

WAIVER OF CONSENT
Peninsula Health Human Research Ethics Committee

Waiver of the Requirement for Consent in Accordance with Sections 2.3.5 - 2.3.8 of the NHMRC National Statement on Ethical Conduct in Human Research 2007

Reporting Period: 1 January 2010 to 30 June 2019

In accordance with the requirements of the NHMRC *National Statement on Ethical Conduct in Human Research 2007* (*National Statement*), sections 2.3.6 - 2.3.8, the Institution's Human Research Ethics Committee (HREC) waived the requirement for consent for research involving the collection, use and/or disclosure of personal information in medical research or personal health information for the research projects listed below.

In reaching the decision to waive the requirement for consent, the HREC considered and applied sections 2.3.6 and 2.3.7 of the National Statement and one or more of the

- a. Statutory Guidelines on Research issued under section 22 of the Health Records Act 2001 (Vic)

<http://www.health.vic.gov.au/hsc/downloads/guideres.doc>;

- b. Guidelines approved under section 95A of the Privacy Act 1988 (Cth)

<http://www.nhmrc.gov.au/publications/synopses/e43syn.htm>; or

- c. Guidelines approved under section 95 of the Privacy Act 1988 (Cth)

<http://www.nhmrc.gov.au/publications/synopses/e26syn.htm>, as applicable.

Project Title

2002-30

Phase III adjuvant trial in pancreatic cancer comparing (1) 5FU and D-L Folinic Acid vs (2) Gemcitabine vs (3) No additional treatment in patients with resected pancreatic ductal adenocarcinoma. (ESPAC-3)

Brief Plain English Summary (maximum 250 words)

The aim of the ESPAC-3 (v2) trial was to compare 5FU/FA vs GEM to identify if either adjuvant chemotherapy was associated with a significantly better survival.

An extension to this trial (ESPAC-T) seeks to collect tissue samples from all patients in ESPAC-3 to identify markers in the primary tumour which predict improved probability of survival with either adjuvant 5-FU or gemcitabine following resection for pancreatic ductal adenocarcinoma.

Project Title

HERC/10/PH/54

Ovarian Cancer Patterns of Care Survey

Brief Plain English Summary (maximum 250 words)

The aim of this project is to:

- describe management patterns for women diagnosed with ovarian/tube/peritoneal cancer in Australia in 2005 and to evaluate variability in management across population sub-groups.

Project Title

HREC/10/PH/26

PROLONGED Outcome Study – RENAL (POST-RENAL)

Brief Plain English Summary (maximum 250 words)

The POST RENAL Study measures long-term outcomes of patients who survive an episode of Acute Kidney Injury and were previously enrolled in the RENAL Study. It seeks to follow-up all patients who were alive at 90 days following enrollment in the RENAL Study.

Project Title

HREC/10/PH/41

Australian and New Zealand Sedation Practices in Intensive Care – ANZ SPICE

Brief Plain English Summary (maximum 250 words)

The aim of this study is to prospectively observe and describe the administration of sedatives and analgesic drugs, the level of sedation achieved, the adequacy of pain relief and the development of delirium during the intensive care stay up to 28 days.

Project Title

QA/11/PH/62

Investigating Malnutrition in Victorian Cancer Services

Brief Plain English Summary (maximum 250 words)

The aim of this project is to determine the prevalence of malnutrition in cancer patients. Results indicate that malnutrition has a significant relationship with outcomes, including 30-day mortality, complications, unplanned admissions and length of hospitalisation.

Project Title

HREC/12/PH/12

Snapshot ACS

Brief Plain English Summary (maximum 250 words)

The aim of this registry is to evaluate the contemporary patterns of care for patients who are admitted to hospital with Acute Coronary Syndrome (ACS) in Australia and New Zealand. The data will inform future strategies to improve ACS care within Australia and New Zealand.

Project Title

HREC/13/PH/11

Hip and knee osteoarthritis in younger people: Wellbeing, work limitations and preferences for self-management and education.

Brief Plain English Summary (maximum 250 words)

This project aims to understand wellbeing, quality of life and ability to work among people aged 20-55 years who have osteoarthritis. It will also investigate the use of arthritis education programs by younger people and explore how younger people with osteoarthritis prefer to receive arthritis education and support.

Brief Plain English Summary (maximum 250 words)

Project Title

HREC/13/PH/1

Immunohistochemical analysis of lymphatic drainage in primary cutaneous squamous cell carcinoma of the head and neck.

Brief Plain English Summary (maximum 250 words)

The aim of this project is to identify the cutaneous lymphatic patterns and density in head and neck SCC of different histological grading and to identify the pattern of local lymphatic growth which will subsequently determine the risk of metastasis. Researchers aim to develop a new classification system which is more relevant with better specificity and sensitivity in determining prognosis and treatment options.

Project Title

LRR/13/PH/30

A prospective evaluation of the impact of the nurse practitioner role on the emergency department service and outcomes.

Brief Plain English Summary (maximum 250 words)

The aim of this research is to evaluate the impact of the Nurse Practitioner role on service indicators and the quality and safety of patient care in Emergency Departments. The study is in two parts. Part A is a national survey of Emergency Departments; Part B is a cohort study of a sample of these Emergency Departments with and without Nurse Practitioners in the team.

Project Title

HREC/12/PH/94

Myeloma and Related Diseases Registry

Brief Plain English Summary (maximum 250 words)

The Myeloma and Related Diseases Registry (MRDR) was established in 2012 at Monash University in Melbourne, Victoria. The MRDR is a bi-national (Australia and New Zealand) register of patients diagnosed with myeloma, plasmacytoma, plasma cell leukaemia and monoclonal gammopathy of undetermined significance (MGUS).

The MRDR collects data on patterns of treatment and variation in patient outcomes (both survival and quality of life). It will help clinicians and hospitals to provide the best possible care to people with these conditions and allow evaluation of the translation of advances in therapy (such as the introduction of new targeted therapies) into long-term outcomes, outside the setting of clinical trials.

Project Title

HREC/14/PH/1

Teens Empowered to Actively Manage Type 1 Diabetes (TEAM T1) Evaluation Study

Brief Plain English Summary (maximum 250 words)

The aim of this research is to will assess the impact of the TEAM T1 program on a range of psychological, behavioural and clinical outcomes of teenagers with Type 1 diabetes. Qualitative methods are also used to explore the perceived experiences of adolescents who have attended the TEAM T1 program, and barriers to implementing changes after the program.

Project Title

HREC/14/PH/27

The Chronic Health Failure Tele-Health Study

Brief Plain English Summary (maximum 250 words)

The aim of this research is to demonstrate that the tele-health monitoring of weight improves the compliance rate of patients with chronic heart failure to self-monitor their daily weight as well as potentially improve their quality of life, management of risk factors and medication and consequently reduce their readmissions to hospital.

Project Title

HREC/49484/PH-2019

Stop for the op, stop for life: Reducing cardiovascular risk through smoking cessation before elective surgery: a randomised controlled trial of mailed nicotine replacement therapy (NRT), behavioural support and relapse prevention.

Brief Plain English Summary (maximum

This extension study aims to evaluate the quit-outcomes and safety of a systematic offer of evidence-based quit support to adult smokers having future surgery at a Victorian public health service. The research will require a waiver of consent limited only to the time-point of inviting participants to be part in the program (i.e. when their name is added to the elective surgery wait-list).