



Government of Western Australia
South Metropolitan Health Service



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.

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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

Dates	Activity	SMHS
1 January 2018 to 31 December 2018	Site Authorisation approved	152

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

Dates	Activity	FSH	FH	RGH
1 January 2018 to 31 December 2018	Site Authorisations	139	26	9

*Note that a project can be conducted across multiple sites

Table 3: 2018 projects not authorised to proceed

Dates	Activity	SMHS
1 January 2018 to 31 December 2018	Projects not authorised	2

Table 4: 2018 projects that did not progress ('on-hold', withdrawn or closed)

Dates	Activity	SMHS
1 January 2018 to 31 December 2018	Projects not progressed	26

Waiver of Consent

The National Health and Medical Research Council (NHMRC) highlights in the National Statement² 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

PRN/project title	Brief description of study and rationale for the approval of a Waiver of Consent
<p>1. RGS 777</p> <p>Characteristics and outcomes of Acute Myeloid Leukaemia in Western Australia</p>	<p>Uses de-identified, retrospective data to examine clinical and laboratory prognostic markers for all patients diagnosed with AML at a tertiary hospital in Western Australia, to determine which are most predictive of survival in this population.</p>
<p>2. RGS 729</p> <p>A review of the epidemiology, management and mortality of patients with penile cancer in Western Australia</p>	<p>To review how patients diagnosed with penile cancer in Western Australia between 1992 to 2018 have been treated and managed. To assess short, intermediate and long-term survival outcomes and to determine whether patients diagnosed with penile cancer in Western Australia are being treated in accordance with international standards and evidence-based care. Uses coded data from WA Cancer Registry and hospital medical records.</p>

3. RGS 812**Post Cardiac Surgery
Leukocytosis - an
investigation of aetiology and
patient outcomes**

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

4. RGS 813**Comparing on pump and
off pump coronary bypass
surgery and long term cancer
outcomes**

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

5. RGS 848**Australia and New Zealand
Emergency Laparotomy Audit
Quality Improvement**

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.

6. RGS 1008**Non-iatrogenic, non-traumatic
spontaneous cerebrospinal
fluid (CSF) otorrhoea**

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.

PRN/project title

Brief description of study and rationale for the approval of a Waiver of Consent

7. RGS 987

The 2017 Severe Influenza Outbreak requiring Extracorporeal Membrane Oxygenation

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.

8. RGS 645

Cost effectiveness of extending the Phase 3 community pulmonary rehabilitation program beyond the recommended 10 weeks

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.

9. RGS 1370

Review of Australian prescribing practices of Eribulin (RAPPER STUDY BCRC122)

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.

10. RGS 1368

The clinical and economic impact of a preoperative anaemia and iron deficiency clinic in elective colorectal surgery

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.

Research showcase

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.



*Associate Professor
Glenn Arendts*

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.



*Dr Oyekoya
Ayonrinde*

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.



SMHS Board Chair Mr Rob McDonald; SMHS Chief Executive Mr Paul Forden; Professor Merrilee Needham; Associate Professor Andrew Redfern; Professor Nigel Laing (event sponsor representative); former Executive Director FSFHG Janet Zagari.

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



Samara is pictured receiving her award from SMHS Chief Executive Mr Paul Forden and award sponsor Spinnaker Chief Executive Officer Ms Dana Henderson.

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'



Jocelyn is pictured receiving her award from SMHS Board Chair Mr Rob McDonald and award sponsor Melanie Wright, Manager RSDU.

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 Dayse Tavora-Vieira and the team.

Dr Tavora-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

RGS PRN	Title	CPI/PI	Lead HREC	Site(s)
09	WA Neck of Femur Fracture Collaboration	Dr Ed O’Loughlin (CPI/PI)	SMHS	FSH FH RGH
12	A cohort study of otitis media in young urban Aboriginal children – prevalence, risk factors and consequences.	Deborah Lehmann (CPI) Peter Richmond (PI)	CAHS	FSH RGH Other WA
24	A randomised trial of anti-inflammatory therapy in gout	Dr Helen Keen (CPI/PI)	RPH	FSH Other WA
27	The efficacy of silicone-film forming dressing versus standard care for the treatment of acute burn injuries not requiring surgery, and donor sites	Rosemary Kendell (CPI) Fiona Poelchow (PI)	SMHS	FSH
43	Evolution of beta-lactam resistance in Pseudomonas aeruginosa during treatment of major burn injury	Dr Ed Raby (CPI/PI)	SMHS	FSH Other national
44	A tailored music therapy and real-time biofeedback mobile phone app (“GotRhythm”) to promote rehabilitation following stroke	Assoc. Professor Christopher Etherton-Beer (CPI) Assoc. Professor Michael Rosenberg (PI)	RPH	FSH FH Other WA
76	National Myringoplasty Audit	Dr Caitlin Chidlow (CPI/PI)	SMHS	FSH
86	Australian Genomics Health Alliance: Preparing Australia for Genomic Medicine	Professor Nigel Laing (CPI) Dr Lloyd D’Orsogna (PI)	CAHS	FSH Other WA
102	TEMPO2- A randomized controlled trial of TNK-tPA versus standard of care for minor ischemic stroke with proven occlusion	Dr Darshan Ghia (CPI/PI)	SMHS	FSH
105	The effect of 4% succinylated gelatine fluid on acute kidney injury in critically ill patients	Assoc. Professor Kwok Ming Ho (CPI) Dr Ed Litton (PI)	SMHS	FSH Other WA
108	The Implementation, User Testing and Validation of the Web-based Application for the Population Pharmacokinetic Service – Hemophilia (WAPPS-HEMO) Phase 2	Dr Stephanie P’Ng (CPI/ PI)	RPH	FSH

RGS PRN	Title	CPI/PI	Lead HREC	Site(s)
125	Enhancing rehabilitation services for Aboriginal Australians after brain injury	Professor Elizabeth Armstrong (CPI) Dr Darshan Ghia (PI)	RPH	FSH FH RGH Other WA
127	Large Cohort, multi-centre, multi-national follow-up of the Saiph Total Knee Replacement (SAIPH MCS)	Professor Piers Yates (CPI/PI)	SMHS	FH
130	A retrospective investigation into the effectiveness of surveillance post-curative colorectal cancer resection in Western Australia	Dr Thomas Ferguson (CPI/PI)	RPH	FSH Other WA
144	Pre-treatment wait time for head and neck cancer in Western Australia	Dr Stephanie Flukes (CPI/PI)	SMHS	FSH
176	Fiona Stanley Diabetes Patient Management System	Dr P. Gerry Fegan (CPI/PI)	SMHS	FSH
184	Biomechanical modelling of type B aortic dissection	Professor Paul Norman (CPI/PI)	SMHS	FSH Other WA
203	The role of executive function in discourse production and health related quality of life in aphasia.	Sarah Wynn (CPI) Lisa Majteles (PI)	SMHS	FSH FH RGH Other WA
216	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)	Dr Paul Cannell (CPI/PI)	RPH	FSH
225	The extent to which a professional development program can support caring nursing practice in Western Australia hospitals	Tonia Naylor (CPI/PI)	RPH	FSH FH Other WA
261	A Post-Marketing Safety Study to Evaluate the Occurrence of Aseptic Meningitis Syndrome (AMS) in an Adult Population (> 18 Years) Treated with Doses of = 1g/kg Intragam® 10 NF	Dr Stephanie P'Ng (CPI/PI)	RPH	FSH
263	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	Dr Huyen Tran (CPI) Dr Stephanie P'Ng (PI)	Alfred Hospital	FSH Other national

RGS PRN	Title	CPI/PI	Lead HREC	Site(s)
275	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	Assoc. Professor Adnan Khattak (CPI/PI)	RPH	FSH
280	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	Professor Tim Davis (CPI/PI)	SMHS	FH
306	Retrospective analysis of clinical efficacy and outcomes of left atrial appendage device occlusion in patients with atrial fibrillation	Dr Mary Nangrahary (CPI/PI)	SMHS	FSH FH Other WA
315	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	Dr Duncan Purtill (CPI/PI)	RPH	FSH
316	ATA129-EBV-302: Multicenter, Open Label, Phase 3 Trial of ATA129 for Solid Organ Transplant Subjects with Epstein-Barr Virus-Associated Post-Transplant Lymphoproliferative Disease after Failure of Rituximab or Rituximab and Chemotherapy (ALLELE Study)	Dr Duncan Purtill (CPI/PI)	RPH	FSH
324	A multi-centre, blinded, randomised, controlled trial to determine whether fluid resuscitation and therapy with a “balanced” crystalloid solution (Plasma-Lyte 148®) compared with 0.9% sodium chloride (saline) decreases 90-day mortality in critically ill patients requiring fluid resuscitation	Assoc. Professor Adrian Regli (CPI/PI) Dr Prithviraj Thyagarajan (PI)	SMHS	FSH RGH
335	Analysis of Cognitive Capabilities in Profoundly Deaf Patients with and without Cochlear Implant: A comparative, prospective, longitudinal study	Dr Dayse Tavora-Vieira (CPI) Andre Wedekind (PI)	SMHS	FSH

RGS PRN	Title	CPI/PI	Lead HREC	Site(s)
379	CINC424C2301: A phase III randomized open-label multi-center study of ruxolitinib versus best available therapy in patients with corticosteroid-refractory acute graft vs. host disease after allogeneic stem cell transplantation	Dr Duncan Purtill (CPI/PI)	RPH	FSH
392	Assessing Interns' Readiness for Practice Using Entrustable Professional Activities (EPAs)	Dr Denese Playford (CPI/PI)	SMHS	FSH Other WA
399	HLA Antibody Response to Non-HLA Antigenic Stimulation by Hepatitis B Vaccination in Potential Renal Transplant Recipients: A Pilot Study	Dr Ashley Irish (CPI/PI)	RPH	FSH
400	Previous Hospital Presentations for Inpatient Alcoholic Liver Deaths: A Multi-tertiary Centre Project	Dr Chloe Attree (CPI/PI)	SMHS	FSH Other
402	Application of Digital Pathology Deep-Learning to Improve Cancer Diagnosis	Dr Jeremy Parry (CPI) Christopher Yeomans (PI)	RPH	PathWest (FSH) Other WA
415	Associations of nadir haemoglobin level and red blood cell transfusion with mortality and length of stay	Kevin Trentino (CPI/PI)	RPH	FSH FH Other WA
416	Altitudes East-West: A randomised controlled trial of Moderated Online Social Therapy for carers of first episode psychosis clients in real world settings	Professor John Gleeson (CPI)	SMHS	FH RGH Other WA
448	IMspire 170: a phase III, open label, multicenter, two arm, randomized study to investigate the efficacy and safety of cobimetinib plus atezolizumab versus pembrolizumab in patients with previously untreated advanced brafv600 wildtype melanoma	Assoc. Professor Adnan Khattak (CPI/PI)	RPH	FSH
451	Defining and Defeating Aboriginal and Torres Strait Islander Disadvantage In Breast Cancer Survival	Dr Andrew Redfern (CPI/PI)	SMHS	FSH FH Other WA
457	Do patients with Foot Ulceration and Type 2 Diabetes have Cognitive Impairment and lower levels of Self-care Behaviour?	Dr Emma Hamilton (CPI/PI)	SMHS	FSH FH

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."

Fiona Stanley Hospital medical oncologist Clinical Professor Adnan Khattak and patient Jane Bartlett undergoing immunotherapy.



RGS PRN	Title	CPI/PI	Lead HREC	Site(s)
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 Daratumumab in Subjects With Relapsed or Refractory Multiple Myeloma	Dr Bradley Augustson (CPI) Dr Matthew Wright (PI)	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) Dr Hilary Martin (PI)	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) Dr Wei-Sen Lam (PI)	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) Dr Simon Troon (PI)	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

RGS PRN	Title	CPI/PI	Lead HREC	Site(s)
541	UNISoN: Phase II Sequential Treatment Trial of Single Agent Nivolumab, then Combination Ipilimumab + Nivolumab in Metastatic or Unresectable Non-Clear Cell Renal Cell Carcinoma (ANZUP1602)	Dr Craig Gedye (CPI) Dr Thomas Ferguson (PI)	Northern Sydney LHD	FSH
552	Prospective Biobank of Immunological and Non-immunological factors associated with renal allograft and patient outcomes	Dr Ashley Irish (CPI/PI)	RPH	FSH Other WA
554	Long-term Outcomes of Lignocaine Infusions for PostOperative Pain (LOLIPOP) Pilot Study	Professor Tomas Corcoran (CPI/PI)	SMHS	FSH FH Other WA
556	COMPARE Constraint Induced or Multi-Modal aphasia rehabilitation: An RCT for stroke related chronic aphasia	Assoc. Professor Miranda Rose (CPI/PI)	The Gold Coast Hospital and Health District	FH Other WA
558	Clinical Outcomes of the bone conduction hearing aid - ADHEAR - in adults and children with conductive hearing loss	Dr Dayse Tavora-Vieira (CPI/PI)	SMHS	FSH Other WA
566	“Solving the Unsolvable”: Uncovering the Active Ingredients in the WA Undiagnosed Diseases Program	Professor Sharon Parker (CPI)	WNHS	FSH Other WA
569	Triple therapy prevention of Recurrent Intracerebral Disease Events Trial	Dr Darshan Ghia (CPI/PI)	Sydney LHD	FSH
573	METHODS - A randomised controlled trial of METHotrexate to treat Hand Osteoarthritis with Synovitis	Dr Helen Keen (CPI/PI)	SMHS	FSH
580	‘Stimulation Of the Left Ventricular Endocardium for Cardiac Resynchronization Therapy in Non-Responders and Previously Untreatable Patients	Dr Vincent Paul (CPI/PI)	SMHS	FSH
586	Exercise as medicine for advanced heart failure: A novel intervention to improve outcomes	Dr Louise Naylor (CPI/PI)	SMHS	FSH
587	Vitamins and delirium in older ED patients	Assoc. Professor Glenn Arendts (CPI/PI)	SMHS	FSH

RGS PRN	Title	CPI/PI	Lead HREC	Site(s)
602	Timeline Analysis of Aboriginal and Torres Strait Islander Childhood Immunisations in Metropolitan Perth 2012-2017 and Analysis of Attitudes, Societal Influence, Perceived Behaviours and Barriers Experienced by Providers who Administer Immunisation Services to Aboriginal and Torres Strait Islander Children in the Perth Metropolitan Region	Rebecca Carman (CPI/PI)	SCGOPHCG	SMHS Other WA
604	Preliminary validation of Sheer Wave Elastography as an outcome tool in muscle disease	Dr Shereen Paramalingam (CPI/PI)	SMHS	FSH Other WA
632	DEFINING NETs - Defining the supportive care needs and psychological morbidity of patients with Functioning versus Non-Functioning Neuroendocrine Tumours (NETs)	Dr David Ransom (CPI/PI)	RPH	FSH
642	Lighthouse Hospital Project Phase 3 - Project Evaluation	Dr Connie Tira (CPI/PI)	WACHS	FSH Other WA
650	Machine learning tools for outcome prediction in patient blood management	Mr Kevin Trentino (CPI/PI)	RPH	FSH FH Other WA
655	The natural history of incidentally detected interstitial lung disease from lung cancer screening	Dr Kuan Pin Lim (CPI) Dr Annette McWilliams (PI)	SCGOPHCG	FSH Other WA
657	Exercise Medicine Prior to Open Radical Cystectomy: Feasibility and Preliminary Efficacy	Professor Dennis Taaffe (CPI) Professor Dickon Hayne (PI)	SMHS	FSH
664	KEYPAD KidnEY cancer Pembrolizumab And Denosumab. Denosumab and Pembrolizumab in clear cell renal carcinoma: a phase II trial	Dr Craig Gedye (CPI) Dr Thomas Ferguson (PI)	Sydney LHD	FSH Other national
668	A radiographic study of the location of bifurcation of the superficial temporal artery – Is there a sound anatomical basis for the Gillies approach in temporal artery biopsy?	Dr Daniel Mina Girgis (CPI/PI)	SMHS	FSH
669	A Randomised Controlled Trial of Exercise Medicine For Men Undergoing Active Surveillance for Prostate Cancer	Professor Daniel Galvao (CPI) Dr Dickon Hayne (PI)	SMHS	FSH
674	Early Anastomotic Outcomes in Lung Transplant Recipients with Idiopathic Pulmonary Fibrosis on Anti-Fibrotic Therapy	Dr John Mackintosh (CPI) Dr Michael Musk (PI)	The Prince Charles Hospital	FSH

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 Piers Yates

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!”

RGS PRN	Title	CPI/PI	Lead HREC	Site(s)
677	Preventing Premature Entry to Residential Aged Care	Meryllyn Ma (CPI) Melissa Edwards (PI)	SMHS	FSH
686	Focussed biliary ultrasound by surgical registrars in an acute surgical unit	Dr Oscar Aldridge (CPI/PI)	SMHS	FSH
700	Diabetic foot INfection LonGitudinal Outcome study (DINGO)	Dr Ed Raby (CPI) Dr Laurens Manning (PI) Dr Paul Ingram (PI)	SMHS	FSH FH Other WA Other national
709	A multicentre, randomised controlled Trial of Exenatide versus standard care in Acute Ischemic Stroke (TEXAIS)	Professor Chris Bladin (CPI) Dr Darshan Ghia (PI)	Austin Health	FSH Other national
713	User experience of adult Outpatient Department Oncological services at Fiona Stanley Hospital: Exploring the ethnic minority perspective	Dr Hilary Martin (CPI/PI)	SMHS	FSH
715	Exploring general surgery patient's experiences to develop an individualised prehabilitation exercise program and targeted education - a qualitative study	Assoc. Professor Dale Edgar (CPI/PI)	SMHS	FSH
722	Spray on skin for diabetic foot ulcers: an open label randomised controlled trial	Assoc. Professor Laurens Manning (CPI/PI)	SMHS	FSH
726	Adrenal Vein Sampling Outcomes Study	Dr Michael Page (CPI/PI)	RPH	PathWest FSH Other WA
731	Randomised Controlled Trial of Celecoxib for Acute Burn Inflammation and Fever	Dr Ed Raby (CPI/PI)	SMHS	FSH
751	IV iron for Treatment of Anaemia before Cardiac Surgery	Dr Ed O'Loughlin (CPI/PI)	Alfred Hospital	FSH
753	Upper Abdominal Surgery: The Patient's Perspective	Catherine Bunting (CPI/PI)	SMHS	FSH
755	Biceps Tendinopathy Project	Mr Sat Gohil (CPI/PI)	SMHS	FH
757	'Onyx ONE Study; A Randomized Controlled Trial with Resolute Onyx in One Month DAPT for High-Bleeding Risk Patients	Dr Paul Garrahy (CPI) Dr Sharrad Shetty (PI)	Metro South	FSH Other national
758	The use of blood and lung tissue for pathway and biomarker analysis in lung disease	Assoc. Professor Yuben Moodley (CPI/PI)	SMHS	FSH
777	Characteristics and outcomes of Acute Myeloid Leukaemia in Western Australia	Dr Shane Gangatharan (CPI/PI)	SMHS	FSH Other WA

RGS PRN	Title	CPI/PI	Lead HREC	Site(s)
779	Factors that influence the intentions of cardiovascular patients in relation to adhering to a treatment plan	Dr Amineh Rashidi (CPI/PI)	SMHS	FSH
796	A Randomized, Double-blind, Placebo-controlled Phase II Multi-Center Evaluation to Assess the Safety and Tolerability of DM199 Administered Intravenously and Subcutaneously in Subjects with Acute Ischemic Stroke (ReMEDy Trial)	Assoc. Professor Bruce Campbell (CPI) Dr Darshan Ghia (PI)	Melbourne Health	FSH
797	TheraP: A randomised phase 2 trial of 177Lu-PSMA617 theranostic versus cabazitaxel in progressive metastatic castration resistant prostate cancer	Assoc. Professor Michael Hofman (CPI) Dr Andrew Redfern (PI)	Peter MacCallum Cancer Centre	FSH Other WA
798	A phase II study evaluating liquid biopsies to profile metastatic colorectal cancer	Siobhan Hussey (CPI) Dr Adnan Khattak (PI)	Austin Health	FSH Other national
805	The relationship between macrovascular disease and retinopathy in type 2 diabetes	Jocelyn Drinkwater (CPI) Professor Timothy Davis (PI)	SMHS	FH
827	A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function	Professor Timothy Davis (CPI /PI)	Hunter New England	FH
833	Understanding the cognitive, physiological, and psychological effects of a heated work environment on burn surgery team members	Professor Fiona Wood (CPI/PI)	SMHS	FSH
840	Steroid Therapy and Outcome of Parapneumonic Pleural Effusions (STOPPE)	Professor Gary Lee (CPI) Dr Ranjan Shrestha (PI)	SCGOPHCG	FSH Other WA Other national
848	Australia and New Zealand Emergency Laparotomy Audit Quality Improvement	Dr Ed O'Loughlin (CPI/PI)	SMHS	FSH Other WA Other national
849	WA Trauma Training and Education Unit - Training Needs Analysis 2018	Hannah Solomon (CPI/PI)	SCGOPHCG	FSH Other WA

RGS PRN	Title	CPI/PI	Lead HREC	Site(s)
852	The success of research implementation strategies on evidence based decision making by allied health managers: a randomised controlled trial	Dr Jenni White (CPI/PI)	SMHS	FSH FH RGH Other WA
858	Illuminate 301. A Randomized Phase 3 Comparison of IMO-2125 with Ipilimumab versus Ipilimumab Alone in Subjects with Anti-PD-1 Refractory Melanoma	Dr Anna Lomax (CPI)	St Vincent's Hospital Melbourne	FSH Other national
859	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)	Professor Finlay Macrae (CPI) Dr Callum Pearce (PI)	Melbourne Health	FSH Other national
863	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	Dr Melanie Burkhardt (CPI/PI)	SMHS	FSH FH
887	The impact of an onsite toxicology service on ICU and medical length of stay in critically ill toxicology patients admitted to tertiary hospitals	Dr Julia George (CPI/PI)	RPH	FSH Other WA
892	A prospective, randomised, Controlled, Open-label, Multicentre phase III study to evaluate efficacy and safety of Peptide Receptor Radionuclide Therapy (PRRT) with ¹⁷⁷ Lu-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)	Dr Andrew Kiberu (CPI/PI)	SMHS	FSH
895	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)	Emily England (CPI) Professor Timothy Davis (PI)	Melbourne Health	FH

RGS PRN	Title	CPI/PI	Lead HREC	Site(s)
901	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)	Dr Alexander Hodge (CPI) Dr Koya Ayonrinde (PI)	Monash Health	FSH
912	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)	Assoc. Professor Andrew Wei Dr Matthew Wright (PI)	Alfred Hospital	FSH
929	Establishing the prevalence and burden of healthcare associated infections in Australian hospitals	Dr Philip Russo (CPI) Ann Whitfield (PI)	Alfred Hospital	FSH Other WA Other national
941	Return to normal diet following mandibular fractures - how long is long enough?	Dr Timothy Manzie (CPI/PI)	RPH	FSH
943	Impact of seasonal temperature variations on symptoms and exercise performance in chronic heart failure (CHF) patients	Assoc. Professor Andrew Maiorana (CPI/PI)	The Prince Charles Hospital	FSH
945	Risk factors for gonorrhoea in young heterosexual people in Perth	Dr Roanna Lobo (CPI) Assoc. Professor Lewis Marshall (PI)	RPH	FH Other WA
971	Perceptions of Permanent Staff Nurses towards Agency Staff Nurses	Aaron Alejandro (CPI/PI)	SMHS	FSH
974	Multiple escalating dose study of BAY 1093884 in adults with hemophilia A or B with or without inhibitors	Dr Stephanie P'Ng (CPI/PI)	SMHS	FSH
987	The 2017 Severe Influenza Outbreak requiring Extracorporeal Membrane Oxygenation	Dr Michael McCann (CPI/PI)	SMHS	FSH
988	Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) Patient Reported Outcome Measures (PROMs) Pilot Project	Professor Stephen Graves (CPI) Dr Omar Khorshid (PI)	Sydney LHD	FH Other WA Other national
991	DYNAMIC-III: Circulating Tumour DNA Analysis Informing Adjuvant Chemotherapy in Stage III Colon Cancer: A Multicentre Phase II/III Randomised Controlled Trial	Assoc. Professor Jeanne Tie Dr Adnan Khattak (PI)	Melbourne Health	FSH

RGS PRN	Title	CPI/PI	Lead HREC	Site(s)
1008	Non-iatrogenic, non-traumatic spontaneous cerebrospinal fluid (CSF) otorrhoea	Dr Thomas Hendriks (CPI/PI)	SMHS	FSH Other WA
1013	The Early Eczema Education Project	Dr Samara Baldwin (CPI/PI)	CAHS	FSH
1029	A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of BG00011 in Patients With Idiopathic Pulmonary Fibrosis	Debra Enever (CPI) Dr Jeremy Wrobel (PI)	The Prince Charles Hospital	FSH Other national
1033	SADAL: Phase 2b Open-label Study of Selinexor (KPT-330) in Patients with Relapsed/Refractory Diffuse Large B-Cell Lymphoma (DLBCL)	Dr Pratyush Giri (CPI) Dr Paul Cannell (PI)	Central Adelaide LHN	FSH
1041	Management, Outcomes and Survival of an Australian IgG4 Cohort	Assoc. Professor William Kemp (CPI) Dr Simon Hazeldine (PI)	Alfred Hospital	FSH Other WA
1049	In general surgery patients, does an individualised prehabilitation exercise program with targeted education, improve patient recovery time and outcomes, compared to usual practice?	Assoc. Professor Dale Edgar (CPI/PI)	SMHS	FSH
1054	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	Dr Wei-Sen Lam (CPI/PI)	SMHS	FSH
1063	ILUMIEN IV: Optical Coherence Tomography (OCT) Guided Coronary Stent IMplantation Compared to Angiography: a Multicenter Randomized Trial in PCI	Professor Carl Schultz (CPI) Dr Matthew Erickson (PI)	SMHS	FSH Other WA
1068	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	Professor Jo Douglass (CPI/PI)	Monash Health	FSH
1073	Viral Metagenome in Lung Transplant patients: The 12 month post-transplant follow up	Dr I-Ly Joanna Chua (CPI/PI)	SMHS	FSH

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.

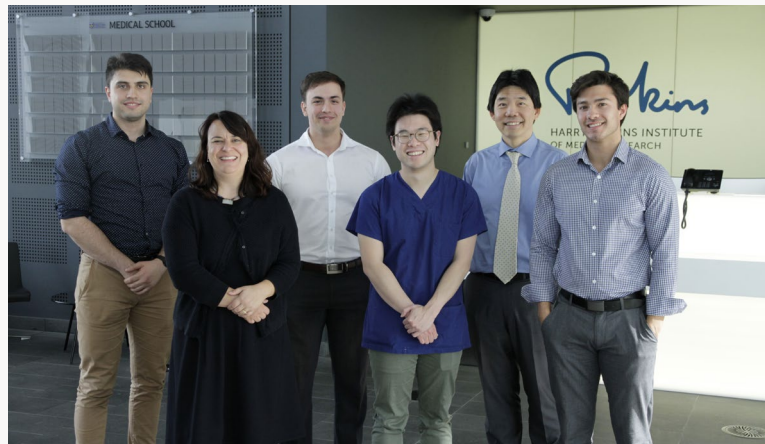
The incidence of diabetes and its healthcare burden is considerable, with diabetic foot ulcers accounting for more hospitalisations than any diabetic complication. Despite best practice management, many patients still experience physical, psychological, and financial health outcomes.

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.



*Dr Emma Hamilton and Professor Bu Yeap
with student researchers*

"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."

RGS PRN	Title	CPI/PI	Lead HREC	Site(s)
1079	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)	Assoc. Professor Glenn Reeves (CPI) Dr Melanie Lavender (PI)	Hunter New England	FSH Other national
1081	DYNAMIC-Pancreas: Circulating Tumour DNA Analysis Informing Adjuvant Chemotherapy in Early Stage Pancreatic Cancer: A Multicentre Randomised Study	Assoc. Professor Jeanne Tie (CPI) Dr Andrew Kiberu (PI)	Melbourne Health	FSH
1089	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	Dr Katrin Sjoquist (CPI) Dr Andrew Redfern (PI)	Sydney LHD	FSH
1091	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	Professor Rupert Leong (CPI) Dr Lena Thin (PI)	Sydney LHD	FSH
1092	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	Professor Rupert Leong (CPI) Dr Lena Thin (PI)	Sydney LHD	FSH
1093	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	Professor Rupert Leong (CPI) Dr Lena Thin (PI)	Sydney LHD	FSH

RGS PRN	Title	CPI/PI	Lead HREC	Site(s)
1098	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)	Professor Georgina Long (CPI) Assoc. Professor Adnan Khattak (PI)	St Vincent's Hospital	FSH
1099	DYNAMIC RECTAL. Circulating Tumour DNA Analysis Informing Adjuvant Chemotherapy in Locally Advanced Rectal Cancer: A Multicentre Randomised Study	Assoc. Professor Jeanne Tie (CPI) Assoc. Professor Adnan Khattak (PI)	Melbourne Health	FSH Other national
1102	THOR: A Phase 3 Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations (42756493BLC3001)	Dr Ben Tran (CPI) Dr Thomas Ferguson (PI)	Peter MacCallum Cancer Centre	FSH Other national
1107	ACTICCA-1. Adjuvant chemotherapy with gemcitabine and cisplatin compared to standard of care after curative intent resection of cholangiocarcinoma and muscle invasive gallbladder carcinoma	Dr David Ransom (CPI/PI)	SMHS	FSH Other national
1108	A sequential mixed methods study of the perceptions of junior doctors on clinical documentation improvement in a large teaching hospital	Mr George Zhou (CPI/PI)	SMHS	FSH
1111	A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Effects of S0tagLiflozin on Clinical Outcomes in Hemodynamically Stable Patients with Type 2 Diabetes POST Worsening Heart Failure	Assoc. Professor Astin Lee (CPI) Dr Kaitlyn Lam (PI)	Joint University of Wollongong and Illawarra Shoalhaven LHD	FSH Other national
1127	The Effects of Computerised Cognitive Training on Cognitive Impairments in Breast Cancer Patients Receiving Adjuvant Chemotherapy	Dr Travis Cruickshank (CPI) Dr Hilary Martin (PI)	SMHS	FSH
1143	Optimal Recovery after Burn: Resources for better coping	Dr Lisa Martin (CPI/PI)	SMHS	FSH Other WA
1146	The BEST-Fluids study: Better Evidence for Selecting Transplant Fluids	Professor Steve Chadban (CPI) Assoc. Professor Jagadish Jamboti (PI)	Sydney LHD	FSH Other WA

\$1.6 million for landmark bladder cancer study

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.




Professor Dickon Hayne

“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.

RGS PRN	Title	CPI/PI	Lead HREC	Site(s)
1150	A Randomised, double-blind, placebo-controlled study to investigate the efficacy and safety of Injectafer® (ferric carboxymaltose) as treatment for iron deficiency	Assoc. Professor Carmine De Pasquale (CPI) Dr Kaitlyn Lam (PI)	Central Adelaide LHN	FSH Other WA Other national
1151	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	Professor Gemma Figtree (CPI) Dr Jamie Rankin (PI)	Central Adelaide LHN	FSH Other WA Other national
1166	Adjuvant Therapy with Pembrolizumab versus Placebo in Resected High-risk Stage II Melanoma: A Randomized, Double-blind Phase 3 Study (KEYNOTE 716)	Assoc. Professor Adnan Khattak (CPI/ PI)	SMHS	FSH
1181	The Australasian Resuscitation In Sepsis Evaluation: FLUID or Vasopressors In Emergency Department Sepsis observational study	Professor Gerben Keijzers (CPI) Assoc. Professor Glenn Arendts (PI) Dr Benjamin Smedley (PI)	The Gold Coast Hospital and Health District	FSH RGH Other WA Other national
1185	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	Dr Annabel Goodwin (CPI) Dr Andrew Redfern (PI)	Sydney LHD	FSH Other national
1188	A pilot study comparing betamethasone dipropionate 0.05% cream vs ointment under wet wrap dressings	Dr Ali Didan (CPI/PI)	SMHS	FSH
1189	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	Dr Siddharth Sood (CPI) Assoc. Professor Adnan Khattak (PI)	Melbourne Health	FSH Other national
1289	The effect of acute foot ulceration on body composition and musculoskeletal function in patients with diabetes	Dr Blake Sanchez (CPI/PI)	SMHS	FSH

RGS PRN	Title	CPI/PI	Lead HREC	Site(s)
1389	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	Dr Christopher Hocking (CPI) Dr Thomas Ferguson (PI)	St Vincent's Hospital Melbourne	FSH Other national
1390	'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)	Dr Christopher Hocking (CPI) Dr Thomas Ferguson (PI)	St Vincent's Hospital Melbourne	FSH Other national
1910	First-ever seizure in adults: clinical features and prognosis	Dr Nicholas Lawn (CPI/PI)	RPH	FH Other WA
2092	Prospective Observational Study on Perioperative anticoagulation management with the Novel Oral Anticoagulant Drugs Dabigatran, Rivaroxaban and Apixaban	Dr Stephanie P'Ng (CPI/PI)	RPH	FSH
2308	A Long-Term Non-Interventional Registry to Assess Safety and effectiveness of HUMIRA© (Adalimumab) in Patients with Moderately to Severely Active Ulcerative Colitis (UC)	Dr Lena Thin (CPI/PI)	SMHS	FSH
2323	Perioperative Administration of Dexamethasone and Infection (PADDI) - Post Operative Nausea and Vomiting Sub-study (The PADDI PONV Sub-study)	Pauline Coutts (CPI/ PI)	SMHS	FSH Other WA
2649	Kalyakool Moort - always family - developing a safe effective approach to screening for perinatal depression and anxiety among Aboriginal families	Professor Rhonda Marriott (CPI/PI)	WNHS	FSH Other WA

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

Lead HREC	HREC approved SMHS projects 2018
Alfred Hospital	5
Austin Health	2
Central Adelaide Local Health Network (LHN)	3
Child and Adolescent Health Service (CAHS)	4
Gold Coast Hospital	2
Hunter New England	2
Melbourne Health	8
Metro South	1
Monash Health	2
North Sydney Local Health District (LHD)	2
Peter MacCallum Cancer Center	2
Royal Perth Hospital (RPH)	25
Sir Charles Gairdner Osborne Park Health Care Group (SCGOPHCG)	6
South Metropolitan Health Service (SMHS)	68
St Vincent's Hospital, Melbourne	4
Sydney Local Health District (LHD)	9
The Prince Charles Hospital	3
University of Wollongong (joint with Illawarra Shoalhaven Local Health District)	1
Western Australia Country Health Service (WACHS)	1
Women and Newborn Health Service (WNHS)	2
Total	152

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

RGS PRN	Title	Reason
463	Reduction of Oxygen After Cardiac Arrest: The EXACT study	Consent issues
1003	Australasian Cardiac Outcomes Registry Ltd TAVI Registry	Consent issues : currently being revised

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

RGS PRN	Title
2015-107	Australasian Cardiac Outcomes Registry (ACOR) Cardiac Procedures Registry
2008-227	CELL: A Screening Instrument for Cognitive Deficits Adapted for Individuals With Language and Speech Impairments
2016-174	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
67	What is the current continence knowledge and practices of non-specialist physiotherapists? A survey of Western Australian hospital physiotherapists
101	Smart phone ECG monitoring in acute ischemic strokes
158	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
208	Efficacy and Safety of Finerenone in Subjects With Type 2 Diabetes Mellitus and the Clinical Diagnosis of Diabetic Kidney Disease (Kidney Outcome Focus)
209	Efficacy and Safety of Finerenone in Subjects With Type 2 Diabetes Mellitus and Diabetic Kidney Disease (Cardiac Outcome Focus)
246	A Randomized, Double-Blind, Placebo Controlled Study of Venetoclax Co-Administered with Low Dose Cytarabine Versus Low Dose Cytarabine in Treatment Naïve Patients with Acute Myeloid Leukemia Who Are Ineligible for Intensive Chemotherapy

RGS PRN	Title
277	Mental health service culture and reform aspirations: What is required for change?
284	The effect of either a pre and post exercise intervention and assessment on patient outcomes for prostate cancer patients undergoing prostatectomy
310	Immigration status and access to hospital care
370	Pre-warming in Burns to prevent intraoperative hypothermia, improve quality of recovery after anaesthesia and improve burn specific scar outcomes and quality of life.
585	Operating Theatre time required for specified DRG's
608	Defining NETs: Defining supportive care needs and psychological morbidity of patients with functioning versus non-functioning neuro-endocrine tumours (NETs)
665	Genetic testing for primary immunodeficiency diseases
714	Fighting Fit: A randomised controlled trial of a structured supervised exercise intervention during treatment for cancer in adolescents and young adults in Western Australia.
720	Exploratory Study of ABC294640 for the Treatment of Moderate to Severe Ulcerative Colitis - Protocol ABC-105
783	Promoting Student Belongingness: the development, implementation and evaluation of the WANTED toolkit for nurses
828	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
842	Long-term Clinical Outcomes in SAPHO – variable responses to diverse treatments including biologic therapies
855	Management of malignant pleural effusions at Fiona Stanley Hospital
867	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
934	A review of patients perspectives on the management of testicular lesions
1139	Pro-phylactic administration of Melatonin for the prevention of Delirium in Intensive Care Units- a randomized placebo controlled trial
1182	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

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



Dr Koya Ayonrinde

\$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

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:

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Produced by Research Support & Development Unit, South Metropolitan Health Service, June 2019

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