South Metropolitan Health Service

RESEARCH REPORT
2018

Excellent health care, every time
Acknowledgement of Country and People

South Metropolitan Health Service respectfully acknowledges the Noongar people both past and present, the traditional owners of the land on which we work. We affirm our commitment to reconciliation through strengthening partnerships and continuing to work with Aboriginal peoples.
Forewords

The South Metropolitan Health Service (SMHS) Research Report describes the research activity occurring in the Fiona Stanley Fremantle Hospital Group (FSFHG) and Rockingham Peel Group (RkPG) in the 2018 calendar year.

The list of research projects for this report was collated by auditing the online Research Governance Service (RGS) reports for new projects that were approved to commence in the 2018 calendar year, i.e. those that had site authorisation. Many projects during this time may have received ethics approval but were still submitting an application to governance, or were pending an outcome from the governance review.

The list of publications was collated following detailed searches on key investigators for 2018 published works. Any publications that stated an affiliation with SMHS or a SMHS site were included in this listing.

From the SMHS Chief Executive

This report highlights the diverse volume of research activity being conducted across SMHS sites during 2018, and the associated research translation activities occurring via publications.

During the year, there have been significant upgrades to the WA Health Research Governance Service (RGS), to incorporate the monitoring function and publications component and the migration of all pre-RGS projects. RGS now provides SMHS with a comprehensive online tool in which to approve, manage and report on our research projects and activity. SMHS research projects include sponsored clinical drug trials, national and international collaborative trials and locally initiated projects aiming to improve patient outcomes.

Research is critical to SMHS and the community it serves. It is a credit to our investigators that this research often has impact beyond the local setting, with the outcomes of these projects having national and international significance for patient quality and safety or clinical and lifestyle outcomes.

SMHS held its inaugural Research Showcase on the 29 November 2018; a fantastic day of ‘sharing, collaborating and celebrating’ research and our researchers. The event was kindly sponsored by the Harry Perkins Institute of Medical Research and Spinnaker Health Research Foundation. Thank you to all the wonderful presenters for giving their time and expertise to support this event and congratulations to the award winners Dr Samara Baldwin and Jocelyn Drinkwater.

I look forward to building on and improving the research culture in SMHS during 2019, by involving our research community in delivering the activities outlined in the SMHS Research Operational Plan (2018-2020), and creating a research environment in which we can all be proud.

Mr Paul Forden
Chief Executive, SMHS.
Executive summary

The SMHS Board has outlined research as a key enabler to deliver on its strategic priority of
Excellence in the delivery of safe, high quality clinical care.1

It is also recognised that research is a pivotal enabler of the other four strategic priorities of SMHS:

- Provide a great patient experience
- Engage, develop and provide opportunities for our workforce
- Strengthen relationships with our community and partners
- Achieve a productive and innovative organisation which is financially sustainable.

This report aims to capture research activity occurring in SMHS during a calendar year.

In 2018, the majority of research in SMHS has been conducted at Fiona Stanley Hospital (FSH); however, a significant number of projects involve collaboration across SMHS sites including Fremantle Hospital (FH) and Rockingham General Hospital (RGH).

Research activity

- 152 projects were approved to proceed at SMHS sites in 2018; 68 of which were approved by the SMHS Human Research Ethics Committee (HREC) (45 per cent)
- 10 waivers of consent were granted by the SMHS HREC
- 2 projects were not authorised to proceed due to participant consent issues
- 26 projects did not proceed as they were placed ‘on-hold’, withdrawn or closed
- 452 publications were sourced that have an affiliation noted with SMHS or a SMHS site.

Acknowledgements

This report was developed with contributions from:

- researchers from multiple departments as detailed within this report
- SMHS/EMHS Library team
- SMHS Communications team
- SMHS Research, Support and Development Unit (RSDU).
Overview
Research environment

The research environment within SMHS has experienced several large scale changes and some exciting new developments to enable research activities and empower researchers:

Research Advisory Group (RAG)
- RAG is an informal gathering of SMHS staff who share and present their research projects and discuss issues or concerns regarding conducting research in the organisation. This group was established by Professor Merrilee Needham as a forum for bringing staff together and collegiately resolving issues or barriers for research.

SMHS Research Advisory Committee (RAC)
- RAC is comprised of a multi-disciplinary group of staff whose main aim is to deliver on the actions outlined in the SMHS Research Operational Plan (2018-2020), and advise executive on research matters.

Research Governance Service (RGS)
- RGS is the WA Health Information Technology platform that manages all Ethics and Governance submissions and approvals across WA Health. In August 2018, the monitoring component went live which ensured that all amendments, safety and annual reports are managed within RGS. In November 2018, all active projects from the old Access database were migrated into RGS, which means that all projects can be managed in one repository with the same processes. This provides a true picture of the research activity across sites and standardises and streamlines workflows.

Workflow management tool
- In April 2018, an in-house workflow management tool was developed and implemented in the RSDU office for managing workflow tasks and queues more effectively. This system is an adjunct to the RGS system and assists the team to manage queues and priorities, rather than using Excel spreadsheets or hand written notes. The system has been extremely effective in helping the team to manage demand, communicate progress internally and externally and improve key performance indicators for approvals and amendments.
SMHS research activity

Details of research project activity in SMHS during 2018 are described in the tables below.

**Table 1: 2018 projects approved to proceed in SMHS**

<table>
<thead>
<tr>
<th>Dates</th>
<th>Activity</th>
<th>SMHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 January 2018 to 31 December 2018</td>
<td>Site Authorisation approved</td>
<td>152</td>
</tr>
</tbody>
</table>

**Table 2: 2018 projects approved to proceed at each site in SMHS**

<table>
<thead>
<tr>
<th>Dates</th>
<th>Activity</th>
<th>FSH</th>
<th>FH</th>
<th>RGH</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 January 2018 to 31 December 2018</td>
<td>Site Authorisations</td>
<td>139</td>
<td>26</td>
<td>9</td>
</tr>
</tbody>
</table>

*Note that a project can be conducted across multiple sites*

**Table 3: 2018 projects not authorised to proceed**

<table>
<thead>
<tr>
<th>Dates</th>
<th>Activity</th>
<th>SMHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 January 2018 to 31 December 2018</td>
<td>Projects not authorised</td>
<td>2</td>
</tr>
</tbody>
</table>

**Table 4: 2018 projects that did not progress (‘on-hold’, withdrawn or closed)**

<table>
<thead>
<tr>
<th>Dates</th>
<th>Activity</th>
<th>SMHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 January 2018 to 31 December 2018</td>
<td>Projects not progressed</td>
<td>26</td>
</tr>
</tbody>
</table>
Waiver of Consent

The National Health and Medical Research Council (NHMRC) highlights in the National Statement\(^2\) that “depending upon the circumstances of an individual project it may be justifiable to employ a waiver of the consent requirement, rather than seeking explicit consent”. In order to apply for a waiver of consent investigators must respond to Section 2.3.10 of the National Statement highlighting the need for a waiver as well as an analysis of the associated risks and benefits of the project.

A waiver of consent can only be granted for low risk projects which pose no more than the risk of discomfort to participants; this does not include any novel interventional research. A waiver can only be granted by a meeting of the full HREC. The SMHS HREC granted 10 waivers of consent in 2018, as per Table 5, which is a decrease from 30 waivers of consent granted in 2017. This is partly due to the legal issues regarding consent for research that were raised across WA Health during 2018. The majority of projects that were granted a waiver of consent in 2018 all included de-identified or non-identifiable data which poses negligible risk to participants. The NHMRC requires that a brief description of all projects with a waiver of consent is publically available.

Table 5: Waiver of consent projects

<table>
<thead>
<tr>
<th>PRN/project title</th>
<th>Brief description of study and rationale for the approval of a Waiver of Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. RGS 777</td>
<td>Characteristics and outcomes of Acute Myeloid Leukaemia in Western Australia</td>
</tr>
<tr>
<td></td>
<td>Uses de-identified, retrospective data to examine clinical and laboratory</td>
</tr>
<tr>
<td></td>
<td>prognostic markers for all patients diagnosed with AML at a tertiary hospital</td>
</tr>
<tr>
<td></td>
<td>in Western Australia, to determine which are most predictive of survival in</td>
</tr>
<tr>
<td></td>
<td>this population.</td>
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<tr>
<td>2. RGS 729</td>
<td>A review of the epidemiology, management and mortality of patients with penile</td>
</tr>
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<td></td>
<td>cancer in Western Australia</td>
</tr>
<tr>
<td></td>
<td>To review how patients diagnosed with penile cancer in Western Australia</td>
</tr>
<tr>
<td></td>
<td>between 1992 to 2018 have been treated and managed. To assess short,</td>
</tr>
<tr>
<td></td>
<td>intermediate and long-term survival outcomes and to determine whether</td>
</tr>
<tr>
<td></td>
<td>patients diagnosed with penile cancer in Western Australia are being</td>
</tr>
<tr>
<td></td>
<td>treated in accordance with international standards and evidence-based care.</td>
</tr>
<tr>
<td></td>
<td>Uses coded data from WA Cancer Registry and hospital medical records.</td>
</tr>
<tr>
<td>PRN/project title</td>
<td>Brief description of study and rationale for the approval of a Waiver of Consent</td>
</tr>
<tr>
<td>-------------------</td>
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</tr>
<tr>
<td><strong>3. RGS 812</strong></td>
<td>Post Cardiac Surgery Leukocytosis - an investigation of aetiology and patient outcomes</td>
</tr>
<tr>
<td></td>
<td>This study seeks to investigate markers for the post-cardiac surgery inflammatory response using a modern cardiac surgery database, and the clinical implications of this. This is a retrospective observational case series. The data in this study is de-identified, but taken from identifiable patient medical records, and therefore is of low risk</td>
</tr>
<tr>
<td><strong>4. RGS 813</strong></td>
<td>Comparing on pump and off pump coronary bypass surgery and long term cancer outcomes</td>
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<tr>
<td></td>
<td>This study seeks to investigate if there is an association between the use of cardiopulmonary bypass in cardiac surgery and long-term cancer rates. Data will be sought as a data linkage analysis using the ANZCTS National Cardiac Surgery Database and the Australian Cancer Database. This is a retrospective observational case series. The data in this study will be de-identified, taken from database records with data linkage with the national cancer registry, and therefore is of low risk</td>
</tr>
<tr>
<td><strong>5. RGS 848</strong></td>
<td>Australia and New Zealand Emergency Laparotomy Audit Quality Improvement</td>
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<tr>
<td></td>
<td>The Australia and New Zealand Emergency Laparotomy Audit Quality Improvement (ANZELA-QI) project is an initiative to provide real-time data on the management of emergency laparotomies in these two countries, to empower clinicians and hospitals to improve the quality of care provided to the vulnerable and sizable cohort of patients that undergo these procedures each year. Waiver of consent was granted with condition that every attempt should be made to ensure the privacy and confidentiality of the participants.</td>
</tr>
<tr>
<td><strong>6. RGS 1008</strong></td>
<td>Non-iatrogenic, non-traumatic spontaneous cerebrospinal fluid (CSF) otorrhoea</td>
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<tr>
<td></td>
<td>Aims to identify the key features on history and examination in patients presenting with non-iatrogenic, non-traumatic spontaneous CSF otorrhoea in order to further characterise this growing cohort and to describe the significance of radiological imaging and biochemical markers in the diagnosis of spontaneous CSF otorrhoea. Retrospective cohort study using non-identifiable data from medical records.</td>
</tr>
<tr>
<td>PRN/project title</td>
<td>Brief description of study and rationale for the approval of a Waiver of Consent</td>
</tr>
<tr>
<td>-------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>7. RGS 987</td>
<td>Retrospective observational study to compare the outcomes of patients who required Extracorporeal Membrane Oxygenation (ECMO) support in the 2009 H1N1 influenza pandemic to those in the 2017 influenza season. The only identifiable data collected will be the patient date of birth; risk to the patient is negligible.</td>
</tr>
<tr>
<td>8. RGS 645</td>
<td>Observational study using linked data. To compare the health-related quality of life (HRQoL) at six-months post-program completion in participants allocated to the extended Phase 3 Pulmonary Rehabilitation program against those not allocated to the extended program. De-identified research data is stored off site.</td>
</tr>
<tr>
<td>9. RGS 1370</td>
<td>This is a negligible risk, retrospective study where the primary objective is to determine the pattern of care of Eribulin use by medical oncologists in Australia who manage metastatic breast cancer (MBC) patients, especially in relation to the line of therapy in which Eribulin is used and comparing real-world survival outcomes to published literature. A de-identified case report form is used.</td>
</tr>
<tr>
<td>10. RGS 1368</td>
<td>A retrospective observational study to compare hospital outcomes in patients admitted for colorectal surgery prior to and after program implementation. The specific objectives study are to assess how many appropriate red blood cell transfusions are avoidable by identifying and appropriately managing iron-deficiency anaemia; determine whether preoperative anaemia screening and management is associated with an improvement in patient outcomes; and assess whether preoperative anaemia screening and management is cost-effective. Data is non-identifiable and uses existing, routinely obtained data.</td>
</tr>
</tbody>
</table>
The inaugural SMHS Research Showcase was held in November 2018. The day encouraged researchers to ‘share, collaborate and celebrate’ their research achievements and consisted of three events:

- Breakfast Research Forum
- Three Minute Project Competition for novice investigators
- Evening Gala and Awards Ceremony.

The breakfast forum, themed ‘Lifestyle factors in disease management’, was well attended by staff and the community.

**Associate Professor Glenn Arendts** who spoke on ‘How to stay out of my emergency department as you age’ and **Dr Oyekoya Ayonrinde**: ‘Fatty Liver Disease Risk – Traversing the risks from maternal and childhood factors’, shared their extensive body of work in a collegiate and interactive session, which generated robust discussion and sparked interest in future collaborations.

An expert panel consisting of **Professor Bu Yeap** (Chair), **Associate Professor Andrew Maiorana** and **Nurse Unit Manager Jo Camilleri** added significant input from their experiences in the areas of diabetes research, exercise physiology and staff burn-out respectively.

The Spinnaker Research Foundation sponsored the Three Minute Project Competition, aimed at encouraging emerging researchers to communicate their research outcomes in a lively engaging format:

1. **Melanie Wright**: Exploring the perspectives of project staff on patient involvement in healthcare projects in Western Australian public hospitals and health services: a mixed method study
2. **Dr Helen Douglas**: Scar hyperpigmentation in pregnancy
3. **Dr Helen Douglas**: Burn injuries secondary to cryolipolysis: freezing fat, burning skin
4. **Dr Niwansa Adris**: Detection of HFE Haemochromatosis using standard haematological tests
5. **Dr Stephanie Lam**: ‘DOAC levels in the elective surgical population’
6. **Dr Samara Baldwin**: ‘Rates of allergic reactions in high risk infants during the first introduction of peanut’
7. **Dr Veenoo Agarwal**: How dense are you?
8. **Jonathon Chee**: Physical health of young people experiencing first episode psychosis: consumers’ experiences
9. **Dr Usha Chandra Sekaran**: Efficacy of 3-Factor PCC in reversal of major bleeding associated with NOAC.
Evening gala and awards ceremony

The showcase culminated in an event sponsored by the Harry Perkins Institute that celebrated the achievements of SMHS researchers to the theme of ‘Embedding Research in Clinical Practice’.

Professor Merrilee Needham delivered a keynote address titled ‘Myositis research in WA: Embedding research in clinical practice’ while Associate Professor Andrew Redfern’s keynote address covered ‘Research translation: from concept to clinic and beyond’.

This was followed by presentation of the awards to the winner of the Three Minute Project Competition Samara Baldwin, and to Jocelyn Drinkwater for the Best Digital Poster.

Finally, Professor Nigel Laing representing the event’s sponsor The Harry Perkins Institute of Medical Research gave an entertaining snapshot of his organisations research capabilities after which guests adjourned to Perkins South foyer to mingle over drinks and canapes.
Award winners

Inaugural Spinnaker Novice Investigator Three Minute Project Competition winner
Dr Samara Baldwin
‘Allergic reactions in high-risk infants during first introduction of peanut’.

Honourable mentions - the judges also awarded honourable mentions to:

- **Dr Stephanie Lam**: Safety of perioperative cessation of direct oral anticoagulants
- **Dr Niwansa Adris**: Detection of HFE Haemochromatosis using standard haematological tests

Inaugural SMHS RSDU Best Digital Poster winner
Jocelyn Drinkwater
Retinopathy predicts stroke in type 2 diabetes: The Fremantle Diabetes Study Phase II

A further 27 digital posters were received and displayed on a rotating schedule via mobile displays throughout the day.

Honourable mentions - the judges also awarded honourable mentions to:

- **Tiffany Ryan**: Travelling for treatment: the experiences of Aboriginal women who relocate to the State Adult Burns Unit at Fiona Stanley Hospital
- **Dr Edmond O’Loughlin and Lucy Glazov**: Anaesthesia Research – Fiona Stanley Hospital
Researcher of the year
Inaugural SMHS researcher of the year

As a patient-focused, clinically-applied researcher, whose work is internationally recognised, Dr Dayse Tavora-Vieira has been named as the inaugural South Metropolitan Health Service (SMHS) Researcher of the Year.

As Head of Audiology at Fiona Stanley Hospital (FSH) and an active researcher for the past 11 years, Dr Tavora-Vieira’s work has resulted in change to internationally accepted practice, benefiting audiology patients worldwide.

Dr Tavora-Vieira’s research has placed FSH on the international stage in the field of hearing restoration, with the largest number of cochlear implant recipients with single-sided deafness in the world, and resulted in Therapeutic Goods Administration approval for this clinical application.

“Providing the best possible care to my patients is what continues to drive my research,” Dr Tavora-Vieira said.

“Routinely incorporating research into my daily work has permitted me to deliver that higher level of care our patients deserve. It is an absolute privilege for me to see the results of my research being implemented and benefiting my patients.

“My research commitments are first and foremost dedicated to my patients and my team who have helped with every single research project.”

Dr Távora-Vieira’s belief in equity of health services access and commitment to evidence-based practice is exemplified by the introduction of an advanced scope audiology clinic to reduce the ENT outpatient waitlist and a telemapping service to remediate hearing impairment in remote patients.

Under the care of Dr Tavora-Vieira and her team, patients have experienced significant improvements in quality of life as a result of improved hearing.

Dr Dayse Tavora-Vieira’s thirst for knowledge and a strong determination to provide the best possible care for her patients exemplify the SMHS vision of Excellent health care, every time.
Projects
## Research projects

Table 6 provides details of 152 research projects that were approved to commence at a SMHS site during 2018, using the site authorisation decision date from RGS reporting (RGO extract, SMHS, 2019-01-25), and data from the completed project list in SHIMS (local IT system to manage research workflow queues).

### Table 6: project details from RGS of projects approved to proceed in 2018

<table>
<thead>
<tr>
<th>RGS PRN</th>
<th>Title</th>
<th>CPI/PI</th>
<th>Lead HREC</th>
<th>Site(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>09</td>
<td>WA Neck of Femur Fracture Collaboration</td>
<td>Dr Ed O’Loughlin (CPI/PI)</td>
<td>SMHS</td>
<td>FSH FH</td>
</tr>
<tr>
<td>12</td>
<td>A cohort study of otitis media in young urban Aboriginal children – prevalence, risk factors and consequences.</td>
<td>Deborah Lehmann (CPI) Peter Richmond (PI)</td>
<td>CAHS</td>
<td>FSH RGH Other WA</td>
</tr>
<tr>
<td>24</td>
<td>A randomised trial of anti-inflammatory therapy in gout</td>
<td>Dr Helen Keen (CPI/PI)</td>
<td>RPH</td>
<td>FSH Other WA</td>
</tr>
<tr>
<td>27</td>
<td>The efficacy of silicone-film forming dressing versus standard care for the treatment of acute burn injuries not requiring surgery, and donor sites</td>
<td>Rosemary Kendell (CPI) Fiona Poelchow (PI)</td>
<td>SMHS</td>
<td>FSH</td>
</tr>
<tr>
<td>43</td>
<td>Evolution of beta-lactam resistance in Pseudomonas aeruginosa during treatment of major burn injury</td>
<td>Dr Ed Raby (CPI/PI)</td>
<td>SMHS</td>
<td>FSH Other national</td>
</tr>
<tr>
<td>44</td>
<td>A tailored music therapy and real-time biofeedback mobile phone app (“GotRhythm”) to promote rehabilitation following stroke</td>
<td>Assoc. Professor Christopher Etherton-Beer (CPI) Assoc. Professor Michael Rosenberg (PI)</td>
<td>RPH</td>
<td>FSH FH Other WA</td>
</tr>
<tr>
<td>76</td>
<td>National Myringoplasty Audit</td>
<td>Dr Caitlin Chidlow (CPI/PI)</td>
<td>SMHS</td>
<td>FSH</td>
</tr>
<tr>
<td>86</td>
<td>Australian Genomics Health Alliance: Preparing Australia for Genomic Medicine</td>
<td>Professor Nigel Laing (CPI) Dr Lloyd D’Orsogna (PI)</td>
<td>CAHS</td>
<td>FSH Other WA</td>
</tr>
<tr>
<td>102</td>
<td>TEMPO2- A randomized controlled trial of TNK-tPA versus standard of care for minor ischemic stroke with proven occlusion</td>
<td>Dr Darshan Ghia (CPI/PI)</td>
<td>SMHS</td>
<td>FSH</td>
</tr>
<tr>
<td>105</td>
<td>The effect of 4% succinylated gelatine fluid on acute kidney injury in critically ill patients</td>
<td>Assoc. Professor Kwok Ming Ho (CPI) Dr Ed Litton (PI)</td>
<td>SMHS</td>
<td>FSH Other WA</td>
</tr>
<tr>
<td>108</td>
<td>The Implementation, User Testing and Validation of the Web-based Application for the Population Pharmacokinetic Service – Hemophilia (WAPPS-HEMO) Phase 2</td>
<td>Dr Stephanie P’Ng (CPI/ PI)</td>
<td>RPH</td>
<td>FSH</td>
</tr>
<tr>
<td>RGS PRN</td>
<td>Title</td>
<td>CPI/PI</td>
<td>Lead HREC</td>
<td>Site(s)</td>
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<td>------------------</td>
</tr>
<tr>
<td>125</td>
<td>Enhancing rehabilitation services for Aboriginal Australians after brain injury</td>
<td>Professor Elizabeth Armstrong (CPI)  Dr Darshan Ghia (PI)</td>
<td>RPH</td>
<td>FSH FH RGH Other WA</td>
</tr>
<tr>
<td>127</td>
<td>Large Cohort, multi-centre, multi-national follow-up of the Saiph Total Knee Replacement (SAIPH MCS)</td>
<td>Professor Piers Yates (CPI/PI)</td>
<td>SMHS</td>
<td>FH</td>
</tr>
<tr>
<td>130</td>
<td>A retrospective investigation into the effectiveness of surveillance post-curative colorectal cancer resection in Western Australia</td>
<td>Dr Thomas Ferguson (CPI/PI)</td>
<td>RPH</td>
<td>FSH Other WA</td>
</tr>
<tr>
<td>144</td>
<td>Pre-treatment wait time for head and neck cancer in Western Australia</td>
<td>Dr Stephanie Flukes (CPI/PI)</td>
<td>SMHS</td>
<td>FSH</td>
</tr>
<tr>
<td>176</td>
<td>Fiona Stanley Diabetes Patient Management System</td>
<td>Dr P. Gerry Fegan (CPI/PI)</td>
<td>SMHS</td>
<td>FSH</td>
</tr>
<tr>
<td>184</td>
<td>Biomechanical modelling of type B aortic dissection</td>
<td>Professor Paul Norman (CPI/PI)</td>
<td>SMHS</td>
<td>FSH Other WA</td>
</tr>
<tr>
<td>203</td>
<td>The role of executive function in discourse production and health related quality of life in aphasia.</td>
<td>Sarah Wynn (CPI) Lisa Majteles (PI)</td>
<td>SMHS</td>
<td>FSH FH RGH Other WA</td>
</tr>
<tr>
<td>216</td>
<td>20150290: A Phase 1b Open Label Study Investigating the Safety and Efficacy of Blinatumomab in Combination with Pembrolizumab In Adult Subjects With Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)</td>
<td>Dr Paul Cannell (CPI/PI)</td>
<td>RPH</td>
<td>FSH</td>
</tr>
<tr>
<td>225</td>
<td>The extent to which a professional development program can support caring nursing practice in Western Australia hospitals</td>
<td>Tonia Naylor (CPI/PI)</td>
<td>RPH</td>
<td>FSH FH Other WA</td>
</tr>
<tr>
<td>261</td>
<td>A Post-Marketing Safety Study to Evaluate the Occurrence of Aseptic Meningitis Syndrome (AMS) in an Adult Population (&gt; 18 Years) Treated with Doses of = 1g/kg Intragam® 10 NF</td>
<td>Dr Stephanie P’Ng (CPI/PI)</td>
<td>RPH</td>
<td>FSH</td>
</tr>
<tr>
<td>263</td>
<td>ATLAS-A/B: A Phase 3 Study to Evaluate the Efficacy and Safety of Fitusiran in Patients With Hemophilia A or B, Without Inhibitory Antibodies to Factor VIII or IX</td>
<td>Dr Huyen Tran (CPI) Dr Stephanie P’Ng (PI)</td>
<td>Alfred Hospital</td>
<td>FSH Other national</td>
</tr>
<tr>
<td>RGS PRN</td>
<td>Title</td>
<td>CPI/PI</td>
<td>Lead HREC</td>
<td>Site(s)</td>
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<tr>
<td>275</td>
<td>T-VEC Liver Mets: A Phase 1b Study of Talimogene Laherparepvec in Combination With Atezolizumab in Subjects With Triple Negative Breast Cancer and Colorectal Cancer With Liver Metastases</td>
<td>Assoc. Professor Adnan Khattak (CPI/PI)</td>
<td>RPH</td>
<td>FSH</td>
</tr>
<tr>
<td>280</td>
<td>A physician-initiated double-blind, randomised, placebo-controlled, phase 2 study evaluating the efficacy and safety of inhibition of NADPH Oxidase with the first-in-class Nox-1/4 inhibitor, GKT137831, in adults with type 1 diabetes and persistently elevated urinary albumin excretion</td>
<td>Professor Tim Davis (CPI/PI)</td>
<td>SMHS</td>
<td>FH</td>
</tr>
<tr>
<td>306</td>
<td>Retrospective analysis of clinical efficacy and outcomes of left atrial appendage device occlusion in patients with atrial fibrillation</td>
<td>Dr Mary Nangrahary (CPI/PI)</td>
<td>SMHS</td>
<td>FSH FH Other WA</td>
</tr>
<tr>
<td>315</td>
<td>ATA129-EBV-301: Multicenter, Open-Label, Phase 3 Trial of Allogeneic Epstein-Barr Virus Cytotoxic T Lymphocytes (EBV-CTLs) for Allogeneic Hematopoietic Cell Transplant (alloHCT) Patients with EBV-Associated Post-Transplant Lymphoproliferative Disease (EBV-PTLD) after Failure of Rituximab</td>
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Simple blood test could unlock responses to cancer therapies

A Fiona Stanley Hospital (FSH) researcher on a quest to find blood markers to help predict a cancer patient’s likelihood of responding to new immunotherapy treatments has been awarded a Raine Medical Research Foundation Clinician Research Fellowship.

FSH medical oncologist Clinical Professor Adnan Khattak is one of five researchers awarded the Department of Health funded fellowships that will enable him to pursue research.

Drugs that stimulate the immune system can significantly improve a patient’s survival outcome but these medications are expensive, don’t work for all patients and can cause debilitating side effects such as diarrhoea, abdominal pain and skin rashes.

Professor Khattak said currently there was no way of telling which patients would benefit from the drugs which can cost up to $10,000 per dose.

“I hope to overcome this by identifying predictive markers and using these to develop a simple blood test,” Professor Khattak said.

“Blood tests are minimally invasive so can be performed regularly to monitor the cancer as it evolves and to identify the mechanisms of drug resistance.

“The study will compare how certain markers in the blood differ between patients who respond well to the immunotherapy drugs and those who don’t.”

The markers of most interest to Professor Khattak are tumour cells that circulate in the blood of cancer patients and genetic defects that can be detected as certain protein expressions.

“Having a reliable means of predicting which patients would benefit from immunotherapies will not only spare many from undergoing treatments that would not help them and could even be harmful, but would also provide significant savings to the health system.”
483  |  A randomized, double-blind, placebo-controlled, six-month study to evaluate the efficacy, safety and tolerability of sarizotan in patients with Rett syndrome with respiratory symptoms  |  Dr Janine Spencer (CPI/PI)  |  CAHS  |  FSH

492  |  COLUMBA - A Phase 3 Randomized, Multicenter Study of Subcutaneous vs. Intravenous Administration of Daratumumbo in Subjects With Relapsed or Refractory Multiple Myeloma  |  Dr Bradley Augustson (CPI)  |  SCGOPHCG  |  FSH  |  Other WA

507  |  IPATunity130: a double-blind, placebo-controlled, randomized phase III study of ipatasertib in combination with paclitaxel as a treatment for patients with PIK3CA/AKT1/PTEN-altered, locally advanced or metastatic, triple-negative breast cancer or hormone receptor– positive, HER2-negative breast cancer  |  Dr Janine Lombard (CPI)  |  Northern Sydney LHD  |  FSH

511  |  Pilonidal Sinus Disease: Western Australia Metropolitan Health Services - Definitive Surgical Practice Preferences, Outcomes and Patient Perspective  |  Dr Munyaradzi Nyandoro (CPI/PI)  |  SMHS  |  FSH  |  FH  |  RGH  |  Other WA

527  |  Assessment of effectiveness and side effects following peptide receptor radionuclide therapy for neuroendocrine tumours  |  Dr David Ransom (CPI/PI)  |  SMHS  |  FSH

534  |  NIVORAD - A randomised phase 2 trial of nivolumab and stereotactic ablative body radiotherapy in advanced non-small cell lung cancer, progressing after first or second line chemotherapy  |  Professor Sankha Mitra (CPI)  |  SCGOPHCG  |  FSH  |  Other WA

536  |  A Randomized, Double-blind, Phase 2 Trial to Assess Safety and Efficacy of Lenvatinib at Two Different Starting Doses (18 mg vs. 14 mg QD) in Combination with Everolimus (5 mg QD) in Renal Cell Carcinoma Following One Prior VEGF-Targeted Treatment  |  Dr Shirley Wong (CPI)  |  Melbourne Health  |  FSH  |  Other national

537  |  Apical pitch perception and channel interaction in single-sided deaf cochlear implant users  |  Dr Dayse Tavora-Vieira (CPI/PI)  |  SMHS  |  FSH
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Improved quality of life for patients drives research

Helping patients return to their previous quality of life or better is a driving force for Fiona Stanley Fremantle Hospitals Group (FSFHG) researcher and orthopaedic surgeon Professor Piers Yates.

Professor Yates is a full time surgeon with clinical interests in arthroplasty, infection, implant design, trauma and joint preservation of the hip and knee. He has also developed an international reputation for his research and development into these areas, amounting to more than 100 journal publications and conference presentations.

His orthopaedic research has been a high priority in his career, completed on top of his clinical work, in a quest to always ensure the patient is receiving the best possible treatment.

“I forever look to improve things, challenge the status quo and ask the difficult questions. This allows me to continually learn but more importantly helps to improve patient outcomes,” Professor Yates said.

A large component of orthopaedic research at FSFHG is safety studies for hip and knee implants with the prime aim of finding the best solution for patients.

“Australian orthopaedic research is highly respected globally due to our regulation requirements. We lead the way in research into implants with the majority of this work undertaken at Fremantle Hospital as the prime site for elective orthopaedic surgery for South Metropolitan Health Service,” Professor Yates said.

Professor Yates has taken his research to the next level through the design and development of more than three implants.

“These hip and knee implants are now in use globally, with another two in production. As a surgeon, I see the different needs of our patients, so it was a natural progression for me to tailor a solution.”

Infected joint replacements is one of the biggest costs associated with joint replacement surgery, which has encouraged Professor Yates and his infectious disease colleagues to develop an international study based at Fiona Stanley Hospital (FSH).

“This is the biggest study we have done in our research group, with FSH being the highest recruiting site amongst the 900 cases and 22 centres involved,” Professor Yates said.

“Finding a better treatment pathway for infected joints, which is the major complication of implant failure is estimated to save upwards of $80,000 per patient!”
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<td>Illuminate 301. A Randomized Phase 3 Comparison of IMO-2125 with Ipilimumab versus Ipilimumab Alone in Subjects with Anti-PD-1 Refractory Melanoma</td>
<td>Dr Anna Lomax (CPI)</td>
<td>St Vincent's Hospital Melbourne</td>
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<td>859</td>
<td>A phase 2A, randomized, double blind, placebo controlled study to evaluate the efficacy, safety, tolerability and pharmacokinetics of PF06687234 as add on therapy to infliximab inactive ulcerative colitis subjects who are not in remission (build UC)</td>
<td>Professor Finlay Macrae (CPI) Dr Callum Pearce (PI)</td>
<td>Melbourne Health</td>
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<td>863</td>
<td>Effects of behavioural intervention on adherence to self-care activities, glycaemic control, diabetes-related psychological distress and quality of life in adults with complex diabetes</td>
<td>Dr Melanie Burkhardt (CPI/PI)</td>
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<td>887</td>
<td>The impact of an onsite toxicology service on ICU and medical length of stay in critically ill toxicology patients admitted to tertiary hospitals</td>
<td>Dr Julia George (CPI/PI)</td>
<td>RPH</td>
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<td>892</td>
<td>A prospective, randomised, Controlled, Open-label, Multicentre phase III study to evaluate efficacy and safety of Peptide Receptor Radionuclide Therapy (PRRT) with 177Lu-Edotreotide compared to targeted molecular therapy with Everolimus in patients with inoperable, progressive, somato-statin receptor-positive (SSTR+), neuroendocrine tumours of gastroenteric or pancreatic origin (GEP-NET)</td>
<td>Dr Andrew Kiberu (CPI/PI)</td>
<td>SMHS</td>
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<td>895</td>
<td>A 26-week Randomized, Double-blind, Placebo-controlled, Parallel group, Multicenter, Phase 3 study with a 78-week Extension Period to Evaluate the Efficacy and Bone Safety of Sotagliflozin in Patients 55 years or older with Type 2 Diabetes Mellitus and Inadequate Glycemic Control (EFC15294)</td>
<td>Emily England (CPI) Professor Timothy Davis (PI)</td>
<td>Melbourne Health</td>
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<td>901</td>
<td>A randomized, double-blind, placebo-controlled, multicenter, dose-range, proof-of-concept, 24-week treatment study of IVA337 in adult subjects with nonalcoholic steatohepatitis (NASH)</td>
<td>Dr Alexander Hodge (CPI) Dr Koya Ayonrinde (PI)</td>
<td>Monash Health</td>
<td>FSH</td>
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<td>912</td>
<td>CPKC412E2301: A phase III, randomized, double-blind study of chemotherapy with daunorubicin or idarubicin and cytarabine for induction and intermediate dose cytarabine for consolidation plus midostaurin (PKC412) or chemotherapy plus placebo in newly diagnosed patients with FLT-3 mutation negative acute myeloid leukemia (AML)</td>
<td>Assoc. Professor Andrew Wei Dr Matthew Wright (PI)</td>
<td>Alfred Hospital</td>
<td>FSH</td>
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<td>929</td>
<td>Establishing the prevalence and burden of healthcare associated infections in Australian hospitals</td>
<td>Dr Philip Russo (CPI) Ann Whitfield (PI)</td>
<td>Alfred Hospital</td>
<td>FSH Other WA Other national</td>
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<td>941</td>
<td>Return to normal diet following mandibular fractures - how long is long enough?</td>
<td>Dr Timothy Manzie (CPI/PI)</td>
<td>RPH</td>
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<td>943</td>
<td>Impact of seasonal temperature variations on symptoms and exercise performance in chronic heart failure (CHF) patients</td>
<td>Assoc. Professor Andrew Maiorana (CPI/PI)</td>
<td>The Prince Charles Hospital</td>
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<td>945</td>
<td>Risk factors for gonorrhoea in young heterosexual people in Perth</td>
<td>Dr Roanna Lobo (CPI) Assoc. Professor Lewis Marshall (Pl)</td>
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<td>971</td>
<td>Perceptions of Permanent Staff Nurses towards Agency Staff Nurses</td>
<td>Aaron Alejandro (CPI/PI)</td>
<td>SMHS</td>
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<td>974</td>
<td>Multiple escalating dose study of BAY 1093884 in adults with hemophilia A or B with or without inhibitors</td>
<td>Dr Stephanie P’Ng (CPI/PI)</td>
<td>SMHS</td>
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<td>987</td>
<td>The 2017 Severe Influenza Outbreak requiring Extracorporeal Membrane Oxygenation</td>
<td>Dr Michael McCann (CPI/PI)</td>
<td>SMHS</td>
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<td>988</td>
<td>Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) Patient Reported Outcome Measures (PROMs) Pilot Project</td>
<td>Professor Stephen Graves (CPI) Dr Omar Khorshid (PI)</td>
<td>Sydney LHD</td>
<td>FH Other WA Other national</td>
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<td>991</td>
<td>DYNAMIC-III: Circulating Tumour DNA Analysis Informing Adjuvant Chemotherapy in Stage III Colon Cancer: A Multicentre Phase II/II Randomised Controlled Trial</td>
<td>Assoc. Professor Jeanne Tie Dr Adnan Khattak (PI)</td>
<td>Melbourne Health</td>
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<td>1008</td>
<td>Non-iatrogenic, non-traumatic spontaneous cerebrospinal fluid (CSF) otorrhoea</td>
<td>Dr Thomas Hendriks (CPI/PI)</td>
<td>SMHS</td>
<td>FSH Other WA</td>
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<td>1013</td>
<td>The Early Eczema Education Project</td>
<td>Dr Samara Baldwin (CPI/PI)</td>
<td>CAHS</td>
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<td>1029</td>
<td>A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of BG00011 in Patients With Idiopathic Pulmonary Fibrosis</td>
<td>Debra Enever (CPI) Dr Jeremy Wrobel (PI)</td>
<td>The Prince Charles Hospital</td>
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<td>1033</td>
<td>SADAL: Phase 2b Open-label Study of Selinexor (KPT-330) in Patients with Relapsed/Refractory Diffuse Large B-Cell Lymphoma (DLBCL)</td>
<td>Dr Pratyush Giri (CPI) Dr Paul Cannell (PI)</td>
<td>Central Adelaide LHN</td>
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<td>1041</td>
<td>Management, Outcomes and Survival of an Australian IgG4 Cohort</td>
<td>Assoc. Professor William Kemp (CPI) Dr Simon Hazeldine (PI)</td>
<td>Alfred Hospital</td>
<td>FSH Other WA</td>
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<td>1049</td>
<td>In general surgery patients, does an individualised prehabilitation exercise program with targeted education, improve patient recovery time and outcomes, compared to usual practice?</td>
<td>Assoc. Professor Dale Edgar (CPI/PI)</td>
<td>SMHS</td>
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<td>1054</td>
<td>KEYNOTE-495/KeyImPaCT: A Phase 2 Precision Oncology Study of Biomarker-Directed, Pembrolizumab (MK-3475, SCH 900475) Based Combination Therapy for Advanced Non-Small Cell Lung Cancer</td>
<td>Dr Wei-Sen Lam (CPI/PI)</td>
<td>SMHS</td>
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<td>1063</td>
<td>ILUMIEN IV: OPTical Coherence Tomography (OCT) Guided Coronary Stent Implantation Compared to Angiography: a Multicenter Randomized Trial in PCI</td>
<td>Professor Carl Schultz (CPI) Dr Matthew Erickson (PI)</td>
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<td>1068</td>
<td>BCX7353-204: An open-label study to evaluate the long-term safety of daily oral BCX7353 in subjects with Type I and II hereditary angioedema</td>
<td>Professor Jo Douglass (CPI/PI)</td>
<td>Monash Health</td>
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<td>1073</td>
<td>Viral Metagenome in Lung Transplant patients: The 12 month post-transplant follow up</td>
<td>Dr I-Ly Joanna Chua (CPI/PI)</td>
<td>SMHS</td>
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</table>
Nurturing the researchers of tomorrow

A study led by medical students on treatment options for diabetic foot ulcers is strengthening South Metropolitan Health Service’s reputation for supporting up-and-coming researchers.

The incidence of diabetes and its healthcare burden is considerable, with diabetic foot ulcers accounting for more hospitalisations than any diabetic complication. Despite best practice management, many patients still experience physical, psychological, and financial health outcomes.

The study was proposed by The University of Western Australia medical students Marcel Nejatian, Blake Sanchez and Salar Sobhi, and runs in parallel with clinical care provided by the Fiona Stanley Hospital Multidisciplinary Diabetic Foot Ulcer Team. The team won the Excellence in Clinical Care category at the inaugural 2019 South Metropolitan Health Service Excellence Awards for its outstanding delivery of safe, high quality clinical care.

“This was our first experience designing and conducting a research project and at the start the whole process seemed overwhelming,” Marcel Nejatian said.

“The easily accessible, one-on-one support provided by the SMHS Human Research Ethics Committee team streamlined the entire process, especially the ethics approval and governance processes.”

Consultant endocrinologist Professor Bu Yeap supervised the study and connected the medical students with other research collaborators.

“This study, led by medical students and supported by both hospital and university staff from multiple disciplines, highlights the role of research in improving patient care,” Professor Yeap said.

“It also firmly cements Fiona Stanley Hospital as a centre of excellence for medical research,” he said.

The study has been an invaluable opportunity for the students to design, conduct and deliver high quality research while building relationships with new colleagues and future mentors.

“We’ve networked with numerous medical and allied health staff from different specialties, developed project management skills and improved our patient communication and clinical skills,” Marcel said.

“Given our journey, we recommend anyone looking at conducting high quality research should consider SMHS – their support of the research environment is exceptional.”
<table>
<thead>
<tr>
<th>RGS PRN</th>
<th>Title</th>
<th>CPI/PI</th>
<th>Lead HREC</th>
<th>Site(s)</th>
</tr>
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<tr>
<td>1079</td>
<td>A Phase 2, Double-Blind, Placebo-Controlled, Randomized Study to Compare the Efficacy and Safety of Sotatercept (ACE-011) Versus Placebo When Added to Standard of Care for the Treatment of Pulmonary Arterial Hypertension (PAH)</td>
<td>Assoc. Professor Glenn Reeves (CPI) Dr Melanie Lavender (PI)</td>
<td>Hunter New England</td>
<td>Other national</td>
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<tr>
<td>1081</td>
<td>DYNAMIC-Pancreas: Circulating Tumour DNA Analysis Informing Adjuvant Chemotherapy in Early Stage Pancreatic Cancer: A Multicentre Randomised Study</td>
<td>Assoc. Professor Jeanne Tie (CPI) Dr Andrew Kiberu (PI)</td>
<td>Melbourne Health</td>
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<tr>
<td>1089</td>
<td>EMBRACE: Phase II clinical trial of the PARP inhibitor, olaparib, in HR-deficient metastatic breast and relapsed ovarian cancer in patients without germline mutations in BRCA1 and BRCA2: The EMBRACE study</td>
<td>Dr Katrin Sjoquist (CPI) Dr Andrew Redfern (PI)</td>
<td>Sydney LHD</td>
<td>FSH</td>
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<tr>
<td>1091</td>
<td>A Multicenter, Randomized, Double-Blind, Placebo-Controlled Maintenance and Long-Term Extension Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Crohn’s Disease who Completed the Studies M14-431 or M14-433</td>
<td>Professor Rupert Leong (CPI) Dr Lena Thin (PI)</td>
<td>Sydney LHD</td>
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<td>1092</td>
<td>A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Moderately to Severely Active Crohn’s Disease Who Have Inadequately Responded to or are Intolerant to Biologic Therapy</td>
<td>Professor Rupert Leong (CPI) Dr Lena Thin (PI)</td>
<td>Sydney LHD</td>
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<tr>
<td>1093</td>
<td>A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Moderately to Severely Active Crohn’s Disease Who Have Inadequately Responded to or are Intolerant to Conventional Therapies but Have Not Failed Biologic Therapy</td>
<td>Professor Rupert Leong (CPI) Dr Lena Thin (PI)</td>
<td>Sydney LHD</td>
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<td>1098</td>
<td>CA224-047 A Randomized, Double-blind Phase 2/3 Study of Relatlimab Combined with Nivolumab versus Nivolumab in Participants with Previously Untreated Metastatic or Unresectable Melanoma (CA224-047)</td>
<td>Professor Georgina Long (CPI) Assoc. Professor Adnan Khattak (PI)</td>
<td>St Vincent’s Hospital</td>
<td>FSH</td>
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<tr>
<td>1099</td>
<td>DYNAMIC RECTAL. Circulating Tumour DNA Analysis Informing Adjuvant Chemotherapy in Locally Advanced Rectal Cancer: A Multicentre Randomised Study</td>
<td>Assoc. Professor Jeanne Tie (CPI) Assoc. Professor Adnan Khattak (PI)</td>
<td>Melbourne Health</td>
<td>Other national</td>
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<td>1102</td>
<td>THOR: A Phase 3 Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrozulimab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations (42756493BLC3001)</td>
<td>Dr Ben Tran (CPI) Dr Thomas Ferguson (PI)</td>
<td>Peter MacCallum Cancer Centre</td>
<td>FSH Other national</td>
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<td>1107</td>
<td>ACTICCA-1. Adjuvant chemotherapy with gemcitabine and cisplatin compared to standard of care after curative intent resection of cholangiocarcinoma and muscle invasive gallbladder carcinoma</td>
<td>Dr David Ransom (CPI/PI)</td>
<td>SMHS</td>
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<td>1108</td>
<td>A sequential mixed methods study of the perceptions of junior doctors on clinical documentation improvement in a large teaching hospital</td>
<td>Mr George Zhou (CPI/PI)</td>
<td>SMHS</td>
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<td>1111</td>
<td>A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Effects of SOTagLiflozin on Clinical Outcomes in HemOdynamically STable Patients with Type 2 Diabetes POST Worsening Heart Failure</td>
<td>Assoc. Professor Astin Lee (CPI) Dr Kaitlyn Lam (PI)</td>
<td>Joint University of Wollongong and Illawarra Shoalhaven LHD</td>
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<td>1127</td>
<td>The Effects of Computerised Cognitive Training on Cognitive Impairments in Breast Cancer Patients Receiving Adjuvant Chemotherapy</td>
<td>Dr Travis Cruickshank (CPI) Dr Hilary Martin (PI)</td>
<td>SMHS</td>
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<td>1143</td>
<td>Optimal Recovery after Burn: Resources for better coping</td>
<td>Dr Lisa Martin (CPI/PI)</td>
<td>SMHS</td>
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<td>1146</td>
<td>The BEST-Fluids study: Better Evidence for Selecting Transplant Fluids</td>
<td>Professor Steve Chadban (CPI) Assoc. Professor Jagadish Jamboti (PI)</td>
<td>Sydney LHD</td>
<td>FSH Other WA</td>
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</table>
A ground-breaking bladder cancer study which began in Western Australia has received almost $1.6 million in funding and will become the largest bladder cancer clinical trial initiated and run in Australia.

The research is led by Professor Dickon Hayne, Head of Urology for South Metropolitan Health Service, who first piloted the study at Fremantle Hospital.

Professor Hayne said bladder cancer was a major public health problem with more than 2500 Australians diagnosed every year, yet bladder cancer was one of the most under-researched cancers.

“Bladder cancer is the only major cancer in Australia with a five year survival rate that has declined in the past 20 years. We are working on how we can improve these outcomes by determining the best possible treatment,” Professor Hayne said.

The trial will test whether combining placing chemotherapy and immunotherapy treatments into the bladder are better than standard immunotherapy treatment alone for localised bladder cancer.

“If this intervention is effective, it would reduce deaths from bladder cancer, reduce the need for complete surgical removal of the bladder and improve quality of life,” Professor Hayne said.

“The new combination of drugs tested in this trial would likely become adopted as the standard treatment method in Australia and internationally.”

Professor Hayne conducted the pilot study at Fremantle Hospital leading to Cancer Australia funding for the first stage of the trial, which recruited 180 patients nationally.

The $1.6 million in funding from National Health and Medical Research Council, the most competitive and prestigious research funding scheme in Australia, will fund the second stage of the trial recruiting a total of 500 patients over the next three years.

“We have been working on this study for almost a decade, which shows the patience and persistence required to perform meaningful clinical trials,” Professor Hayne said.
“Preliminary findings support the new treatment method and this next stage will show if it is indeed the best option and will provide us with truly vital, lifesaving information.

“This trial has already established Australia’s first collaborative network of urologists conducting trials in bladder cancer and we are proudly the first large scale clinical trial in this field in Australia.”

Patients will be recruited from 15 centres across Australia, including Fiona Stanley Hospital.
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<tr>
<td>1150</td>
<td>A Randomised, double-blind, placebo-controlled study to investigate the efficacy and safety of Injectafer® (ferric carboxymaltose) as treatment for iron deficiency</td>
<td>Assoc. Professor Carmine De Pasquale (CPI) Dr Kaitlyn Lam (PI)</td>
<td>Central Adelaide LHN</td>
<td>FSH Other WA Other national</td>
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<td>1151</td>
<td>A Phase 3, Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Investigate the Efficacy and Safety of CSL112 in Subjects with Acute Coronary Syndrome</td>
<td>Professor Gemma Figtree (CPI) Dr Jamie Rankin (PI)</td>
<td>Central Adelaide LHN</td>
<td>FSH Other WA Other national</td>
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<td>1166</td>
<td>Adjuvant Therapy with Pembrolizumab versus Placebo in Resected High-risk Stage II Melanoma: A Randomized, Double-blind Phase 3 Study (KEYNOTE 716)</td>
<td>Assoc. Professor Adnan Khattak (CPI/PI)</td>
<td>SMHS</td>
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<td>1181</td>
<td>The Australasian Resuscitation In Sepsis Evaluation: FFLuid or Vasopressors In Emergency Department Sepsis observational study</td>
<td>Professor Gerben Keijzers (CPI) Assoc. Professor Glenn Arends (PI) Dr Benjamin Smedley (PI)</td>
<td>The Gold Coast Hospital and Health District</td>
<td>FSH RGH Other WA Other national</td>
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<td>1185</td>
<td>Phase 1B/2 Study to Evaluate Safety and Anti Tumor Activity of Avelumab in Combination with the Poly (Adenosine Diphosphate [ADP]-Ribose) Polymerase (PARP) Inhibitor Talazoparib in Patients with Locally Advanced or Metastatic Solid Tumors</td>
<td>Dr Annabel Goodwin (CPI) Dr Andrew Redfern (PI)</td>
<td>Sydney LHD</td>
<td>FSH Other national</td>
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<td>1188</td>
<td>A pilot study comparing betamethasone dipropionate 0.05% cream vs ointment under wet wrap dressings</td>
<td>Dr Ali Didan (CPI/PI)</td>
<td>SMHS</td>
<td>FSH</td>
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<td>1189</td>
<td>APOLLO. A phase 1/2 open label, multi-center dose escalation and expansion study of combination immunotherapy CBT-501 (anti-PD-1) or nivolumab with CBT-101 (c-Met inhibitor) in locally advanced or metastatic hepatocellular carcinoma and renal cell carcinoma</td>
<td>Dr Siddharth Sood (CPI) Assoc. Professor Adnan Khattak (PI)</td>
<td>Melbourne Health</td>
<td>FSH Other national</td>
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<td>1289</td>
<td>The effect of acute foot ulceration on body composition and musculoskeletal function in patients with diabetes</td>
<td>Dr Blake Sanchez (CPI/PI)</td>
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<td>1389</td>
<td>NILE: A Phase III, Randomized, Open-Label, Controlled, Multi- Center, Global Study of First-Line Durvalumab in Combination with Standard of Care Chemotherapy and Durvalumab in Combination with Tremelimumab and Standard of Care Chemotherapy Versus Standard of Care Chemotherapy Alone in Patients with Unresectable Locally Advanced or Metastatic Urothelial Cancer</td>
<td>Dr Christopher Hocking (CPI)</td>
<td>St Vincent’s Hospital Melbourne</td>
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<tr>
<td>1390</td>
<td>‘NIAGARA: A Phase III, Randomized, Open-Label, Multi-Center, Global Study to Determine the Efficacy and Safety of Durvalumab in Combination with Gemcitabine+Cisplatin for Neoadjuvant Treatment Followed by Durvalumab Alone for Adjuvant Treatment in Patients with Muscle-Invasive Bladder Cancer (NIAGARA)</td>
<td>Dr Christopher Hocking (CPI)</td>
<td>St Vincent’s Hospital Melbourne</td>
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<td>1910</td>
<td>First-ever seizure in adults: clinical features and prognosis</td>
<td>Dr Nicholas Lawn (CPI/PI)</td>
<td>RPH</td>
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<td>2092</td>
<td>Prospective Observational Study on Perioperative anticoagulation management with the Novel Oral Anticoagulant Drugs Dabigatran, Rivaroxaban and Apixaban</td>
<td>Dr Stephanie P’Ng (CPI/PI)</td>
<td>RPH</td>
<td>FSH</td>
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<td>2308</td>
<td>A Long-Term Non-Interventional Registry to Assess Safety and effectiveness of HUMIRA© (Adalimumab) in Patients with Moderately to Severely Active Ulcerative Colitis (UC)</td>
<td>Dr Lena Thin (CPI/PI)</td>
<td>SMHS</td>
<td>FSH</td>
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<td>2323</td>
<td>Perioperative Administration of Dexamethasone and Infection (PADDI) - Post Operative Nausea and Vomiting Sub-study (The PADDI PONV Sub-study)</td>
<td>Pauline Coutts (CPI/ PI)</td>
<td>SMHS</td>
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<td>2649</td>
<td>Kalyakool Moort - always family - developing a safe effective approach to screening for perinatal depression and anxiety among Aboriginal families</td>
<td>Professor Rhonda Marriott (CPI/PI)</td>
<td>WNHS</td>
<td>FSH Other WA</td>
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Lead HREC

Table 7 provides a summary of the number of approved SMHS projects in 2018 and the lead HREC. SMHS HREC was the lead HREC for 68 of the projects (45 per cent).

Table 7: Lead HREC for projects approved to proceed at a SMHS site in 2018

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<thead>
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<th>HREC approved SMHS projects 2018</th>
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<td>Austin Health</td>
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<td>Central Adelaide Local Health Network (LHN)</td>
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<td>Child and Adolescent Health Service (CAHS)</td>
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<td>Gold Coast Hospital</td>
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<td>Hunter New England</td>
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<td>Melbourne Health</td>
<td>8</td>
</tr>
<tr>
<td>Metro South</td>
<td>1</td>
</tr>
<tr>
<td>Monash Health</td>
<td>2</td>
</tr>
<tr>
<td>North Sydney Local Health District (LHD)</td>
<td>2</td>
</tr>
<tr>
<td>Peter MacCallum Cancer Center</td>
<td>2</td>
</tr>
<tr>
<td>Royal Perth Hospital (RPH)</td>
<td>25</td>
</tr>
<tr>
<td>Sir Charles Gairdner Osborne Park Health Care Group (SCGOPHCG)</td>
<td>6</td>
</tr>
<tr>
<td>South Metropolitan Health Service (SMHS)</td>
<td>68</td>
</tr>
<tr>
<td>St Vincent’s Hospital, Melbourne</td>
<td>4</td>
</tr>
<tr>
<td>Sydney Local Health District (LHD)</td>
<td>9</td>
</tr>
<tr>
<td>The Prince Charles Hospital</td>
<td>3</td>
</tr>
<tr>
<td>University of Wollongong (joint with Illawarra Shoalhaven Local Health District)</td>
<td>1</td>
</tr>
<tr>
<td>Western Australia Country Health Service (WACHS)</td>
<td>1</td>
</tr>
<tr>
<td>Women and Newborn Health Service (WNHS)</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>152</strong></td>
</tr>
</tbody>
</table>
Projects not approved

Table 8 provides details of two projects that were not authorised to progress by the site Executive Director in 2018.

**Table 8: projects not approved to proceed**

<table>
<thead>
<tr>
<th>RGS PRN</th>
<th>Title</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>463</td>
<td>Reduction of Oxygen After Cardiac Arrest: The EXACT study</td>
<td>Consent issues</td>
</tr>
<tr>
<td>1003</td>
<td>Australasian Cardiac Outcomes Registry Ltd TAVI Registry</td>
<td>Consent issues : currently being revised</td>
</tr>
</tbody>
</table>

Projects not progressed

Table 9 provides details of twenty-six projects that did not progress in 2018; they were either placed ‘on-hold’, withdrawn or closed (for various reasons) and they required different levels of administrative effort by the RSDU team.

**Table 9: projects not progressed**

<table>
<thead>
<tr>
<th>RGS PRN</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015-107</td>
<td>Australasian Cardiac Outcomes Registry (ACOR) Cardiac Procedures Registry</td>
</tr>
<tr>
<td>2008-227</td>
<td>CELI: A Screening Instrument for Cognitive Deficits Adapted for Individuals With Language and Speech Impairments</td>
</tr>
<tr>
<td>2016-174</td>
<td>Defying the Odds: Exploring the impact of perinatal outcomes, maternal social and health outcomes and level of culturally appropriate service availability on the health of Western Australian Aboriginal infants and children</td>
</tr>
<tr>
<td>67</td>
<td>What is the current continence knowledge and practices of non-specialist physiotherapists? A survey of Western Australian hospital physiotherapists</td>
</tr>
<tr>
<td>101</td>
<td>Smart phone ECG monitoring in acute ischemic strokes</td>
</tr>
<tr>
<td>158</td>
<td>A Phase 3, Randomized, Double-Blinded, Placebo-Controlled, Multicentre Study to Investigate the Efficacy and Safety of Mongersen (GED-0301) for the Treatment of Adult and Adolescent Subjects with Active Crohns Disease</td>
</tr>
<tr>
<td>208</td>
<td>Efficacy and Safety of Finerenone in Subjects With Type 2 Diabetes Mellitus and the Clinical Diagnosis of Diabetic Kidney Disease (Kidney Outcome Focus)</td>
</tr>
<tr>
<td>209</td>
<td>Efficacy and Safety of Finerenone in Subjects With Type 2 Diabetes Mellitus and Diabetic Kidney Disease (Cardiac Outcome Focus)</td>
</tr>
<tr>
<td>246</td>
<td>A Randomized, Double-Blind, Placebo Controlled Study of Venetoclax Co-Administered with Low Dose Cytarabine Versus Low Dose Cytarabine in Treatment Naive Patients with Acute Myeloid Leukemia Who Are Ineligible for Intensive Chemotherapy</td>
</tr>
<tr>
<td>RGS PRN</td>
<td>Title</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>277</td>
<td>Mental health service culture and reform aspirations: What is required for change?</td>
</tr>
<tr>
<td>284</td>
<td>The effect of either a pre and post exercise intervention and assessment on patient outcomes for prostate cancer patients undergoing prostatectomy</td>
</tr>
<tr>
<td>310</td>
<td>Immigration status and access to hospital care</td>
</tr>
<tr>
<td>370</td>
<td>Pre-warming in Burns to prevent intraoperative hypothermia, improve quality of recovery after anaesthesia and improve burn specific scar outcomes and quality of life.</td>
</tr>
<tr>
<td>585</td>
<td>Operating Theatre time required for specified DRG’s</td>
</tr>
<tr>
<td>608</td>
<td>Defining NETs: Defining supportive care needs and psychological morbidity of patients with functioning versus non-functioning neuro-endocrine tumours (NETs)</td>
</tr>
<tr>
<td>665</td>
<td>Genetic testing for primary immunodeficiency diseases</td>
</tr>
<tr>
<td>714</td>
<td>Fighting Fit: A randomised controlled trial of a structured supervised exercise intervention during treatment for cancer in adolescents and young adults in Western Australia.</td>
</tr>
<tr>
<td>720</td>
<td>Exploratory Study of ABC294640 for the Treatment of Moderate to Severe Ulcerative Colitis - Protocol ABC-105</td>
</tr>
<tr>
<td>783</td>
<td>Promoting Student Belongingness: the development, implementation and evaluation of the WANTED toolkit for nurses</td>
</tr>
<tr>
<td>828</td>
<td>A 26-week Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter, Phase 3 Study with a 78-week Extension Period to Evaluate the Efficacy and Bone Safety of Sotagliflozin in Patients 55 years or Older with Type 2 Diabetes Mellitus and Inadequate Glycemic Control</td>
</tr>
<tr>
<td>842</td>
<td>Long-term Clinical Outcomes in SAPHO – variable responses to diverse treatments including biologic therapies</td>
</tr>
<tr>
<td>855</td>
<td>Management of malignant pleural effusions at Fiona Stanley Hospital</td>
</tr>
<tr>
<td>867</td>
<td>The relation between pericardial fluid, Rt atrial and pericardial tissue characteristics (Biochemical/inflammatory markers, Histology, Free radicals) and patients outcome and comorbidities after cardiac surgery</td>
</tr>
<tr>
<td>934</td>
<td>A review of patients perspectives on the management of testicular lesions</td>
</tr>
<tr>
<td>1139</td>
<td>Pro-phyllactic administration of Melatonin for the prevention of Delirium in Intensive Care Units- a randomized placebo controlled trial</td>
</tr>
<tr>
<td>1182</td>
<td>An openlabel, multicentre Phase Ib study of the safety and tolerability of IV infused PG545 in combination with nivolumab in patients with advanced solid tumours with an expansion cohort in patients with metastatic pancreatic cancer. Protocol ZU545102</td>
</tr>
</tbody>
</table>
Clinical trials to unlock treatment for liver disease

Finding a treatment for his patients is what drives gastroenterologist and hepatologist Dr Koya Ayonrinde, who has been researching non-alcoholic fatty liver disease (NAFLD) and its severe form, non-alcoholic steatohepatitis (NASH), for more than a decade.

Leading four international clinical trials at Fiona Stanley Hospital (FSH) Dr Ayonrinde has his sights set on contributing to finding a treatment to help people with NASH.

NASH is present when there is inflammation and scarring of an already fatty liver that is not due to alcohol. It is a more severe form of NAFLD, which affects about 25 per cent of the population, including 15 per cent of teenagers in Perth.

Dr Ayonrinde said NASH increases the risk of other chronic health conditions such as diabetes, heart attack and stroke and is on the rise.

“We have seen an increase in prevalence of NASH. In the South Metropolitan Health Service catchment, the population has a high prevalence of risk factors for NAFLD and NASH, consequently rates of liver cirrhosis and liver cancer developing from NASH are rising,” Dr Ayonrinde said.

NASH is commonly seen in overweight or obese people, those with diabetes or pre diabetes, abnormal cholesterol levels or high blood pressure and is commonly associated with an unhealthy diet and inadequate exercise. Yet Dr Ayonrinde said intervention beyond lifestyle changes was needed.

“Finding a way to improve the health of our patients is critical as there is no approved treatment for NASH in Australia, yet it is a $35 billion a year disease worldwide, which is flying under the radar,” Dr Ayonrinde said.

“One in 20 people with NAFLD will have NASH, of those one in 10 people will progress to liver cirrhosis, while about one in 250 will develop liver cancer. We hope by identifying this cohort of people early and intervening with treatment, such complications can be reduced.

“We currently have four clinical trials underway at FSH, testing different drugs to determine which can help reduce the burden of disease on sufferers and the community.”

FSH is one of the highest recruiting sites for these clinical trials in Australia, with almost 20 participants.

Participants are required to undergo a pre-screening biopsy to confirm diagnosis of NASH, then take oral medication once a day. Follow up assessments and a repeat biopsy mid-way and at the end of treatment help assess for efficacy.

Study participation varies between the clinical trials, but can range from two to seven years, which includes follow up visits.

Dr Ayonrinde continues his quest into this burgeoning disease and is hopeful of an outcome for patients soon.

“These trials are a good opportunity to examine a disease without treatment and one that is not well understood, as we have a real potential to make a difference with later interventions.”
Publications
The publications listing below provides details of 452 published works by SMHS researchers, or researchers who have conducted research at an affiliated SMHS site.

Publications listing:


Chieng D, Paul V, Denman R. Current Device Therapies for Sudden Cardiac Death Prevention - the ICD, Subcutaneous ICD and Wearable ICD. Heart Lung Circ. 2018; In Press.


Corica T, Nowak AK, Saunders CM, Bulsara MK, Taylor M, Williams NR, Keshtgar M, Joseph DJ, Vaidya JS. Cosmetic outcome as rated by patients, doctors, nurses and BCCT.core software assessed over 5 years in a subset of patients in the TARGIT-A Trial. Radiat Oncol. 2018; 13 (1) (no pagination) (68).


Daneshvar C, William T, Davis TME. Clinical features and management of Plasmodium


Davis TME. Author reply: The data used in the analysis were collected in the ‘Caring Does Matter’ (CDM) programme. Intern Med J. 2018; 48(3):367-8.


Ghaly S, Kaakoush NO, Lloyd F, Gordon L, Forest C, Lawrance IC, Hart PH. Ultraviolet irradiation of skin alters the faecal microbiome independently of vitamin D in mice. Nutrients. 2018; 10 (8) (no pagination) (1069).


Golledge J, Hankey GJ, Almeida OP, Flicker L, Norman PE, Yeap BB. Plasma free thyroxine in the upper quartile is associated with an increased incidence of major cardiovascular events in older men that do not have thyroid dysfunction according to conventional criteria. Int J Cardiol. 2018; 254:316-21.


Kumarasinghe P. Pigmentary Skin Disorders. Cham, Switzerland: Springer; 2018.


Litton E. Intravenous iron for the treatment of anaemia in critical illness [Doctor of Philosophy]. Nedlands, WA: University of Western Australia; 2018.


Mackle DM, Bailey MJ, Beasley RW, Bellomo R,


Milne NT, Bucks RS, Davis WA, Davis TME, Pierson R, Starkstein SE, Bruce DG. **Hippocampal atrophy, asymmetry, and cognition in type 2 diabetes mellitus.** Brain Behav. 2018; 8(1):e00741.


Ng TF, Wright M, De Kraa R. **Approximately 1% of chronic myeloid leukaemia cases present with isolated thrombocytosis and express common major breakpoints: a finding from a laboratory audit.** Pathology. 2018; 24:24.


Nossent J, Raymond W, Keen H, Inderjeeth C, Preen DB. **Hospitalisation rates and characteristics for adult and childhood IgA vasculitis in Western Australia.** Intern Med J. 2018; 08:08.


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Stamp N. Can you die from a broken heart?: a heart surgeon’s insight into what makes us tick. Crows nest, NSW: Murdoch Books Australia; 2018.


Stanley SH, Ng SM, Laughane JDE. The ‘fit for life’ exercise programme: Improving the physical health of people with a mental illness. Psychol Health Med. 2018;No Pagination Specified.


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