interim analysis and the research would stop if such causation was verified by robust data.

The Committee queried whether any hazards identified in the homes of the control group would be pointed out to participants to avoid leaving them exposed to dangerous risks. [REDACTED] confirmed that assessment of the control group homes would follow a standardised procedure and any dangers discovered would be pointed out to the participants. However it was up to the participant to remediate any dangers.

It was noted that ACC is not funding this study.

The proposal was approved.

**5.2 Factors affecting artificial eye wear, [REDACTED], University of Auckland. #188**

The Committee noted that the Central Regional Ethics Committee had approved the research as a clinical trial and therefore participants injured as a result of treatment received in this trial will be eligible to be considered for compensation in respect of those injuries under the ACC scheme. The committee agreed that this should be stated on the information sheet.

Although the information sheet had been approved by the Central Regional Ethics Committee, the ACC Committee were surprised by this and noted the complex and technical language used which they considered inappropriate for lay people. It was suggested that the title and purpose of the study be up front and the names of the researchers only at the end of the sheet.

The study was approved.

**6 Other Business**

**6.1 ACC Research Ethics Committee Terms of Reference**

The Terms of Reference were discussed in light of the minor changes. The committee were happy with the Terms of Reference with the proviso that [REDACTED] (Co-Chair) have the opportunity to comment.

**6.2 The Committee meetings for next year, 2011, will continue to be held on the first Wednesday of the month. There will be no meeting in January**

**Next meeting: Wednesday 3 November 2010.**

# Research Ethics Committee



Te Kaporehanga Āwhina Hunga Whara

## Minutes of the ACC Research Ethics Committee, 3 November 2010

### Members Present



In attendance:  (Secretary)

#### 1 Apologies

No apologies were received.

#### 2. Confirmation of Minutes

Minutes of the meeting held on 6 October were confirmed.

#### 3. Matters arising

None

#### 4 Conflict of interest declarations

None declared.

#### 5 Approval of research and data requests

##### 5.1 A population based study of falls after stroke , University of Auckland. #191

It was noted that the information supplied on the information sheet did not match the research proposal in terms of declaring which ACC data will be accessed by the researchers. The research proposal states that information on gender and ethnicity will be accessed but this is not included on the information sheet and therefore any potential participant would not be fully informed about what they were consenting to.

The committee did not like the use of the word "burden" in relation to persons who had suffered a stroke and also agreed that the sentence, "any concerns regarding the nature of this project should be notified in the first....." should be simplified to, "if you have any concerns please contact.....".

The Committee noted that the study is based on the assumption that all costs from a fall will be recorded in ACC data. However some falls may not be reported to ACC and the cost of the injury may fall on the family who care for the individual rather than be attributed to ACC. Therefore the ACC data will potentially under estimate the prevalence and cost of falls.

The research proposal did not cover how the researchers would manage the issue of informed consent where a potential participant was significantly cognitively impaired and the Committee expected a protocol to be in place for this scenario.

The Committee also requested to see a copy of the approval from the Northern Regional Ethics Committee.

The proposal was approved subject to the above matters being addressed.

5.2 **Approval to undertake telephone survey to understand the purpose of a traffic journey resulting in an ACC motor vehicle traffic crash (MVTTC) injury claim, [REDACTED] ACC. #192**

The Committee noted that the purpose of the research was not openly explained in either the letter or the "Frequently asked questions" sheet for potential participants. It was suggested that, although complex to explain in full, a sentence or statement should be added to explain the purpose of the research which would be to assist ACC to allocate claims in terms of funding decisions.

The Committee felt that it was important that those conducting the telephone interviews should be prepared for informed questions from the public about ACC accounts and apportioning of claims and be able to answer any queries correctly and appropriately.

It was also suggested that the term road traffic "crashes" be replaced by road traffic "accidents" to sound less dramatic.

The study was approved subject to the above matters being addressed.

5.3 **Proposed pilot of a pain screening questionnaire and decision tool – Committee advice**

Information on this proposed pilot was circulated to the committee prior to the meeting and in view of the committee's email comments was placed on the agenda for consideration by the Committee. It was explained that this pilot is in the early stages of design and the Committee's guidance was being sought at an early stage.

The Committee are expecting a paper with firmer ideas about the proposal and addressing the ethical issues. However it was advised that pre-testing of the questionnaires and decision tool would be advisable and that the results of this should be presented to the Committee

**6 Other Business**

6.1 ACC Research Ethics Committee Terms of Reference

The Terms of Reference were discussed in light of [REDACTED]'s additional comments [REDACTED] will amend the TOR and once agreed by the Committee, these will be signed off by [REDACTED], General Manager, Governance, Policy and Research.

6.2 Membership of the Ethics Committee

Grant suggested that Maori interest in research could be represented by [REDACTED], Chief Advisor, Maori and that another external member be considered to increase the membership of the Committee and in order to ensure a quorum at meetings.

**Next meeting:** Wednesday 1 December 2010.



# Research Ethics Committee



## Minutes of the ACC Research Ethics Committee 1 December 2010

### Members Present

[REDACTED]

[REDACTED]

In attendance: [REDACTED]

### 1 Apologies

[REDACTED]

### 2. Confirmation of Minutes

Minutes of the meeting held on 3 November 2010 were confirmed.

### 3. Matters arising

3.1 [REDACTED] reported that one of the respondents contacted for "Factors affecting Artificial Eyewear", a study by [REDACTED], had phoned to complain about [REDACTED] and also had been contacted for an ACC satisfaction survey. The list of the sample of clients supplied to [REDACTED] will be forwarded to [REDACTED] to check that all those included on the list are flagged so that they cannot be contacted for other research purposes.

3.2 The finalised Terms of Reference for the ACC Research Ethics Committee were distributed to members.

3.3 [REDACTED] announced that [REDACTED], Chief Advisor, Maori, ACC, will act in the role of representing the interests of Maori for the Committee in the New Year. Also in the New Year ACC will begin the formal process of selecting an additional external member

### 4 Conflict of interest declarations

[REDACTED] declared his involvement in the proposal to be considered at the meeting.

### 5 Approval of research and data requests

#### 5.1 ACC Branch Pain Screening Tool Pilot. #193

[REDACTED], Programme Manager and [REDACTED], Rehabilitation Practice Advisor, attended the meeting.

With regard to the questionnaires being administered by non-clinical case managers, it was emphasised that the questionnaire is one factor that will be used to assess clients for potential pain intervention. They will also be using flags, the information held on a client's file, GP information and interaction with the client and family to

inform decisions. The case managers will also be utilising the advice and assistance of Branch Medical Advisors and Branch Advisors, Psychology to make decisions.

The Committee suggested that the demographics of clients who complete the questionnaire be collected so as to understand the representativeness of the sample and for which groups the questionnaire may be unacceptable.

It was clarified that where a client declines to take part in the pilot, and the usual case management in that Branch is for a questionnaire to be used, the client will be assured that their questionnaire will not be used in the pilot.

The Committee requested that the information sheet be amended to include contact details for [REDACTED] should clients want more information about the pilot and that information be added to explain that the questionnaires are commonly used in New Zealand and validated in Australia. It was also requested that the information sheet state that the pilot has ACC Research Ethics Committee approval.

The proposal was approved subject to the above matters being addressed.

**6 Other Business**

No other business.

**Next meeting:** Wednesday 2 February 2011.