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

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| **The HRC Ethics Committee (HRC EC) 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 HRC EC.**  **\*\*\*\*\*\*\*\*\*\***  **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 2020 and/or the Health Information Privacy Code 2020.** |

# SUBMISSION

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

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

Email: [***llon@hrc.govt.nz***](mailto: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

**Xx Jan 20xx – xx Dec 20xx**

## 3. Administrator

Name             \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title First Name Last Name

Phone (  )

E-mail

## 4. Chairperson

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 Jan 20XX – Dec 20XX** |

## 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; andis 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 mātauranga Māori tikanga Māori, and te reo 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 or minority 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 Describe the role that lay persons play in the leadership of the committee.**

**1.3 How do you ensure that voices outside the institution play a meaningful part in the decisions and workings of the committee?**

## 1.4 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)** |

**1.5 For an EC that reviews 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*** |  |  |

**1.6 If there was only one 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.**

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| **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 | Gender | Membership  Category (L/NL) | Expertise and experience | How  Appointed | 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-** |
|  |  |  |  |  |  | - |
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|  |  |  |  |  |  | - |

## 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)*** |
|  |  |  |  |  |
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**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**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 |
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| **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. OPERATIONS OF COMMITTEE

**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.)**

**4.2 Indicate the scope of the Chairperson’s delegation.**

## 4.3 Indicate the number of decisions made by the Chairperson under delegated authority.

## 4.4. List and provide details of any occasions in which the committee has consulted with experts or groups outside the committee over the last 12 months.

### **4.5 List and provide details of any complaints received over the last 12 months. Describe how the complaints were dealt with. (Include the nature of the complaint (for instance, administrative, or regarding process or decision-making), the actions taken to resolve the complaint and a comment on the outcome. Please ensure that no individuals/participants are identified.)**

### **4.6 List and provide details of any incidental findings/unexpected events that occurred during the course of research over the last 12 months. Describe how the events were dealt with. (Please ensure that no individuals/participants are identified.)**

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

|  |  |
| --- | --- |
| No. of applications approved at first review |  |
| No. of applications approved subject to conditions / pending at first review |  |
| No. of applications deferred at first review 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/whānau/iwi/hāpu |  |
| 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/whānau/iwi/hāpu/cultural group.) **(Complete question 4.10)** |  |
| 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 4.11)** |  |
| **(extra category for committee use)** |  |
| **Total number of applications received by full EC** |  |

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

**(All outcomes refer to outcome of first 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** |  |

|  |  |  |
| --- | --- | --- |
| **4.9** | **Total number of applications received (combine the total number of applications in 4.7 and 4.8).** |  |

## 4.10 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.

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

**4.12 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.**

**4.13 Briefly outline any issues the EC has with regards to researchers’ consultation with Māori/whānau/iwi/hāpu.**

**4.14 Describe the requirements for researchers to report upon the status or outcomes of their research and how those reports are reviewed.**

* 1. **Describe any auditing of research undertaken by, or for, the EC.**

## 5. SPECIFIC RESEARCH CONTEXTS

**5.1 Describe in broad terms the issues associated with research involving vulnerable persons in your institution and how the EC has managed them. (For explanation of vulnerability, please refer to National Ethical Standards Section 6: Ethical Management of Vulnerability). Comment in particular upon research involving the following:**

* adults unable to give informed consent
* children and young people aged under 16 years
* people vulnerable as a result of a situation involving conflict of interest
* people in a dependent situation (for example: people with a disability who require care or support; residents of a hospital, nursing home or prison; patients highly dependent on medical care)
* people vulnerable for other reasons (for example: elderly, persons who have suffered abuse, persons who are not competent in English, new immigrants)

**5.2 Comment on ethical issues that the EC has considered in relation to research involving data pertaining to humans and how the EC has responded to them.**

**5.3 Comment upon intervention studies not related to health and disability research which have been reviewed by your EC and any special issues they may have raised.**

**5.4 Describe trends in applications related to research conducted overseas, the challenges they pose for the EC and how the EC responds to those challenges.**

**6. DETAILS OF PROTOCOLS**

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| **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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| **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.**