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| *Central Health and Disability Ethics Committee*  **Annual Report**  **2013** |

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# About the Committee

The Central Health and Disability Ethics Committee (HDEC) is a Ministerial committee established under section 11 of the [New Zealand Public Health and Disability Act 2000](http://www.legislation.govt.nz/act/public/2000/0091/latest/DLM80051.html). Its members are appointed by the Minister of Health through the public appointments process.

The primary function of the Committee is to provide independent ethical review of health research and innovative practice in order to safeguard the rights, health and wellbeing of consumers and research participants and, in particular, those persons with diminished autonomy.

The Committee is required by its [Terms of Reference](http://www.ethicscommittees.health.govt.nz/moh.nsf/indexcm/ethics-about-central#tor) to submit an Annual Report to the Minister of Health. The Annual Report must include information on the membership of the Committee, a summary of the applications reviewed during the year, details of any complaints received (and how they were resolved), and areas of review that caused difficulty when making decisions, among other matters.

### Approvals and registrations

The Central HDEC is approved by the Health Research Council Ethics Committee for the purposes of section 25(1)(c) of the [Health Research Council Act 1990](http://legislation.govt.nz/act/public/1990/0068/latest/DLM213017.html).

The Central HDEC is registered (number IRB00008712) with the United States’ Office for Human Research Protections. This registration enables the committee to review research conducted or supported by the US Department of Health and Human Services.

# Chairperson’s report

Another busy year has passed for the Central HDEC. The Committee has reviewed some outstanding research projects and is continually impressed with the research New Zealand accomplishes. The Central HDEC has done exceedingly well in safeguarding participants and working with researchers to make research as safe as possible.

2013 was the first full year using the online system, which received two system updates during 2013. The continued support for the system is appreciated as it helps make reviewing easier and faster.

The Central HDEC received 128 applications in 2013. Ninety applications were reviewed by the full committee and 38 were reviewed through the expedited pathway. The Chair and Deputy Chair have had a high workload over 2013 due to the large amount of post-approval activity, including progress reports, amendments and final reports.

I would like to thank all members of the Central Committee for their hard work and high attendance. We are sad to see Dr Angela Ballantyne and Dr Lynne Russell go; they both contributed value and knowledge to the Committee. We wish them the best in their endeavours.

I would like to extend a huge thank you to the Secretariat who has provided great support and advice throughout the year. The HDEC team changed significantly during 2013 with the addition of three advisors. The Committee welcomes the help and knowledge of the advisors that attend each meeting. Helen Colebrook and her team are doing a great job.

The Committee looks forward to having training for researchers and committee members in future to ensure researchers understand why some of the questions for studies are being asked in the applications. The Committee also requests that lay titles be written in lay language English, not anagrams without a description or explanation.

The Committee thanks researchers who have attended the meeting in person or through teleconference – it makes a big difference to the review process.

The Central HDEC is there for the safety of the public, this should be uppermost in everyones minds.

****

Helen Walker

Chairperson

Central Health and Disability Ethics Committee

# Membership and attendance

No meetings were postponed or cancelled due to inability to make quorum. Two members resigned during 2013.

## Membership

### Lay members

|  |  |
| --- | --- |
| Mrs Helen Walker (Chair) | |
| Membership category: | Community Representative |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2015 |

Mrs Helen Walker is currently the Chairman of the Medical Sciences Council, Chairman of Audit for Health Hawkes Bay Ltd, a Kaitiaki/Guardian of the Turnbull Library and the owner and financial controller of Kilgaren Farming Partnership. She completed a Bachelor of Science at Massey University (1975) and a Certificate in Company Direction through the New Zealand Institute of Directors (2002). Mrs Walker is a previous Director of Unison Networks Ltd (2004-2010), the Hawke’s Bay District Health Board (2001-2007) and Chairman of the Central Hawke’s Bay Consumers Power Trust (1993-2003). On a voluntary basis she is the President of the Waipawa Musical and Dramatic Club (1999-present), a member of the Waipawa Municipal Theatre Refurbishment Trust and Trustee of the New Zealand Singing School.

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| Mr Paul Barnett | |
| Membership category: | The Law |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2014 |

Mr Paul Barnett is currently the Principal /Director at Barnett Law, Solicitor, (2004-present). Prior to this, he was a Wellington Partner of at the national law firm Chapman Tripp, (1980-2004). He has completed a Master of Laws (1973) and a Bachelor of Laws with Honours (1971) at Victoria University of Wellington. He was appointed a Notary Public in 1984.He is Deputy Chair of the Board of Ronald McDonald House Wellington Trust (2005-present), a cost reviser for the Wellington branch of the New Zealand Law Society (2009-present) and was a cost reviser for the Wellington District Law Society (1990-2008). He is also a member of a Standards Committee of the New Zealand Law Society and a member of the Ethics Committee of the Wellington branch of that Society.

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| Ms Sandy Gill | |
| Membership category: | Community Perspectives |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2014 |

Ms Gill has her own consulting company and also works on a voluntary basis with various community groups assisting with policy and procedure, writing programmes and evaluations, clinical supervision of staff, business plans and strategic planning. Her qualifications include an MA in Management (Massey), a MA in Criminal Justice (Victoria) along with post graduate qualifications in Dispute Resolution (Massey) and Human Resources (Victoria). She was a member of the New Zealand Parole Board from 2002 through to 2008, and has been a guest lecturer at Victoria University in the field of criminology. Prior to that she was Standards Manager at the Medical Council of New Zealand. She has also been involved in counseling and reintegration planning for offenders and youth at risk, and in the area of Maori mental health. She has a lifelong addiction to learning and loves to travel and learn about different cultures and history. She is Nga Puhi and the proud mother of three and nana of one and an Associate Member of AMINZ.

### Non-lay members

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| --- |
| Dr Dean Quinn |
| Membership category: | | Interventional Studies |
| Date of appointment: | | 1 July 2012 |
| Current term expires: | | 1 July 2015 |
|  | |  |
| Dr Dean Quinn is a registered medical practitioner, currently the Manager of the Wellington P3 Research unit (2004-present). He has a particular interest in early phase respiratory clinical trials. Prior to this, he has completed a BSc (Hons) (1988) Victoria University of Wellington and MBChB (1993) at the University of Otago. He was formerly a member of the Central ethics committee (2009-2011) and Multi-region ethics committee (2011-2012).   |  |  | | --- | --- | | Mrs Gael Donoghue | | | Membership category: | Pharmacist/Pharmacologist | | Date of appointment: | 1 July 2012 | | Current term expires: | 1 July 2014 |   Mrs Gael Donoghue is a pharmacist working as a pharmaceutical manager at Lucanus Corporation (2004-present), and worked at the Open Polytechnic of New Zealand as a tutor and assessor (2000-2011). Prior to this she worked in the Central Districts region as a Field Educator for the Pharmaceutical Society of New Zealand (1993-2003). Mrs Donoghue is a Fellow of the Pharmaceutical Society of New Zealand, of which she was also made the first Life Member in 2010. She was a member of the Drugs Advisory Committee (1984-1988). She was also the pharmacist member on the Manawatu Well Child Health Forum (2003-2010) and a member of the Executive of the New Zealand College of Pharmacists (1995-2000). She has held the post of President of the Central Districts Pharmaceutical Society of New Zealand on a number of occasions (most recently in 2004-2005) and has a history of community service and committee membership. Gael was awarded MNZM in this year’s Queen's Birthday Honours for services to the Pharmaceutical Profession. | | |

**Dr Patries Herst**

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| Membership category: | Intervention Studies |
| Date of appointment: | 1 July 2013 |
| Current term expires: | 1 July 2015 |

Dr Patries Herst is currently a senior lecturer at the Department of Radiation Therapy, University of Otago, Wellington and a visiting scientist at Victoria University and the Malaghan Institute. She completed a PhD in cancer cell biology at the Malaghan Institute of Medical Research/Otago University in Wellington (2006), a Master of Philosophy (microbiology) at Waikato University in Hamilton (1984) and a Master of Science (biology) at Nijmegen University (Netherlands) in 1982. Dr Herst conducts cell based medical research at the Malaghan Institute as well as clinical trials that investigate better management options for acute side effects caused by radiation therapy in various hospitals in New Zealand. She is the secretary of the New Zealand Oncological Society and the immediate past president of the Wellington Health and Biomedical Research Society. She is also a committee member of the Animal Ethics Committee at the University of Otago, Wellington and joined the Central HDEC as a non-lay member in July 2012.

### Former Members

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| --- | --- | --- | --- | --- |
| Dr Lynne Russell (resigned August 2013) | | | | |
| Membership category: | Health Practitioner (non-lay) | | | |
| Date of appointment: | 1 July 2012 | | | |
|  | | |
| Dr Angela Ballantyne (resigned November 2013) | | | |
| Membership category: | | Ethicist (lay) | |
| Date of appointment: | | 1 July 2012 | |

## Attendance

The Central HDEC held 11 meetings in 2013.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Members** | | | **Meetings** | | | | | | | | | | | | **Total** |
| Jan | Feb | May | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec |  |
| Lay members | Cm | Mrs Helen Walker | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** |  | 10/11 |
| L | Mr Paul Barnett | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** |  | 11/11 |
| E | Dr Angela Ballantyne | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | ***A*** | **✓** | **✓** |  | 9/11 |
| Cm | Ms Sandy Gill | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** |  | 11/11 |
| Non-lay members | P | Mrs Gael Donoghue | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** |  | 11/11 |
| HR | Dr Lynne Russell | **✓** | **✓** | ***A*** | **✓** | **✓** | ***A*** | **✓** | ***A*** | ***A*** |  |  |  | 5/9 |
| HR | Dr Dean Quinn | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** |  | 11/11 |
| HR | Dr Patries Herst | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** |  | 9/11 |

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| --- | --- | --- | --- | --- | --- | --- |
| Key: | L | Lawyer | P | Pharmacist/pharmacologist | **✓** | present |
|  | E | Ethicist | B | Biostatistician | ***A*** | apologies |
|  | Cm | Community representative | HP | Health practitioner | **X** | absent |
|  | Cn | Consumer representative | HR | Health researcher |  | not applicable |

## Training and conferences

The Central HDEC did not have training during 2013.

Committee members were invited to attend the Annual Cartwright Conference held in Auckland. No Central members attended.

## Chairpersons’ meetings

Mrs Helen Walker attended two Chairs’ day meetings in 2013. Both meetings were held in Wellington in the Medsafe Boardroom.

The first meeting was held on 5 April. The Chairs were updated by the Secretariat about:

* appointments of new members
* annual reports to the Minister
* preliminary trends and measuring quality
* upcoming changes to the online system.

The Chairs and Secretariat identified seven key issues that were discussed.

* Bio-banking.
* Peer review.
* Restrictions on publication.
* Remuneration.
* Data safety monitoring.
* Examples of good practice.
* The possibility of a protocol template.

The Chairs spent the afternoon participating in a training session on ‘Managing Meetings’.

The second meeting was held on 23 August. The Chairs were updated by the Secretariat about:

* annual reports to the Minister
* further improvements planned for the online system.

The Chairs and Secretariat identified four key issues that were discussed.

* Peer review.
* Conflicts of interests.
* Restrictions on publication.
* Data safety monitoring.

Mr John Hancock, a legal adviser for the Office of the Commissioner for Children, gave a videoconference presentation to the Chairs about children’s consent in health research. The Chairs had a presentation and discussion with Associate Professor Martin Tolich on his recent academic work and practical observations of HDECs.

# Applications reviewed

The Central HDEC received 128 applications in 2013. From the 128 applications 90 applications were reviewed by the full committee and 38 were reviewed through the expedited pathway.

At each of its meetings in 2013 the Committee reviewed an average of eight applications.

|  |  |  |
| --- | --- | --- |
| Full | Approved | 80 |
| Declined | 7 |
| Provisional Approval (as at 31 December 2013) | 3 |
| *Total (with a decision at 31 December 2013)* | 90 |
| Expedited | Approved | 31 |
| Declined | 1 |
| Provisional Approval (as at 31 December 2013) | 6 |
| *Total (with a decision at 31 December 2013)* | 38 |
| **Total applications reviewed** | | **128** |

A summary of these applications can be found in Appendix A.

## Applications processed by Secretariat

The Central HDEC received 48 applications that were screened by the HDEC Secretariat and were deemed out of scope for HDEC review.

The Central HDEC received 102 Minimal Dataset Forms (MDF). These forms are used to broker applications from the previous HREC Lotus Notes database to the new HDEC database.

## Average review time

Average review times take into account the time taken for the Secretariat to process applications and the time taken for the Committee to review applications. The clock is stopped when a decision letter is emailed to applicants. Average review times exclude time taken for researchers to respond to requests for further information.

The average review time for full applications was 30 days compared to a target timeframe of 35 calendar days.

The average review time for expedited applications was 21 days compared to a target timeframe of 15 calendar days.

# Post approval items reviewed

The Central HDEC reviewed a total of 459 post approval items. A graph of the different types reviewed is below.

**Post approval items reviewed during 2013**

# Reasons for declining

The Central HDEC is required to clearly identify the ethical standard(s) that it considers not to be met by an application. These ethical standards are contained in the *Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes (GFUR), Ethical Guidelines for Observational Studies (EGOS) and Ethical Guidelines for Intervention Studies (EGIS)*. The references in the tables below are to paragraph numbers in these documents.

**Reference:** 13/CEN/11  
**Review Type:** Intervention

**Short title:** Subliminal Priming differences between people with, and without depression

**Co-ordinating Investigator:** Miss Caitlin Aberhart

|  |  |
| --- | --- |
| **Reference** | **Reason** |
| 3.11 *EGIS* | It was not clear to the committee that the risks of the research were proportional to the benefits of the research. The researcher needs to be more explicit about the possible benefits of this research to people with depression and needs to mitigate the risks of the research. |
| 5.30 *EGIS* | Intervention studies should be conducted with vulnerable participants only if the risk to vulnerable people is at an acceptable minimum. The study should ask questions that matter to the participant’s community, and the answers should benefit the community.  “Studies should be undertaken only by investigators and research teams with the necessary skills and resources to do so. These skills and resources include those needed to deal with any contingencies that may affect participants.”  The committee noted that the CI was a Masters student dealing with a vulnerable group of participants, a difficult study design involving deception, and working in the context of Christchurch with significant undiagnosed depression. Given the sensitive nature of the research the CI’s supervisors should be more actively involved ensuring that the safety of participates is met. For example, in the revised application please include the supervisors’ CVs. |
| 6.31 *EGIS* | The committee believes the researcher has to do further work to explain why the concealment does not pose an “increased risk of harm” to participants. |
| 6.66 *EGIS* | “Investigators have an obligation to ensure the availability of health care services that are essential to the safe conduct of a study and for any participants who suffer injury as a consequence of study interventions”.  The committee noted that no contact numbers were provided should a participant who is “depressed” or “non-depressed” have an adverse reaction following participation in the study. The committee believes that in a study of this nature, safety measures are paramount. Given that there is the possibility that a participant may experience a flashback not only during, but also sometime after an event, appropriate safety measures must be in place. The committee noted that assessment for possible depression prior to participation in the study would help ensure participant safety at the onset, but safety measures must also be available to participants after they have completed the study. |

**Reference:** 13/CEN/31  
**Review Type:** Intervention

**Short title:** Acetazolamide to reduce lithium induced NDI

**Co-ordinating Investigator:** Professor Robert Walker

|  |  |
| --- | --- |
| **Reference** | **Reason** |
| N/A | The Committee has considered your application and believe you have submitted an incomplete application as the protocol relevant to the NZ study was not supplied. As per section 5 of the NEAC Guidelines [July 2012]. Please note the Committee tried to contact you by phone [mobile and work number] but were unsuccessful. |
| 5.1 *EGIS* | Investigators should undertake studies that address important health and/or disability problems. |
| 5.2 *EGIS* | Investigators should develop clear study questions that identify the participant population, the intervention and the main outcome of interest. Normally the outcome(s) to be studied should be clinically significant. |
| 5.3 *EGIS* | Every study question should be based on a thorough review of the relevant literature. |
| 5.4 *EGIS* | The study design should be the one best suited to answer the study question, while minimising harm, maximising benefit and meeting other ethical standards. |
| 5.5 *EGIS* | Scientific soundness is ethically important. Projects without scientific merit needlessly expose participants to risk, misuse their time and waste resources. |
| 5.6 *EGIS* | The intended number of participants in an intervention study should be sufficient to generate reliable study findings, and the consequent recruitment targets should be realistic. Statistical issues relating to trial design, sample size and analysis can be complex, and usually require expert advice. |
| 5.7 *EGIS* | The study protocol should contain an overview of the planned statistical analyses, and these planned analyses should be adhered to in conducting the study. |
| 5.8 *EGIS* | Assignment of participants to study groups is best done by randomisation. This process tends to make study groups reliably comparable and minimises biases, especially uncontrolled confounding. Quasi-randomised or non-random methods are generally less reliable in this regard because of their potential to allow other factors to influence the assignment of participants to study groups. Allocation concealment also improves study validity and design through preventing selection bias (see also ‘Features of intervention studies’, paragraphs 2.7–2.11). |
| 5.9 *EGIS* | Use of blinding is desirable in an intervention study design when it can be shown that it has methodological advantages and minimal risks (see also ‘Blinding’, paragraph 2.11). |
| 5.10 *EGIS* | Every effort should be made to ensure complete follow-up of all study participants. Incomplete follow-up means there is data missing from the study. This will be for non­random reasons and has the potential to compromise the reliability of the study findings (see also paragraph 6.20). |
| 5.11 *EGIS* | Peer review of the scientific validity of a study’s protocols is beneficial, and is advised for all studies that pose more than minimal risk. Further advice about features of robust peer review is provided in Appendix 1. |
| 5.12 *EGIS* | Investigators should treat actual and potential study participants fairly, both in relation to one another and in relation to similarly placed non-participants. |
| 5.13 *EGIS* | An intervention study meets the best intervention standard if the intervention(s) in the study are tested against the best proven intervention(s) available outside the study. In many settings there might be more than one intervention that is equivalent to the best, according to the current evidence. |
| 5.14 *EGIS* | All intervention studies should meet the best intervention standard, unless there are only temporary and minimal departures from the best intervention standard and the departure (and any risk posed) is justified in relation to the overall potential benefits of the study. |
| 5.15 *EGIS* | Withholding a proven intervention for a short time, whether or not it is replaced by a placebo, can sometimes be ethically justified to validate a measurement technique or to confirm the sensitivity of a therapeutic study design. An investigator who proposes any such approach should justify this to an ethics committee and explain how it can be undertaken without significant risk of harm to participants. |
| 5.16 *EGIS* | In some cases, one or more interventions provided in an intervention study are equivalent to the best proven intervention available locally outside the study but are known to be inferior to the best proven intervention available internationally. In such cases, the study can be justified only if the world-best intervention is unlikely to be available locally for the duration of the study and if the study can be justified in terms of its potential benefit to the community from which the participants are drawn. The same considerations apply to New Zealand-sponsored studies conducted in countries with less access to health interventions than New Zealand. |
| 5.17 *EGIS* | Investigators should ensure that participants understand that their participation in an intervention study is not designed to benefit them more than the benefit they would gain if they were instead receiving the best proven intervention available outside the study. (See also ‘Equipoise standard’, paragraphs 5.18–5.21.) |

**Reference:** 13/CEN/113  
**Review Type:** Observational

**Short title:** Testing biomarkers for diabetic complications  
**Co-ordinating Investigator:** Dr Renwick Dobson

|  |  |
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| **Reference** | **Reason** |
| 5.4 *EGOS* | The committee is unclear about the study design and therefore is unable to judge whether the protocol and information provided best answers the study question. |

**Reference:** 13/CEN/116 **Review Type:** Observational

**Short title:** Filaggrin mutations in atopic dermatitis in Māori

**Co-ordinating Investigator:** Professor Peter R. Hull

|  |  |
| --- | --- |
| **Reference** | **Reason** |
| 4.3 *EGOS* | The committee was satisfied that the research is not damaging but that there are outstanding issues relating to Māori cultural aspects that need to be addressed. |

**Reference:** 13/CEN/128  
**Review Type:** Observational

**Short title:** Does free primary health care access reduce secondary care use in a vulnerable patient group?

# Co-ordinating Investigator: Dr Lik Loh

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| --- | --- |
| **Reference** | **Reason** |
| 5.5- 6 *EGOS* | The committee recommends the researchers reassess the methodology and as a consequence also revise the participant information sheet and consent form so that it is more appropriate and accessible for the population they intend to reach. |

**Reference:** 13/CEN/154  
**Review Type:** Observational

**Short title:** Neurocognitive impairment in long term paediatric liver transplant recipients  
**Co-ordinating Investigator:** Dr Rachael Harry

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| **Reference** | **Reason** |
| 5.5 *EGOS* | The Committee considered the application was incomplete in respect of a material requirement, viz: provision (on a confidential basis) of copies of the questionnaires to be used. |

**Reference:** 13/CEN/181  
**Review Type:** Interventional

**Short title:** An interventional study looking at caregiver education in managing BPSD.  
**Co-ordinating Investigator:** Dr Bhamini Patel

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| **Reference** | **Reason** |
| 5.2 *EGIS* | Investigators should develop clear study questions that identify the participant, population, the intervention and the main outcome of interest. |

**Reference:** 13/CEN/140  
**Review Type:** Observational

**Short title:** Te Poipoia Tūkino o Hauraki - transforming & healing Whānau violence in Hauraki

**Co-ordinating Investigator:** Dr Stephanie Palmer

|  |  |
| --- | --- |
| **Reference** | **Reason** |
| 5.5 *EGOS* | The Committee acknowledged that the research is worthwhile but had concerns about whether the study design addressed the risk of harm to participants. |
| 40.4.5 *EGOS* | In studies involving participants, the Standard Operating Procedures for Health and Disability Ethics Committees require an application to be accompanied by a participant information sheet and consent form. |
| 40.4.6 *EGOS* | In the case of studies involving the administration of surveys or questionnaires, copies of the surveys or questionnaires. |
|  | The Committee recommended that the application be resubmitted with a revised participant information sheet, consent form and the questionnaire that will be used for the study. In addition, the Committee recommended consulting the Guidelines for Researchers on Health Research involving Māori (http://www.hrc.govt.nz/news-and-publications/publications/maori#guidelines-for-researchers-on-health-research-involving-māori) |

# Issues and complaints

This section outlines issues faced by the Committee during 2013.

**Issues causing difficulty in review**

* Online system issues.
* Lack of appropriate peer review.
* Provisional responses not being submitted in tracked changes format.

# Action taken

* New online system updates have been drafted, tested and implemented.
* Peer review template developed and published on HDEC website.
* Newsletter containing reminder to track changes was published on HDEC website.

## Issues referred to NEAC and/or the HRC Ethics Committee

NIL

## Complaints received

None cited by the Chair.

## Overdue review

During 2013 there were 26 instances where the review time was over 35 days for full applications and 23 where the review time was over 15 days for expedited applications.

See Appendix 1 for more information.

**Issues causing delays in reported review times**

* Online system issues prevented Committee members from reviewing effectively.
* The online system clock that records time taken to receive a decision includes all *calendar* days which results in public holidays and weekends being included in the timeframes.
* The standard operating procedures state that the HDEC review should be paused over the period 25 December to 15 January the following year. This does not occur automatically and as a result any applications awaiting review during this period have been identified and are not considered overdue.

**Action taken**

* The online system issues have been addressed with the latest system update.
* Any applications that were running over the public holidays have been identified in Appendix 1.

# Appendix 1: Details of applications reviewed

## Applications reviewed by full committee

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study reference** | **Study status** | **Short title** | **Co-ordinating Investigator** | **Other Investigators** | **Locality/ies** | **Application type** |
| 12/CEN/1 | Approve | Walking routes programme for people with rheumatoid arthritis | Ms Susan Baxter |  |  | Intervention |
| 12/CEN/6 | Approve | Could local 'Aunties' facilitate better Maori pregnancy outcomes? | Dr Marewa Glover |  |  | Intervention |
| 13/CEN/1 | Approve | Mortality in a population with bipolar disorder. | Dr Claudia Grott Zanicotti | Dr Christopher Gale,Professor Paul Glue | Health Research South, Ruth Sharpe | Observational |
| 13/CEN/10 | Approve | Open-Label study to assess safety of PF-00547659 for Ulcerative Colitis (Protocol A7281010) | Dr Richard Gearry | Dr Michael Schultz,Dr Mark Lane,Dr Jim Brooker | CDHB Research Office,Dayle Matthews,Jan Adams, COO | Intervention |
| 13/CEN/101 | Approve | Topical vs intravenous tranexamic acid in total knee arthroplasty | Dr James Aoina |  | BOPDHB | Intervention |
| 13/CEN/102 | Approve | Amgen 416 H2H Study | Dr Mark Marshall |  | CMDHB Research Office,Jan Adams, COO,Waitemata District Health Board | Intervention |
| 13/CEN/103 | Approve | Laboratory production and functional studies on Mesenchymal Stromal Cells | Dr James M (Jim) Faed |  | Amity Health Centre | Observational |
| 13/CEN/104 | Approve | LeAPP study | Dr Sophie Chien-Hui Wen | Professor David Murdoch,Dr Tony Walls | CDHB | Observational |
| 13/CEN/105 | Approve | Acetazolamide as an adjunct to non-invasive ventilation in the treatment of obesity hypoventilation syndrome | Dr Alister Neill | Dr James Pickering |  | Intervention |
| 13/CEN/106 | Approve | Identity in a community rehabilitation service for acquired brain injury | Dr. Maxine Bevin |  |  | Observational |
| 13/CEN/109 | Approve | Swallowing safety and efficacy with the Swallow Expansion Device (SED) | Dr Jacqueline Allen |  | Waitemata DHB | Intervention |
| 13/CEN/11 | Decline | Subliminal Priming differences between people with, and without depression | Miss Caitlin Aberhart | Associate Professor Janet Carter,Associate Professor Janet Carter,Dr Ewald Neumann |  | Observational |
| 13/CEN/110 | Approve | Levonorgestrel 1 x 1.5 mg tablet bioequivalence study conducted under fasting conditions | Dr Noelyn Hung |  | Zenith Technology Corporation Limited,Zenith Technology Corporation Limited | Intervention |
| 13/CEN/111 | Approve | E-cigarette acceptability | Dr Penelope Truman |  | CCDHB,Dr Penelope Truman | Observational |
| 13/CEN/112 | Approve | Clinical Utility of Cognitive Screening Tools (CUTCOST) | Dr April Clugston |  | Auckland District Health Board,cdhb,Lakes District Health Board,Lakes District Health Board | Observational |
| 13/CEN/113 | Decline | Testing biomarkers for diabetic complications | Dr Renwick Dobson | Professor Juliet Gerrard |  | Observational |
| 13/CEN/114 | Approve | A study to evaluate the efficacy, safety and tolerability of topically applied tretinoin formulated with TPM as an anti-acne preparation in human subjects with acne vulgaris. | Dr Marius Rademaker |  | David Appleton,Eileen Bisley | Intervention |
| 13/CEN/115 | Approve | A study to evaluate if the study drug refametinib works and is safe in patients with liver cancer carrying a specific gene mutation (RAS mutation). | Prof Ed Gane |  | Auckland District Health Board | Intervention |
| 13/CEN/116 | Decline | Filaggrin mutations in atopic dermatitis in Māori | Professor Peter R. Hull |  |  | Intervention |
| 13/CEN/117 | Approve | Free lymph node transfer in the treatment of lymphoedema | Mr Winston McEwan | Dr Sarah Shugg | Jan Adams, COO | Intervention |
| 13/CEN/118 | Approve | Investigation of the use of Manuka honey to treat rosacea | Professor Richard Beasley |  |  | Intervention |
| 13/CEN/119 | Approve | Investigation of the use of Manuka honey to treat Acne | Professor Richard Beasley |  |  | Intervention |
| 13/CEN/120 | Approve | Investigation of the use of Manuka honey to treat Nappy Rash | Professor Richard Beasley |  |  | Intervention |
| 13/CEN/124 | Approve | CLDK378A2301 | Associate Professor Mark McKeage |  | ADHB | Intervention |
| 13/CEN/125 | Approve | Apollo Phaco System Prototype Field Investigation | Dr Dean Corbett |  | Auckland Eye | Intervention |
| 13/CEN/126 | Approve | The EVARREST Liver Study | A/Prof Jonathan Koea | Dr Michael Rodgers | Waitemata DHB | Intervention |
| 13/CEN/128 | Decline | Does free primary health care access reduce secondary care use in a vulnerable patient group? | Dr Lik Loh | Associate Professor Chrys Jaye,Professor Peter Crampton |  | Observational |
| 13/CEN/129 | Approve | Child TBI Genetics Study | Dr Kelly Jones | Dr Alice Theadom,Professor Valery Feigin |  | Observational |
| 13/CEN/130 | Approve | Vascular Anomalies Study | Professor Swee T Tan |  | Hutt Valley DHB | Observational |
| 13/CEN/131 | Approve | R3ACT CTL Study | Dr Nyree Cole |  |  | Intervention |
| 13/CEN/132 | Approve | Stressors and autoregulation | Dr Shieak YC Tzeng |  |  | Observational |
| 13/CEN/133 | Approve | Safety study of PF582 versus Lucentis in patients with age-related macular degeneration | A/Prof Philip Polkinghorne |  | Auckland Eye,Eye Institute Ltd | Intervention |
| 13/CEN/134 | Approve | Pesticide Exposure and Neuropsychological Effects in Children | Prof Jeroen Douwes |  |  | Observational |
| 13/CEN/135 | Approve | Cognitive stimulation using exer-games (Able-X) for people with dementia | Mrs Jeanette Drury-Ruddlesden | Dr Kay de Vries | Jenny Prentice,Kay de Vries | Observational |
| 13/CEN/144 | Approve | Beneficial effects of food on human health | Dr Juliet Ansell |  | Jocelyn Eason, General Manager of Science, Food Innovation, Plant & Food Research Ltd | Observational |
| 13/CEN/146 | Approve | ACCT007: Rap-CV | Dr Stephen Laughton |  | Auckland District Health Board | Intervention |
| 13/CEN/150 | Approve | STEP-UP | Dr Mark O’Carroll |  | Auckland District Health Board | Intervention |
| 13/CEN/152 | Approve | Oxycodone 5 mg bioequivalence study conducted under fasting conditions | Dr Noelyn Hung |  | Zenith Technology Corporation Limited,Zenith Technology Corporation Limited | Intervention |
| 13/CEN/153 | Approve | Psychotropic Obesity Observational Study | Dr Mark Huthwaite |  | Alison Masters, Clinical Director, CCDHB | Observational |
| 13/CEN/154 | Decline | Neurocognitive impairment in long term paediatric liver transplant recipients | Dr Rachael Harry | Dr Helen Evans |  | Observational |
| 13/CEN/162 | Approve | COG ALTE07C1 - Neuropsychological, Social, Emotional, and Behavioural Outcomes in Children with Cancer | Dr Stephen Laughton | Dr Amanda Lyver | Auckland District Health Board | Observational |
| 13/CEN/163 | Approve | COG ACNS0822 | Dr Stephen Laughton |  |  | Intervention |
| 13/CEN/168 | Provisionally approve | COG ASCT1221 | Dr Lochie Teague |  |  | Intervention |
| 13/CEN/175 | Approve | BRAin Injury and NeuroAid Supplementation (BRAINS) | Professor Valery Feigin |  |  | Intervention |
| 13/CEN/177 | Approve | “A study comparing how fast the trial drug GS-5816 is cleared from the body, in healthy adults and in adults with severely reduced kidney function” | Dr Richard Robson |  | Chris Taylor, CCST | Intervention |
| 13/CEN/181 | Decline | An interventional study looking at caregiver education in managing BPSD. | Dr Bhamini Patel |  | BOPDHB | Intervention |
| 13/CEN/182 | Approve | MK5172-017. Phase II Long Term Safety Follow up | Mrs Sherryl Hayett |  |  | Observational |
| 13/CEN/183 | Approve | Transfer from Methadone to Buprenorphine | Dr David Newcombe |  |  | Intervention |
| 13/CEN/185 | Approve | The ASCOLT Study | Dr Mark Jeffery |  |  | Intervention |
| 13/CEN/186 | Provisionally approve | A study of PF-04950615 versus placebo for the reduction of cardiovascular events (B1481022) | Dr John Baker |  |  | Intervention |
| 13/CEN/187 | Provisionally approve | A Study Comparing GDC-0199 and Rituximab to Bendamustine and Rituximab in Patients with Relapsed/Refractory Chronic Lymphocytic Leukaemia. | Dr Andrew Butler |  |  | Intervention |
| 13/CEN/20 | Approve | CLDK378A2203 | Associate Professor Mark McKeage |  | ADHB | Intervention |
| 13/CEN/24 | Approve | Maxigesic 325 OA Study | Dr Douglas White |  |  | Intervention |
| 13/CEN/25 | Approve | Tivantinib vs Placebo for the treatment of Inoperable Hepatocellular Carcinoma | Prof Ed Gane |  | Auckland District Health Board | Intervention |
| 13/CEN/26 | Approve | ICEOBAR-STEMI Clinical Study | Dr Mark Webster |  | ADHB | Intervention |
| 13/CEN/27 | Approve | A clinical trial for children with low and intermediate risk Neuroblastoma | Dr Robin Paul Corbett |  | CDHB Research Office | Intervention |
| 13/CEN/28 | Approve | Multi-sensory Integration and Tinnitus | Dr Grant D Searchfield |  |  | Intervention |
| 13/CEN/3 | Approve | Diagnosis of Coeliac disease in New Zealand children | Dr Jonathan Bishop |  | Auckland District Health Board | Observational |
| 13/CEN/30 | Approve | Mothers and Babies Bodies. | Assoc. Professor Jane Coad |  |  | Observational |
| 13/CEN/31 | Decline | Acetazolamide to reduce lithium induced NDI | Professor Robert Walker |  |  | Intervention |
| 13/CEN/39 | Approve | COG ANBL1221 Refractory, relapsed, progressive Neuroblastoma | Dr Mark Winstanley |  | Auckland District Health Board,CDHB Research Office | Intervention |
| 13/CEN/4 | Approve | A study evaluating MK8742 in Hepatitis C Infected Males. | Prof Ed Gane |  | Auckland Clinical Studies Limited | Intervention |
| 13/CEN/40 | Approve | Preoperative anxiety in children | Dr Ramesh Menon |  | CDHB Research Office | Observational |
| 13/CEN/42 | Approve | Triple Antiplatelets for Reducing Dependency after Ischaemic Stroke (TARDIS) | Dr Annemarei Ranta |  |  | Intervention |
| 13/CEN/43 | Approve | Light treatment for sleep and circadian disruption in kidney donor patients | Dr Guy Warman |  | Auckland District Health Board | Intervention |
| 13/CEN/44 | Approve | Assessment of the trial drug ledipasvir, when taken by healthy adults and by adults with severely reduced kidney function | Dr Richard Robson |  | Chris Taylor, CCST | Intervention |
| 13/CEN/45 | Approve | Executive Functioning, Social Cognition and Adaptive Behaviour in Children with Fetal Alcohol Spectrum Disorders (FASD) | Ms Andi Crawford |  | Sally Houliston c/- Hawke's Bay District Health Board | Observational |
| 13/CEN/46 | Approve | Frequency of BRAF mutations in melanoma | Dr Peter Ferguson |  | CCDHB | Observational |
| 13/CEN/53 | Approve | A Study of Carfilzomib, Melphalan, and Prednisone Compared with Bortezomib, melphalan, and prednisone in patients with newly Diagnosed multiple Myeloma that are Not Eligible for Stem Cell Transplant. | Dr Peter Ganly |  | Auckland District Health Board,CCDHB,CDHB Research Office,Waitemata DHB | Intervention |
| 13/CEN/54 | Approve | A study to compare a new drug to an existing drug in patients with rheumatoid arthritis who are taking Methotrexate and had an inadequate response to a specified prior treatment. | Dr Alan Doube | DR SUNIL KUMAR,Dr David Porter,Dr Simon Stebbings | CMDHB Research Office,David Porter,Health Research South,Jan Adams, COO | Intervention |
| 13/CEN/55 | Approve | Breast cancer tumour profiles and disparities | Dr Lis Ellison-Loschmann |  |  | Observational |
| 13/CEN/61 | Approve | SIRROUND T | Dr Ketna Parekh |  | CCDHB,Chris Taylor, CCST,Jan Adams, COO | Intervention |
| 13/CEN/63 | Approve | Asenapine 1 x 10 mg bioequivalence study conducted under fasting conditions | Dr Noelyn Hung |  |  | Intervention |
| 13/CEN/64 | Approve | REnal SymPathECTomy in Heart Failure (RESPECT-HF) | Professor Mark Richards |  | Auckland District Health Board,CCDHB,CDHB Research Office | Intervention |
| 13/CEN/65 | Approve | Hospital readmission after Neonatal Intensive Care | Dr Susan Joubert |  | Jan Adams, COO | Observational |
| 13/CEN/67 | Approve | LCH-IV | Dr Scott Macfarlane |  | Auckland District Health Board,CDHB Research Office | Intervention |
| 13/CEN/68 | Approve | Parenting Whispering: Parent-Child Interaction Therapy in New Zealand | Mrs Tania Anne Cargo |  |  | Intervention |
| 13/CEN/69 | Approve | Flixene Silver Registry | Mr Thodur Vasudevan |  | Jan Adams, COO | Intervention |
| 13/CEN/70 | Approve | A study to investigate the duration of the effects of an investigational treatment for asthma on lung function | Professor Richard Beasley | Dr James Fingleton,Dr Sharon Power | CCDHB,Medical Research Institute of New Zealand | Intervention |
| 13/CEN/71 | Approve | The effect of remote ischaemic preconditioning on the late immune response and nervous system. | Ms Jenni Williams | Associate Professor Anne Camille La Flamme |  | Intervention |
| 13/CEN/72 | Approve | Effect of early exercise engagement on the health of stroke patients | Dr James Faulkner | Dr Anna Pilbrow,Dr Danielle Lambrick,Dr Lee Stoner,Dr. Jeremy Lanford,Dr Yu-Chieh Tzeng | CCDHB,University of Otago Wellington (Authorised by William Levack) | Intervention |
| 13/CEN/77 | Approve | Management of xerostomia following radiotherapy. | Dr Olivia Apperley |  |  | Intervention |
| 13/CEN/78 | Approve | RELIEF Trial | Dr Felicity Pugh |  | Auckland District Health Board | Intervention |
| 13/CEN/81 | Approve | TOTAL Trial | Dr Gerard Devlin |  |  | Intervention |
| 13/CEN/82 | Approve | A Phase III study to assess the efficacy and safety of Lebrikizumab in patients with uncontrolled asthma. | Dr Irene Braithwaite |  | Auckland District Health Board,CDHB,Medical Research Institute of New Zealand,Professor Richard Stubbs, P3 Research | Intervention |
| 13/CEN/83 | Approve | A Phase III study to assess the efficacy and safety of Lebrikizumab in patients with uncontrolled asthma. | Dr Ben D.J Brockway |  | Dr Dean Quinn P3 Research Wellington unit,Health Research South,NZRSI Dr A G Veale,RMC Medical Research | Intervention |
| 13/CEN/84 | Approve | An assessment of how the new psoriasis medicine Brodalumab is processed by the body when taken by men and women with psoriasis. | Dr Christian Schwabe |  | Auckland Clinical Studies Limited,Chris Taylor, CCST | Intervention |
| 13/CEN/86 | Approve | Tibolone 1 x 2.5 mg bioequivalence study conducted under fasting conditions | Dr Noelyn Hung |  |  | Intervention |
| 13/CEN/9 | Approve | PF-00547659 versus placebo for ulcerative colitis (Protocol A7281009) | Dr Richard Gearry | Dr Michael Schultz,Dr Mark Lane,Dr Jim Brooker | CDHB Research Office,Dayle Matthews,Jan Adams, COO | Intervention |
| 13/CEN/97 | Approve | The TrACY Study | Associate Professor Sally N. Merry | Dr Ana Maria Ugueto,Dr Chris Frampton,Dr Mathijs Lucassen,Dr Ainsleigh Cribb-Su'a,Dr. Jennifer Herren,Dr Jik Loy,Professor John Weisz,Dr Karolina Stasiak,Dr Monique Faleafa,Assistant Professor Sarah Kate Bearman,Dr Sue Crengle | CCDHB,Dr Michael Roberts, Chief Medical Officer, Northland District Health Board,Jan Adams, COO,Waitemata DHB | Intervention |

## Applications reviewed by expedited review

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| **Study reference** | **Study status** | **Short title** | **Co-ordinating Investigator** | **Other Investigators** | **Locality/ies** | **Application type** |
| 13/CEN/108 | Approve | Taking the best NRT direct to smokers | Dr Brent Caldwell |  | University of Otago Wellington (Authorised by William Levack) | Intervention |
| 13/CEN/122 | Approve | Phobic postural vertigo | Dr Stuart Mossman |  | CCDHB | Intervention |
| 13/CEN/136 | Approve | Medical Research Institute of New Zealand - Recruitment Tool |  |  |  | Observational |
| 13/CEN/138 | Approve | Te Waiata a Hinetitama | Dr Debra Tepora Emery |  | Heddell Raerino | Observational |
| 13/CEN/139 | Approve | Burden of Asthma and COPD in NZ | Dr Barry Gribben |  |  | Observational |
| 13/CEN/140 | Decline | Transforming & Healing Whānau Violence in Hauraki | Dr Stephanie Palmer |  |  | Observational |
| 13/CEN/15 | Approve | How’s it going? Youth Wellbeing Study 2012-2016: Stories of people working with youth | Associate Professor Marc Wilson |  |  | Observational |
| 13/CEN/157 | Provisionally approve | BASEL IX | Dr MARTIN THAN |  |  | Observational |
| 13/CEN/16 | Approve | Low carbohydrate diet vs carbohydrate counting in type 1 diabetes | Dr Amber Parry Strong | Dr Jeremy Krebs | CCDHB | Intervention |
| 13/CEN/160 | Approve | The Glenn Inquiry | Associate Professor Denise Wilson |  |  | Observational |
| 13/CEN/164 | Approve | Does lycopene bioavailability improve in tomatoes with novel lycopene compounds? | Dr Kerry Bentley-Hewitte |  |  | Intervention |
| 13/CEN/165 | Approve | Oculeve Nasal Stimulator Study | Dr Dean Corbett | Mr Ernest Smolej,Dr Jennifer Craig,Mr Nicholas Mathew | Auckland Eye,Fendalton Eye Clinic,Mr Nicholas J Mathew,Prof Charles McGhee HOD, Dept of Ophthalmology, University of Auckland | Intervention |
| 13/CEN/166 | Approve | Kraft data analysis | Mrs Catherine Crofts |  |  | Observational |
| 13/CEN/169 | Provisionally approve | Effect of fruit on physical fitness and innate immunity | Dr Suzanne Hurst |  | Jocelyn Eason, General Manager Science Food Innovation, Plant & Food Research,Waikato Institute of Technology | Intervention |
| 13/CEN/189 | Provisionally approve | The TRICS-III study | Dr Paul Poung |  | CCDHB | Intervention |
| 13/CEN/194 | Provisionally approve | Psoriasis and Geothermal Water Investigation | Mr Peter Sharplin |  |  | Intervention |
| 13/CEN/195 | Provisionally approve | Parents' and children's reactions to testing for genetic risk of diabetes | Dr Nikki Kerruish |  |  | Observational |
| 13/CEN/202 | Approve | (duplicate) Transforming & Healing Whānau Violence in Hauraki | Dr Stephanie Palmer |  |  | Observational |
| 13/CEN/203 | Provisionally approve | Exercise, Chronic Fatigue Syndrome and Multiple Sclerosis | Dr Lynette Hodges |  | S Stannard | Intervention |
| 13/CEN/21 | Approve | Pilot trial: Retinal blood flow imaging using biospeckle | Professor Anthony Wells |  |  | Intervention |
| 13/CEN/211 | Approve | Effect of leg position on venous flow in patients undergoing endoscopic surgery | Dr Stephen Coppinger |  | Dr Kenneth Clark | Intervention |
| 13/CEN/22 | Approve | Chewing the facts on fat! | Dr Ridvan Firestone |  |  | Observational |
| 13/CEN/29 | Approve | Glutathione peroxidase system and stable coronary disease | Dr Scott Harding | Ms Lisa Johnston | CCDHB | Observational |
| 13/CEN/34 | Approve | Structural Magnetic Resonance Imaging (MRI) in individuals with aphasia | Dr Carolyn Wilshire |  | James Entwisle, Radiology CCDHB | Observational |
| 13/CEN/35 | Approve | Treatment of Substance Use Disorders | Dr Giles Newton-Howes |  | Sally Houliston on behalf of HBDHB | Observational |
| 13/CEN/47 | Approve | The Effect of Berryfruit Extract on Asthma | Dr James Fingleton | Doctor sharon power | Medical Research Institute of New Zealand | Intervention |
| 13/CEN/51 | Approve | Promoting health literacy on cardio-vascular diseases (CVD) to improve health outcomes for Samoan people | Mrs Tua Taueetia-Su'a |  |  | Observational |
| 13/CEN/52 | Approve | Anatomical variation and MR imaging features of the tibiofibular interosseous ligament | Dr James Campbell |  | Auckland District Health Board | Observational |
| 13/CEN/59 | Approve | Topical diclofenac and imiquimod in treatment of periocular actinic keratosis | Dr Andrea Zarkovic |  |  | Intervention |
| 13/CEN/60 | Approve | Acupuncture for Dysmenorrhea | Mr Mike Armour | Dr Caroline Smith,Professor Hannah Dahlen,Professor Cindy Farquhar,Dr Xiaoshu Zhu | Mike Armour,Mike Armour - Auckland Investigator | Intervention |
| 13/CEN/79 | Approve | The composition of breast milk according to different ethnicities of individuals living in New Zealand | Dr Christine Butts | Ms Hannah Smith,Dr Juliet Ansell,Ms Sarah Eady,Mrs Sheridan Martell | Dr Jocelyn Eason, General Manager Food Innovation, Plant and Food Research | Observational |
| 13/CEN/80 | Approve | Communication in the hospital ward | Dr Craig Webster | A/Prof Andy Wearn,Associate Professor Jennifer Weller,Senior Lecturer Marcus Henning,Dr Papaarangi Reid |  | Observational |
| 13/CEN/85 | Approve | Cognitive Function during exacerbations of Chronic Obstructive Pulmonary Disease (COPD) | Dr Justin Travers |  | Cate Tyrer, Quality & Risk Manager | Observational |
| 13/CEN/91 | Approve | The effect of a formulated honey in type 2 diabetes. | Dr Jeremy Krebs | Dr Amber Parry Strong | CCDHB | Intervention |
| 13/CEN/93 | Approve | Neonatal pneumococcal disease | Dr Emma Best |  |  | Observational |
| 13/CEN/95 | Approve | Patient comfort after heart surgery | Mrs Cynthia Wensley |  | Auckland District Health Board | Observational |
| 13/CEN/96 | Approve | Addressing the burden and preventability of severe acute maternal morbidity | Associate Professor Beverley Lawton |  | CCDHB,Dr Kenneth Clark,Health Research South,Jan Adams, COO,Research Office, Hawke's Bay District Health Board | Observational |
| 13/CEN/99 | Approve | New Zealand Smoking Monitor (NZSM) | Judy Li |  |  | Observational |

## Minimal dataset form applications

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| **Study reference** | **Study status** | **Short title** | **Co-ordinating Investigator** | **Other Investigators** | **Locality/ies** | **Application type** |
| 99/R-4 | Approve | International Bone Marrow Transplant Registration | Associate Professor John Carter | n/a |  | Intervention |
| AKY/03/03/065 | Approve | THE NEW ZEALAND MENTAL HEALTH SURVEY | Professor Mark Oakley Browne | n/a |  | Intervention |
| CEN/06/02/006 | Approve | Older Maori and Medicine | Mr Bevan Clayton-Smith | n/a |  | Intervention |
| CEN/07/12/082 | Approve | Discipline, Guidance and Punishment | Ms Patricia Thompson | n/a |  | Intervention |
| CEN/07/12/086 | Approve | DCV TMZ GBM trial | Dr David Hamilton | n/a |  | Intervention |
| CEN/08/02/EXP | Approve | Access to Rheumatology Services in the Greater Wellington Region | Ms Valerie Milne | n/a |  | Intervention |
| CEN/08/03/008 | Approve | A Qualitative study to explore factors which may impact the effectiveness of interventions provided by the Psycho-Oncology Service at Massey University. | Mrs Colette Nixon | n/a |  | Intervention |
| CEN/08/09/044 | Approve | Wahine Hauora - Inequalities in Uterine Cancer | Associate Professor Beverley Lawton | n/a |  | Intervention |
| CEN/09/04/07 | Invalid Application | Tenofovir plus Pegylated Interferon in Chronic Hepatitis B | Prof Ed Gane | n/a |  | Intervention |
| CEN/09/08/EXP | Approve | Infective Endocarditis in New Zealand Children 1992-2008 | Dr Rachel Webb | n/a |  | Intervention |
| CEN/09/10/072 | Approve | Brain blood flow control study | Dr Shieak YC Tzeng | n/a |  | Intervention |
| CEN/09/11/081 | Approve | Link between bone health and cardiovascular disease in post-menopausal women | Mr Dean Rankin | n/a |  | Intervention |
| CEN/09/47/EXP | Approve | Alcohol related Harm | Mr Zhi-ling (Jim) Zhang | n/a |  | Intervention |
| CEN/10/05/017 | Approve | Comparison of DIST versus euglycaemic hyperinsulinaemic clamp | Professor Richard Stubbs | n/a |  | Intervention |
| CEN/10/09/036 | Approve | 'E Hine' -Barriers to access to care for pregnant Maori women <20 | Associate Professor Beverley Lawton | n/a |  | Intervention |
| CEN/10/10/050 | Approve | Randomised controlled trial of Nicotine Inhaler and nicotine patch for smoking cessation in highly nicotine dependent smokers | Professor Julian Crane | n/a |  | Intervention |
| CEN/10/EXP/04 | Approve | An audit of uterine biopsy laboratory results | Associate Professor Beverley Lawton | n/a |  | Intervention |
| CEN/11/03/015 | Approve | Effect of the rehabilitation setting on motivation post stroke - a pilot study | Associate Professor Will Taylor | n/a |  | Intervention |
| CEN/11/04/026 | Approve | Pilot study of gastric bypass surgery in non-obese individuals with type 2 diabetes | Professor Richard Stubbs | n/a |  | Intervention |
| CEN/11/06/031 | Approve | AMPLE Study | Dr Sharon Power | n/a | CCDHB,Dr Samantha Everitt (CMDHB) | Intervention |
| CEN/11/06/031 | Approve | A Study to Compare Two Procedures for Symptom Relief | Dr Nicola Smith | n/a |  | Intervention |
| CEN/11/07/035 | Approve | Memory aids after traumatic brain injury | Miss Hannah Bos | n/a |  | Intervention |
| CEN/11/09/045 | Approve | Nationwide SUDI Case-control Study | Professor Edwin Mitchell | n/a |  | Intervention |
| CEN/11/09/055 | Approve | A novel approach to caries management in New Zealand children | Dr Lyndie Foster Page | n/a |  | Intervention |
| CEN/11/09/056 | Approve | Biomarker discovery in colorectal cancer | Professor Richard Stubbs | n/a |  | Intervention |
| CEN/11/11/060 | Invalid Application | Enhancing Postural Adjustments After Stroke | Dr James Stinear | n/a |  | Intervention |
| CEN/11/12/074 | Approve | High Concentration Oxygen in Fibrotic Lung Disease | Dr Janine Pilcher | n/a |  | Intervention |
| CEN/11/12/076 | Approve | Sleep and circadian rhythm disruption in kidney donar patients | Dr Andrew Kennedy-Smith | n/a |  | Intervention |
| CEN/11/EXP/002 | Approve | The Blue Brain : The Effects of Hemispheric Asymmetry in Depression on Working Memory | Miss Kathryn Campbell | n/a |  | Intervention |
| CEN/11/EXP/051 | Approve | Investigation of a Panel of Proteins Novel Prognostics Markers for Colorectal Cancer | Professor Richard Stubbs | n/a |  | Intervention |
| CEN/11/EXP/076 | Approve | COMMEND-study: | Ms Natasja JH Raijmakers | n/a |  | Intervention |
| CEN/11/EXP/081 | Approve | Delivery outcomes of macrosomia based on customised birth weight centiles | Dr Nicola Dykes | n/a |  | Intervention |
| CEN/12/04/008 | Approve | Ultrasound assessment of uterine cavity length in women who are breastfeeding vs. women who are not breastfeeding | Dr Helen Paterson | n/a |  | Intervention |
| CEN/12/06/027 | Approve | How do we know what we're doing works? Evaluating Kapiti Youth Support | Ms Robyn Bailey | n/a |  | Intervention |
| CEN/12/06/029 | Invalid Application | The PROGNOSIS Study | Dr Joanna Gullam | n/a |  | Intervention |
| CEN/12/06/029 | Approve | PROGNOSIS | Dr. Peter Abels | n/a |  | Intervention |
| CEN/12/EXP/003 | Approve | Relationships in Palliative Care | Mr Michael Barry O'Donnell Keane | n/a |  | Intervention |
| CEN/12/EXP/012 | Approve | The values of nurses working in New Zealand medical ward environments | Mrs Mary Helen Rook | n/a | Hutt Valley DHB | Intervention |
| CEN/12/EXP/030 | Approve | Open label use of tissue plasminogen activator (tPA) and DNase in the treatment of pleural infection | Dr Nicola Smith | n/a |  | Intervention |
| CEN/12/EXP/035 | Approve | Ethical Climate - An Exploratory Study | Ms Anne Humphries | n/a |  | Intervention |
| CEN/12/EXP/036 | Approve | Nutritional management of paediatric oncology patients with acute lymphoblastic leukaemia (ALL) in a shared care centre | Dr Varsha Gandhi | n/a |  | Intervention |
| CNE/12/Exp/012 | Invalid Application | The values of nurses working in New Zealand medical ward environments | Mrs Mary Helen Rook | n/a |  | Intervention |
| LRS/10/07/032 | Approve | Well-LaD Study | Assoc. Professor Jane Coad | n/a |  | Intervention |
| LRS/11/EXP/026 | Approve | Unidentified Viruses in Gastrointestinal Disease Outbreaks | Dr Richard Hall | n/a |  | Intervention |
| MEC/05/09/108 | Invalid Application | PPROMT | Professor Jonathan Morris | n/a |  | Intervention |
| MEC/06/08/090 | Approve | VEG107769 | Dr Anne O'Donnell | n/a |  | Intervention |
| MEC/07/06/078 | Invalid Application | A study to evaluate the safety and efficacy of golimumab versus placebo in people with Ulcerative Colitis | Dr James Brooker | n/a |  | Intervention |
| MEC/07/062 | Invalid Application | Warm Homes for elder New Zealanders (WHEZ) | Prof Philippa Howden-Chapman | n/a |  | Intervention |
| MEC/08/03/030 | Approve | CO20 | Dr Garry Forgeson | n/a |  | Intervention |
| MEC/08/03/032 | Approve | 6 months total androgen ablation + external beam radiation therapy +/- Docetaxel | Professor David S. Lamb | n/a |  | Intervention |
| MEC/08/04/044 | Approve | DAL- outcomes | Dr Jocelyne Benatar | n/a |  | Intervention |
| MEC/08/08/095 | Approve | DAAAG | Professor Jonathan Golledge | n/a |  | Intervention |
| MEC/08/08/102 | Approve | Stomach cancer in Maori | Dr Lis Ellison-Loschmann | n/a |  | Intervention |
| MEC/09/02/010 | Approve | BM07 | DR Alwyn D'Souza | n/a |  | Intervention |
| MEC/09/02/018 | Approve | The R-100 ITP study | Dr. Kenneth Romeril | n/a |  | Intervention |
| MEC/09/07/075 | Approve | A study to evaluate levodopa-carbidopa intestinal gel in People with Parkinson's disease. | Prof Tim Anderson | n/a |  | Intervention |
| MEC/09/11/122 | Approve | Nature and Extent of Informal Coercion | Prof Sunny Collings | n/a |  | Intervention |
| MEC/10/01/003 | Approve | Media Influences on Self-harm among Young Men | Mrs Susan Knox | n/a |  | Intervention |
| MEC/10/01/012 | Invalid Application | A study of a new drug compared to Formoterol Fumarate in patients with severe Chronic Obstructive Pulmonary Disease | Professor Richard Beasley | n/a |  | Intervention |
| MEC/10/055/EXP | Approve | Pacific mental health intervention | Dr Karlo Mila-Schaaf | n/a |  | Intervention |
| MEC/10/08/083 | Invalid Application | Neurotoxic Effects of Occupational solvent exposure | Prof Jeroen Douwes | n/a |  | Intervention |
| MEC/10/10/103 | Approve | New Zealand Health Survey (or NZHS) | Bridget Murphy | n/a |  | Intervention |
| MEC/10/11/109 | Invalid Application | Trial of a brief treatment for common mental health syndromes in primary care | Ms Fiona Mathieson | n/a |  | Intervention |
| MEC/11/01/003 | Approve | A study to investigate the treatment of pneumothorax | Dr Kyle Perrin | n/a | Auckland District Health Board,University of Otago | Intervention |
| MEC/11/02/020 | Approve | Mixed Presenters in emergency departments | Ms Silke Kuehl | n/a |  | Intervention |
| MEC/11/04/040 | Approve | Long term follow up on metabolic characteristics and nutritional aspects following gastric bypass surgery compared with a non surgical group. | Dr Jeremy Krebs | n/a |  | Intervention |
| MEC/11/04/043 | Approve | A case-control study on human illness of E. coli in New Zealand | Prof. Nigel P. French | n/a |  | Intervention |
| MEC/11/12/098 | Approve | KH01 A Pilot Study of Topical honey for the treatment of Eczema | Dr James Fingleton | n/a |  | Intervention |
| MEC/11/EXP/041 | Approve | Te Whare Io programme evaluation | Mrs Joanne Rosandich | n/a |  | Intervention |
| MEC/11/EXP/076 | Approve | Family carers doing technical health procedures at home - their learning experiences | Ms Janet McDonald | n/a |  | Intervention |
| MEC/12/03/021 | Approve | MOBI-KIDS New Zealand | Dr Andrea Mannetje | n/a | Auckland District Health Board | Intervention |
| MEC/12/03/022 | Approve | KH02 A Pilot Study of Topical honey for the treatment of Psoriasis | Dr James Fingleton | n/a |  | Intervention |
| MEC/12/03/023 | Approve | KH03 A Pilot Study of Topical honey for the treatment of Nappy Rash | Dr James Fingleton | n/a |  | Intervention |
| MEC/12/03/024 | Approve | KH04 A Pilot Study of Topical honey for the treatment of Cold Sores | Dr James Fingleton | n/a |  | Intervention |
| MEC/12/03/025 | Approve | KH05 A Pilot Study of Topical honey for the treatment of Rosacea | Dr James Fingleton | n/a |  | Intervention |
| MEC/12/06/059 | Approve | Does mutation help Candida albicans to cause disease? | Dr Jan Schmid | n/a | Auckland District Health Board,Health Research South (Ruth Sharpe) | Intervention |
| MEC/12/EXP/002 | Approve | The Empathy project | Dr Helen Moriarty | n/a |  | Intervention |
| MEC/12/EXP/012 | Approve | Comparison of core and peripheral temperature measurement in adult critically ill patients with brain injury and sepsis | Dr Paul Young | n/a |  | Intervention |
| MEC/12/EXP/017 | Approve | Late career nurses in New Zealand | Dr Jill Clendon | n/a |  | Intervention |
| MEC/12/EXP/046 | Approve | National Retrospective Audit of peri-natal outcomes | Associate Professor Beverley Lawton | n/a |  | Intervention |
| MEC/12/EXP/047 | Approve | Family carers doing technical health procedures at home - their learning and experiences | Ms Janet McDonald | n/a |  | Intervention |
| MEC/12/EXP/051 | Approve | An audit of temperature regulation in intensive care patients with traumatic brain injury in Australia and New Zealand (CLARITY) | Dr Paul Young | n/a |  | Intervention |
| MEC/12/EXP/052 | Approve | Early Activity and Mobility in the Intensive Care Unit (The TEAM Study) | Dr Paul Young | n/a |  | Intervention |
| MEC/12/EXP/053 | Approve | Business Practices in the Health Sector | Professor David Crick | n/a |  | Intervention |
| MEC/12/EXP/065 | Approve | Testicular cancer and cryptorchidism | Dr Jason Gurney | n/a |  | Intervention |
| MEC/12/EXP/066 | Approve | The Wahakura: A qualitative study of the flax bassinet as a safe infant. The Wahakura Qualitative Study | Dr Sally Abel | n/a |  | Intervention |
| MEC09/11/122 | Invalid Application | Nature and Extent of Informal Coercion | Ms Nandika Currey | n/a |  | Intervention |
| NTX/10/04/029 | Approve | Constructing the lives of 'care recipients' under the Intellectual Disability (Compulsory Care and Rehabilitation) Act 2003: a discourse analysis | Ms Amanda Smith | n/a |  | Intervention |
| NTY/08/09/090 | Approve | SPIRIT-ICD | Dr Spencer Heald | n/a |  | Intervention |
| NTY/10/11/090 | Invalid Application | Aged Residential Care Healthcare Utilization Study (ARCHUS)Phase 2 | Professor Martin Connolly | n/a |  | Intervention |
| NTY/12/01/008 | Approve | The Airvo Device and Oxygen Administration in Chronic Obstructive Pulmonary Disease | Professor Richard Beasley | n/a |  | Intervention |
| NTY/12/05/033 | Approve | HRC 11/793 He Kokonga Whare: Maori Intergenerational Trauma and Healing | Dr Paul Reynolds | n/a |  | Intervention |
| NTY/12/05/041 | Approve | Evaluation of PCR assays of blood versus CSF for three common causes of meningitis | Dr Mary Nulsen | n/a |  | Intervention |
| URA/12/02/003 | Approve | Fall prevention using metronomes in PD | Professor Mark Weatherall | n/a |  | Intervention |
| URA102/02/03 | Invalid Application | Fall prevention using metronomes in PD | Professor Mark Weatherall | n/a |  | Intervention |
| URA12/02/003 | Invalid Application | Fall prevention using metronomes in PD | Professor Mark Weatherall | n/a |  | Intervention |
| WGT/00/04/030 | Approve | Search for a humoral factor causing insulin resistance and type 2 diabetes | Professor Richard Stubbs | n/a |  | Intervention |
| WGT/00/09/111 | Approve | TROG 99.03 | Dr Carol Johnson | n/a |  | Intervention |
| WGT/02/02/002 | Approve | Phase III trial of an immunotherapy for Stage III (AJCC) melanoma based on cultured autologous dendritic cells presenting autologous tumour cell antigens | Dr Carol Johnson | n/a |  | Intervention |
| WGT/03/12/126 | Approve | The New Zealand breast cancer study | Dr Lis Ellison-Loschmann | n/a |  | Intervention |
| WTG/00/05/044 | Approve | CO-7 | Dr Andrew Simpson | n/a |  | Intervention |
| 02/02/002 | Invalid Application | Phase III trial of an immunotherapy for Stage III (AJCC) melanoma based on cultured autologous dendritic cells presenting autologous tumour cell antigens | Dr Carol Johnson | n/a |  | Intervention |

## Overdue full applications

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| --- | --- | --- | --- |
| **Reference** | **Short Title** | **Days overdue** | **Reason** |
| 13/CEN/10 | Open-Label study to assess safety of PF-00547659 for Ulcerative Colitis (Protocol A7281010) | 3 | Committee Response Overdue |
| 13/CEN/102 | Amgen 416 H2H Study | 9 | Committee Response Overdue |
| 13/CEN/103 | Laboratory production and functional studies on Mesenchymal Stromal Cells | 9 | Committee Response Overdue |
| 13/CEN/106 | Identity in a community rehabilitation service for acquired brain injury | 1 | Committee Response Overdue |
| 13/CEN/118 | Investigation of the use of Manuka honey to treat rosacea | 1 | Committee Response Overdue |
| 13/CEN/119 | Investigation of the use of Manuka honey to treat Acne | 1 | Committee Response Overdue |
| 13/CEN/120 | Investigation of the use of Manuka honey to treat Nappy Rash | 1 | Committee Response Overdue |
| 13/CEN/132 | Stressors and autoregulation | 4 | Committee Response Overdue |
| 13/CEN/133 | Safety study of PF582 versus Lucentis in patients with age-related macular degeneration | 7 | Committee Response Overdue |
| 13/CEN/135 | Cognitive stimulation using exer-games (Able-X) for people with dementia | 10 | Committee Response Overdue |
| 13/CEN/144 | Beneficial effects of food on human health | 10 | Committee Response Overdue |
| 13/CEN/162 | COG ALTE07C1 - Neuropsychological, Social, Emotional, and Behavioural Outcomes in Children with Cancer | 5 | Public Holidays |
| 13/CEN/163 | COG ACNS0822 | 19 | Public Holidays |
| 13/CEN/175 | BRAin Injury and NeuroAid Supplementation (BRAINS) | 4 | Public Holidays |
| 13/CEN/177 | “A study comparing how fast the trial drug GS-5816 is cleared from the body, in healthy adults and in adults with severely reduced kidney function” | 16 | Public Holidays |
| 13/CEN/183 | Transfer from Methadone to Buprenorphine | 11 | Public Holidays |
| 13/CEN/25 | Tivantinib vs Placebo for the treatment of Inoperable Hepatocellular Carcinoma | 15 | Committee Response Overdue |
| 13/CEN/40 | Preoperative anxiety in children | 34 | Committee Response Overdue |
| 13/CEN/44 | Assessment of the trial drug ledipasvir, when taken by healthy adults and by adults with severely reduced kidney function | 6 | Committee Response Overdue |
| 13/CEN/61 | SIRROUND T | 1 | Committee Response Overdue |
| 13/CEN/64 | REnal SymPathECTomy in Heart Failure (RESPECT-HF) | 8 | Committee Response Overdue |
| 13/CEN/65 | Hospital readmission after Neonatal Intensive Care | 4 | Committee Response Overdue |
| 13/CEN/67 | LCH-IV | 8 | Committee Response Overdue |
| 13/CEN/69 | Flixene Silver Registry | 25 | Committee Response Overdue |
| 13/CEN/70 | A study to investigate the duration of the effects of an investigational treatment for asthma on lung function | 2 | Committee Response Overdue |
| 13/CEN/77 | Management of xerostomia following radiotherapy. | 11 | Committee Response Overdue |

## Overdue expedited applications

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| --- | --- | --- | --- |
| **Study reference** | **Short title** | **Days Overdue** | **Reason** |
| 13/CEN/122 | Phobic postural vertigo | 9 | Committee Response Overdue |
| 13/CEN/138 | Te Waiata a Hinetitama | 8 | Committee Response Overdue |
| 13/CEN/15 | How’s it going? Youth Wellbeing Study 2012-2016: Stories of people working with youth | 2 | Committee Response Overdue |
| 13/CEN/16 | Low carbohydrate diet vs carbohydrate counting in type 1 diabetes | 14 | Committee Response Overdue |
| 13/CEN/164 | Does lycopene bioavailability improve in tomatoes with novel lycopene compounds? | 18 | Committee Response Overdue |
| 13/CEN/165 | Oculeve Nasal Stimulator Study | 10 | Committee Response Overdue |
| 13/CEN/202 | (duplicate) Transforming & Healing Whānau Violence in Hauraki | 18 | Public Holidays |
| 13/CEN/211 | Effect of leg position on venous flow in patients undergoing endoscopic surgery | 12 | Public Holidays |
| 13/CEN/29 | Glutathione peroxidase system and stable coronary disease | 2 | Committee Response Overdue |
| 13/CEN/34 | Structural Magnetic Resonance Imaging (MRI) in individuals with aphasia | 5 | Committee Response Overdue |
| 13/CEN/35 | Treatment of Substance Use Disorders | 2 | Committee Response Overdue |
| 13/CEN/47 | The Effect of Berryfruit Extract on Asthma | 6 | Committee Response Overdue |
| 13/CEN/51 | Promoting health literacy on cardio-vascular diseases (CVD) to improve health outcomes for Samoan people | 3 | Committee Response Overdue |
| 13/CEN/59 | Topical diclofenac and imiquimod in treatment of periocular actinic keratosis | 6 | Committee Response Overdue |
| 13/CEN/60 | Acupuncture for Dysmenorrhea | 4 | Committee Response Overdue |
| 13/CEN/79 | The composition of breast milk according to different ethnicities of individuals living in New Zealand | 32 | Committee Response Overdue |
| 13/CEN/80 | Communication in the hospital ward | 4 | Committee Response Overdue |
| 13/CEN/85 | Cognitive Function during exacerbations of Chronic Obstructive Pulmonary Disease (COPD) | 23 | Committee Response Overdue |
| 13/CEN/91 | The effect of a formulated honey in type 2 diabetes. | 18 | Committee Response Overdue |
| 13/CEN/93 | Neonatal pneumococcal disease | 8 | Committee Response Overdue |
| 13/CEN/95 | Patient comfort after heart surgery | 9 | Committee Response Overdue |
| 13/CEN/96 | Addressing the burden and preventability of severe acute maternal morbidity | 3 | Committee Response Overdue |
| 13/CEN/99 | New Zealand Smoking Monitor (NZSM) | 3 | Committee Response Overdue |