Government of **Western Australia**
Department of **Health**

Department of Health Western Australia Human Research Ethics Committee

Project Summaries for Approved Proposals

July 2022 to September 2022 Quarter

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Project summaries for proposals approved by the Department of Health Human Research Ethics Committee – July 2022 to September 2022 quarter.

The material contained in this document is made available to assist researchers, institutions and the general public in searching for projects that have ethics approval from the Department of Health Human Research Ethics Committee (DoH HREC). It contains lay descriptions/summaries of projects approved in the July to September 2022 quarter.

Project Title	Vaccine effectiveness of COVID-19 vaccines in Western Australia
Principal Investigator	Paul Effler
Institution	Department of Health
Ethics Approval Date	Wednesday, 13 July 2022

In April 2021, the Western Australia (WA) Department of Health (DOH) established the COVID-19 Vaccine Linked Data Repository (CVLDR) which links an individual's COVID-19 vaccination data in the Australian Immunisation Register (AIR) to WA emergency department, hospitalisation and COVID-19 testing datasets in order to enable rigorous, timely assessments of vaccine effectiveness (VE) and safety.

In mid-February 2022 WA began experiencing widespread community transmission of the SARS-CoV-2 Omicron variant in a highly vaccinated population. WA is now in a unique position globally to assess how effective COVID-19 vaccinations are against Omicron in a largely COVID-19 infection naïve population.

We propose to use data already extant in the CVLDR to assess VE using a test negative, case-control study design. Polymerase chain reaction (PCR) positive cases and match negative controls will be compared to each other in regards to vaccination status. Vaccine effectiveness against hospitalisation, ICU admissions and death will also be assessed if case numbers permit. Sub-analysis will look at vaccine brand and dosing schedules.

The covariates of age, sex, region, Aboriginal status, PCR test week, previous hospitalisation (proxy for morbidity status) and the number of previous PCR tests (proxy for high risk exposure occupations), will be assessed for potential confounding and included in matching or regression analysis as appropriate.

The CVLDR will be used to obtain this information required. No additional data collection will be required as these datasets are already existing for other purposes.

Findings from assessment will include how effective each of the COVID-19 vaccines are against infection and serious outcomes, the effects of waning immunity, and if different dosing schedules impact the outcomes of interest.

Project Title	Determining the speed of registration of COVID_19 clinical trials compared to non-COVID_19 clinical trials
Principal Investigator	Bruce Neal
Institution	The George Institute for Global Health
Ethics Approval Date	Tuesday, 26 July 2022

This project aims to measure the impact of ethics committee process modifications introduced because of the COVID_19 emergency on the speed of project approvals in research facilities throughout Australia.

Project Title	Ovarian cancer: investigating variation in care and survival, aetiology and risk factors to improve outcomes in Australia via national data linkage. The OVARIAN Study.
Principal Investigator	Penelope Webb
Institution	QIMR Berghofer Medical Research Institute
Ethics Approval Date	Wednesday, 10 August 2022

There are many unanswered questions about ovarian cancer that can only be answered with information from large, representative groups of women with this disease. These questions span aetiology, diagnosis, treatment and survival. For example, do modern hormonal contraceptives confer the same protection as older types? Do reproductive hormones also affect risk of non-epithelial ovarian cancers? Does pelvic infection increase a woman's risk of developing ovarian cancer? What medical encounters occur prior to ovarian cancer diagnosis? Do these offer opportunities for earlier diagnosis? How are menopausal hormones used after diagnosis of ovarian cancer and does this affect recurrence or survival? Are apparent survival differences between the states real and, if so, can they be explained by differences in treatment? Have management patterns changed over time? Do they vary by patient age, geography or affluence? Are they different for women from a non-English-speaking background or for Aboriginal and Torres Strait Islander women? If so, are the variations associated with differences in survival and/or cost of care? What are the real costs of healthcare for women with ovarian cancer?

We will answer these and other important questions by creating a comprehensive national dataset linking existing routine data collections. We will work with the Population Health Research Network, Australian Institute of Health and Welfare and state/territory Data Linkage Units to identify three cohorts comprising (A) all individuals diagnosed with ovarian cancer since 1995 (1984 in WA) identified via the State and Territory Hospital Cancer Registries, (B) individuals diagnosed with a borderline ovarian tumour (BOT) identified via hospital records and the Western Australia Cancer Registry and (C) a matched group of ovarian cancer-free controls. We will then link all three cohorts to health datasets held at AIHW: Medicare (PBS, MBS), the Australian Cancer Database (ACD, to identify prior and subsequent cancers), the National Death Index (NDI), Admitted Patient Care (APC) and Non-admitted Patient Emergency Department Care (EDC). We will additionally link Cohorts A and B to other relevant health datasets held at the state/territory level including hospital (admitted and, where available, non-admitted patient data), emergency and hospital cost data, perinatal/birth records, Notifiable Disease Registers (to look at pelvic inflammatory diseases) and BreastScreen (where available). Where feasible, linkage will be updated biennially to ensure data are up to date. The resulting resource will allow us to answer a wide range of questions in a very cost-effective way to increase knowledge about risk factors, diagnosis, variations in care and survival in order to reduce the burden of ovarian cancer in Australia.

Project Title	Nutrition Monitoring Survey Series (Nutrition Monitoring Survey 2022)
Principal Investigator	Lauren Humphreys
Institution	Department of Health
Ethics Approval Date	Wednesday, 10 August 2022

The Nutrition Monitoring Survey Series (NMSS) is a series of surveys which have been administered by the Department of Health every three to five years in Western Australia since 1995. It is currently the longest running state-based nutrition survey in Australia.

The NMSS aims to monitor knowledge, attitudes, behaviours and intentions of Western Australian adults as they relate to nutrition; measure attempts at dietary change, and barriers and promoters to making behaviour changes consistent with dietary recommendations; and knowledge, perceptions and attitudes towards government public health nutrition activities.

Data collected through the NMSS are used to inform the development and delivery of tailored public health nutrition interventions. The data are also used for developing evidence-based policy responses to poor nutrition, including guiding the strategic directions for agencies implementing these policy responses.

The next iteration of the NMSS (NMS 2022) will use a stratified random sample of adults aged 18 to 64 years drawn from a sample of participants from past Health and Wellbeing Surveillance System (HWSS) surveys who have consented to being contacted again and invited to participate in other research projects conducted by the Department of Health (from here on, referred to as the 'HWSS recall sample').

All persons from the selected sample will be sent an invitation letter which contains an option to complete a survey online via QR code or weblink, or by Computer-assisted Telephone Interview (CATI). Data will be collected by the Survey Research Centre at Edith Cowan University, the contracted entity for survey data collection. De-identified data will be analysed by the WA Department of Health. Summary reports will be published for the general public via the Department of Health consumer website and scientific audiences in peer-reviewed journals.

Project Title	The Busselton Family Heart Study: Investigations into the relationship between lipid metabolism and health outcomes.
Principal Investigator	Peter Meikle
Institution	Baker Heart and Diabetes Institute
Ethics Approval Date	Monday, 8 August 2022

The aim of this project is to identify serum lipid species that are associated with cardiometabolic disease, cancer, neurodegenerative disease and their risk factors in the Busselton Health Study. We will further link these lipid species through to genetic data, blood measures, and questionnaire data. This project will utilise service data collected as part of the Busselton Health Study as well as cardiovascular, diabetes and neurodegenerative disease mortality and hospital morbidity data collected from the Department of Health Western Australia.

Project Title	Review of prescribing practices, authorisations for and harms due to Schedule 8 Opioids in Western Australia
Principal Investigator	Katharine Noonan
Institution	Department of Health
Ethics Approval Date	Wednesday, 10 August 2022

WA Department of Health recently implemented a new online regulator portal (ERRCD), a platform for authorisation and notification of Schedule 8 medications. The Medicines and Poisons Regulatory Branch (MPRB) is also implementing a Real Time Prescribing Monitoring (RTPM) platform which will provide clinicians with a greater level of oversight of the S8 medications prescribed to their patients, including by other doctors. Concurrently, MPRB is reviewing the Medicines and Poisons Regulations 2016 and the S8 Medicines Prescribing Code.

This project aims to:

- Identify the current prescribing and dispensing patterns of opioids in WA;
- Describe the burden of opioid-related harm in WA; and
- Produce a discussion document to inform consultation on changes to the S8 Prescribing Code pertaining to opioid medicines.

Project Title	Improving diet quality of patients living with obesity: A randomised controlled trial to build effective dietetic service delivery using technology in a primary health care setting
Principal Investigator	Deborah Kerr
Institution	Curtin University
Ethics Approval Date	Tuesday, 30 August 2022

This application is for an innovative primary health care implementation research study to address a gap in weight management care for the delivery of dietetic services to improve patient outcomes for people living with obesity using cutting edge new technology we have developed and validated. Almost a third of Australian adults are living with obesity, yet most cannot access specialist dietetic weight management services. Whilst General Practitioners (GPs) are ideally placed to intervene with their patients living with obesity, they have limited time and few dietetic referral options. By directly addressing these barriers to care this application seeks to improve the referral pathway by: 1) improving community access to high quality dietetic care by more effectively utilising the dietetics workforce; and; 2) resourcing dietitians with an image-based dietary assessment methods and tailored feedback system; thereby improving the effectiveness of dietetics weight management services. Dietitians are the experts in providing evidence informed weight management but are under-resourced and rely on outdated dietary assessment methods. This limits the depth and scope of individual dietary feedback and monitoring; key components of effective weight management. To address this resource gap, this project will develop and trial a digital platform for dietary assessment and feedback to ensure timely, evidence-based high quality dietetic care. The randomised controlled trial will compare a 1-year digital tailored feedback dietary intervention with control (standard care). If successful, this model of care will build capacity for GPs and dietitians to deliver effective evidence-based weight management advice using new technologies, increasing reach and improving patient outcomes.

Project Title	ICBP-COVID19: Assessing the COVID-19 impact on cancer in the International Cancer Benchmarking Partnership
Principal Investigator	David Ransom
Institution	Fiona Stanley Hospital
Ethics Approval Date	Wednesday, 14 September 2022

The main aim of this project is assess the impact of the COVID 19 pandemic on cancer services for jurisdictions and nations of the International Cancer Benchmarking Partnership through the development of a surveillance framework. The project will evaluate the potential impact of the COVID-19 pandemic on access to, and availability of, cancer diagnostic services using the most up-to-date population level data. In addition, this study will provide important insights on indirect impact of COVID-19 on cancer service, burden and best practice, drawing on the wealth of variation in the organization and provision of health care, which vary more across countries than within countries.

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