

Southern Health and Disability Ethics Committee

Annual Report  
2015

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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.

2015 was the busiest year since the new system was implemented. 179 applications were considered, 101 at full meetings and 78 through the expedited review pathway. The Committee also reviewed 709 post approval items.

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.

I would like to thank researchers who are making more effort to attend the meetings, either in person or by teleconference. Attending makes the review process much easier.

Three Chairs’ days were held in 2015. The ongoing work of the Chairs in developing national consistency and tackling the ethical issues at the forefront of health research has been rewarding and thought-provoking.

The HDECs are in a good position to consider these issues due to the outstanding group of people on the committees 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.

****

Raewyn Idoine

Chairperson

Southern Heath and Disability Ethics Committee

# Membership and attendance

No meetings were postponed or cancelled due to inability to make quorum. Seven members were appointed during 2015 and one member’s term expired.

## Membership

### Lay members

|  |  |
| --- | --- |
| Ms Raewyn Idoine (Chair) | |
| Membership category: | Consumer representative / community perspectives |
| Date of appointment: | 27 October 2015 |
| Current term expires: | 27 October 2018 |

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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| **Ms Fiona McCrimmon** | |
| Membership category: | The law |
| Date of appointment: | 27 October 2015 |
| Current term expires: | 27 October 2018 |

Ms 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: | Consumer representative / community perspectives |
| Date of appointment: | 27 October 2015 |
| Current term expires: | 27 October 2018 |

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.

### Non-Lay members

|  |  |
| --- | --- |
| Dr Sarah Gunningham | |
| Membership category: | Health researcher / intervention studies |
| Date of appointment: | 27 October 2015 |
| Current term expires: | 27 October 2018 |

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: | Health researcher / intervention studies |
| Date of appointment: | 27 October 2015 |
| Current term expires: | 27 October 2018 |

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

|  |  |
| --- | --- |
| Dr Nicola Swain | |
| Membership category: | Health researcher / observational studies |
| Date of appointment: | 27 October 2015 |
| Current term expires: | 27 October 2018 |

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 Devonie Waaka** | |
| Membership category: | Health researcher / Intervention studies |
| 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: | 27 October 2015 |
| Current term expires: | 27 October 2018 |

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

### Ms Gwen Neave

|  |  |
| --- | --- |
| Membership category: | Consumer representative / community perspectives |
| Date of appointment: | 1 July 2012 |
| Term ended: | 1 July 2015 |

## Attendance

The Southern HDEC held 11 meetings in 2015.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Members** | | | **Meetings** | | | | | | | | | | | | **Total** |
| Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec |  |
| Lay members | Cn | Ms Raewyn Idoine |  | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | 11/11 |
| L | Dr Fiona McCrimmon |  | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | 10/11 |
| Cn | Mrs Angelika Frank-Alexander |  | **✓** | **✓** | ***A*** | **✓** | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** | ***A*** | 8/11 |
| Cm | Mrs Maliaga Erick(Co-Opt from NTB HDEC) |  |  |  |  |  |  |  |  |  |  |  | **✓** | 1/1 |
| Cm | Ms Sandy Gill (Co-Opted from CEN HDEC) |  |  |  |  |  |  | **✓** |  |  |  |  |  | 1/1 |
| Non-Lay | HR | Dr Nicola Swain |  | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | 10/11 |
| HP | Dr Mathew Zacharias |  | ***A*** | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | ***A*** | **✓** | **✓** | ***A*** | 7/11 |
| HR | Dr Sarah Gunningham |  | **✓** | **✓** | ***A*** | ***A*** | **✓** | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | 8/11 |
| HR | Dr Devonie Eglinton |  | ***A*** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | **✓** | 10/11 |
| HR | Dr Mira Harrison-Woolrych |  | **✓** | **✓** | ***A*** | ***A*** | ***A*** | ***A*** | ***A*** | ***A*** | ***A*** | **✓** | **✓** | 4/11 |

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

HDEC members were invited to attend the following conferences in 2015:

* Ethics in Practice - Dunedin
* Maori Health Research Ethics Symposium – Wellington
* Indigenous Approaches to Research and Tissue Banking – Auckland.

There was no new member training held in 2015.

## Chairpersons’ meetings

There were three Chairs’ day meetings in 2015. The meetings were held at the Freyberg Building in Wellington. Ms Idoine attended three meetings.

# Applications reviewed

The Southern HDEC reviewed 179 applications in 2015. From the 179 applications, 101 applications were reviewed by the full committee and 78 were reviewed through the expedited pathway.

|  |  |  |
| --- | --- | --- |
| Full | Approved | 83 |
| Declined | 7 |
| Provisional Approval (as at 31 December 2015) | 11 |
| *Total (with a decision at 31 December 2015)* | **101** |
| Expedited | Approved | 75 |
| Declined | 1 |
| Provisional Approval (as at 31 December 2015) | 2 |
| *Total (with a decision at 31 December 2015)* | **78** |
| **Total applications reviewed** | | **179** |

A summary of these applications can be found in Appendix 1.

# Complaints and overdue application summary

This section outlines complaints about decisions made by the Committee during 2015.

## Complaints received

The Southern Committee did not receive any complaints about the decision making process in 2015.

## Overdue review

During 2015, there were 10 instances where the review time was over 35 days for full applications and 16 where the review time was over 15 days for expedited applications.

See Appendix 1 for more information.

# Appendix 1: Details of applications reviewed

## 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 |
| 15/STH/10 | Approve | PEACE Study | Dr Rachael Parke | Observational | 5/02/2015 |  |  | 19/02/2015 |
| 15/STH/11 | Decline | Impact of Dietary Protein Supplementation on Diabetic Rehabilitation | Dr Lee Stoner | Intervention | 5/02/2015 |  |  | 19/02/2015 |
| 15/STH/12 | Decline | Assessing specificty and sensitivity of a computerized system, supporting the diagnostic process of ADHD | Dr Yariv Doron | Intervention | 5/02/2015 | 19/02/2015 | 29/04/2015 | 11/06/2015 |
| 15/STH/16 | Approve | M14-867: A study of ABT493 and ABT530 with or without RBV in patients with chronic HCV Genotype 1, 4, 5 and 6 | Prof Edward Gane | Intervention | 5/02/2015 |  |  | 19/02/2015 |
| 15/STH/18 | Approve | Emotional stress and force control in Parkinson’s disease | Dr Rebekah Blakemore | Intervention | 5/02/2015 | 19/02/2015 | 19/02/2015 | 20/02/2015 |
| 15/STH/19 | Approve | Efficacy of varenicline in Huntington's Disease | Dr Ailsa McGregor | Intervention | 5/02/2015 | 19/02/2015 | 7/04/2015 | 22/04/2015 |
| 15/STH/20 | Approve | REGENERON - A Study to test REGN2222 in preventing respiratory syncytial virus (RSV) in preterm infants | Dr Michael Meyer | Intervention | 5/02/2015 | 19/02/2015 | 7/04/2015 | 29/04/2015 |
| 15/STH/31 | Approve | Study Evaluating GS-9857 Pharmacokinetics in Subjects with Normal Hepatic Function and Moderate or Severe Hepatic Impairment | Prof Edward Gane | Intervention | 5/03/2015 |  |  | 20/03/2015 |
| 15/STH/33 | Approve | Clonidine 100 mcg bioequivalence study conducted under fasting conditions | Dr Noelyn Hung | Intervention | 5/03/2015 |  |  | 20/03/2015 |
| 15/STH/34 | Approve | Bosentan 125 mg bioequivalence study conducted under fasting conditions | Dr Noelyn Hung | Intervention | 5/03/2015 |  |  | 20/03/2015 |
| 15/STH/35 | Approve | MK3475 versus Paclitaxel for Advanced Gastric Cancer | Dr Katriona Clarke | Intervention | 5/03/2015 | 20/03/2015 | 8/04/2015 | 18/05/2015 |
| 15/STH/36 | Approve | New biomarkers to detect sepsis in critically ill patients | Associate Professor Geoffrey Shaw | Observational | 5/03/2015 | 20/03/2015 | 17/06/2015 | 17/06/2015 |
| 15/STH/45 | Approve | Biomarkers of outcomes related to anticoagulants | Dr Paul Chin | Observational | 9/04/2015 | 28/04/2015 | 2/06/2015 | 24/06/2015 |
| 15/STH/49 | Approve | Switch to MK-1439A from a ritonavir-boosted PI-containing regimen in HIV-1-infected participants | Dr Alan David Pithie | Intervention | 9/04/2015 | 28/04/2015 | 8/05/2015 | 18/05/2015 |
| 15/STH/52 | Approve | Body composition in term and preterm NZ babies | Prof Frank Bloomfield | Observational | 9/04/2015 |  |  | 28/04/2015 |
| 15/STH/54 | Approve | MK-1439A versus ATRIPLA™ in treatment-naïve HIV-infected subjects | Dr Rupert Handy | Intervention | 9/04/2015 |  |  | 28/04/2015 |
| 15/STH/60 | Approve | HAUSER-RCT | Prof Russell Scott | Intervention | 9/04/2015 | 28/04/2015 | 9/06/2015 | 13/07/2015 |
| 15/STH/70 | Approve | BGB-3111 AU-003 | Dr David Simpson | Intervention | 7/05/2015 | 22/05/2015 | 8/06/2015 | 22/06/2015 |
| 15/STH/72 | Approve | ANZ 1401 / ELIMINATE: oEstrogen Lowering Intervention May Increase NeoAdjuvant Therapy Efficacy | Dr Marion Kuper-Hommel | Intervention | 7/05/2015 | 22/05/2015 | 23/06/2015 | 8/07/2015 |
| 15/STH/73 | Approve | BARISTa Tissue Bank | Associate Professor Cathy Stinear | Observational | 7/05/2015 |  |  | 22/05/2015 |
| 15/STH/74 | Approve | Adjuvant Immunotherapy with anti PD-1 in Stage III melanoma | Dr Rosalie Fisher | Intervention | 7/05/2015 |  |  | 22/05/2015 |
| 15/STH/75 | Approve | Four Dosing Regimens of Ramucirumab in Patients with Gastric or Gastroesophageal Adenocarcinoma | Dr Dragan Damianovich | Intervention | 7/05/2015 |  |  | 22/05/2015 |
| 15/STH/76 | Approve | GS-US-337-1431: A study to follow up Subjects with Cirrhosis Who Achieve a Sustained Virologic Response Following Treatment for Chronic Hepatitis C Infection in Gilead-Sponsored Trials | Prof Edward Gane | Observational | 7/05/2015 |  |  | 22/05/2015 |
| 15/STH/83 | Approve | PAEAN - Erythropoietin for hypoxic ischaemic encephalopathy | Dr Arun Nair | Intervention | 4/06/2015 | 18/06/2015 | 26/08/2015 | 28/08/2015 |
| 15/STH/84 | Approve | Organisational case studies of sensory modulation | Mr Gilberto Azuela | Observational | 4/06/2015 |  |  | 18/06/2015 |
| 15/STH/85 | Approve | DECT Study in Allopurinol-Treated Patients With Gout | Prof Nicola Dalbeth | Observational | 4/06/2015 | 18/06/2015 | 1/07/2015 | 10/07/2015 |
| 15/STH/86 | Approve | Ketamine in anxiety disorders | Professor Paul Glue | Intervention | 4/06/2015 | 18/06/2015 | 22/07/2015 | 3/08/2015 |
| 15/STH/87 | Approve | Oral Paclitaxel for the Treatment of Cancer | Dr Christopher Jackson | Intervention | 4/06/2015 |  |  | 18/06/2015 |
| 15/STH/88 | Approve | A Safety Study of Oraxol (HM30181 + oral paclitaxel) in Cancer Patients | Dr Christopher Jackson | Intervention | 4/06/2015 |  |  | 18/06/2015 |
| 15/STH/89 | Approve | FG-3019 therapy in patients with Idiopathic Pulmonary Fibrosis | A/Prof Lutz Beckert | Intervention | 4/06/2015 |  |  | 18/06/2015 |
| 15/STH/90 | Approve | Painbuster rectus sheath infusion device for analgesia following laparotomy | Dr Kelly Byrne | Intervention | 4/06/2015 | 18/06/2015 | 25/08/2015 | 2/09/2015 |
| 15/STH/91 | Approve | A study to evaluate the efficacy and safety of two doses of Anifrolumab compared to placebo in patients with Active Systemic Lupus Erythematosus | Dr Alan Doube | Intervention | 4/06/2015 |  |  | 18/06/2015 |
| 15/STH/93 | Approve | Acerta 006 | Dr Peter Ganly | Intervention | 4/06/2015 | 18/06/2015 | 3/07/2015 | 29/07/2015 |
| 15/STH/102 | Approve | A Study of Oral RPC1063 as a Therapy for Moderate to Severe Ulcerative Colitis | Prof Richard Gearry | Intervention | 2/07/2015 | 24/07/2015 | 13/10/2015 | 20/10/2015 |
| 15/STH/103 | Approve | Comparison of the blood levels of two forms of desvenlafaxine 100 mg tablets under fasting conditions | Dr Noelyn Hung | Intervention | 2/07/2015 |  |  | 24/07/2015 |
| 15/STH/104 | Approve | Comparison of the blood levels of two forms of desvenlafaxine 100 mg tablets under fed conditions | Dr Noelyn Hung | Intervention | 2/07/2015 |  |  | 24/07/2015 |
| 15/STH/105 | Approve | Comparison of the blood levels of two forms of desvenlafaxine 50 mg tablets under fasting conditions | Dr Noelyn Hung | Intervention | 2/07/2015 |  |  | 24/07/2015 |
| 15/STH/106 | Approve | LAMiNAR | Dr Alex Kazemi | Observational | 2/07/2015 |  |  | 24/07/2015 |
| 15/STH/107 | Approve | Play and Anxiety in Hospitalised Children | Ms Esther Leauanae | Observational | 2/07/2015 |  |  | 24/07/2015 |
| 15/STH/108 | Approve | Intensive urate-lowering therapy for bone erosion in gout | Prof Nicola Dalbeth | Intervention | 2/07/2015 |  |  | 24/07/2015 |
| 15/STH/110 | Decline | Pfizer A4091058 | Dr Simon Carson | Intervention | 2/07/2015 |  |  | 24/07/2015 |
| 15/STH/111 | Approve | Comparison of the blood levels of two forms of desvenlafaxine 100 mg tablets under steady state conditions | Dr Noelyn Hung | Intervention | 2/07/2015 |  |  | 24/07/2015 |
| 15/STH/112 | Decline | A4091064 | Dr Simon Carson | Observational | 2/07/2015 |  |  | 24/07/2015 |
| 15/STH/114 | Approve | Formative Evaluation of Youth AOD Exemplar Services | Mrs Elizabeth Smith | Observational | 2/07/2015 |  |  | 24/07/2015 |
| 15/STH/119 | Approve | Prostate artery embolization for treatment of acute urinary retention due to benign prostate hyperplasia (PRO-FLOW) | Dr Martin Krauss | Intervention | 6/08/2015 |  |  | 20/08/2015 |
| 15/STH/121 | Approve | Validation of transcutaneous monitoring | Dr Janine Pilcher | Observational | 6/08/2015 |  |  | 20/08/2015 |
| 15/STH/122 | Approve | Telemedicine in rural palliative care patients | Dr Gordon Giddings | Observational | 6/08/2015 | 20/08/2015 | 24/09/2015 | 5/10/2015 |
| 15/STH/123 | Approve | Use of Optiflow in the paediatric recovery room | Dr. Paul A. Baker | Observational | 6/08/2015 |  |  | 20/08/2015 |
| 15/STH/124 | Approve | Leuprolide Acetate 45 mg in Subjects with Central (Gonadotropin-Dependent) Precocious Puberty | Prof Paul Hofman | Intervention | 6/08/2015 | 20/08/2015 | 18/09/2015 | 5/10/2015 |
| 15/STH/125 | Approve | A Clinical Trial to assess the Efficacy and Safety of ISIS 420915 in Patients with Familial Amyloid Polyneuropathy | Prof Edward Gane | Intervention | 6/08/2015 |  |  | 20/08/2015 |
| 15/STH/126 | Approve | M15-461 RUBYII | Prof Edward Gane | Intervention | 6/08/2015 |  |  | 20/08/2015 |
| 15/STH/127 | Approve | Intercytoplasmic bridges in bone marrow aspirates | Dr Robert Weinkove | Observational | 6/08/2015 |  |  | 20/08/2015 |
| 15/STH/128 | Approve | Urocanate in human specimens | Dr Stephen Ritchie | Observational | 6/08/2015 | 20/08/2015 | 31/08/2015 | 24/09/2015 |
| 15/STH/129 | Approve | Protocol 16277: Riociguat in diffuse cutaneous systemic sclerosis (dcSSc) | Dr Kamal Solanki | Intervention | 6/08/2015 |  |  | 20/08/2015 |
| 15/STH/135 | Approve | To evaluate the concentration of nicotine in the blood and its effects,safety and tolerability, following the use of a new nicotine delivery system (P3L). | Dr Chris Wynne | Intervention | 6/08/2015 |  |  | 20/08/2015 |
| 15/STH/136 | Approve | AML 19 | Dr Ruth Spearing | Intervention | 6/08/2015 | 20/08/2015 | 19/10/2015 | 23/10/2015 |
| 15/STH/140 | Approve | Assessment of the investigational psoriasis cream Icotinib Hydrochloride | Dr Chris Wynne | Intervention | 3/09/2015 |  |  | 17/09/2015 |
| 15/STH/141 | Provisionally approve | NN8022-4179: Effect of liraglutide for weight management in paediatric subjects with Prader-Willi Syndrome | Prof Paul Hofman | Intervention | 3/09/2015 | 17/09/2015 | 7/12/2015 |  |
| 15/STH/145 | Approve | Vitamin C for Colorectal Cancer | Prof Margreet Vissers | Intervention | 3/09/2015 |  |  | 17/09/2015 |
| 15/STH/148 | Approve | CLS001-CO-PR-006: Open-Label Extension Study to Evaluate the Long-Term Safety of Omiganan Topical Gel in Subjects with Rosacea | Assoc. Prof Marius Rademaker | Intervention | 3/09/2015 |  |  | 7/10/2015 |
| 15/STH/149 | Approve | CLS001-CO-PR-004: Safety and effectiveness of once-daily CLS001 gel in Papulopustular Rosacea with extended treatment | Assoc. Prof Marius Rademaker | Intervention | 3/09/2015 | 7/10/2015 | 5/10/2015 | 7/10/2015 |
| 15/STH/152 | Approve | Epaderm ointment for eczema in children | Dr Stanley Thorsten | Intervention | 3/09/2015 |  |  | 17/09/2015 |
| 15/STH/153 | Approve | Harmoni Feasibility | Dr. Dean Corbett | Intervention | 3/09/2015 | 17/09/2015 | 5/10/2015 | 30/10/2015 |
| 15/STH/154 | Approve | Empagliflozin as Adjunctive to InSulin thErapy over 26 weeks (EASE-3) in patients with Type 1 Diabetes Mellitus (EASE-3) | Professor Russell Scott | Intervention | 3/09/2015 |  |  | 17/09/2015 |
| 15/STH/155 | Approve | OMS721-TMA-001: A dose-escalation study to evaluate the safety and clinical activity of OMS721 in adults with TMA | Dr Mark Smith | Intervention | 3/09/2015 | 17/09/2015 | 7/10/2015 | 21/10/2015 |
| 15/STH/158 | Approve | Safety and efficacy of Sitagliptin compared with Dapagliflozin in type 2 diabetes | Professor Russell Scott | Intervention | 3/09/2015 |  |  | 17/09/2015 |
| 15/STH/159 | Decline | Yoga practice in Gestational diabetes | Dr Sornalatha Vasan | Intervention | 3/09/2015 |  |  | 17/09/2015 |
| 15/STH/171 | Approve | Implanted Stimulators To Augment Rehabilitation Therapy (ISTART trial) | Prof Dirk de Ridder | Intervention | 8/10/2015 | 22/10/2015 | 10/11/2015 | 16/11/2015 |
| 15/STH/172 | Approve | Evicel Neuro Study | Mr Andrew Law | Intervention | 8/10/2015 |  |  | 22/10/2015 |
| 15/STH/173 | Approve | M13-590: A study of ABT-493/ABT-530 in chronic hepatitis C genotype 1 patients | Prof Edward Gane | Intervention | 8/10/2015 |  |  | 22/10/2015 |
| 15/STH/174 | Approve | M13-594: A study of ABT-493/ABT-530 compared to Sofosbuvir and Daclatasavir in chronic hepatitis C genotype 3 patients | Prof Edward Gane | Intervention | 8/10/2015 |  |  | 22/10/2015 |
| 15/STH/175 | Approve | A Study Comparing Generic to Reference Liposome Encapsulated Doxorubicin Hydrochloride in Subjects with Ovarian Carcinoma Who Have Failed PlatinumBased Chemotherapy | Dr Joanna Jones | Intervention | 8/10/2015 |  |  | 22/10/2015 |
| 15/STH/176 | Decline | Measuring how antibiotics are removed by dialysis in the Intensive Care | Professor Robert Walker | Intervention | 8/10/2015 |  |  | 22/10/2015 |
| 15/STH/177 | Approve | A phase III study of Pomalidomide and low dose Dexamethasone with or without Pembrolizumab (MK3475) in refractory or relapsed and refractory Multiple Myeloma (rrMM). (KEYNOTE 183) | Dr Peter Ganly | Intervention | 8/10/2015 | 22/10/2015 | 16/11/2015 | 4/12/2015 |
| 15/STH/178 | Approve | Clonidine in bronchiectasis | Dr Conroy Wong | Intervention | 8/10/2015 |  |  | 22/10/2015 |
| 15/STH/179 | Approve | RACE Early Categorisation for Personalised Outcome Assessment | Dr Paul Young | Observational | 8/10/2015 |  |  | 22/10/2015 |
| 15/STH/180 | Approve | A study assessing the similarity of Avastin® and the trial drug DRL\_BZ | Dr Chris Wynne | Intervention | 8/10/2015 |  |  | 22/10/2015 |
| 15/STH/182 | Approve | Pharmacokinetics and Safety of Oral Docetaxel | Dr Christopher Jackson | Intervention | 8/10/2015 |  |  | 22/10/2015 |
| 15/STH/183 | Provisionally approve | Low-dose epidural study | Dr Catherine Bryant | Intervention | 8/10/2015 | 22/10/2015 |  |  |
| 15/STH/192 | Decline | Genetic variation and human disease | Dr Louise Bicknell | Observational | 5/11/2015 |  |  | 23/11/2015 |
| 15/STH/194 | Provisionally approve | Single Agent Pembrolizumab vs Single Agent Chemotherapy for metastatic triple negative breast cancer | Professor Bridget Robinson | Intervention | 5/11/2015 | 23/11/2015 |  |  |
| 15/STH/197 | Approve | ROBUST DLBCL study | Dr Peter Ganly | Intervention | 5/11/2015 |  |  | 23/11/2015 |
| 15/STH/198 | Approve | GS-US-367-1173: A study of Sofosbuvir/Velpatasvir/GS-9857 in chronic genotype 3 hepatitis C patients with cirrhosis and naive to direct acting antiviral treatment | Prof Edward Gane | Intervention | 5/11/2015 |  |  | 23/11/2015 |
| 15/STH/199 | Approve | GS-US-367-1170: A study of Sofosbuvir/Velpatasvir/GS-9857 compared to Sofosbuvir/Velpatasvir in chronic hepatitis C patients previously treated with a direct acting antiviral | Prof Edward Gane | Intervention | 5/11/2015 |  |  | 23/11/2015 |
| 15/STH/203 | Approve | Doxycycline and Microdacyn versus standard care for prevention of intra-operative wound contamination | Mrs Amelia Howard-Hill | Intervention | 5/11/2015 |  |  | 23/11/2015 |
| 15/STH/204 | Provisionally approve | THE QT AND CGMS STUDY | Dr Craig Jefferies | Observational | 5/11/2015 | 23/11/2015 |  |  |
| 15/STH/205 | Approve | MST-188-09: Vepoloxamer in Chronic Heart Failure Vepoloxamer in Chronic Heart Failure | Professor Richard Troughton | Intervention | 5/11/2015 |  |  | 23/11/2015 |
| 15/STH/207 | Provisionally approve | RBP in urine | Dr Mirjana Jaksic | Observational | 5/11/2015 | 23/11/2015 |  |  |
| 15/STH/208 | Approve | Psychometric properties of the needs of children's questionnaire | Dr Mandie Jane Foster | Observational | 5/11/2015 | 23/11/2015 | 26/11/2015 | 16/12/2015 |
| 15/STH/209 | Approve | An Open Label Extension Study of RPC1063 | Prof Richard Gearry | Intervention | 5/11/2015 |  |  | 23/11/2015 |
| 15/STH/236 | Provisionally approve | OptiMuM | Prof David Cameron-Smith | Intervention | 19/11/2015 | 18/12/2015 |  |  |
| 15/STH/219 | Provisionally approve | CTLA4-Ig (Abatacept) Prevention Trial | Professor Russell Scott | Intervention | 26/11/2015 | 18/12/2015 |  |  |
| 15/STH/221 | Provisionally approve | L-Theanine and Cognition | Dr Angela Campbell | Intervention | 26/11/2015 | 18/12/2015 |  |  |
| 15/STH/222 | Approve | Shoulder region surgical preparation and Propionobacterium acnes | Mr Ilia Elkinson | Intervention | 26/11/2015 |  |  | 18/12/2015 |
| 15/STH/226 | Approve | RAIDER | Dr Steve Williams | Intervention | 26/11/2015 |  |  | 18/12/2015 |
| 15/STH/229 | Provisionally approve | Maxi-IV PK Study (AFT-MXIV-06) | Dr. Richard Robson | Intervention | 26/11/2015 | 18/12/2015 |  |  |
| 15/STH/230 | Approve | BO25430: Extension Study of trastuzumab emtansine in patients previoulsy enrolled in a parent study | Dr Reuben Broom | Intervention | 26/11/2015 |  |  | 18/12/2015 |
| 15/STH/231 | Provisionally approve | M13-549 Rheumatoid Arthritis | Dr David Porter | Intervention | 26/11/2015 | 18/12/2015 |  |  |
| 15/STH/232 | Provisionally approve | 747-303: The REGENERATE Study | Dr David Orr | Intervention | 26/11/2015 | 18/12/2015 |  |  |
| 15/STH/233 | Approve | Comparison of the blood levels of two forms of clobazam tablet in healthy male and female volunteers under fasting conditions | Dr Noelyn Hung | Intervention | 26/11/2015 |  |  | 18/12/2015 |
| 15/STH/234 | Approve | Comparison of the blood levels of two forms of clobazam tablet in healthy male and female volunteers under fed conditions | Dr Noelyn Hung | Intervention | 26/11/2015 |  |  | 18/12/2015 |

## Applications reviewed by expedited review

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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 |
| 15/STH/2 | Approve | CRC-ctDNA | Dr Christopher Jackson | Observational | 15/01/2015 |  |  | 21/01/2015 |
| 15/STH/14 | Approve | Hyperkalaemia secondary to crush syndrome in victims of the 22nd February 2011 Christchurch earthquake | Ms Sarah Standring | Observational | 2/02/2015 | 18/02/2015 | 23/03/2015 | 30/03/2015 |
| 15/STH/23 | Approve | Hip fracture at Auckland City Hospital: a follow up study | Dr Tom Moodie | Observational | 9/02/2015 |  |  | 23/02/2015 |
| 15/STH/113 | Approve | Study of Foot Problems in a population of older patients | Dr Tom Moodie | Observational | 29/06/2015 | 8/07/2015 | 16/07/2015 | 20/07/2015 |
| 15/STH/109 | Approve | STI Partner Notification Study | Dr Sally Rose | Observational | 1/07/2015 |  |  | 16/07/2015 |
| 15/STH/116 | Approve | Improving cardiopulmonary fitness before surgery | Doctor John Woodfield | Intervention | 3/07/2015 |  |  | 16/07/2015 |
| 15/STH/117 | Approve | The determinants of resolving infertility | Professor Wayne Gillett | Observational | 7/07/2015 |  |  | 16/07/2015 |
| 15/STH/118 | Approve | Quantifying the effect and variability of neuromuscular blocking drugs on patients undergoing surgery | Assoc Prof Dr RR Kennedy | Observational | 17/07/2015 |  |  | 28/07/2015 |
| 15/STH/120 | Approve | Music, Movement and Memory Study | Miss Kristina Zawaly | Intervention | 29/07/2015 | 3/08/2015 | 6/08/2015 | 17/08/2015 |
| 15/STH/130 | Approve | Understanding why urate crystals form | Prof Nicola Dalbeth | Observational | 3/08/2015 |  |  | 17/08/2015 |
| 15/STH/133 | Approve | OE-MRI in head and neck cancer | Dr Andrew Macann | Intervention | 10/08/2015 |  |  | 17/08/2015 |
| 15/STH/131 | Approve | Non-alcoholic fatty liver dsease and Hepatocellular Carcinoma | Prof Edward Gane | Observational | 14/08/2015 |  |  | 18/08/2015 |
| 15/STH/138 | Approve | SHELTER | Dr Nevil Pierse | Observational | 14/08/2015 |  |  | 25/08/2015 |
| 15/STH/139 | Approve | Assessing specificity and sensitivity of a computerized system, supporting the diagnostic process of ADHD | Dr Yariv Doron | Intervention | 18/08/2015 |  |  | 31/08/2015 |
| 15/STH/147 | Approve | Karanga | Dr Helen Wihongi | Observational | 31/08/2015 |  |  | 4/09/2015 |
| 15/STH/160 | Approve | Statin use and risk of diverticulitis | CR fellow Pamela Buchwald | Observational | 4/09/2015 |  |  | 17/09/2015 |
| 15/STH/161 | Approve | Haemophilia Carriers in Auckland | Dr Laura Young | Observational | 11/09/2015 | 22/09/2015 | 30/09/2015 | 7/10/2015 |
| 15/STH/162 | Approve | Non-epileptic seizures in individuals attending neurological services | Dr Frederick Sundram | Observational | 11/09/2015 | 22/09/2015 | 25/09/2015 | 28/09/2015 |
| 15/STH/167 | Approve | DiNGo Trial | Prof David Cameron-Smith | Intervention | 17/09/2015 | 24/09/2015 | 17/11/2015 | 24/11/2015 |
| 15/STH/168 | Approve | Prognostic Factors Determining Outcomes Following Renal Replacement Therapy in the Intensive Care Unit at Middlemore Hospital | Doctor Jonathan Chen | Observational | 21/09/2015 |  |  | 28/09/2015 |
| 15/STH/170 | Approve | Child cancer in New Zealand 1978-1999: Incidence, survival, second malignancies and late mortality | Mrs Kirsten Ballantine | Observational | 23/09/2015 |  |  | 28/09/2015 |
| 15/STH/169 | Approve | CAST in Older Normal | Dr Kevin Ellyett | Intervention | 25/09/2015 |  |  | 30/09/2015 |
| 15/STH/184 | Approve | Improving health in breast cancer survivors, a novel dietary approach | Dr Andrea Braakhuis | Intervention | 5/10/2015 | 15/10/2015 | 2/11/2015 | 6/11/2015 |
| 15/STH/185 | Approve | CNP and Renal Dysfunction | Dr Timothy Prickett | Observational | 9/10/2015 |  |  | 20/10/2015 |
| 15/STH/186 | Approve | A Kaupapa Māori approach to CVD risk reduction | Dr Anna Rolleston | Intervention | 13/10/2015 |  |  | 21/10/2015 |
| 15/STH/187 | Approve | Pilot of FitBit One® to Measure Physical Activity | Dr. Robert Matthew Strother | Intervention | 16/10/2015 |  |  | 30/10/2015 |
| 15/STH/188 | Approve | A pilot study of changes in the central venous pressure waveform | DR Michael Harrison | Observational | 20/10/2015 |  |  | 3/11/2015 |
| 15/STH/191 | Approve | Early warning of the deteriorating patient | Professor Geoffrey Shaw | Observational | 26/10/2015 |  |  | 9/11/2015 |
| 15/STH/200 | Approve | Prof AMI Trop | Associate Professor John W Pickering | Observational | 30/10/2015 | 9/11/2015 | 24/11/2015 | 27/11/2015 |
| 15/STH/193 | Approve | C3 Comorbidity CRC Pilot Study | Dr Christopher Jackson | Intervention | 4/11/2015 |  |  | 9/11/2015 |
| 15/STH/214 | Approve | Intermittent hypoxia and outcome | Dr Jane Alsweiler | Observational | 6/11/2015 |  |  | 16/11/2015 |
| 15/STH/215 | Approve | Nicotine e-cigarette use in New Zealand | Ms Fraser Patricia | Observational | 6/11/2015 | 16/11/2015 | 24/11/2015 | 27/11/2015 |
| 15/STH/212 | Approve | An evaluation of St John's ePRF | Ms Gayl Humphrey | Observational | 11/11/2015 |  |  | 24/11/2015 |
| 15/STH/217 | Approve | Cranberry capsules for radiation-cystitis | Dr Patries Herst | Intervention | 12/11/2015 |  |  | 24/11/2015 |
| 15/STH/218 | Approve | Chiropractic and strength in athletes | Dr Heidi Haavik | Intervention | 18/11/2015 |  |  | 2/12/2015 |
| 15/STH/223 | Approve | Amaurosis fugax and carotid artery disease | Dr Manar Khashram | Observational | 23/11/2015 |  |  | 4/12/2015 |
| 15/STH/224 | Approve | ETHICUS II | Dr Alex Kazemi | Observational | 26/11/2015 |  |  | 16/12/2015 |
| 15/STH/239 | Approve | A metabolomics-based approach for the diagnosis of fetal malformations | Professor Lesley McCowan | Observational | 26/11/2015 |  |  | 11/12/2015 |
| 15/STH/237 | Approve | NuSeD trial | Dr Alexandra Chisholm | Intervention | 2/12/2015 |  |  | 18/12/2015 |
| 15/STH/220 | Approve | Benign enhancing foramen magnum lesions on MRI | Dr Ben McGuinness | Observational | 3/12/2015 |  |  | 21/12/2015 |

## Overdue full applications

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| Reference | Short title | Days overdue | Reason overdue |
| 15/STH/149 | CLS001-CO-PR-004: Safety and effectiveness of once-daily CLS001 gel in Papulopustular Rosacea with extended treatment | 1 | Committee member delay in Response |
| 15/STH/20 | REGENERON - A Study to test REGN2222 in preventing respiratory syncytial virus (RSV) in preterm infants | 1 | Committee member delay in Response |
| 15/STH/128 | Urocanate in human specimens | 3 | Committee member delay in Response |
| 15/STH/208 | Psychometric properties of the needs of children's questionnaire | 3 | Committee member delay in Response |
| 15/STH/153 | Harmoni Feasibility | 4 | Committee member delay in Response |
| 15/STH/93 | Acerta 006 | 5 | Committee member delay in Response |
| 15/STH/45 | Biomarkers of outcomes related to anticoagulants | 6 | Committee member delay in Response |
| 15/STH/60 | HAUSER-RCT | 18 | Incomplete provisional Response |
| 15/STH/35 | MK3475 versus Paclitaxel for Advanced Gastric Cancer | 20 | Committee member delay in Response |
| 15/STH/12 | Assessing specificity and sensitivity of a computerized system, supporting the diagnostic process of ADHD | 22 | Committee member delay in Response |

## Overdue expedited applications

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| --- | --- | --- | --- |
| Reference | Short title | Days overdue | Reason overdue |
| 15/STH/120 | Music, Movement and Memory Study | 1 | Secretariat Failed to Action Decision |
| 15/STH/237 | NuSeD trial | 1 | Secretariat Failed to Action Decision |
| 15/STH/30 | Joint replacement in RA | 1 | Committee member delay in Response |
| 15/STH/95 | The PORTAL study | 2 | Secretariat Failed to Action Decision |
| 15/STH/161 | Haemophilia Carriers in Auckland | 3 | Committee member delay in Response |
| 15/STH/220 | Benign enhancing foramen magnum lesions on MRI | 3 | Secretariat Failed to Action Decision |
| 15/STH/40 | The 2015 ANZAC cohort | 4 | Committee member delay in Response |
| 15/STH/65 | (duplicate) Study to determine if bacteria present in the vagina and semen as determined by using standard routine microbiological culture at embryo transfer affects pregnancy outcome | 4 | Secretariat Failed to Action Decision |
| 15/STH/224 | ETHICUS II | 5 | Incomplete provisional Response |
| 15/STH/58 | Brain Imaging in Anorexia Nervosa | 5 | Secretariat Failed to Action Decision |
| 15/STH/63 | Extensor tendon randomised controlled trial | 5 | Secretariat Failed to Action Decision |
| 15/STH/64 | Validating 1 minute Sit-to-Stand testing for use in Pulmonary Rehabilitation | 5 | Secretariat Failed to Action Decision |
| 15/STH/28 | Lymphoedema Drainage Project Part 3 | 7 | Committee member delay in Response |
| 15/STH/29 | Pelvic girdle assessments in non-radiographic spondyloarthritis | 7 | Committee member delay in Response |
| 15/STH/14 | Hyperkalaemia secondary to crush syndrome in victims of the 22nd February 2011 Christchurch earthquake | 8 | Committee member delay in Response |
| 15/STH/55 | The genetics of Idiopathic scoliosis | 13 | Secretariat Failed to Action Decision |