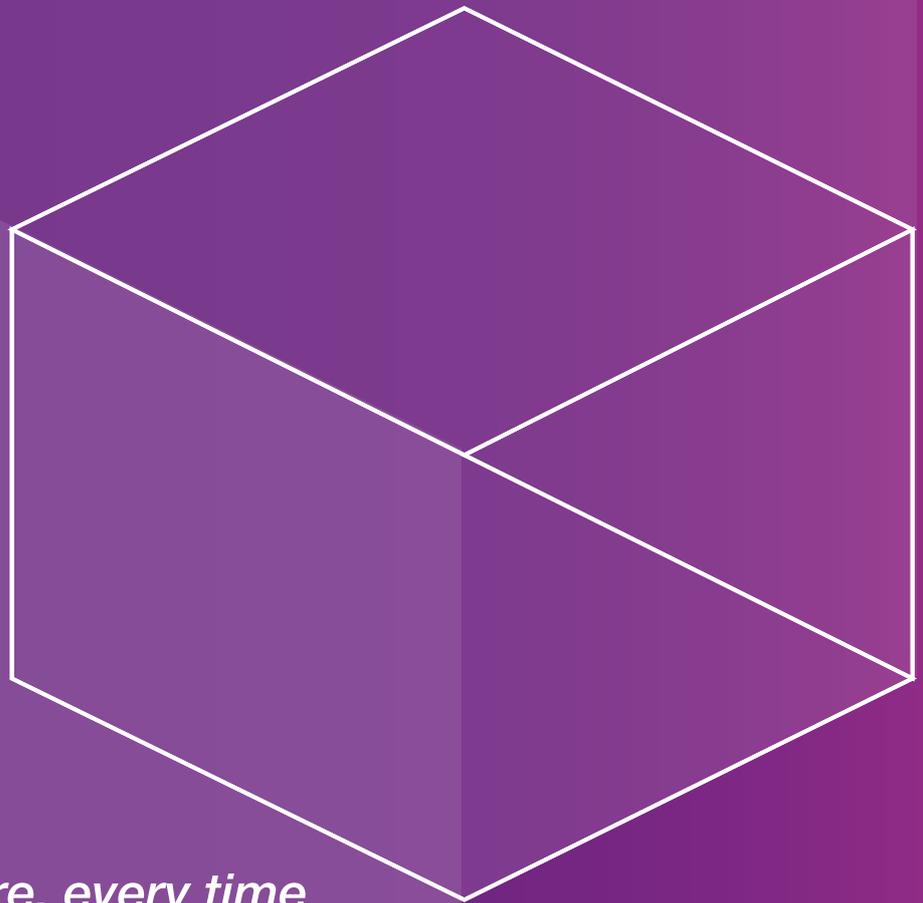




Government of Western Australia  
South Metropolitan Health Service

# RESEARCH REPORT 2020



*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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# Foreword

The South Metropolitan Health Service (SMHS) Research Report 2020 highlights research activity undertaken across the Fiona Stanley Fremantle Hospitals Group (FSFHG) and Rockingham Peel Group (RkPG) in the 2020 calendar year.

## From the SMHS Chief Executive

This report highlights the impressive volume of diverse research activity conducted across SMHS sites during 2020 and associated research translation activities occurring via publications. It also details the growth in our research culture, capacity and capability as we build our collaborative research strategy.

I am very proud of the achievements made during an incredibly difficult year with the onset of the COVID-19 pandemic; existing research projects were maintained and many new research projects commenced. COVID related research was also prioritised to ensure we provided the best possible care to our community.

The format of the third annual SMHS Research Showcase differed this year due to the impact of COVID, with the team facilitating three separate events to celebrate and showcase our researchers' work. Thank you to all the wonderful presenters and judges for giving their time and expertise to support these events and congratulations to award winner **Ellen Ffoulkes**, Intern Audiologist at Fiona Stanley Hospital.

“ I am very proud of the achievements made during an incredibly difficult year with the onset of the COVID-19 pandemic.”

**Mr Paul Forden**  
Chief Executive, SMHS



# Acknowledgements

This report was developed with contributions from:

- researchers from multiple departments as detailed within this report
- SMHS Research Advisory Committee
- SMHS/East Metropolitan Health Service Library team
- SMHS Corporate Communications team
- SMHS Research, Support and Development Unit (RSDU) team.

## 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**.<sup>1</sup>

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 and environmentally sustainable.

This report captures research activity that occurred in SMHS during the 2020 calendar year.

While the majority of research was conducted at Fiona Stanley Hospital (FSH), a significant number of projects involved collaboration across SMHS sites including Fremantle Hospital (FH), Rockingham General Hospital (RGH) and community services.

As a high level summary of research activity:

- **88** projects received SMHS Human Research and Ethics Committee (HREC) approval.
- **14** waivers of consent were granted by the SMHS HREC.
- **183** projects were approved to proceed at SMHS sites (via governance).
- **536** publications that have an affiliation noted with SMHS or a SMHS site were sourced.
- The top three research areas were cancer (**34**), oral and gastrointestinal (**23**), and infection (**16**).

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1 <https://ww2.health.wa.gov.au/-/media/Files/Corporate/general-documents/SMHS/PDF/SMHS-Strategic-Plan-2021-2025.pdf>



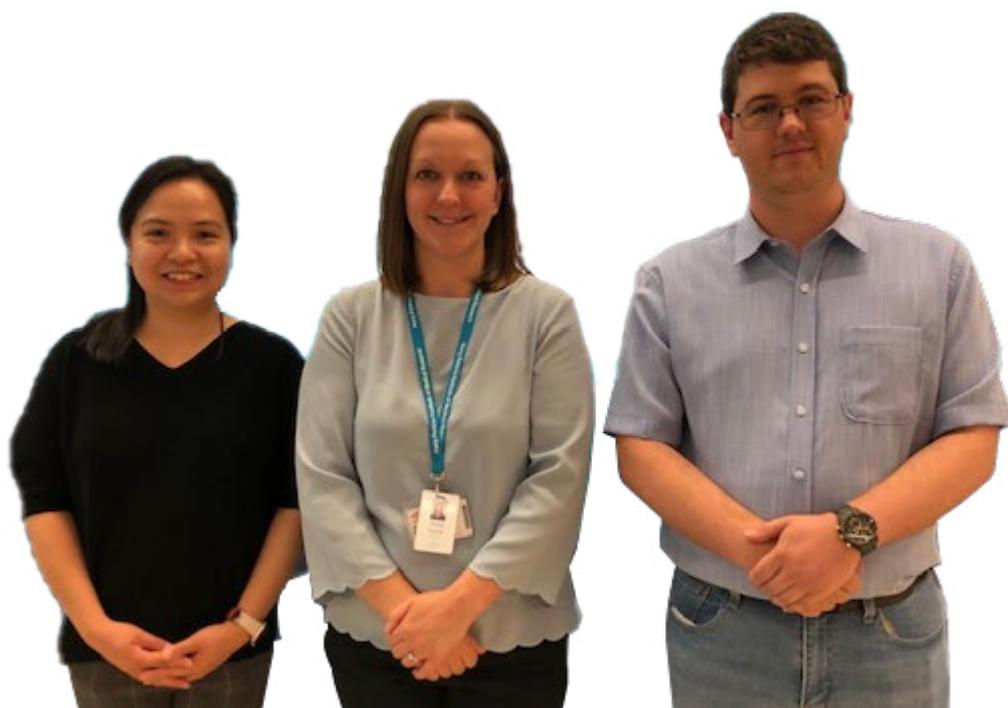
TRANSFORM team: Mel Wright, Sarala Matthews, Merrilee Needham, Vidya Finlay and Glenn Boardman

“The Research Support and Development Unit (RSDU) expanded in 2020 from the existing ethics and governance teams.”

# Research Support and Development Unit

The Research Support and Development Unit (RSDU) expanded in 2020 from the existing ethics and governance teams to include the following teams and responsibilities:

- Oversight of the SMHS allocated spaces in the Harry Perkins South Building in consultation with the SMHS Contract Management team and Harry Perkins Facilities Management. Research clinics are operating from the ground floor consulting rooms with staff allocated office, desk and lab space to conduct their research projects.
- The SMHS Research Business Support team, led by Senior Business Officer – Research Verity Appel, is rolling out the WA Health Standard Model for Managing Clinical Research Funds to all research specialties across SMHS. The team manage invoicing, cost centre reports and research staff contracts to assist busy research clinicians.
- The TRANSFORM team, led by Clinical Trials Manager Vidya Finlay, is developing a digital platform to streamline data capture and accessibility for clinicians and researchers across WA Health to use in patient care, quality improvement and research. The TRANSFORM structured database will allow staff to access WA Health clinical data combined with patient provided health information, supplementing disease specific data collection within a centralised secure governance framework.



SMHS Research Business Support team members Anna Boy, Verity Appel and Laurance O'Connor

# Research leadership

During 2020, three key leadership appointments were made to enhance research development, support and strategy across SMHS.



SMHS Executive Director Transformation  
Jemma Greene

“ I am looking forward to driving transformation initiatives that empower our people across SMHS to be responsive to change and continue to strive for excellence.”

## Executive Director Transformation

Jemma Greene was appointed as Executive Director Transformation in August 2020 and leads the Kaartdijin Innovation, Informatics, Research and Development, and Organisational Development teams. Prior to joining SMHS, Jemma was Chief Innovation Officer of a local government area and responsible for developing its innovation strategy, building the innovation capability of employees and embedding a culture of innovation that embraced technology and digital enablement. Jemma also brings a wealth of experience from the private sector in human resources, organisational development and business improvement leadership.

Most recently, Jemma was involved in establishing and co-leading a ‘pop up’ WA Innovation Hub evaluating citizen ideas related to COVID-19 response challenges submitted through the Public Sector Commission’s iThink ideas platform.

Jemma was a Western Australian finalist in this year’s 2020 Telstra Business Women’s Award for the Public Sector and Academia category and winner of the Public Sector Leadership Award with the Perth Business Women’s Alliance in 2019. She is also an active Australian Ambassador with the Global Innovation Management Institute based out of Boston, USA.

“People are the drivers of transformation, therefore a culture that fosters innovation with individuals, across teams and an organisation is essential,” Jemma said.

## Head of Research and Development

Melanie Wright was permanently appointed to this role in October 2020 after holding it in an acting capacity since November 2017. Melanie has 37 years of healthcare experience and is a qualified emergency nurse, PRINCE2 Practitioner, Six Sigma Green Belt and has completed a Master of Health Service Management and Master of Philosophy.

In addition to significantly streamlining processes, Melanie has changed and shaped the positive, inclusive research culture, collaborated with internal and external staff and companies, and completed many strategic research projects that have formed the service into what we see today.

Dedicated to empowering staff, providing great customer service, and striving for patient excellence, Melanie advocates for genuine consumer involvement and partnerships. Melanie's vision for the future is that SMHS will become a great place to do research and a global research leader.



SMHS Head of Research and Development  
Melanie Wright

“ I am so proud to lead such great teams of motivated people and work with some inspiring, world class research leaders. I am committed to enabling high-quality research projects to ensure our patients receive the very best care.”

## Mental Health Research Professor

Professor Wai Chen is a child, adolescent and youth psychiatrist. He has been appointed Professor of Youth Mental Health and Developmental Neuropsychiatry at the Mental Health Service, Fiona Stanley Hospital (FSH). He is also adjunct professor at UWA, at Murdoch University and at School of Medicine (Fremantle), Notre Dame University Australia.

He served as an external peer reviewer for the DSM-5 Clinical and Public Health Committee (DSM-5 CPHC) during the DSM-5 revision. He is a member of the Eunethydis (European Network for Hyperkinetic Disorders); and a member of the international HiTOP (The Hierarchical Taxonomy of Psychopathology) Consortium, which addresses the limitations of traditional taxonomy. Currently, he represents SMHS on the Statewide Mental Health Research Strategy Advisory Group. His research interests include attention deficit hyperactivity disorder, neurodevelopmental disorders, emotional dysregulation, dissociation, psychopharmacology, resilience and social recovery.



Mental Health Research Professor Wai Chen

In 2019, his published research on deliberate self-harm was selected as one of 19 presentations showcasing health and medical research in Western Australia in the ‘Science Land in Parliament’ event hosted by Minister for Health event at State Parliament.

The appointment aims to provide additional academic and research-informed perspectives to Youth Mental Health Service. The roles also encompass teaching, training, evidence-based service innovation as well as research development. “I feel highly honoured and privileged to serve in these roles,” Professor Chen said.

# Overview of SMHS research activity

Table 1 and Table 2 provide an overview of research approval activity in SMHS from 1 January – 31 December 2020.

**Table 1: SMHS HREC approvals**

Activity	Number of projects
SMHS HREC approved	88
Waiver of consent granted	14

\*Note: projects may have approval from other approved ethics committees; therefore not all projects need SMHS HREC approval.

**Table 2: SMHS site authorisation (governance) approvals and associated sub-data**

Activity	Number of projects
<b>Site Authorisation approved – total</b>	<b>183</b>
<b>Health site*</b>	
Fiona Stanley Hospital	174
Fremantle Hospital	20
Rockingham General Hospital	13
Community Physiotherapy Service	2
Mandurah Community Health Centre	2
<b>Commercial or non-commercial</b>	
Commercial	52
Non-commercial	131
<b>Clinical trials**</b>	
<b>Total number of new clinical trials</b>	<b>82</b>
Phase I	4
Phase II	27
Phase III	35
Phase IV	5

\*As one project can be conducted across multiple sites, the sub-data will not always equal the total

\*\*Some projects in Research Governance Service (RGS) have no listing or 'not applicable' for phase of clinical trial

Research projects can also be filtered by 'Broad research area' in the Research Governance Service (RGS) data reporting. Table 3 provides an overview of the clinical areas that research projects are conducted in, grouped by the naming conventions available in the system:

- In 2019 the top three research areas were cancer (**33**), cardiovascular (**18**) and blood (**12**).
- In 2020, the top three research areas were cancer (**34**), oral and gastrointestinal (**23**) and infection (**16**).

**Table 3: Broad research area**

Broad research area	Number of approved projects
Anaesthesiology	5
Blood	10
Cancer	34
Cardiovascular	13
Diet and nutrition	1
Ear	1
Eye	1
Emergency medicine	3
Infection	16
Inflammatory and immune system	7
Injuries and accidents	4
Mental health	2
Metabolic and endocrine	8
Musculoskeletal	8
Neurological	7
Oral and gastrointestinal	23
Other	9
Physical medicine/rehabilitation	2
Renal and urogenital	5
Reproductive health and childbirth	1
Respiratory and sleep	10
Stroke	2
Surgery	9
<b>Total</b>	<b>183</b>

Table 4 provides a comparison of ethics and governance (site authorisation) activity, as well as publications sourced from 2017 to 2020.

**Table 4: Comparative data 2017–20**

Descriptor	2017	2018	2019	2020
<b>Ethics approvals</b>	92	79	79	88
<b>SMHS HREC waiver of consent</b>	30	10	12	14
<b>Site authorisation approvals</b>	155	152	161	183
<b>Publications</b>	357	452	479	536

In 2017, the National Mutual Acceptance (NMA) scheme was introduced, which had an associated minor reduction in projects requiring ethical review from SMHS HREC in 2018 and 2019.

In 2018, the legislative issues around consent to research in WA were reviewed causing a reduction in waivers of consent being approved by the SMHS HREC.

Site authorisation approvals and publications sourced increased during 2020.

# SMHS Human Research Ethics Committee

As a certified lead Human Research Ethics Committee (HREC) the SMHS HREC (EC00265), can approve any project in Australia regardless of whether it is being conducted at a SMHS site.

The HREC membership changed significantly in 2020:

- Professor David Fletcher was appointed as the new HREC Chair in March 2020, following the retirement of the previous Chair Mr Richard Wojnor-Horton.
- Deborah Matthews was permanently appointed as Ethics Coordinator in April 2020.
- A volunteer recruitment drive ensured SMHS an enhanced roster of new HREC volunteers to comply with category guidelines, attend monthly meetings and perform out of session reviews.

With the introduction of the NMA Scheme, some projects may have been approved by another certified lead HREC; therefore they do not require SMHS HREC approval, but do require site authorisation via the governance process.

## Waiver of consent

The National Health and Medical Research Council (NHMRC) highlights in the National Statement<sup>2</sup> that, depending upon the circumstances of an individual project it may be justifiable to employ a waiver of the requirement for consent, rather than seeking explicit consent. In order to apply for a waiver of consent investigators must respond to Section 2.3.10 (a-i) 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. Table 5 documents 14 waivers of consent granted in 2020, a slight increase from the 12 waivers of consent granted in 2019. The NHMRC requires that a brief description of all projects with a waiver of consent is publically available.

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<sup>2</sup> <https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#block-views-block-file-attachments-content-block-1>

**Table 5: Waiver of consent projects**

RGS Number	Title	CPI / Site
4316	Emergency Department management of patients presenting with constipation	CPI: Mr Piers Truter Site: Fiona Stanley Hospital (FSH)
4307	Disease behaviour and evolution of Unclassifiable Interstitial Lung Disease - a retrospective single-centre review	CPI: Dr Jeremy Wrobel Site: FSH
4477	(NMA) POST-operative Variations in anaemia Treatment and Transfusions	CPI: Prof Toby Richards Sites: Fiona Stanley Hospital, Royal Perth Hospital, Sir Charles Gairdner Hospital, Alfred Health (VIC), Flinders Medical Centre (SA), Royal Adelaide Hospital (SA), John Hunter
4179	Fistulising Crohn's Disease and Anti-TNF Level Study – FISCAL	CPI: Dr Lena Thin (FSH) Site: FSH
3476	Fusobacterium Necrophorum isolates in Western Australia: 14 years of data from a statewide pathology service	CPI: Dr Vijay Pather (FSH) Sites: FSH, PathWest FSH, PathWest QEII, FHHS, SCGH, RPH
3802	Factors affecting ossiculoplasty hearing outcomes	CPI: Dr Jarfi Kuthubutheen Sites: FSH, PCH, RPH
3783	Use of video formats and machine learning video analysis algorithms to help pathologists diagnose cancer in tissue specimens	CPI: Dr Jeremy Parry Site: FSH (Pathwest)
3626	Outcomes of conservative management of large liver abscesses	CPI: Dr Kwang Sim Sites: FSH, FHHS
3584	Radiology AI (RAI)	CPI: Dr Ashu Gupta Sites: FSH, FHHS, RKGH
4206	Review of patient management and complications post image guided lung biopsy	CPI: Dr Samantha Tan Site: FSH
3965	Defining exercise blood pressure thresholds to inform clinical guidelines and practice: The EXERcise stress Test collaboration	CPI: Dr Martin Schultz Site: FSH
3906	Predicting the success of vaginal birth after caesarean delivery in a large tertiary West Australian hospital	CPI: Dr Emma O'Hara Site: FSH
3918	Observational study looking at right ventricular free wall longitudinal strain to predict post-operative acute kidney injury in patients undergoing cardiopulmonary bypass and cardiothoracic surgery	CPI: Dr Richard Hunt Site: FSH
3493	NMA Scheme. The Monitoring with Advanced Sensors, Transmission and EResuscitation in Traumatic Brain Injury (MASTER-TBI) Collaborative	CPI: Dr Robert McNamara (RPH) Sites: WA – RPH; VIC – Alfred Health, Royal Melbourne Hospital

# Research showcase

For the third consecutive year, SMHS celebrated its researchers and their inspiring work by hosting a research showcase event. Due to the COVID19 pandemic, fewer events were hosted and the showcase split over several days.

The Research Grand Round titled **'Adventures in Research'** was held on the 11 November 2020, with the following speakers:

- **Consultant Oncologist Professor Adnan Khattak** – Clinical Trials in Research
- **Allied Health Research Director Associate Professor Vin Cavalheri** – Building a research culture within a clinical service: the importance of research grants
- **Consultant Rheumatologist Dr Shereen Paramalingam** – Journey of a junior clinician researcher: investigator initiated institutional sponsored research.

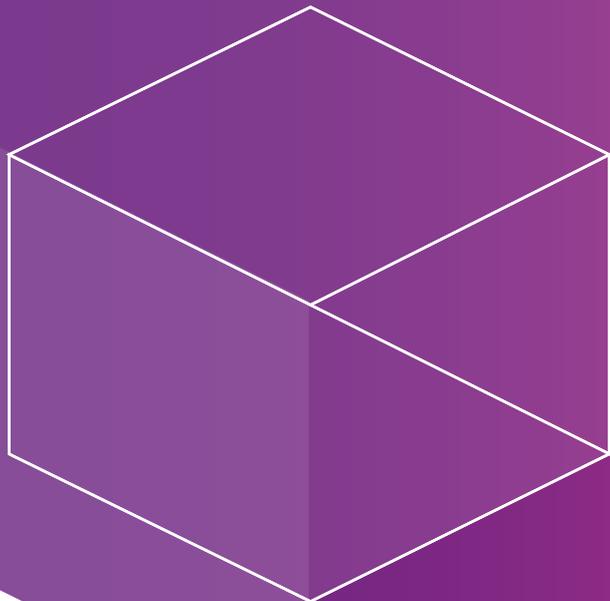
This event was immediately followed by the Three Minute Project Competition which was won by FSH Intern Audiologist Ellen Ffoulkes, for her presentation **'Using brain activity to objectively optimise cochlear implants'**.

The SMHS Research Breakfast Forum, held on 18 November 2020, celebrated International Men's Day and showcased the work of three of our male researchers into improving men's health:

- **Consultant Endocrinologist Professor Bu Yeap** – Men's Health: Testosterone, Diabetes and Heart Disease
- **Senior Physiotherapist Rehabilitation in the Home Ashan Weerakkody** – Upper limb rehabilitation after stroke: the male perspective
- **Clinical Nurse Researcher Inflammatory Bowel Disease and Rheumatology Daniel Lightowler** – Inflammatory Bowel Disease and Testosterone



Left to right: Three Minute Project entrants Marcus Voala, Evan Gow, Andre Wedekind, Cynthia Hawkes, 2020 winner Ellen Ffoulkes, with judges Jemma Greene, Glenn Arendts and Vin Cavalheri



Top left to bottom right: Ashan Weerakkody, Daniel Lightowler, Bu Yeap, Adnan Khattak, Vin Cavalheri and Shereen Paramalingam

# Spotlight on COVID-19

In March 2020, the RSDU team responded to the COVID-19 pandemic by working in new, agile ways to ensure current research was maintained and supported while prioritising COVID research.

The following snapshot highlights some research activities specifically related to COVID:

- The SMHS HREC convened special ad-hoc meetings and out of session panel reviews to fast track ethical approval of COVID related projects.
- The governance team prioritised reviews of COVID related projects.
- One project received site authorisation in **2** days, and another secured both ethics and governance (site authorisation) approvals in **11** days.
- SMHS rapidly appointed an onsite team, led by Associate Professor Dale Edgar, to manage the patient facing aspects of COVID related research (consent, data collection and blood sampling) in the COVID clinic, Emergency Department (ED), Intensive Care Unit (ICU) and wards to support the Covid Research Response led by Professor Toby Richards.
- The RSDU team worked with the FSFHG Executive Director and senior managers to move research clinics to the Harry Perkins Institute of Medical Research South Building, ensuring the area was stocked, had basic clinical equipment and clerical support to manage patient administration. Emergency drills were conducted in the consulting room clinic area and the Facilities Management team at Harry Perkins worked collaboratively with SMHS staff to ensure the area was safe for research participants

and staff. Clinical Trials Liaison Officer Vidya Finlay was the project lead for this initiative and developed a Departmental Service Plan for the consulting room area which was approved by Executive. As Site Lead, Clinical Research Nurse Daniel Lightowler assisted with multiple queries and process redesign

- The RSDU team assisted other areas urgently as required, for example by calling 120 patients with their COVID test results – a project led by Ethics Coordinator Deborah Matthews.
- To ensure Western Australian patients would have access to the latest COVID treatments, a legislative amendment to the *Guardianship and Administration Act 1990* was enacted to allow a next of kin or guardian to provide consent for patients who could not provide consent or for research to be started urgently on the advice of an independent medical practitioner. The implementation of the updated legislation at SMHS was led by RSDU Manager Selina Metternick-Jones and involved a new process and checklist for researchers as well as training for the HREC members.

According to a Department of Health report (WA Health EEO RGO Shared file 01/12/2020), 61 COVID related research projects were opened in 2020 in RGS across WA Health. Of these research projects, **27** were conducted at one or multiple SMHS sites. A further two research projects were identified when conducting a review for this report, giving SMHS a total of **29** COVID research projects running in 2020. Of the 7 other COVID related projects not processed via RGS, **1** was a Quality Improvement project conducted at two of the SMHS sites.



Main photo: SMHS COVID team: Ali Alishum, Lucy Glazov, Dale Edgar and Sheeraz Mohd.

Top left to bottom right: Toby Richards, Daniel Lightowler, Deborah Matthews, Selina Metternick-Jones and Vidya



## Study examines life changing impacts of COVID-19

Researchers from FSH have spent the past year examining the long term physical and mental health effects of COVID-19 on almost 350 people.

Life AFTER COVID-19, known as the LATER-19 study, is being led by FSH Senior Physiotherapist Associate Professor Dale Edgar with researchers gathering data from patients across Western Australia's three tertiary hospital sites.

"We believe that through the LATER-19 trial we have been able to recruit one of the largest long term follow up cohorts in the world," Associate Professor Edgar said.

"Of the 350 trial participants, around 150 were COVID-19 positive and we have 200 symptomatic controls for comparison.

"We continued to recruit after the first wave of the pandemic in early 2020 with a number of participants joining the trial after returning from overseas and completing their isolation period."

In the initial stages, the study monitored patient symptoms in hospital before moving on to physical assessments over time that tracked participant grip strength and sit-to-stand ability.

In addition to the physical testing, there was also a focus on the mental wellbeing of participants with over 50 participants followed up to determine if they would benefit from a referral to professional support.

"We really needed the full picture of each person's health and wellbeing so we could enhance our understanding of the long-term recovery after COVID-19," Associate Professor Edgar said.



Associate Professor Dale Edgar

"This infection definitely has long lasting effects; participants have shared stories of being unable to return to their private business or accelerating their retirement plans because of persistent severe fatigue, brain fog and muscle aches as well as permanently altered senses of smell and taste.

"It has been remarkable to see how generous participants have been with their time, often preferring to come into the hospitals to complete their physical assessments, and it just shows how committed people are to helping us find out as much as we can about this deadly and evolving infection."

The final round of data collection is scheduled for early 2021 with summary statistics for all recruited patients available mid-year to model the long term recovery from COVID-19 and compare to other respiratory diseases.

Given the anticipated continuing global impact of COVID-19, the research findings will inform rehabilitation and other treatment interventions in Australia and beyond.

## Researcher puts database on the frontline for COVID-19

Fiona Stanley Hospital surgeon Professor Toby Richards put research on the frontline for COVID-19 with the setup of a statewide database and biobank, enabling WA researchers to contribute data to global efforts, and in collaboration with the Australian National Phenome Centre, contribute to a new body of knowledge around the impact of COVID-19 on the body.

Despite the massive number of infections worldwide, the clinical trial data on COVID-19 treatments is poor based on less than 50,000 patients (0.05%). In response, Toby setup the COVID Research Response (CRR) Trial to ensure WA could contribute data to aid in the search for COVID-19 treatments.

Toby, who is also Michael Lawrence Brown Chair of Surgery at The University of Western Australia (UWA), worked with Pathwest, the other Perth Metropolitan hospitals, the Australian National Phenome Centre (Murdoch University) and UWA to create the database, biobank and a state-wide process for data collection, ethics and governance, translational research, and clinical trial coordination for COVID-19 treatment research.

“Over the last year we’ve collected over 118 patient data sets and over 1500 bio samples from across all Perth metropolitan hospitals,” Toby said. “Hospital data was integrated into the REDCap system, including electronic consent, and serum samples into clinical pathways at Path West.”

“Sequential groups of patient data have provided a rich source of information for the development of potential COVID-19 treatments,



Professor Toby Richards

and so far we’ve distributed this data for seven separate research projects.”

Toby and his team have collaborated internationally via the National COVID Research Group with data from WA being shared for research projects in the UK, America and Europe, resulting in two Lancet series manuscripts and nine translational science articles, and submission of a patent for new technology.

“The speed at which the global pandemic progressed highlighted the importance of collaboration and international research, and it was great to contribute to the worldwide fight against the virus,” Toby said.

“I hope the CRR will produce significant results with great benefit to patients, WA, national and international COVID-19 research, and serve as a platform to build research in WA moving forward.”

The database was based on a World Health Organisation International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC) platform.

## BRACE trial puts BCG vaccine to the test to protect healthcare workers against COVID-19

At the height of the COVID-19 pandemic in March 2020, FSH Infectious Disease Specialist, Dr Laurens Manning was one of the first to put his hand up to participate in the BRACE trial.

The trial in Western Australia is a collaborative team effort between FSH, Sir Charles Gairdner Hospital, Perth Children's Hospital and Telethon Kids Institute and was designed to find out whether the Bacille Calmette-Guérin (BCG) vaccine, used over the last 100 years to protect against tuberculosis, could protect against COVID-19 or reduce the severity of the virus in healthcare workers.

As Principal Investigator, Dr Manning led the recruitment of healthcare workers at FSH and with support from the FSH Infection Prevention and Management team, the annual influenza vaccination program was brought forward to early April 2020.

"By embedding the BRACE trial with the influenza vaccine, the recruitment rate was extremely high," Dr Manning said.

"Of the 2,000 Western Australian BRACE participants, 750 of these were FSH healthcare workers, randomised for either BCG plus influenza vaccine, or influenza alone."

Dr Manning was one of those participants.

"I have to be prepared to do whatever I ask the participants to do," he said.

The BRACE trial, led by Murdoch Children's Research Institute (MCRI), is the largest and most ambitious trial of the BCG vaccine globally

and was the first to start in Australia during the height of the COVID-19 pandemic. Participants have also been recruited throughout Australia, Spain, Netherlands, UK and Brazil.

While developed to protect against tuberculosis, in more recent times the BCG vaccine has been shown to boost immunity to protect against other viral infections.

As part of the trial, BRACE participants have blood samples taken every three months and must track their symptoms weekly via an app.

"Though there haven't been many primary outcomes so far due to the rate of COVID-19 being much lower than expected, there is still a lot to be gained from this ongoing trial," Dr Manning said.

"We are learning so much about the biology of the BCG vaccine.

"We will be able to look at whether the combined BCG vaccine and flu vaccine has a much more robust response to the just the standalone flu vaccine which has a low success rate and then, who knows, we may even start using BCG in the future to prevent the flu or other respiratory tract infections. "

While Fiona Stanley Hospital participants will be one of the first groups to finish the trial in April 2021, it will be another 12 months before primary outcomes of all BRACE participants are known worldwide.



BRACE team: (left to right) Laurens Manning, Erin Latkovic (research nurse), Alana Di Giacomo (research assistant), Michelle England (research nurse).

“Of the 2,000 Western Australian BRACE participants, 750 of these were FSH healthcare workers, randomised for either BCG plus influenza vaccine, or influenza alone.”

## WA mother and newborn biobank contributing to global COVID-19 research collaboration

At work, Professor Shail Mehta is a neonatologist but at home he is a dad to three young children.

When the COVID-19 pandemic reached Western Australia early in 2020, it was both of these important roles that inspired the FSH consultant to take on Lead Principal Investigator for the Pregnancy, Newborn and Paediatrics Database and Biobanking Project, also known as the PANDA project.

“Being a neonatal paediatrician, my first thoughts were about my little patients who I look after every day but being a father of three children, I was also worried about my kids getting the infection,” Professor Mehta said.

“When COVID-19 became a worldwide pandemic, everybody was naturally concerned about this new virus and how it spread amongst children, or from pregnant women to their babies or from one baby to another baby.

“There were also a lot of unknowns regarding the short and long term effects of the infection on the health of pregnant women, children and newborns including changed lifestyle and stress that could influence multiple aspects of pregnancy, neonatal life and early childhood.”

To obtain answers to these questions, the PANDA project was formed as a collaborative platform to prospectively collect data and biological samples for COVID-19 positive mothers, newborns and older children across the South Metropolitan Health Service.

In anticipation of a global pandemic, the World Health Organisation (WHO) supported the International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC) to develop a rapid response platform for clinical trials for Severe Acute Respiratory Infection.

“Through the PANDA project, we are submitting our COVID-19 data into the WHO ISARIC which enables statistics and biological samples to be collected in a globally harmonised manner,” Professor Mehta said.

“There are a number of benefits that come with these standardised processes including improved data quality, reduced error of measurement and increased statistical power through the ability to combine and compare outcomes on a grand scale.”

The Western Australian Health Translation Network (WAHTN) COVID Research Response team leads the WHO ISARIC platform and comprises senior clinicians, researchers and administrators within the WAHTN network.



Professor Shail Mehta

“ Being a neonatal paediatrician, my first thoughts were about my little patients who I look after every day but being a father of three children, I was also worried about my kids getting the infection.”



## Aiming for the ‘StARS’ in testing at risk healthcare workers for asymptomatic COVID-19 infection

The COVID-19 pandemic highlighted the urgent need for researchers to know if a person had been exposed to the virus and had antibodies to protect against COVID-19 infection.

To facilitate what is known as a serological assay, FSH Cardiac Anaesthetist, Dr Warren Pavey and Heart and Lung Research Institute WA (HLRI-WA) scientist, Dr Herbert Ludewick developed the Sero-testing At Risk Hospital Staff for COVID-19 (StARS Project), funded by the Department of Health COVID-19 Research Grants Program.

As StARS Project Chief Investigator, Dr Pavey and his team at HLRI-WA, in collaboration with Royal Perth Hospital (RPH), tested a total of 804 ‘at risk’ healthcare workers across Emergency, Theatres, ICU and COVID-19 Clinics at FSH and RPH for evidence of past symptomatic and asymptomatic infection.

“Of the 804 ‘at risk’ staff tested, 406 were from FSH,” Dr Pavey said.

“At the time, the rate of spread of asymptomatic infection in the community and amongst healthcare workers was unknown; we wanted to find out if healthcare workers were at risk of getting COVID-19 from patients.”

An assay such as this provides a means of determining the rate of asymptomatic infection and who may have developed immunity and who has not. It’s also a way to identify individuals who have mounted a strong immune response who may then be able to donate their antibodies to protect or treat another person who is not immune and to study the immune response of those infected and assess the antibody response to vaccines.

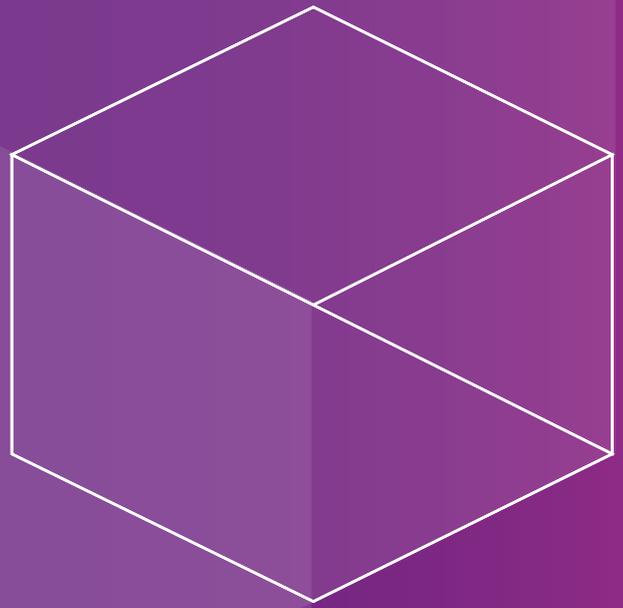


Warren Pavey

In partnership with Professor Florian Kramer’s group at Icahn School of Medicine, Mount Sinai, NY, USA, the StARS Project group synthesised the COVID-19 spike protein as a whole as well as the important receptor binding domain. Both of these proteins are critical for virus entry into the body as well as targets for host antibodies.

“Using these, our group developed the first Enzyme Linked Immune Sorbent Assay (ELISA) based serological assay to accurately confirm COVID-19 infection in WA,” Dr Pavey said.

“Reassuringly though, very few staff returned serology results indicating previously unknown COVID-19 infection.”



# Research Projects

# Research projects

Research projects listed in this report were collated by reviewing the WA Health online RGS reports, the South Health Information Management System (SHIMS) database and SMHS Monthly Research approval reports to identify new projects approved to commence in the 2020 calendar year i.e. only those that had received site authorisation (governance) were included.

Table 7 details **183** research projects approved to commence at a SMHS site during 2020.

**Table 7: Projects approved to proceed at a SMHS site in 2020**

12	A cohort study of otitis media in young urban Aboriginal children – prevalence, risk factors and consequences
19	A double-blind, randomised, controlled trial to compare allergic outcomes in children following vaccination with acellular pertussis antigen given at 2 months of age versus whole cell pertussis in the infant vaccine schedule
607	Vasopressor dependent shock intravenous vitamin C versus placebo on vasopressor use
699	Efficacy and Safety Outcomes of Drainage of Intensive Care Pleural Effusions
1120	A multi-centre randomised non-inferiority trial of chewing gum versus ondansetron to treat postoperative nausea and vomiting in female patients after breast or laparoscopic surgery
1123	Evaluating the Implementation of an Artificial Intelligence-based Image Detection System for Diabetic Retinopathy at Selected EMHS and SMHS Tertiary Hospitals
1238	Western Australian Shared Diabetes Database
1443	A Multi-Center, Observational Study in Males with Hemophilia A
1471	Trajectories of Outcome in Neurological Conditions (TONIC) for people with Motor Neurone Disease in Western Australia
1761	Perth Systemic Lupus Erythematosus Registry and Biobank
2046	Novel Drivers of Progression and Treatment Resistance in Breast Cancer
2123	Short period incidence study of severe acute respiratory infection SPRINT-SARI
2662	PAEAN: Preventing Adverse Outcomes of Neonatal Hypoxic Ischaemic Encephalopathy with Erythropoietin: A Phase III Randomised Placebo Controlled Multicentre Clinical Trial
2876	Is the incidence of heart attack still decreasing in Australia? Developing more reliable methods for monitoring trends in myocardial infarction and coronary heart disease (AUS-MOCHA)
3017	Case registry of Scedosporium and Lomentospora mould infections: epidemiology, risk factors, disease syndromes and outcomes - in partnership with the FungiScope™ Global Rare Fungal Infection Registry
3032	Comprehensive Understanding of the effects of inflammation during Pregnancy and early life on Infant immune Development (CUPID) study

3042	Next generation sequencing in haematological malignancies - genomics risk stratification and health economics analysis
3076	Assessing the effectiveness, efficiency and cost-effectiveness of rural and remote telehealth implementation: Part B - WACHS Qualitative and Quantitative
3121	A 54-Week Treatment, Multicenter, Randomized, Double-Blind, Double-Dummy, Placebo and Active-Controlled, Parallel-Group Phase 2 Study to Assess the Efficacy and Safety of Brazikumab in Participants with Moderately to Severely Active Ulcerative Colitis
3141	Clinical correlation of disease with 3-hydroxy-3-methyl-glutaryl-CoA reductase (HMGCoA R) antibody levels in patients with antibody positive immune-mediated necrotising myopathy - a retrospective study
3162	DIAAMOND Ava: Diagnosis of aplastic anaemia, management and outcomes, utilising a national dataset. Cohort A: Avatrombopag in untreated Severe Aplastic Anaemia - a Bayesian Optimal Phase II study (DIAAMOND Ava-FIRST). Cohort B: Avatrombopag in Relapsed or Refractory Severe Aplastic Anaemia – a Bayesian Optimal Phase II study (DIAAMOND-Ava NEXT)
3180	Defining the vaccine preventable burden of lower limb cellulitis: a systems serology approach. Study 1: defining the vaccine preventable burden of lower limb cellulitis. Study 2: defining the vaccine preventable burden of invasive streptococcal disease
3187	The clinical and economic benefits of early use of clozapine in first episode schizophrenia
3234	An observational study of feeding practices and growth outcomes for ELBW and VLBW infants in Australian and New Zealand neonatal intensive care units
3271	A Retrospective Study analysing the relationship between febrility, Odontogenic infection and patient outcome
3279	SUNRRRISE Australia. Single Use Negative pResure dressing for Reduction In Surgical site infection following Emergency laparotomy
3289	Identification of liquid biopsy biomarkers for diagnosis and prognosis of cancer
3298	A phase 3 trial of the efficacy and safety of Bardoxolone Methyl in patients with Autosomal Dominant Polycystic Kidney Disease (FALCON)
3321	The Western Australian Lung Biobank
3324	R3ACT Randomised (R3R): A randomised trial of most closely HLA-matched third-party donor-derived pathogen-specific cytotoxic T-lymphocytes in patients with untreated viral infection post-allogeneic stem cell transplantation
3325	A multi-centre, double-blinded randomised placebo-controlled trial to investigate honey use to reduce pain and enhance recovery in children post tonsillectomy (Bee - Pain Free)
3337	The Western Australian Biologics and Immunosuppressant Registry for IBD
3339	Bronchial NET and the use of PRRT - an Australian experience
3362	ANZMIG case registry of invasive Aspergillus infections: epidemiology, risk factor disease syndromes and outcomes
3381	Does exercise influence burn induced inflammation?
3387	Does personalised soft tissue balance data improve outcomes in patients undergoing medially stabilised knee arthroplasty? A prospective randomised study investigating the clinical utility of the NextAR Navigation System (NextAR)

## Pre-screening clinic provides double the benefits

A ground breaking study has found pre-screening of patients' blood through a specialised clinic set up at FSH is improving post-surgery outcomes and reducing hospital admission costs.

FSH clinicians, in collaboration with researchers from the University of Western Australia, examined for the first time both the clinical and economic impacts of pre-screening clinics to determine if patients awaiting surgery had anaemia or low iron stores.

FSH Consultant Anaesthetist Dr Hamish Mace said around 30 per cent of the population has anaemia or iron deficiency, which increases the need for patient blood transfusions after surgery, and can lead to complications and longer recovery time.

"As part of the study, we used the clinic to analyse the blood screening results of 441 patients having bowel cancer surgery," Dr Mace said.

"There have long been financial concerns around setting up pre-screening clinics but through this study we found the benefits of pre-screening far outweighed the costs."

"This study provides us with the bigger picture, not only is it patient centred care at its best, but it also has the potential to reduce the burden on the health care system globally."

This was particularly evident in reduced costs of hospital admission with results showing significant savings of \$3776 per patient.

Patients screened as part of the study also received half the amount of red blood cell transfusions.

Kylie Symons has been Patient Blood Management Nurse since the clinic's implementation.

"It is an honour to be involved in an area of healthcare where improving the pre-surgical management of individual patients has also resulted in a reduction of hospital costs," Kylie said.

You can read more about the research, which was published late last month, in the world renowned [Anaesthesia journal \(external link\)](#).



Kylie Symons (Clinical Nurse Consultant), Kevin Trentino (UWA Adjunct Research Fellow) and Dr Hamish Mace (FSH Consultant Anaesthetist)

“ This study provides us with the bigger picture, not only is it patient centred care at its best, but it also has the potential to reduce the burden on the health care system globally.”

3407	Short term postoperative glycaemic management in cardiac surgical patients
3426	The impact of an m-health recovery program on the mental health and wellbeing of intensive care survivors: A randomized controlled trial.
3431	Insulin pump use in Western Australian children and adults with type 1 diabetes
3438	Understanding Lifestyle and Environmental Risk Factors in Motor Neurone Disease (MND)/Amyotrophic Lateral Sclerosis (ALS)
3441	Vedolizumab Immunomodulator Enforced Withdrawal Study
3472	First retrospective real-world data on unresectable stage III NSCLC treated with durvalumab after chemoradiotherapy
3473	ARMARON BIO: A Phase II Randomised, Double-blind, Placebo-controlled Study of the Efficacy, Safety and Tolerability of Oral NP202 in Reducing the Incidence of Atrial Fibrillation in Adults who have undergone Cardiac Surgery
3476	Fusobacterium Necrophorum isolates in Western Australia: 14 years of data from a statewide pathology service
3477	A Phase 2 Multi-Center, Randomized, Double-Blind, Placebo Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Induction Therapy with 2 Doses of TD-1473 in Subjects with Moderately-to-Severely Active Crohn's Disease
3494	DREAMM6: A Phase I/II, Open-label, Dose Escalation and Expansion Study to Evaluate Safety, Tolerability, and Clinical Activity of the Antibody-Drug Conjugate GSK2857916 Administered in Combination with Lenalidomide Plus Dexamethasone (Arm A), or Bortezomib Plus Dexamethasone (Arm B) in Participants with Relapsed / Refractory Multiple Myeloma
3495	IMbrave050. A Phase III, multicenter, randomized, open-label study of Atezolizumab (anti-pd-l1 antibody) plus Bevacizumab versus active surveillance as adjuvant therapy in patients with hepatocellular carcinoma at high risk of recurrence after surgical resection or ablation
3501	Towards visualising and understanding patient-specific biomechanics of abdominal aortic aneurysms (AAA) using time-resolved computed tomography and ultrasound
3503	V937-011. Phase 2, Randomized Clinical Study of Intravenous or Intratumoral Administration of V937 in Combination with Pembrolizumab (MK-3475) Versus Pembrolizumab Alone in Participants with Advanced/Metastatic Melanoma
3504	RAGNAR study: A Phase 2 Study of Erdafitinib in Subjects with Advanced Solid Tumors and FGFR Gene Alterations
3513	Transitions in Gout Research Study
3518	Testosterone for Atherosclerosis Reduction (T4AR): a multi-centre, randomised, double blind, placebo-controlled 2 year trial to determine if testosterone (Reandron (R)) therapy reduces progression of coronary atheroma in middle-aged and older men.
3520	A Phase 2b/3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Ulcerative Colitis
3526	HbA1c trajectory across childhood, adolescence and young adulthood in a Western Australian population
3528	Community based education and exercise training in heart failure: Harnessing an existing resource to bridge a gap

3531	Primary Care Adherence To Heart Failure guidelines IN Diagnosis, Evaluation & Routine management (PATHFINDER) Study
3548	Ultrasound Guided Hamstrings Block for Autologous Graft Harvest Site in Anterior Cruciate Ligament Reconstruction: A Technical Description and Prospective Single Blinded Randomised Control Trial
3552	Severe Acute Respiratory Distress Syndrome: Generating Evidence in Australia and New Zealand (SAGE-ANZ)
3563	Comparative Persistence With Prolia and Weekly Alendronate in 6 Asia-Pacific countries: a Prospective Observational Study
3574	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo- and Active- Controlled, Treat-Through Study to Evaluate the Efficacy and Safety of Mirikizumab in Patients with Moderately to Severely Active Crohn's Disease
3581	A multicentre prospective cohort study to evaluate intestinal ultrasound as a predictor of treatment response in Acute Severe Ulcerative Colitis Study Protocol
3584	Radiology AI (RAI)
3585	A prospective observational study to determine if non-anaemic iron deficiency increases the risk of poor post-operative outcome relative to an iron replete control in patients undergoing surgery for colorectal malignancy.
3588	A Phase III Randomized Multicenter Open Label Study in Adolescent and Adult Participants Comparing the Efficacy and Safety of Gepotidacin to Ceftriaxone plus Azithromycin in the treatment of Uncomplicated Urogenital Gonorrhoea caused by Neisseria gonorrhoeae
3599	Occupational therapists' perspectives on the factors influencing Occupational therapy education for stroke survivors and their caregivers, along the continuum of care in Western Australia
3605	DASL-HiCaP: Darolutamide Augments Standard Therapy for Localised Very High-Risk Cancer of the Prostate (ANZUP1801). A randomised phase 3 double-blind, placebo-controlled trial of adding darolutamide to androgen deprivation therapy and definitive or salvage radiation in very high risk, clinically localised prostate cancer
3609	The Contribution of Interpersonal Interactions to the Comfort of Patients Attending for Short Stay Surgery: A Grounded Theory Study of the Patient's Perspective
3615	A Phase 2b/3 Multi-Center, Randomized, Double-Blind, Multi-Dose, Placebo-Controlled, Parallel-Group Set of Studies to Evaluate the Efficacy and Safety of Induction and Maintenance Therapy with TD 1473 in Subjects with Moderately-to-Severely Active Ulcerative Colitis
3620	Western Australian Barrett's Oesophagus Registry
3626	Outcomes of conservative management of large liver abscesses
3627	Factors associated with delayed active listing for deceased donor kidney transplantation in patients receiving dialysis in Australia
3628	A Phase 3 Randomized, Double-blind, Placebo-controlled, Parallel-group Efficacy and Safety Study of SHP647 as Induction Therapy in Subjects With Moderate to Severe Crohn's Disease
3629	A Phase 3 Long-term Safety Extension Study of SHP647 in Subjects with Moderate to Severe Ulcerative Colitis or Crohn's Disease
3630	A Phase 3 Randomized, Double-blind, Placebo-controlled, Parallel-group Efficacy and Safety Study of SHP647 as Maintenance Therapy in Subjects With Moderate to Severe Crohn's Disease
3632	Efficacy of a lacto-ovo vegetarian diet in ulcerative colitis: a randomised controlled trial

3633	A 3-Year, Multi-Center, Long-Term Safety (LTS) Study to Evaluate the Safety and Tolerability of TD-1473 in Subjects with Ulcerative Colitis (UC)
3653	Health service use for people with disability living in supported accommodation-an intervention to improve health literacy in disability service organisations
3657	Evaluation of clinical pathways and patient outcomes for breast MRI in preoperative assessment and staging of breast cancer: establishing when MRI improves patient outcomes and when it does not. A multicentre prospective trial (Population B prospective observational study)
3658	ALLG AMLM23/HOVON 150 AML/AML5G 29-18: A phase 3, multicenter, double-blind, randomized, placebo-controlled study of ivosidenib or enasidenib in combination with induction therapy and consolidation therapy followed by maintenance therapy in patients with newly diagnosed acute myeloid leukemia or myelodysplastic syndrome with excess blasts-2, with an IDH1 or IDH2 mutation, respectively, eligible for intensive chemotherapy
3662	A Phase 3 Open-Label, Multicenter Study of the Safety, Efficacy, and Pharmacokinetics of Intravenous Recombinant Coagulation Factor VIII Fc-von Willebrand Factor-XTEN Fusion Protein (rFVIII-Fc-VWF-XTEN BIVV001) in Previously Treated Patients $\geq 12$ Years of Age With Severe Haemophilia A
3663	A Phase IIa, Double-Blind, Randomised, Intracohort Placebo-Controlled, Multicentre Study to Evaluate the Safety, Tolerability and Preliminary Efficacy of EHP-101 in Patients with Diffuse Cutaneous Systemic Sclerosis
3673	Emerging Drugs Network of Australia
3676	Healthcare professionals' perceptions and experiences of readmissions in the Coronary Care Unit
3683	Facilitating best practice dementia care in hospitals: Evaluation of the Dementia Change Champions Project
3692	CARTITUDE-4: A Phase 3 Randomized Study Comparing JNJ-68284528, a Chimeric Antigen Receptor T cell (CAR-T) Therapy Directed Against BCMA, versus Pomalidomide, Bortezomib and Dexamethasone (PvD) or Daratumomab, Pomalidomide and Dexamethasone (DPd) in Subjects with Relapsed and Lenalidomide-Refractory Multiple Myeloma
3696	Eurobact II: a multinational cohort study on the epidemiology and determinants of outcomes of Hospital Acquired Blood Stream Infections in the Intensive Care
3704	Alone we can do so little; together we can do so much - optimising access to pulmonary rehabilitation in Perth
3710	The Noisy Guts Project: A feasibility study for the use of an acoustic belt for differential diagnosis of gastrointestinal diseases and disorders
3711	A Phase 2b, Multicenter, Randomized, Double-Blind, Placebo-Controlled Dose-Ranging Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of PF-06480605 in Adult Participants with Moderate to Severe Ulcerative Colitis
3714	A pilot cross sectional observational study looking at the role of positron emission tomography in the diagnostic evaluation of idiopathic inflammatory myopathies
3715	MK-8591A-017. A Phase 3 Randomized, Active-Controlled, Open-Label Clinical Study to Evaluate a Switch to Doravirine/Islatravir (DOR/ISL) Once-Daily in Participants With HIV-1 Virologically Suppressed on Antiretroviral Therapy
3718	Keynote 991 A Phase 3, Randomized, Double-blind Trial of Pembrolizumab (MK-3475) Plus Enzalutamide Plus ADT Versus Placebo Plus Enzalutamide Plus ADT in Participants With Metastatic Hormone-Sensitive Prostate Cancer (mHSPC)

3719	The BALANCE Study. Bacteremia Antibiotic length Actually needed for Clinical Effectiveness: Randomised Controlled Trial
3724	IRIL: A prospective Phase II study of Isatuximab Rescue for Inadequate response to Lenalidomide and Dexamethasone in transplant ineligible patients with newly diagnosed multiple myeloma
3726	A feasibility study of optical elastography for the differentiation of cancerous and non-cancerous ex vivo human breast tissue
3731	MK-8591A-018. A Phase 3, Randomized, Active-Controlled, Double-Blind Clinical Study to Evaluate a Switch to Doravirine/Islatravir (DOR/ISL) Once-Daily in Participants With HIV-1 Virologically Suppressed on Bictegravir/Emtricitabine/Tenofovir Alafenamide (BIC/FTC/TAF)
3732	Australasian Severe Asthma Registry
3733	Australian Benralizumab Registry
3735	M16-109: A Phase 2 Open-Label Study Evaluating Tolerability and Efficacy of Navitoclax Alone or in Combination with Ruxolitinib in Subjects with Myelofibrosis
3749	Testosterone treatment to reduce disease activity and improve symptoms in men with mild to moderate Crohn's disease
3751	PROTOCOL CAI001: A 2-stage, multicenter, randomized, placebo-controlled study to evaluate safety/ tolerability, pharmacokinetics, and efficacy of UCB7858 in adult kidney transplant recipients with chronic allograft injury. Phase 1/2
3757	Postoperative vasopressor usage: a prospective international observational study (SQUEEZE)
3763	'Being bilingual' – Consequences for cross-cultural bilingual speakers with aphasia
3765	Left Behind: Exploring the concerns of Emergency Department staff when personnel are utilised for Inter-Hospital Transfer
3766	UpFrontPSMA : A Randomised Phase 2 Study of Sequential 177Lu- PSMA617 and Docetaxel versus Docetaxel in Metastatic Hormone-Naive Prostate Cancer
3770	Retrospective chart review of patients who underwent open reduction internal fixation of bilateral mandibular angle fractures over the last 11 years in the East and South Metropolitan Health Services
3775	Decibel – Phase 1b Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Repeated Doses of DB-020 in Patients Receiving Cisplatin
3776	A Randomised Controlled Trial of Early valve replacement in severe ASymptomatic Aortic Stenosis (EASY-AS)
3777	NAPOLI 3: An open-label, randomised, multicentre, phase III study of irinotecan liposome injection, oxaliplatin, 5-fluorouracil/leucovorin versus nab-paclitaxel plus gemcitabine in subjects who have not previously received chemotherapy for metastatic adenocarcinoma of the pancreas
3789	NET SANGUIS; the potential role of circulating DNA in the management of pancreatic neuroendocrine tumours
3790	The Treatment of BBooking Gestational diabetes Mellitus Study: TOBOGM
3795	A two-year, Phase III randomized, double-blind, parallel-group, placebo-controlled trial to evaluate the safety, efficacy, and tolerability of 300mg s.c. secukinumab versus placebo, in combination with SoC therapy, in patients with active lupus nephritis (SELUNE)

## New drug trial offers hope for Crohn's patients

Fiona Stanley Hospital is the first hospital in Australia to recruit a patient for a clinical trial of a new drug to manage Crohn's Disease.

Run by the FSH Inflammatory Bowel Disease (IBD) Research Unit, the VIVID-1 study explores the effects of the drug, Mirikizumab, and its ability to inhibit an inflammatory pathway which causes inflammation in Crohn's Disease known as Interleukin 23.

IBD Research Lead, Doctor Lena Thin, said by inhibiting Interleukin 23 with the new drug, the aim was to improve inflammation and patient disease outcomes.

"It's a very exciting milestone for our dedicated research team as we're the first in Australia to use Mirikizumab in a clinical trial for Crohn's Disease," Dr Thin said.

"In Australia, IBD is becoming more prevalent, more complex, and more severe so by taking part in this ground breaking study we're offering those who live with these debilitating conditions hope."

Crohn's Disease and Ulcerative Colitis, the predominant IBD conditions, are chronic and lifelong diseases that affect approximately 1 in 250 people aged 5–40.

Almost 75,000 Australians have IBD with this number projected to increase to 100,000 by 2022.

Australia has one of the highest rates of prevalence and incidence in the world and each year more people are burdened with a constant and often hidden struggle that affects a sufferer's personal, social and work life.

FSH Clinical Nurse Daniel Lightowler said trial therapies offer these patients a broader range of treatment options.

"It is studies like VIVID-1 that allow health professionals to provide tailored and cutting edge care for IBD patients," he said.

"Our research unit is involved in several of the latest clinical trials, using many novel agents to treat Crohn's Disease and Ulcerative Colitis, receiving referrals from across the state to consider patients who are on last line therapies."

The first patient was recruited in June and the study is expected to run for the next three years.



Left to right: Dr Lena Thin (IBD Research Lead & Consultant Gastroenterologist), Tanya (Day Medical Procedure Unit Registered Nurse), Karen Martin (IBD Research Nurse), Daniel Lightowler (IBD Research Nurse) with clinical trial patient Abel Abraham seated centre.

“ In Australia, IBD is becoming more prevalent, more complex, and more severe so by taking part in this ground breaking study we’re offering those who live with these debilitating conditions hope.”

3796	KEYNOTE-U02A. A Phase 1/2 Open-Label Rolling-Arm Umbrella Platform Design of Investigational Agents With or Without Pembrolizumab or Pembrolizumab Alone in Participants with Melanoma (KEYNOTE-U02): Substudy 02A
3797	KEYNOTE-U02B. A Phase 1/2 Open-Label Rolling-Arm Umbrella Platform Design of Investigational Agents With or Without Pembrolizumab or Pembrolizumab Alone in Participants with Melanoma (KEYNOTE-U02): Substudy 02B
3798	KEYNOTE-U02C. A Phase 1/2 Open-Label Rolling-Arm Umbrella Platform Design of Investigational Agents With or Without Pembrolizumab or Pembrolizumab Alone in Participants with Melanoma (KEYNOTE-U02): Substudy 02C
3805	Evaluation of allied health research capacity and culture across the South Metropolitan Health Service
3807	Determining novel markers of bone marrow failure in myeloproliferative neoplasms
3808	Planning and Preparing a Nurse Led Wellbeing Support Program for Staff working in a Hospital Cancer Centre
3811	Australian & New Zealand College of Anaesthetists (ANZCA) Perioperative Clinical Outcomes Registry (PCORE): Pilot
3812	A Phase 2B, Randomized, double-blind, parallel, placebo-controlled study followed by an open label extension treatment to evaluate the safety and Efficacy of PF-06826647 in participants with MODERATE TO SEVERE ulcerative colitis
3818	A Phase 3, Prospective, Multicenter, Double-blind, Double-dummy, Randomized, Active controlled, Parallel-group, Group-sequential, Adaptive, Event-driven Study to Compare Efficacy, Safety, and Tolerability of Macitentan 75 mg Versus Macitentan 10 mg in Patients with Pulmonary Arterial Hypertension, Followed by an Open-label Treatment Period With Macitentan 75 mg
3833	Domestic and Family Violence Screening and Referral Practices in QLD and WA Emergency Departments
3837	A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of BMS-986165 in Subjects with Moderate-to-Severe Crohn's Disease
3838	The Effect of Tirzepatide versus Dulaglutide on Major Adverse Cardiovascular Events in Patients with Type 2 Diabetes (SURPASS-CVOT)
3848	Safety and Immunogenicity of Early Quadrivalent Influenza Vaccine: A phase 2 prospective randomised open-label feasibility study (FluBub Study)
3850	Beyond NARNIA: Examining the effectiveness of a novel communication intervention for post-stroke aphasia in the clinical setting
3851	Is There a Genetic Predisposition to the Development of ALVAL?
3857	EPIK-B3: A Phase III, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of alpelisib (BYL719) in combination with nab-paclitaxel in patients with advanced triple negative breast cancer with either phosphoinositide-3-kinase catalytic subunit alpha (PIK3CA) mutation or phosphatase and tensin homolog protein (PTEN) loss without PIK3CA mutation
3859	Multicenter, randomized, placebo-controlled, double-blind, parallel group, dose-finding Phase 2 study to evaluate efficacy and safety of BAY 2433334 in patients following an acute non cardioembolic ischemic stroke
3870	A Phase 3 multicenter, open-label study to evaluate the safety of daily oral dosing of tafamidis meglumine (PF-06291826-83) 20 mg or 80 mg [or tafamidis (PF-06291826-00) 61 mg] in subjects diagnosed with transthyretin cardiomyopathy (ATTR-CM)

3876	The relationship between sagittal stability and patient reported outcome measures following total knee arthroplasty (TKA); a blinded comparison between a high congruency and low congruency TKA design (SAGITTAL STABILITY)
3879	Incidence of Gastrointestinal Malignancy in Non-Anaemic Iron Deficiency and Significance for Endoscopic Screening: A Retrospective Cohort Study in Western Australia
3881	DREAMM 7: A Multicenter, Open-Label, Randomized Phase III Study to Evaluate the Efficacy and Safety of the Combination of Belantamab Mafodotin, Bortezomib, and Dexamethasone (B-Vd) Compared with the Combination of Daratumumab, Bortezomib and Dexamethasone (D-Vd) in Participants with Relapsed/ Refractory Multiple Myeloma
3885	A Global, Phase 2, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study of BMS-986177, an Oral Factor XIa Inhibitor, for the Prevention of New Ischemic Stroke or New/Covert Brain Infarction in Patients Receiving Aspirin and Clopidogrel Following Acute Ischemic Stroke or Transient Ischemic Attack (TIA) AXIOMATIC-SSP: Antithrombotic Treatment with Factor XIa Inhibition to Optimize Management of Acute Thromboembolic Events in Secondary Stroke Prevention
3887	Volatile Anaesthesia and Perioperative Outcomes Related to Cancer: The VAPOR-C Study
3906	Predicting the success of vaginal birth after caesarean delivery in a large tertiary West Australian hospital
3915	A Phase 3, Multinational, Multicenter, Double-Blind, Placebo-Controlled Clinical Study to Evaluate the Efficacy and Safety of Aramchol in Subjects with Nonalcoholic Steatohepatitis (NASH)
3930	Improving physical health and quality of life and reducing cognitive decline and the rate of falls for people with mild cognitive impairment: a randomised controlled trial
3944	PREVALENCE: Biomarker Study to Determine Frequency of DNA-Repair Defects in Men with Metastatic Prostate Cancer
3946	A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of BMS-986165 in Subjects with Moderate to Severe Ulcerative Colitis
3971	Assess the validity & reliability of wearable activity trackers within a burns ward environment, where an altered gait may be observed
3972	A Phase 3b, Single Arm, Open-Label Study to Evaluate the Efficacy and Safety of BMN 270, an Adeno-Associated Virus Vector-Mediated Gene Transfer of Human Factor VIII, with Prophylactic Corticosteroids in Hemophilia A Patients
3974	BO41843. A Phase III randomized, double-blind, placebo-controlled, multicenter study evaluating the efficacy and safety of GDC-9545 combined with palbociclib compared with letrozole combined with palbociclib in patients with estrogen receptor-positive, HER2-negative locally advanced or metastatic breast cancer
3976	ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections
3986	BCG vaccination to Reduce the impact of COVID-19 in Australian healthcare workers following Coronavirus Exposure (BRACE) Trial
3988	An Australian Study into the use of Complementary and Alternative Medicine in Inflammatory Bowel Disease patients
4001	ENZA-p. A randomised Phase II trial using PSMA as a therapeutic agent and prognostic indicator in men with metastatic castrate-resistant prostate cancer treated with enzalutamide (ANZUP 1901)
4002	The COVID-19 pandemic: Nurse leaders' experiences of decision-making to prepare a tertiary hospital in Western Australia

4003	West Australian APRV Ventilation Study
4019	HIS BUNDLE PACING REGISTRY: A prospective, observational, multi-center registry
4023	Pharmacokinetic evaluation of Novel Agents in COVID-19 induced exaggerated inflammation (PK-NAVigate)
4025	DISTINCT: Dual Mobility Versus Standard Total Hip Arthroplasty In Femoral Neck Fractures, A Registry-Nested, Cluster-Randomised Trial
4027	COVID-19 in Cancer Patients: A Multi-Centre National study of COVID-19 infection in Cancer patients
4030	Sero-testing At Risk hospital Staff for SARS CoV2 Starter Project (StARS 1 Project)
4031	A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 2 Study of the Efficacy and the Safety and Tolerability of BMS-986278 in Participants with Pulmonary Fibrosis
4037	Skyscraper-03. A Phase III, open-label, randomized study of atezolizumab and tiragolumab compared with durvalumab in patients with locally advanced, unresectable stage iii non-small cell lung cancer who have not progressed after concurrent platinum-based chemoradiation
4040	Life After COVID-19 (LATER-19): a prospective, longitudinal, cohort study of symptoms, physical function and psychological outcomes
4051	Nurse-led smoking cessation service utilising motivational interviewing and nicotine replacement therapy (NRT) versus standard of care counselling in IBD patients
4053	R1979-ONC-1625: An Open-Label Study To Assess The Anti-Tumor Activity and Safety of REGN1979, An Anti-CD20 X Anti-DC3 Bispecific Antibody, In Patients With Relapsed or Refractory B-Cell Non-Hodgkin Lymphoma
4054	Australian Cardiovascular COVID-19 Database (AUS-COVID)
4056	Protocol for a prospective cross-sectional, study using Poisson renewal theory to study phase singularity formation and destruction rates in atrial fibrillation
4058	Australian Neonatal Covid-19 Study
4062	Is serum angiotensin-converting enzyme 2 a risk marker for SARS-CoV2 infectivity or disease severity?
4090	A retrospective review of long-term laryngotracheal complications after inhalation injury: A Western Australia State Burns Unit experience
4099	CATALYST Trial: Clinical trial of atrial fibrillation patients comparing left atrial appendage occlusion therapy to non-vitamin K antagonist oral anticoagulants
4113	COVER-AU Study: COVID-19 Vascular Service Study Australia The impact of COVID-19 pandemic on the provision, practice and outcomes of vascular surgery in Australia
4115	Prevalence of Asymptomatic SARS-Cov-2 Infection in Elective Surgical Patient in Australia
4127	AML M25 ALLG - An ALLG Phase 2 study to Investigate Novel triples to Extend Remission with Venetoclax in Elderly (INTERVENE) Acute Myeloid Leukaemia
4138	Can an online, active learning modality, promote belief changes about Knee OA?
4139	Identifying the barriers to exercise in patients with non-alcoholic fatty liver disease (NAFLD): A short survey study

4140	The Effect of Dietary Resistant Starch on Maternal Glycaemia and Gut Microbiome in Gestational Diabetes
4141	CO42177: A Phase Ib, open-label, multi cohort study of the safety, efficacy, and pharmacokinetics of tiragolumab in combination with atezolizumab and chemotherapy in patients with triple-negative breast cancer
4173	Exercise in patients admitted to hospital with diabetes-related foot ulcers – A pilot study of feasibility and safety
4179	Fistulising Crohn's Disease and Anti-TNF Level Study - FISCAL
4184	Lymphoma in pregnant women: the Australian experience
4200	M15-531: A Phase 1b Dose Escalation Study Evaluating the Safety and Pharmacokinetics of Venetoclax in Combination with Azacitidine in Subjects with Treatment-Naïve Higher-Risk Myelodysplastic Syndromes (MDS)
4203	Low-intensity rTMS in human spinal cord injury: a translational approach
4250	The effects of working in hot ambient operating theatres on staff and the use of cooling/hydration strategies to improve working conditions
4286	A qualitative study with multidisciplinary ICU clinicians to explore barriers and enablers for early mobilisation of patients with burns in the ICU
4296	Intensive Care Unit (ICU) Consumer Research Survey
4305	Development, testing, implementation and evaluation of a graduate mentoring program to optimise the likelihood of midwife retention in Western Australia
4324	"Kaya Nitcha Nicha Karlamurruny Winjar Noonuk Moorditjabinj". (Welcome Here to this Place of Burns where you become Well and Strong)
4336	A Single Centre, Investigated-blinded, Randomized, Parallel-group, Superiority Pilot Study to Compare Traditional Training for Chest Drain Insertion to a Novel Immersive Virtual Reality Training Software Program

## Prehabilitation study to improve outcomes for lung cancer patients

Patients will be recruited for a study to see if an exercise program delivered in the time between diagnosis and medical treatment could improve physical and psychological outcomes for people with non-surgical lung cancer.

The feasibility study into prehabilitation for these patients will be undertaken by Thoracic Cancer Clinical Nurse Consultant Kirsten Mooney, from the WA Cancer and Palliative Care Network with support from the SMHS Innovation Team.

“The time period from when a person first has investigations for lung cancer until the start of treatment can be extremely stressful,” Kirsten said.

“The patient has to go through a number of tests then wait for results before a diagnosis can be confirmed and a treatment plan decided upon. Treatment planning can then take several weeks.

“This provides a window of opportunity to try to optimise the fitness and psychological well-being of these patients through prehabilitation,” said Kirsten.

The five year survival rate for lung cancer is only 16%, and as the majority of lung cancer patients present with advanced disease, treatment usually involves both chemotherapy and radiotherapy.

The disease also has one of the highest symptom burdens including fatigue, depression, loss of appetite and weight loss, but prehabilitation has been shown to improve treatment tolerance and outcomes, and could potentially increase treatment options.



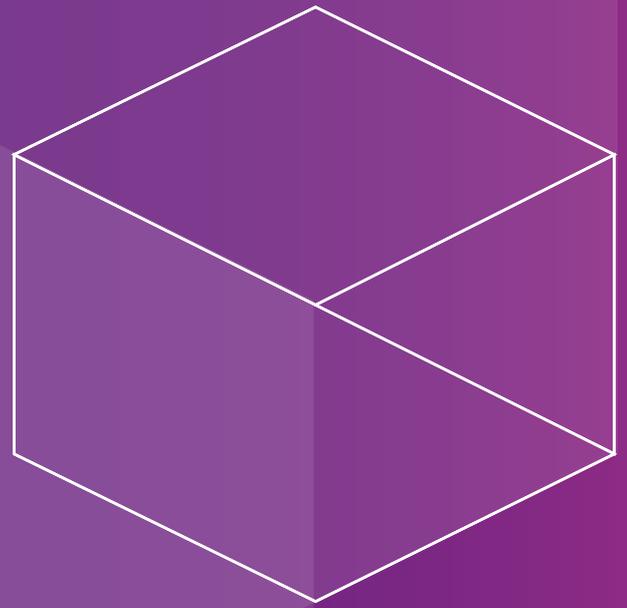
Paul Gittings, Kirsten Mooney and Vinicius Cavalheri

“We know that engaging in exercise and prehabilitation prior to treatment or surgery has been shown to be not only safe, but also beneficial in a number of ways for patients with other types of cancer.”

“The outcomes of this study could provide a great opportunity to demonstrate the benefit of an expanded role of Physiotherapy in the management of patients with lung cancer.”

The SMHS Innovation Team helped Kirsten progress the study by engaging PhD students to assess current resources available, which enabled access to a gym and physiotherapists at FSH.

“This provides a window of opportunity to try to optimise the fitness and psychological well-being of these patients through prehabilitation.”



# Publications

# Publications

## Support for publications

In October 2020, the SMHS Research Advisory Committee approved investment into a capped funding source to assist researchers with their publication costs. This grant funding will launch in early 2021 and be reported on in the 2021 Research Report.

The publications list below was collated following detailed searches by the library team for published works in 2020 and documents **536** published works by SMHS researchers or staff, or researchers who have conducted research at an affiliated SMHS site. This list is not exhaustive as the data is difficult to obtain and if staff have not cited their organisational affiliation they may not appear in the results.

Further information about SMHS publications can be found online:

[Lens.org – SMHS Staff Publications 2017–Jan 2021](#)

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