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# Health research council of new zealand

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| **REPORT FROM AN ETHICS COMMITTEE SEEKING RE-APPROVAL** |

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| **The HRC Ethics Committee (HRCEC) is established under the Health Research Council Act (1990) as a committee of the Health Research Council. Section 25 covers the Committee’s functions. Set out below are the functions relevant to the approval of ethics committees:*** **To ensure that, in respect of each application submitted to the Council for a grant for the purposes of health research, an independent ethical assessment of the proposed research is made either by the Ethics Committee itself or by a committee approved by the Ethics Committee (section 25(1)(c)).**
* **To give, in relation to ethics committees established by other bodies, advice on –**
1. **the membership of those committees; and**
2. **the procedures to be adopted and the standards to be observed, by those committees (section 25(1)(f)).**

**Approved ethics committees are able to undertake independent assessment on behalf of the HRCEC.****\*\*\*\*\*\*\*\*\*\*****Health and Disability Ethics Committees (HDECs)** are established as Ministerial committees under section 11 of the New Zealand Public Health and Disability Act 2000. The function of an HDEC is to secure the benefits of health and disability research by checking that it meets or exceeds established ethical standards. The HDECs act in accordance with procedural rules contained in *The* *Standard Operating Procedures for Health and Disability Ethics Committees (the SOPs*).**Institutional Ethics Committees (IECs)** are established by organisations, such as universities or private companies and review research applications directly related to the organisation or their agent. Often the research that they review is not health related and they have policies and procedures that reflect the nature of the research that they review. |

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| **NOTE:** **In compiling the report, ethics committees should take care to not provide information which would involve a breach of the Privacy Act 1993 and/or the Health Information Privacy Code 1994.**  |

# SUBMISSION

Please complete the form electronically and send to the Secretary of the HRCEC by e-mail.

Relevant declaration page with signatures may also be submitted electronically via email.

Email: ***llon@hrc.govt.nz***

# INQUIRIES

If you have any queries, please contact the Secretary of the HRCEC at the above e-mail address or by telephone on (09) 303 5221.

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| **PART A:****GENERAL INFORMATION**  |

## 1. Name of Ethics Committee (EC)

**Pre-populated by HRC**

## Dates of current HRC EC approval

**Pre-populated by HRC**

## 3. Mailing address

**All EC Chairperson and Administrator correspondence will be sent to this address**.

**(Provide address exactly as it should appear on a mailing label.)**

      Address line 1

      Address line 2

      Address line 3

      Address line 4

Suburb/City Postcode

**Website**

 **(Specific URL for EC information.)**

## 4. Administrator

Name

 Title First Name Last Name

Phone (  )

E-mail

## 5. Chairperson

**(All correspondence to the chairperson will be sent to the “EC Mailing Address” as indicated in question 3.)**

Name

 Title First Name Last Name

Phone (  )

E-mail

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| **PART B:****RE-APPROVAL SUMMARY REPORT** |

## 1. CHAIRPERSON’S REPORT

**1.1 Please provide a summary of the performance of the committee over the last 3 years. The main issues faced by the committee and any important trends in the overall functioning of the committee should be depicted here. This is also an opportunity to highlight the achievements of the committee within this time.**

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**2. POLICIES AND PROCEDURES**

(Please reference the specific section and/or page number in your attached materials.)

## 2.1 Provide a brief comment on the changes, if any, in the policies and procedures of the EC over the last 3 years and how these changes have positively or negatively affected the EC in terms of its stability and functioning.

## 2.2 Describe the function of the EC.

**2.3 What are the Committee’s Terms of Reference?**

**2.4 Outline the decision making process.**

 **(For example: consensus, majority vote.)**

**2.5 Provide a description of how the EC has ensured that appropriate peer review for scientific validity has been carried out.**

**2.6 Describe the normal procedure for review.**

**2.7 Describe any variations to normal procedure for review, including the types of research protocols that can be reviewed under these variations.**

 **(For example: review under departmental level, by delegated or subcommittee; expedited review; low risk review.)**

**2.8 Describe the complaints procedure.**

 **(This includes complaint against decisions, research processes, researchers and administration.)**

**2.9 Outline any other specific policies and guidelines.**

## 3. COMPOSITION OF COMMITTEE

**3.1 Identify any gaps within membership expertise over the last 3 years and explain what initiatives have been implemented to address these issues.**

## MEMBERSHIP

## 4.1 Provide a brief comment on the annual turnover of membership over the last 3 years and how it has positively or negatively affected the EC.

## TRAINING FOR COMMITTEE

* 1. **Outline the strategies that had been used in inducting new members and developing the expertise of committee members over the last 3 years.**

# Reporting mechanism(s)

**6.1 Describe the reporting mechanism(s) that has been established between the EC and the organisation responsible for it.**

[ ]  Minutes of EC meetings are provided to management level of organisation(s), e.g. to DVC or Board.

[ ]  Regular reports are provided by EC to management level of organisation(s), e.g. to DVC or Board, at least annually.

[ ]  Other mechanism(s). **(Provide details below.)**

 [ ]  If no reporting mechanism has been established, provide reasons below.

# application review process

**7.1 Outline the EC’s application review process. This includes the method of submitting and reviewing application.**

**(If appropriate, a flow chart diagram can also be included with your description.)**

**7.2 Provide a comment on the effectiveness of the application review process over the last 3 years. Outline the initiatives that had been implemented, or planned, to enhance the process.**

**7.3 Describe the issues, if any, the EC had with reaching quorum over the last 3 years and explain what have been done to address these issues.**

**7.4 Indicate the process used by the EC to ascertain feedback from stakeholders.**

**7.5 Describe the process for researchers whose application for ethical review is deferred or approved subject to conditions (or equivalent).**

# 8. chairperson’s delegation

**8.1 Describe when the Chair is delegated work on behalf of the committee.**

**(Please provide a concise summary of this policy and specify if any parts of this process are routinely electronic or by email.)**

**9. RESPONSE TO CULTURAL ISSUES**

**9.1** **Provide a brief profile of the EC policy in ensuring Treaty and Māori responsiveness.**

**(Please highlight how the EC implements the relationship in terms of formal input, shared decision making, recruitment of members and support mechanisms to ensure all committee members share the responsibility of working towards giving value to the principle provisions of the Treaty of Waitangi.)**

## 9.2 Describe how the EC has ensured that researchers have sought appropriate Māori consultation.

## 9.3 Describe the arrangements that are made for review of proposals involving ethnic communities.

**(For example: Pacific peoples or Asian.)**

[ ]  Referring relevant research proposals to an appropriate cultural group for consultation.

[ ]  Establishing a sub-committee or advisory group for culturally specific research proposal(s).

[ ]  Expanding membership of committees to include an appropriate number of members from participating ethnic groups.

[ ]  Other: **(Provide details below.)**

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| **PART C:****ANNUAL REPORT FOR (Reporting period: This will be pre-populated by HRC)** |

## 1. COMPOSITION OF COMMITTEE

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| **NOTE:** 1. Abbreviations:

L = lay person NL = non-lay person 1. A “lay person” is a person who:

has no affiliation to the instituion that sponsors, funds, or conducts research reviewed by that committee; and is not a registered health practitioner, and has not been a registered health practitioner at any time during the five years preceding the date of their appointment; andis not involved in conducting health or disability research, or employed by an organisation whose primary purpose relates to health and disability research; and * may not otherwise be construed by virtue of employment, profession, and relationship or otherwise to have a potential conflict of bias with the work of the committee.
 |

## 1.1 Summary of experience and expertise of members.

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No****(Provide reasons where necessary)** |
| Person with a recognised awareness of te reo Māori and understanding of tikanga Māori | [ ]  | [ ]  |
| Person with experience and expertise in ethical and moral reasoning | [ ]  | [ ]  |
| Lawyer | [ ]  | [ ]  |
| Person from the wider community**(Indicate from which community: e.g. person with experience and expertise in the perspectives of consumers of health and disability services, person from an ethnic community.)**      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  | [ ]  |
| Person with experience and expertise in the design and conduct of intervention studies  | [ ]  | [ ]  |
| Person with experience and expertise in the design and conduct of observational studies | [ ]  | [ ]  |
| Person with experience and expertise in the provision of health and disability services | [ ]  | [ ]  |
| Person with experience and expertise to review either qualitative or quantitative research  | [ ]  | [ ]  |
| Person from student community | [ ]  | [ ]  |
| Other experience and expertise **(specify)**  |       |

**1.2 Status of Chairperson and Deputy Chairperson of the EC.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Chairperson** | **Deputy Chairperson** | **Yes** | **No****(Provide reasons below)** |
| Lay person | Non-lay person | [ ]  | [ ]  |

## 1.3 No. of members in the following core membership categories.

**(Each member should only be listed under one core membership category: For Māori member, only list as Māori. For other members, only list under L/NL).**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | ***Māori*** | ***L*** | ***NL*** | **Total** |
| ***Male*** |       |       |       |       |
| ***Female*** |       |       |       |       |
| **Total** |       |       |       | **(combine the total of all columns)** |

**1.4 For an EC that reviews low risk health research, identify the members who are appropriately qualified health professionals and note their affiliations.**

|  |  |  |
| --- | --- | --- |
|  | Name of qualified health professional  | Affiliation |
| ***Clinically trained*** |  |  |
| ***In active practice***  |  |  |

**1.5 If there was only 1 qualified health professional, explain how the EC ensured that the review of low risk health research was carried out appropriately.**

## 2. MEMBERSHIP

**2.1 List of EC members within the reporting period.**

|  |
| --- |
| **NOTE:** 1. As long as a member attended at least one meeting they need to be included in this list. This includes both new and retired members.
2. An ‘\*’ after a name indicates Māori member.
 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| # | Name of member | GenderM/F | MembershipCategory (L/NL) | Expertise and experience | HowAppointed | Start - finish date |
| **1** | **Dr John Smith\*** | **M**  | **NL** | **e.g. Ethics and moral reasoning,** **Law,****Tikanga Māori** | **e.g. public nomination and interview by the committee**  | **03/02/07 - 05/02/10-** |
|    |               |    |    |        |         |       -        |
|    |               |    |    |        |        |       -       |
|    |               |    |    |        |        |       -       |
|    |               |    |    |        |        |       -       |
|    |               |    |    |        |        |       -       |
|    |               |    |    |        |        |       -       |
|    |               |    |    |        |        |       -       |
|    |               |    |    |        |        |       -       |

## 2.2 Provide a short biography for each member on the list.

|  |  |  |
| --- | --- | --- |
| **#** | **Name of member**  | **Short biography** |
| **1** | **Dr John Smith\*** | **Dr John Smith (Ngāti Hine) is a lawyer. He specialises in Māori issues. He completed a PhD in Law at the University of ABC. He was previously a member of XYZ Ethics Committee.** |
|  |  |  |

**2.3 Include any additional comments specific to the list of membership over the last 12 months.**

 **(For example: “Clarify members augmented on the committee or used as consultants”.)**

**2.4 Indicate all retirements / resignations of members over the last 12 months.**

|  |  |
| --- | --- |
| ***Name of Member***  | ***Retirement / Resignation date (dd/mm/yyyy)*** |
|  |  |
|  |  |
|  |  |

**2.5 Indicate all new appointments over the last 12 months.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Name of member*** | ***Membership category*** ***(L/NL)*** | ***Expertise and experience*** | ***Gender (m/f)*** | ***Dates of Appointment (dd/mm/yyyy – dd/mm/yyyy)*** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**2.6 Complete the attendance grid.**

**(Note: Please refer to the legend below for the membership attendance grid.)**

LEGEND:

* **\* After name indicates Māori member**
* **Y = Present**
* **A = Apology**
* **X = Meeting cancelled / No meeting scheduled**
* **/ = Not a member of committee during this time**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Members** | ***Membership category*** ***(L/NL)*** | **Jan** | **Feb** | **Ma**r | **Apr** | **May** | **Jun** | **Jul** | **Aug** | **Sep** | **Oct** | **Nov** | **Dec** | **Total** |
| John Smith \* | NL | X  | Y  | Y  | Y  | Y  | A  | Y  | Y  | Y  | / | / | / | 7/8 |
|       |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
|       |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
|       |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| **Total no. of members present** |  |    |    |    |    |    |    |    |    |    |    |    |    |  |
| **No. of applications considered** |  |    |    |    |    |    |    |    |    |    |    |    |    |    |

**2.7 Include any additional comments specific to the membership attendance grid.**

 **(For example: “No meeting was scheduled for May because the committee did not meet quorum”.)**

## 3. TRAINING FOR COMMITTEE

## 3.1 Specify the training undergone by new members.

|  |  |  |
| --- | --- | --- |
| **Date** **(dd/mm/yyyy)** | **Details of training for new members** | **No. of attendees** |
|       |       |       |

## 3.2 Specify the on-going training for EC members.

|  |  |  |
| --- | --- | --- |
| **Date** **(dd/mm/yyyy)** | **Details of on-going training for EC members** **(This includes seminars and conferences that EC members attend.)** | **No. of attendees** |
|       |       |       |

**3.3 If no training was undertaken over the last 12 months, provide reasons below.**

## 4. ASSESSMENT TIME

**4.1 Indicate the assessment time for ethics approvals.**

 **(Assessment time is the time the EC starts the review process of the application to the time decision is made.)**

# 5. chairperson’s delegation

**5.1 Indicate the number of decisions made by the Chairperson under delegated authority.**

# 6. Second opinions

## 6.1 List and provide details of any second opinions sought / provided during the reporting period.

# 7. COMPLAINTS

### **List and provide details of any complaints received during the reporting period.**

**(Include the nature of the complaint (administrative, or complaint regarding process or decision-making), the actions taken to resolve the complaint and a comment on the outcome. Specify the relevant meeting in which the original application was heard. Please ensure that no individuals/participants are identified.)**

# 8. Incidental findings/UNexpected Events

### **8.1 List and provide details of any incidental findings/unexpected events during the reporting period.**

### **(Please ensure that no individuals/participants are identified.)**

# 9. review of applications

**9.1 Summary of applications received by full EC.**

|  |  |
| --- | --- |
| No. of applications approved |       |
| No. of applications approved subject to conditions / pending |       |
| No. of applications deferred and subsequently approved |       |
| No. of applications deferred as at time of report |       |
| No. of applications that were declined because of no/insufficient consultation with appropriate Māori/whanau/iwi/hapu |       |
| No. of applications that were declined because of no/insufficient consultation with appropriate cultural group |       |
| No. of applications declined (This excludes those with no/insufficient consultation with appropriate Māori/whanau/iwi/hapu/cultural group) **(Complete question 9.4)** |       |
| No. of applications which do not require ethics committee approval  |       |
| No. of studies withdrawn by researcher |       |
| No. of studies terminated by sponsor |       |
| No. of studies transferred to another EC **(Complete question 9.5)**  |       |
|       (extra category for committee use) |       |
| **Total number of applications received by full EC**  |  |

**9.2 Summary of applications received under expedited / low risk review.**

|  |  |
| --- | --- |
| No. of applications approved |       |
| No. of applications approved subject to conditions / pending |       |
| No. of applications which do not require ethics committee approval  |       |
| No. of applications referred for full committee review |       |
|       (extra category for committee use) |       |
| **Total number of applications received under expedited / low risk review** |       |

|  |  |  |
| --- | --- | --- |
| **9.3** | **Total number of applications received (combine the total number of applications in 9.1 and 9.2).** |       |

## 9.4 If any research proposals were declined (other than no/insufficient consultation with appropriate Māori/whanau/iwi/hapu/cultural group), briefly outline the general reasons for declining approval for these research proposals.

**9.5 If any research proposals were transferred to another EC, briefly outline the reason for the transfer.**

**9.6 If a particular core membership category had no member present at a meeting, explain the process that ensure the Chair was satisfied, prior to a decision being reached, that the absent core member(s) were informed, had an opportunity to contribute their views, and these views were recorded and considered.**

**10. RESPONSE TO CULTURAL ISSUES**

**10.1 Briefly outline any issues the EC has with regards to researchers’ consultation with Māori/whanau/iwi/hapu.**

**11. DETAILS OF PROTOCOLS**

|  |
| --- |
| **NOTE:**1. Please provide details of all protocols considered by the EC over the last 12 months.
2. In the “outcome of first review” and “status at time of report” columns, please use the categories (as indicated in 7.6 and 7.7) “Approved/ Approved subsequent to conditions/ Declined/ Deferred/ Transferred”.

(For outcome category “transferred”, please include the name of the committee the proposal was transferred to or from.)1. In the “locality column”, specify the location where the research will be undertaken. For example, in the hospital, at school.
 |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Reference no.** | **Protocol title** | **Name of principal****investigator** | **Date****received** | **Date of first review** | **Outcome of first review** | **Status at time of report** | **Date of final outcome** | **Locality**  | **Funder** | **Consultation undertaken**  |
|    |         |        |        |        |        |        |      |       |       |        |
|    |         |        |        |        |        |        |      |       |       |        |
|    |         |        |        |        |        |        |      |       |       |        |
|    |         |        |        |        |        |        |      |       |       |        |
|    |         |        |        |        |        |        |      |       |       |        |
|    |         |        |        |        |        |        |      |       |       |        |
|    |         |        |        |        |        |        |      |       |       |        |
|    |         |        |        |        |        |        |      |       |       |        |
|    |         |        |        |        |        |        |      |       |       |        |
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|    |         |        |        |        |        |        |      |       |       |        |

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| **SECTION 12:****ADDITIONAL QUESTIONS FOR INSTITUTIONAL ETHICS COMMITTEES** |

**12.1 Indicate the number of applications involving vulnerable persons which had been reviewed by your EC.**

Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable. (Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, World Health Organisation).

|  |  |
| --- | --- |
| No. of applications involving adults unable to give informed consent |       |
| No. of applications involving children aged under 16 years |       |
| No. of applications involving people vulnerable as a result of a situation of conflict of interest  |       |
| No. of applications involving people in a dependent situation (for example: people with a disability; residents of a hospital, nursing home or prison; patients highly dependent on medical care) |       |
| No. of applications involving people who were vulnerable for some other reasons (for example: elderly, persons who have suffered abuse, persons who are not competent in English, new immigrants) |       |
| **Total number of applications involving vulnerable persons which have been reviewed by your EC** |       |

**12.2 Indicate the number of intervention studies not related to health and disability research which had been reviewed by your EC.**

**12.2.1 Briefly outline any issues encountered during review of these applications.**

|  |
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| **PART D:****DECLARATION** |

## Declaration by EC Chairperson

**Name of EC: Pre-populated by HRC**

**I declare for the above named EC:**

• that the information supplied on this form and any attachment(s) is true and correct; and

• that, for the period to which this form relates, the EC has operated in accordance with
relevant Guidelines and Legislation.

**Name:**      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature: Date:**

## Declaration by Head of Organisation with Primary Responsibility for the EC

**Name of EC: Pre-populated by HRC**

**Name of Organisation: Pre-populated by HRC**

**On behalf of the above named organisation, and in relation to the above named EC,
I declare that:**

• I am duly authorised to sign this declaration;

• the information supplied on this form and any attachment(s) is true and correct;

• the EC is adequately resourced and maintained;

• for the period to which this form relates, the organisation ensured that the EC’s Terms
of Reference included information on the:

- scope of its responsibilities,

- relationship to non-affiliated researchers,

- accountability,

- mechanisms of reporting, and

- remuneration (if any) for members;

• the organisation accepts legal responsibility for decisions and advice received from the EC; and

• EC members are indemnified.

**Name:**

 Title First Name Last Name

**Position :**

**E-mail :**

**Signature: Date:**

**Thanks for completing the report.**