

Southern Health and Disability Ethics Committee

Annual Report  
2014

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# About the committee

The Southern 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 Southern 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 Southern HDEC is registered (number IRB00008713) 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

On behalf of the Southern HDEC, I am pleased to present this report, which provides a summary of the work and other activities undertaken by the committee.

2014 was another busy year for the committee.

The Southern HDEC has functioned very well with the new system and continuous information technology improvements will ensure it continues to meet our needs. We are grateful for the support from the Ministry of Health.

The Southern HDEC received 139 applications in 2014. 68 applications were reviewed by the full committee and 71 were reviewed through the expedited pathway. We also reviewed 767 post approval items (amendments, annual progress reports, protocol deviations/violations, notifications of conclusion of study).

The Southern HDEC has an outstanding group of people with a wide variety of professional expertise and I am grateful for the significant work undertaken by them. Ethical review is often challenging and the sincerity and integrity with which each member has applied themselves has been greatly appreciated.

The Committee in particular would like to thank outgoing members Dr Martin Than and Ms Gwen Neave for their expertise and contribution to the Committee and welcome Associate Professor Mira Harrison-Woolrych and Dr Fiona McCrimmon who joined the committee in September.

****

Raewyn Idoine

Chairperson

Southern Heath and Disability Ethics Committee

# Membership and attendance

No meetings were postponed or cancelled due to inability to make quorum. Two members were appointed during 2014, and two members’ terms expired.

## Membership

### Lay members

|  |  |
| --- | --- |
| Ms Raewyn Idoine (Chair) | |
| Membership category: | Consumer representative |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2015 |

Ms Raewyn Idoine is a director of the NZ Blood Service. Her recent roles include Stakeholder Engagement Manager for the Tertiary Education Commission (2007-2009) and Owner/Manager of a number of large private Tertiary institutions. Ms Idoine was registered as a Nurse at Auckland Public Hospital (1976). Other positions she has undertaken include: Judge of the New Zealand Hospitality Awards (2004-2007), Head Assessor of the New Zealand Tourism Awards (1999-2006) and member of the Ministry of Education Tertiary Advisory Group (1996-2004).

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| **Dr Fiona McCrimmon** | |
| Membership category: | Lay/legal |
| Date of appointment: | 1 September 2014 |
| Current term expires: | 1 September 2015 |

Dr Fiona McCrimmon is Principal of McCrimmon Law, a firm specialising in healthcare law (2003-present). She is a member of the New Zealand Law Society Health Law Committee (2008-present) and was previously a Deputy Chair of the Health Practitioners Disciplinary Tribunal (2004-2007) and a member of the Auckland District Law Society Mental Health and Disability Law Committee (2011). Dr McCrimmon holds a Bachelor of Medicine and Bachelor of Surgery from the University of Otago (1994) and a Bachelor of Law (Hons) from the University of Auckland (1981).

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| **Mrs Angelika Frank-Alexander** | |
| Membership category: | Community representative |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2014 |

Mrs Angelika Frank-Alexander is currently a property manager with the Christchurch Rudolph Steiner School (2006-present). Prior to this she was the Owner/Manager of a restaurant in Christchurch (1994-2002) and a manager of an island resort in the Kingdom of Tonga (1982-1994). Mrs Frank-Alexander is currently the President of the German Society of Canterbury (2003 to present). She was previously a school trustee (2004 to 2007) and a Board member of the Canterbury Playcentre Association (2000 to 2002). Mrs Frank-Alexander was appointed a Justice of the Peace in 2006.

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| Ms Gwen Neave | |
| Membership category: | Consumer/Community perspectives |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2014 |

Gwen is a Marriage, Funeral and Civil Union Celebrant. She was made a Director of Sister Cities New Zealand earlier this year and is a long serving member of the Southland District Council Friendship Committee. Gwen chairs Toi Rakiura Arts Trust Stewart Island, and is the local Victim Support Co-ordinator. She serves on the Southland Museum and Art Gallery Board and the Venture Southland Trust.

### Non-Lay members

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| --- | --- |
| Dr Sarah Gunningham | |
| Membership category: | Intervention studies |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2015 |

Dr Sarah Gunningham is currently a Postdoctoral Fellow at the University of Otago (2008-present). Prior to this she was an Assistant Research Fellow and PhD student at the University of Otago (1996-2008). Dr Gunningham completed a PhD at the University of Otago (2008), a Master of Science at the University of Otago (2003) and a Bachelor of Science at the University of West of England (1995). She was registered as a General Nurse at Royal United Hospital (1982) and worked as a nurse 1982-1996 completing a Diploma of Nursing at London University (1986) and Certificates of Teaching and Assessing in Clinical Practice (1989), and General Intensive Care (1987) at the Bristol and Weston School of Nursing. Dr Gunningham has published one book, 15 refereed journal articles and presented papers at six conference proceedings.

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| Associate Professor Mira Harrison-Woolrych | |
| Membership category: | Intervention studies |
| Date of appointment: | 1 September 2014 |
| Current term expires: | 1 September 2015 |

Dr Harrison-Woolrych is the former director of the Intensive Medicines Monitoring Programme for the Department of Preventative and Social Medicine, University of Otago. She has extensive research experience in pharmacovigilance and pharmacoepidemiology and is a former member of the executive of the International Society of Pharmacovigilence (2009-2012) and the Medicines Assessment Advisory Committee (2003-2011). Dr Harrison-Woolrych holds a Bachelor of Medicine (1989), Doctor of Medicine (1995) University of Southhampton, and is a Fellow of the Royal College of Obstetricians and Gynaecologists.

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| Dr Nicola Swain | |
| Membership category: | Health researcher |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2014 |

Dr Nicola Swain is currently a Senior Lecturer at the University of Otago (2007-present). Prior to this she was a Research Fellow with the Christchurch Health and Development Study. She has completed a Doctor of Philosophy (1998) and a Bachelor of Science, with honours (1994) at the University of Otago. Dr Swain holds professional memberships with the Centre for Applied Positive Psychology, the International Positive Psychology Association and the New Zealand Pain Society. Dr Swain specialises in health psychology and pain research. She has published over 20 refereed journal articles and regularly contributes to conferences. She teaches Health Psychology and Pain to medical students at the Dunedin School of Medicine. She also supervises students studying for PhDs, Masters and summer research projects in fields such as doctor-patient communication, child well-being, child-birth satisfaction and on-line interventions for pain.

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| **Dr Martin Than** | |
| Membership category: | Intervention studies |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2014 |

Dr Martin Than is currently a Consultant Specialist in Emergency Medicine at Christchurch Public Hospital and a Senior Clinical Lecturer at the University of Otago (2001-present). Prior to this he was the Co-Director of the Clinical Decision Support Unit (2003-2006). Dr Than was made a Fellow of the Royal College of Surgeons of Edinburgh in Accident and Emergency, the Faculty of Accident and Emergency Medicine United Kingdom and the Australasian College of Emergency Medicine. He completed a Post Graduate Certificate in Research Methods in Health Care at the University of Exeter (2003) and a Bachelor of Medicine and Surgery at the University of London (1991). In 2010 the Health Research Council awarded Dr Than the inaugural Beaven Medal for excellence in translational research.

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| **Dr Devonie Waaka** | |
| Membership category: | Health researcher |
| Date of appointment: | 1 July 2013 |
| Current term expires: | 1 July 2016 |

Dr Waaka graduated in medicine from the University of Otago in 1996. She worked as a medical registrar for a number of years, developing an interest in nephrology and rheumatology, before joining an early phase clinical trials unit as a research physician in 2004. Over the past decade she has been involved in the planning and implementation of numerous early phase trials in New Zealand and Australia. In 2011 Devonie completed a Master of Medical Science in Drug Development from the University of New South Wales. In addition to her clinical duties, Dr Waaka has been on the teaching staff for the Pharmaceutical Medicine and Drug Development Master Program, University of New South Wales (2012 – present).

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| Dr Mathew Zacharias | |
| Membership category: | Health/disability service provision |
| Date of appointment: | 1 July 2012 |
| Current term expires: | 1 July 2015 |

Dr Mathew Zacharias is currently a Specialist Anaesthetist at Southern District Health Board (1989-present) and is also a Clinical Senior Lecturer at the University of Otago (1989-present). Prior to this he was a Specialist Anaesthetist at Southland District Health Board (1985-1989). Dr Zacharias completed a Postgraduate Diploma in Public Health at the University of Otago (2005) and was made a Fellow of the Australian and New Zealand College of Anaesthetists (1992) and a Fellow of the Faculty of Anaesthetists, Royal Australasian College of Surgeons (1991). He was also made a Fellow of the Royal College of Anaesthetists (1991), completed a Doctor of Philosophy at Queen’s University of Belfast (1979) and was made a Fellow of the Faculty of Anaesthetists of the Royal College of Surgeons (1976). Dr Zacharias also completed a Master of Surgery (Anaesthesia) at Guru Nanak University (1971) and a Bachelor of Medicine and Bachelor of Surgery at the University of Kerala (1968). He is on the Editorial Board of the Cochrane Anaesthesia Review Group (2001 – present). Dr Zacharias has published over 20 refereed journal articles and four book chapters.

### Former Members

|  |  |  |
| --- | --- | --- |
| Dr Martin Than (1 July 2014) | | |
| Membership category: | | Intervention studies |
| Date of appointment: | | 1 July 2012 |
| Current term expired: | | 1 July 2014 |
| Ms Gwen Neave (1 July 2014) | | |
| Membership category: | Consumer/Community Perspectives | |
| Date of appointment: | 1 July 2012 | |
| Current term expired: | 1 July 2014 | |

## Attendance

The Southern HDEC held 10 meetings in 2014.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Members** | | | **Meetings** | | | | | | | | | | | | | **Total** | |
| Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec |  | |
| Lay members | Cn | Ms Raewyn Idoine |  | **✓** | **✓** | **✓** | ***A*** |  | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | 9/10 | |
| L | Dr Fiona McCrimmon |  |  |  |  |  |  |  |  | **✓** | **✓** | ***A*** | ***A*** | 2/4 | |
| Cn | Mrs Angelika Frank-Alexander |  | **✓** | **✓** | ***A*** | **✓** |  | ***A*** | **✓** | **✓** | ***A*** | **✓** | ***A*** | 6/10 | |
| Cn | Ms Gwen Neave |  | ***A*** | **✓** | ***A*** | ***A*** | ***A*** |  |  |  |  |  |  | 1/5 | |
| Cn | Mrs Helen Walker  co-opted from Central Committee |  |  |  | **✓** |  |  |  |  |  |  |  | **✓** | 2/2 | |
|  | Cm | Ms Susan Buckland  co-opted from Northern A Committee |  |  |  |  | **✓** |  |  |  |  |  |  |  | 1/1 | |
|  |  | Ms Michele Stanton  co-opted from Northern A Committee |  |  |  |  |  |  | **✓** |  |  |  |  |  | 1/1 | |
| Non-Lay | HR | Dr Nicola Swain |  | **✓** | ***A*** | **✓** | **✓** |  | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | 8/10 | |
| HR | Dr Martin Than |  | ***A*** | **✓** | ***A*** | ***A*** |  | ***A*** | **✓** |  |  |  |  | 2/6 | |
| HP | Dr Mathew Zacharias |  | **✓** | **✓** | **✓** | **✓** |  | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | 9/10 | |
| HR | Dr Sarah Gunningham |  | ***A*** | ***A*** | ***A*** | **✓** |  | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | 7/10 | |
| HR | Dr Devonie Waaka |  | **✓** | **✓** | ***A*** | **✓** |  | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | 8/10 | |
|  | HR | Dr Mira Harrison-Woolrych |  |  |  |  |  |  |  |  | **✓** | **✓** | **✓** | **✓** | 4/4 | |
|  | HR | Ms Stephanie Pollard co-opted from Northern B Committee |  |  |  | **✓** |  |  |  |  |  |  |  |  | 1/1 | |
|  | HR | Dr Patries Herst  co-opted from Central Committee |  |  |  |  |  |  | **✓** |  |  |  |  |  | 1/1 | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 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

New Southern Committee members attended an ethics training day in Auckland in October 2014.

## Chairpersons’ meetings

Ms Raewyn Idoine attended two Chairs’ day meetings in 2014. Both meetings were held in Wellington.

# Applications reviewed

The Southern HDEC reviewed 139 applications in 2014. From the 139 applications, 68 applications were reviewed by the full committee and 71 were reviewed through the expedited pathway.

|  |  |  |
| --- | --- | --- |
| Full | Approved | 57 |
| Declined | 0 |
| Provisional Approval (as at 31 December 2014) | 11 |
| *Total (with a decision at 31 December 2014)* | 68 |
| Expedited | Approved | 69 |
| Declined | 0 |
| Provisional Approval (as at 31 December 2014) | 2 |
| *Total (with a decision at 31 December 2014)* | 71 |
| **Total applications reviewed** | | **139** |

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

# Complaints and overdue applications

This section outlines complaints about decisions made by the Committee during 2014.

## Complaints received

The Southern Committee did not receive any complaints about the decision making process in 2014.

## Overdue review

During 2014 there were four instances where the review time was over 35 days for full applications and 17 where the review time was over 15 days for expedited applications.

See Appendix 1 for more information.

# Appendix 1: Details of applications reviewed[[1]](#footnote-1).

## Applications reviewed by full committee

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study reference | Study status | Short title | Co-ordinating investigator | Application type | Date application validated | Date of first decision | Provisional response received | Date of final decision |
| 14/STH/10 | Approve | A Study of IPI-145 and Ofatumumab in Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Previously Enrolled in Study IPI-145-07 | Dr Bart Baker | Intervention | 6/02/2014 |  | 9/04/2014 | 21/02/2014 |
| 14/STH/11 | Approve | A Study of IPI145 versus Ofatumumab to treat Patients with Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma | Dr Bart Baker | Intervention | 6/02/2014 |  | 9/04/2014 | 21/02/2014 |
| 14/STH/12 | Approve | Oraxol PK Study | Dr Christopher Jackson | Intervention | 6/02/2014 |  |  | 21/02/2014 |
| 14/STH/14 | Approve | Voriconazole 200 mg bioequivalence study conducted under fasting conditions | Dr Noelyn Hung | Intervention | 6/02/2014 |  |  | 21/02/2014 |
| 14/STH/7 | Approve | Innovative assessment of myocardial architecture in congenital heart disease | Dr. Beau Pontré | Observational | 6/02/2014 |  |  | 21/02/2014 |
| 14/STH/8 | Approve | Enzalutamide | Dr Peter Gilling | Intervention | 6/02/2014 | 21/02/2014 | 20/03/2014 | 21/03/2014 |
| 14/STH/20 | Approve | Developing a blood test for Parkinson's Disease | Dr Nick Cutfield | Observational | 6/03/2014 | 24/03/2014 | 4/04/2014 | 9/05/2014 |
| 14/STH/22 | Approve | Smoking status and cognition in patients with HD | Dr Chris Kenedi | Intervention | 6/03/2014 | 24/03/2014 | 12/06/2014 | 27/06/2014 |
| 14/STH/24 | Approve | A new nucleotide analog to suppress HCV infection | Professor Edward Gane | Intervention | 6/03/2014 |  |  | 24/03/2014 |
| 14/STH/25 | Approve | MK-8228-001: MK8228 vs. Placebo in Prevention of CMV infection in HSCT Recipients | Dr Andrew Butler | Intervention | 6/03/2014 | 24/03/2014 | 9/04/2014 | 30/04/2014 |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 14/STH/26 | Approve | HINT 2 | Dr Kathryn Williamson | Intervention | 6/03/2014 |  |  | 24/03/2014 |
| 14/STH/30 | Approve | LosmApimod To Inhibit p38 MAP kinase as a TherapeUtic target and moDify outcomes after an acute coronary syndromE (LATITUDE)-TIMI 60 | Prof Ralph Stewart | Intervention | 3/04/2014 |  |  | 28/04/2014 |
| 14/STH/35 | Approve | Mk5172-062: MK5172 and MK8742 in HepC patients on opiate substitution therapy | Prof Ed Gane | Intervention | 3/04/2014 | 24/04/2014 | 12/05/2014 | 12/05/2014 |
| 14/STH/36 | Approve | Assessment of single dose of the trial drug REGN1908-1909, in men and women allergic to cats. | Dr Richard Robson | Intervention | 3/04/2014 |  |  | 24/04/2014 |
| 14/STH/37 | Approve | Vado™ Steerable Sheath Clinical Study | Dr Ian Crozier | Intervention | 3/04/2014 |  |  | 24/04/2014 |
| 14/STH/39 | Approve | Subclinical Congenital Hypothyroidism | Professor Paul Hofman | Observational | 3/04/2014 | 24/04/2014 | 12/05/2014 | 28/05/2014 |
| 14/STH/40 | Approve | Tecemotide versus placebo in participants with unrespectable NSCLC | Dr Dean Harris | Intervention | 3/04/2014 | 24/04/2014 | 12/05/2014 | 14/05/2014 |
| 14/STH/41 | Approve | MK-5172 in Combination with MK-8742 with and without Ribavirin (RBV) in HCV Patients who Failed Prior Pegylated Interferon (peg- IFN) and RBV Treatment | Dr Alan David Pithie | Intervention | 3/04/2014 | 24/04/2014 | 9/05/2014 | 14/05/2014 |
| 14/STH/48 | Approve | PROTECT-ICD Trial | Dr Martin Stiles | Intervention | 8/05/2014 |  |  | 23/05/2014 |
| 14/STH/50 | Approve | Pacritinib in patients with thrombocytopaenia in Myelofibrosis | Dr Peter Ganly | Intervention | 8/05/2014 |  |  | 23/05/2014 |
| 14/STH/51 | Approve | Efficacy, safety and immunogenicity of BI 695501 versus adalimumab in patients with active rheumatoid arthritis | Dr Nigel Gilchrist | Intervention | 8/05/2014 |  |  | 23/05/2014 |
| 14/STH/53 | Approve | Darifenacin bioequivalence study conducted under fasting conditions | Dr Noelyn Hung | Intervention | 8/05/2014 | 23/05/2014 | 12/06/2014 | 19/06/2014 |
| 14/STH/54 | Approve | Darifenacin bioequivalence study conducted under fed conditions | Dr Noelyn Hung | Intervention | 8/05/2014 | 23/05/2014 | 12/06/2014 | 23/06/2014 |
| 14/STH/57 | Approve | A study to evaluate GS-9620 for the treatment of virally-suppressed subjects with chronic HBV | Professor Edward Gane | Intervention | 8/05/2014 |  |  | 23/05/2014 |
| 14/STH/73 | Approve | SErial biomArker profiling in tRansCoronary ablation of septal Hypertrophy: the SEARCH study | Dr John Lainchbury | Observational | 3/07/2014 | 18/07/2014 | 10/09/2014 | 24/09/2014 |
| 14/STH/86 | Approve | Comparison of mobile vs fixed bearing total ankle replacement | Mr Mathhew Tomlinson | Intervention | 3/07/2014 |  |  | 18/07/2014 |
| 14/STH/87 | Provisionally approve | Dasatinib versus Imatinib for Chronic Phase Chronic Myeloid Leukemia (CA 180399) | Dr Stephen Gibbons | Intervention | 3/07/2014 | 18/07/2014 |  |  |
| 14/STH/88 | Approve | Thiamine pre-CABG to improve stem cell function | Dr Michael Williams | Intervention | 3/07/2014 | 18/07/2014 | 6/10/2014 | 20/10/2014 |
| 14/STH/90 | Approve | Prematurity and Gut Microbiome | Prof. Wayne Cutfield | Observational | 3/07/2014 |  |  | 18/07/2014 |
| 14/STH/103 | Approve | DARE-C II | Professor Edward/EJG Gane | Intervention | 7/08/2014 |  |  | 21/08/2014 |
| 14/STH/104 | Approve | Efficacy and Safety of MEDI-551 in Subjects with Neuromyelitis Optica and Neuromyelitis Optica Spectrum Disorders | Dr Deborah Fleur Mason | Intervention | 7/08/2014 |  |  | 21/08/2014 |
| 14/STH/107 | Approve | Preparation in Capsule Endoscopy Study | Dr Gary Lim | Intervention | 7/08/2014 |  |  | 21/08/2014 |
| 14/STH/109 | Approve | Study of MK + Ipilimumab for advanced Melanoma | Dr Bernie Fitzharris | Intervention | 7/08/2014 | 21/08/2014 | 16/09/2014 | 1/10/2014 |
| 14/STH/110 | Approve | ENZARAD | Dr Stephen Williams | Intervention | 7/08/2014 | 21/08/2014 | 23/09/2014 | 9/10/2014 |
| 14/STH/112 | Approve | Demonstrating proof-of-concept for a continuous positive airway pressure (CPAP) breathing therapy mask | Doctor Andrew Veale | Intervention | 7/08/2014 | 21/08/2014 | 26/08/2014 | 8/09/2014 |
| 14/STH/113 | Approve | A study of how the body processes and clears Maxigesic® IV, following single doses in healthy adults | Dr Richard Robson | Intervention | 7/08/2014 |  |  | 21/08/2014 |
| 14/STH/115 | Approve | The Anorexia Nervosa Genetics Initiative (New Zealand) | Professor Martin Kennedy | Observational | 7/08/2014 | 21/08/2014 | 14/10/2014 | 23/10/2014 |
| 14/STH/119 | Approve | Neuromodulation as a treatment for alcohol addiction | Professor Dirk De Ridder | Intervention | 4/09/2014 | 22/09/2014 | 3/10/2014 | 6/10/2014 |
| 14/STH/128 | Approve | Human papilloma virus (HPV) associated oropharyngeal cell carcinoma (OPSCC): Case prevalence, diagnosis, and the potential for screening in New Zealand | Ms Rebecca Lucas-Roxburgh | Observational | 4/09/2014 | 22/09/2014 | 9/10/2014 | 23/10/2014 |
| 14/STH/129 | Approve | TRANSDIAB | Associate Professor Helen Pilmore | Intervention | 4/09/2014 | 22/09/2014 | 29/09/2014 | 3/10/2014 |
| 14/STH/131 | Approve | The effectiveness of a community psycho-education group for people who have self-harmed | Dr David Carlyle | Intervention | 4/09/2014 |  |  | 22/09/2014 |
| 14/STH/132 | Approve | Optimising mechanical ventilation in ICU | Associate Professor Geoffrey Shaw | Intervention | 4/09/2014 |  |  | 22/09/2014 |
| 14/STH/145 | Approve | Efficacy and Safety Study of RPC1063 in Relapsing Multiple Sclerosis | Dr Deborah Mason | Intervention | 2/10/2014 | 20/10/2014 | 3/11/2014 | 11/11/2014 |
| 14/STH/148 | Approve | BO28984: A randomized, phase III study comparing alectinib versus crizotinib in treatment-naïve ALK-positive advanced non-small cell lung cancer | Associate Professor Mark McKeage | Intervention | 2/10/2014 | 20/10/2014 | 7/11/2014 | 7/11/2014 |
| 14/STH/149 | Approve | CLDK378A2205 | Associate Professor Mark McKeage | Intervention | 2/10/2014 | 20/10/2014 | 9/12/2014 | 19/12/2014 |
| 14/STH/150 | Approve | Ipratropium bromide bioavailability study administered with and without concurrent oral charcoal | Dr Noelyn Hung | Intervention | 2/10/2014 |  |  | 20/10/2014 |
| 14/STH/152 | Approve | Echocardiographic Review of Dynamic Diastolic Function and Preload Markers in Age Matched Normal Population and Fontan Patients | Doctor Kathryn Rice | Observational | 2/10/2014 | 20/10/2014 | 1/12/2014 | 12/12/2014 |
| 14/STH/155 | Approve | Study to evaluate the efficacy of IPI-145 administered in combination with rituximab vs placebo in combination with rituximab in subjects with previously treated CD20 positive Follicular Lymphoma | Dr Peter Ganly | Intervention | 2/10/2014 | 20/10/2014 | 24/11/2014 | 12/12/2014 |
| 14/STH/156 | Approve | Metformin renal handling | Dr Dan Wright | Intervention | 2/10/2014 | 20/10/2014 | 23/10/2014 | 5/11/2014 |
| 14/STH/170 | Provisionally approve | Investigating the high incidence of Maori and Polynesian children with autoimmune neurological disease in New Zealand | Dr Hannah Jones | Observational | 6/11/2014 | 24/11/2014 |  |  |
| 14/STH/175 | Approve | KCP-330-501-Selinexor in Diabetic Foot Ulcer Patients | Dr Edward Watson | Intervention | 6/11/2014 |  |  | 24/11/2014 |
| 14/STH/176 | Provisionally approve | Functional outcomes after Fontan surgery | Dr Tom Gentles | Observational | 6/11/2014 | 24/11/2014 |  |  |
| 14/STH/177 | Provisionally approve | MLN9708 Plus Lenalidomide and Dexamethasone Versus Placebo Plus Lenalidomideand Dexamethasone in Adult Patients With Newly Diagnosed Multiple Myeloma | Dr Stephen Gibbons | Intervention | 6/11/2014 | 24/11/2014 |  |  |
| 14/STH/178 | Approve | WB28182: A Study of Lebrikizumab in patients with severe asthma who depend on oral corticosteroids | Dr Benedict D J Brockway | Intervention | 6/11/2014 |  |  | 24/11/2014 |
| 14/STH/179 | Approve | (duplicate) 747-302: Effect of OCA on Outcomes in People with PBC | Dr David William Orr | Intervention | 6/11/2014 |  |  | 24/11/2014 |
| 14/STH/180 | Approve | Managing transitions in care for people with advanced progressive illness | Professor Maureen Coombs | Observational | 6/11/2014 | 24/11/2014 | 28/11/2014 | 12/12/2014 |
| 14/STH/208 | Approve | LATE EFFECTS OF PREMATURITY | Dr Stephanie Moor | Observational | 3/12/2014 |  |  | 18/12/2014 |
| 14/STH/210 | Approve | Tiotropium inhalation powder bioavailability study | Dr Noelyn Hung | Intervention | 3/12/2014 |  |  | 18/12/2014 |
| 14/STH/211 | Provisionally approve | Desvenlafaxine bioequivalence study conducted under fasting conditions | Dr Noelyn Hung | Intervention | 3/12/2014 | 18/12/2014 |  |  |
| 14/STH/212 | Provisionally approve | Desvenlafaxine bioequivalence study conducted under fed conditions | Dr Noelyn Hung | Intervention | 3/12/2014 | 18/12/2014 |  |  |
| 14/STH/213 | Provisionally approve | Desvenlafaxine bioequivalence study conducted under fasting conditions and at steady state | Dr Noelyn Hung | Intervention | 3/12/2014 | 18/12/2014 |  |  |
| 14/STH/214 | Provisionally approve | Desvenlafaxine 50 mg bioequivalence study conducted under fasting conditions | Dr Noelyn Hung | Intervention | 3/12/2014 | 18/12/2014 |  |  |
| 14/STH/216 | Approve | A study to see how the trial drug Orbactiv affects blood clotting tests, following single doses in healthy adults | Dr Richard Robson | Intervention | 3/12/2014 |  |  | 18/12/2014 |
| 14/STH/183 | Provisionally approve | A Single-Dose Study to Assess the Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of Odanacatib in Adolescents and Young Adults Treated with Glucocorticoids. | Dr Chris Wynne | Intervention | 4/12/2014 | 18/12/2014 |  |  |
| 14/STH/192 | Approve | COG ANBL1232: Response and Biology Based Risk factors Guiding Therapy in Non-high Risk Neuroblastoma | Dr Rob Corbett | Intervention | 4/12/2014 |  |  | 18/12/2014 |
| 14/STH/202 | Provisionally approve | GS-US-367-1169:Phase 2 Study of GS-9857 and Sofosbuvir + GS-5816 in Subjects with Chronic Non-Genotype 1 HCV Infection | Professor Ed Gane | Intervention | 4/12/2014 | 18/12/2014 |  |  |
| 14/STH/204 | Provisionally approve | GS-US-367-1168:Phase 2 Study of GS-9857 and Sofosbuvir + GS5816 in Subjects with Chronic Genotype 1 HCV Infection | Professor Ed Gane | Intervention | 4/12/2014 | 18/12/2014 |  |  |
| 14/STH/205 | Approve | The HUMBA (Healthy mUMs and BAbies) Demonstration Trial | Professor Lesley McCowan | Intervention | 4/12/2014 |  |  | 18/12/2014 |

## Applications reviewed by expedited review

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study reference | Study status | Short title | Co-ordinating investigator | Application type | Date application validated | Date of first decision | Provisional response received | Date of final decision |
| 14/STH/6 | Approve | CareSens Glucose Meter Survey | Dr Christy Macdonald | Observational | 21/02/2014 |  |  | 27/02/2014 |
| 14/STH/18 | Approve | Active Manuka Honey in Periodontal Disease Treatment | Dr Helen English | Intervention | 3/03/2014 |  |  | 20/03/2014 |
| 14/STH/28 | Approve | Lay perceptions of risk management for hereditary diffuse gastric cancer | Dr Alison McEwen | Observational | 25/03/2014 |  |  | 4/04/2014 |
| 14/STH/34 | Approve | Pre-operative exercise programme for people awaiting hip replacement | Dr Stephanie Woodley | Intervention | 3/04/2014 |  |  | 17/04/2014 |
| 14/STH/43 | Approve | Monitoring of disabled people's rights | Ms Sue Purdie | Observational | 8/04/2014 | 16/04/2014 | 6/05/2014 | 7/05/2014 |
| 14/STH/44 | Approve | Heat Conditioning for Health | Professor Andre M. van Rij | Intervention | 14/04/2014 |  |  | 30/04/2014 |
| 14/STH/45 | Approve | SEPTH 2 | Mr Lindsay McTavish | Intervention | 14/04/2014 | 30/04/2014 | 20/05/2014 | 11/06/2014 |
| 14/STH/46 | Approve | What are the effects of an electronic memory book on the quality and quantity of conversations in adults with mild to moderate dementia? | Miss Katrina Aitken | Intervention | 17/04/2014 |  |  | 1/05/2014 |
| 14/STH/58 | Approve | Pilot Study of Cryoablation Device for Treatment of Rhinitis | Dr. Tom Kuruvilla | Intervention | 9/05/2014 | 27/05/2014 | 30/05/2014 | 10/06/2014 |
| 14/STH/59 | Approve | National case-control study of non-Hodgkin lymphoma | Assoc. Prof. Brian Cox | Observational | 14/05/2014 |  |  | 28/05/2014 |
| 14/STH/60 | Approve | GLP1 Adipose Tissue Study | Associate Professor Patrick Manning | Intervention | 22/05/2014 | 9/06/2014 | 27/06/2014 | 30/06/2014 |
| 14/STH/71 | Approve | Suicide attempt in older people | Dr Gary Cheung | Observational | 5/06/2014 |  |  | 18/06/2014 |
| 14/STH/74 | Approve | Assessment of depression with InterRAI | Dr Gary Cheung | Observational | 11/06/2014 |  |  | 24/06/2014 |
| 14/STH/75 | Approve | Extraperitoneal vs transperitoneal stomas: occurrence of parastomal hernias | Associate Professor Ian Bissett | Observational | 11/06/2014 | 24/06/2014 | 1/07/2014 | 7/07/2014 |
| 14/STH/77 | Approve | Kiwifruit modulation of post-prandial glycaemia and its cognitive effects | Dr John Monro | Intervention | 19/06/2014 | 24/06/2014 | 22/07/2014 | 28/07/2014 |
| 14/STH/79 | Approve | Exploring reasons for childhood hospitalisations for skin infections | Dr Deborah Williamson | Observational | 23/06/2014 |  |  | 3/07/2014 |
| 14/STH/82 | Approve | IPC haemodynamics in lower limb cast | Dr Irene Braithwaite | Intervention | 24/06/2014 |  |  | 3/07/2014 |
| 14/STH/83 | Approve | Recruitment pilot study: infant paracetamol / ibuprofen RCT | Dr Irene Braithwaite | Observational | 25/06/2014 |  |  | 3/07/2014 |
| 14/STH/85 | Approve | Earlier diagnosis of HIV infection | Dr Simon Briggs | Observational | 2/07/2014 |  |  | 7/07/2014 |
| 14/STH/92 | Approve | Monitoring of hearing during vestibular schwannoma surgery | Mr Philip Bird | Observational | 2/07/2014 |  |  | 18/07/2014 |
| 14/STH/93 | Approve | Weber C Ankle Fracture Audit | Dr Logan Walker | Observational | 8/07/2014 |  |  | 22/07/2014 |
| 14/STH/81 | Approve | TEVAR for traumatic aortic transection- Optimal Surveillance Programme | Miss Qiao He | Observational | 9/07/2014 | 22/07/2014 | 1/09/2014 | 3/09/2014 |
| 14/STH/94 | Approve | Optic Nerve Sheath Diameter and Raised Intracranial Pressure | Dr Swarna Baskar Sharma | Observational | 15/07/2014 |  |  | 28/07/2014 |
| 14/STH/96 | Approve | Maternity Consumer Survey 2014 | Mrs Katrina Magill | Observational | 21/07/2014 | 30/07/2014 | 22/08/2014 | 26/08/2014 |
| 14/STH/97 | Approve | Audit of urines from elderly patients | Dr Arlo Upton | Observational | 22/07/2014 |  |  | 4/08/2014 |
| 14/STH/95 | Approve | The diagnostic usefulness of pleural fluid ADA for diagnosing TB in a low prevalence population | Dr Nicola Smith | Observational | 29/07/2014 |  |  | 6/08/2014 |
| 14/STH/98 | Approve | Retrospective Review of Inguinal Hernia Surgery | Assoc Prof Philip F Bagshaw | Observational | 29/07/2014 |  |  | 6/08/2014 |
| 14/STH/99 | Approve | Quality of Life of Immediate, Delayed or no breast reconstruction (QoLID) Pilot Study | A/Prof Ian Campbell | Observational | 31/07/2014 |  |  | 11/08/2014 |
| 14/STH/100 | Approve | Pacific Suicide Postvention | Dr Jemaima Tiatia-Seath | Observational | 1/08/2014 | 11/08/2014 | 15/09/2014 | 18/09/2014 |
| 14/STH/101 | Approve | Transforming way of ageing | Prof Ngaire Kerse | Intervention | 1/08/2014 |  |  | 13/08/2014 |
| 14/STH/102 | Approve | ICare-ACS | Dr MARTIN THAN | Observational | 1/08/2014 |  |  | 19/08/2014 |
| 14/STH/108 | Approve | Communication Skills Training for Healthcare Workers | Miss Maria Baby | Intervention | 7/08/2014 |  |  | 19/08/2014 |
| 14/STH/116 | Approve | Benzbromarone use in New Zealand | Professor Lisa Stamp | Observational | 13/08/2014 |  |  | 25/08/2014 |
| 14/STH/117 | Approve | Validity of InterRAi outcome scales | Dr Susan Gee | Observational | 19/08/2014 |  |  | 26/08/2014 |
| 14/STH/118 | Approve | Faster Cancer Treatment Indicators: Any faster or any better? | Dr. Siti Aisyah binti Haji Ibrahim | Observational | 19/08/2014 |  |  | 26/08/2014 |
| 14/STH/120 | Approve | Experiences of dialysis treatment | Dr Suetonia Palmer | Observational | 22/08/2014 |  |  | 4/09/2014 |
| 14/STH/121 | Approve | The relationship between oral microbiota and head and neck cancer disease progression and treatment outcomes | Associate Professor Richard Douglas | Observational | 26/08/2014 |  |  | 4/09/2014 |
| 14/STH/123 | Approve | LSVT®, swallowing and cough | Dr Anna Miles | Observational | 26/08/2014 |  |  | 5/09/2014 |
| 14/STH/122 | Approve | Attention in pain | Miss Hazel Godfrey | Observational | 27/08/2014 |  |  | 5/09/2014 |
| 14/STH/144 | Approve | Proof of concept weight management trial | Dr Glenn Vile | Intervention | 28/08/2014 |  |  | 1/10/2014 |
| 14/STH/126 | Approve | Assessment of 3D Heart Shape in Congenital Heart Disease | Professor Alistair Young | Observational | 29/08/2014 |  |  | 5/09/2014 |
| 14/STH/133 | Approve | Sugar intake and child health | Dr Simon Thornley | Observational | 5/09/2014 |  |  | 24/09/2014 |
| 14/STH/134 | Approve | DWI after Echo Bubble Study | Dr Ben McGuinness | Observational | 8/09/2014 |  |  | 24/09/2014 |
| 14/STH/138 | Approve | IPC in-cast feasibility study | Dr Irene Braithwaite | Intervention | 9/09/2014 |  |  | 24/09/2014 |
| 14/STH/139 | Approve | Does a total laparoscopic hysterectomy for uterine prolapse decrease recurrence of prolapse at one year when compared to vaginal hysterectomy? A Pilot Study | Dr Keryn Harlow | Observational | 12/09/2014 |  |  | 24/09/2014 |
| 14/STH/140 | Approve | Outcomes in cognitive impairment and incontinence: a national cohort study | Dr Hamish Jamieson | Observational | 15/09/2014 |  |  | 29/09/2014 |
| 14/STH/141 | Approve | Impact of Human Papillomavirus (HPV) Immunisation on Rates of High-Grade Cervical Intraepithelial Neoplasia (CIN2/3) in Young Women | Dr Carrie Innes | Observational | 15/09/2014 |  |  | 29/09/2014 |
| 14/STH/137 | Approve | Evaluation of Kiosk Pilot in Thames Hospital Emergency Department | Dr Ruth Large | Observational | 18/09/2014 |  |  | 1/10/2014 |
| 14/STH/142 | Approve | Temperature, humidity and oxygen content in the trachea in standard conditions | A/Prof Lutz Beckert | Observational | 22/09/2014 |  |  | 6/10/2014 |
| 14/STH/154 | Approve | Shoulder Dystocia: A retrospective observational review | MS Lesley Ansell | Observational | 7/10/2014 |  |  | 20/10/2014 |
| 14/STH/157 | Approve | PAST | Dr Kim Jamieson | Observational | 7/10/2014 | 16/10/2014 | 13/10/2014 | 28/10/2014 |
| 14/STH/158 | Approve | The effect of kiwifruit on gastrointestinal comfort in healthy males | Associate Professor Richard Gearry | Intervention | 8/10/2014 |  |  | 20/10/2014 |
| 14/STH/159 | Provisionally approve | Conceiving Family Relationships and Identities in Surrogacy Arrangements | Ms Alice Aickin | Observational | 8/10/2014 | 20/10/2014 |  |  |
| 14/STH/162 | Approve | SMS4BG | Ms Rosie Dobson | Intervention | 20/10/2014 | 28/10/2014 | 3/11/2014 | 5/11/2014 |
| 14/STH/163 | Approve | Whaia Te Ahi Kā - Ahi Kā and its role in Oranga | Ms Kiri Parata | Observational | 20/10/2014 |  |  | 30/10/2014 |
| 14/STH/161 | Approve | What determines a person's haemaglobin? | Dr. Krishna Badami | Observational | 23/10/2014 |  |  | 5/11/2014 |
| 14/STH/164 | Approve | RMES vs CAM | Mrs Shirley Collocott | Intervention | 23/10/2014 |  |  | 5/11/2014 |
| 14/STH/165 | Approve | Isolated Forearm Technique Audit | Dr Amy Gaskell | Intervention | 28/10/2014 |  |  | 10/11/2014 |
| 14/STH/168 | Approve | Peri-operative analgesic requirements and quality of recovery | Assoc Prof Dr R Ross Kennedy | Observational | 30/10/2014 |  |  | 11/11/2014 |
| 14/STH/172 | Approve | Transferring from BiPAP to CPAP in patients with Obesity Hypoventilation Syndrome(OHS) | Dr Michael Epton | Intervention | 4/11/2014 |  |  | 20/11/2014 |
| 14/STH/174 | Approve | Prevention of sleep apnoea-related brain damage | Mr. Russell Buckley | Intervention | 6/11/2014 |  |  | 24/11/2014 |
| 14/STH/182 | Approve | Periarticular Surgical Environment | Dr Marinus Stowers | Observational | 11/11/2014 | 24/11/2014 | 27/11/2014 | 1/12/2014 |
| 14/STH/184 | Provisionally approve | Metabolic effects of palmitic acid rich fats | Prof David Cameron-Smith | Intervention | 12/11/2014 | 25/11/2014 |  |  |
| 14/STH/188 | Approve | Patients' views of IBD transition | Associate Professor Richard Gearry | Observational | 17/11/2014 |  |  | 1/12/2014 |
| 14/STH/189 | Approve | A study to validate software that may be helpful in diagnosing cancer | Dr Chris Wynne | Intervention | 19/11/2014 |  |  | 4/12/2014 |
| 14/STH/191 | Approve | Burden of MRSA on Far North Communities | Miss Kennedy Sarich | Observational | 19/11/2014 |  |  | 4/12/2014 |
| 14/STH/194 | Approve | The detection of endometrial cancer by the cervical smear | Assoc. Prof. Brian Cox | Observational | 26/11/2014 |  |  | 12/12/2014 |
| 14/STH/195 | Approve | Evaluation of the Community Rehabilitation, Enablement and Support Team | Dr Claire Heppenstall | Observational | 26/11/2014 | 12/12/2014 | 16/12/2014 | 19/12/2014 |
| 14/STH/203 | Approve | Incidence of complications after radiotherapy for prostate cancer | Dr Melissa James | Observational | 1/12/2014 |  |  | 12/12/2014 |
| 14/STH/219 | Approve | Improving baked egg and milk allergy diagnosis | Dr Kahn Preece | Observational | 6/01/2015 |  |  | 24/12/2014 |
| 14/STH/220 | Approve | New collection tubes for measuring glucose | Dr Helen Lunt | Intervention | 10/01/2015 |  |  | 22/12/2014 |

## Overdue full applications

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| --- | --- | --- | --- |
| Reference | Short title | Days overdue | Reason |
| 14/STH/155 | Study to evaluate the efficacy of IPI-145 administered in combination with rituximab vs placebo in combination with rituximab in subjects with previously treated CD20 positive Follicular Lymphoma. | 1 | Reviewer delay |
| 14/STH/39 | Subclinical Congenital Hypothyroidism | 2 | Reviewer delay |
| 14/STH/25 | MK-8228-001: MK8228 vs. Placebo in Prevention of CMV infection in HSCT Recipients | 4 | Reviewer delay |
| 14/STH/20 | Developing a blood test for Parkinson's Disease. | 14 | Reviewer delay |

## Overdue expedited applications

|  |  |  |  |
| --- | --- | --- | --- |
| Reference | Short title | Days overdue | Reason |
| 14/STH/134 | DWI after Echo Bubble Study | 1 | Reviewer delay/ Secretariat delay |
| 14/STH/172 | Transferring from BiPAP to CPAP in patients with Obesity Hypoventilation Syndrome(OHS) | 1 | Reviewer delay |
| 14/STH/194 | The detection of endometrial cancer by the cervical smear | 1 | Reviewer delay |
| 14/STH/44 | Heat Conditioning for Health | 1 | Reviewer delay |
| 14/STH/92 | Monitoring of hearing during vestibular schwannoma surgery | 1 | Secretariat delay |
| 14/STH/18 | Active Manuka Honey in Periodontal Disease Treatment | 2 | Reviewer delay |
| 14/STH/182 | Periarticular Surgical Environment | 2 | Reviewer delay |
| 14/STH/102 | ICare-ACS | 3 | Reviewer delay |
| 14/STH/174 | Prevention of sleep apnoea-related brain damage | 3 | Reviewer delay |
| 14/STH/133 | Sugar intake and child health | 4 | Secretariat delay |
| 14/STH/195 | Evaluation of the Community Rehabilitation, Enablement and Support Team | 4 | Reviewer delay |
| 14/STH/75 | Extraperitoneal vs transperitoneal stomas: occurrence of parastomal hernias | 4 | Reviewer delay |
| 14/STH/60 | GLP1 Adipose Tissue Study | 6 | Reviewer delay |
| 14/STH/157 | PAST | 9 | Reviewer delay |
| 14/STH/58 | Pilot Study of Cryoablation Device for Treatment of Rhinitis | 14 | Reviewer delay |
| 14/STH/144 | Proof of concept weight management trial | 19 | Secretariat delay |
| 14/STH/45 | SEPTH 2 | 23 | Reviewer delay |

1. This information is a direct report from user entries. [↑](#footnote-ref-1)