

## **2019 Annual report on waivers of consent granted by the SAC HREC**

According to the National Statement on Ethical Conduct in Human Research (2007, updated 2018) paragraph 2.3.12, SALHN is responsible for making summary descriptions of all research projects for which consent has been waived under paragraphs 2.3.10 and 2.3.11 available annually.

The SAC HREC grants waivers of consent based on the following criteria outlined in paragraph 2.3.10 of the National Statement

- a) Involvement in the research carries no more than low risk.
- b) The benefits from the research justify any risks of harm associated with not seeking consent.
- c) It is impracticable to obtain consent.
- d) There is no known or likely reason for thinking that participants would not have consented had they been asked.
- e) There is sufficient protection of participants' privacy.
- f) There is an adequate plan to protect the confidentiality of data.
- g) In case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them.
- h) The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled.
- i) The waiver is not prohibited by state, federal, or international law.

The following studies were granted a waiver of consent by the SAC HREC in 2019:

**Office for Research**

Flinders Medical Centre  
 Ward 6C, Room 6A219  
 Flinders Drive, Bedford Park SA 5042  
 Tel: (08) 8204 6453  
 E: Health.SALHNOfficeforResearch@sa.gov.au



**Health**  
 Southern Adelaide  
 Local Health Network

OFR reference	Study Title	Principal Investigator
3.19	Validation of the Hospital Frailty Risk Score in predicting clinical outcomes in older hospitalised patients in Australian Health Care settings	Dr Yogesh Sharma
<p><u>Summary description</u></p> <p>The SAC HREC granted a waiver of consent for the investigators to access the medical records of potential participants to determine whether they are eligible to participate in this study.</p>		
305.08	Identification of novel glaucoma genes through the Australian and New Zealand Registry of Advanced Glaucoma.	Professor Jamie Craig
<p><u>Summary description</u></p> <p>The SAC HREC granted a waiver of consent for de-identified DNA samples and clinical data to be sent to Regeneron for the purpose of exome sequencing.</p>		
54.18	Safety of an Ultra Low Gluten (ULG) Barley in Coeliac Disease	Dr Sze Pheh Yeap
<p><u>Summary description</u></p> <p>The SAC HREC granted a waiver of consent for the investigators to access the medical records of potential participants to determine whether they are eligible to participate in this study.</p>		
1.19	Prognostic impact of histological lymph node volume in oesophageal adenocarcinoma; an observational study	Dr Robyn Zeelie
<p><u>Summary description</u></p> <p>The SAC HREC granted a waiver of consent for the investigators to use the participant's data for the purpose of the study. There was no intervention in the participant's routine medical care.</p>		
52.19	The utility of health data and predictive analytics in developing prognostic cardiac event and mortality models for patients presenting to the emergency department	Professor Derek Chew
<p><u>Summary description</u></p> <p>The SAC HREC granted a waiver of consent for the investigators to use the participant's data for the purpose of the study. There was no intervention in the participant's routine medical care.</p>		
307.14	SA-PCCOC: the South Australian Prostate Cancer Clinical Outcomes Collaborative	Dr Michael O'Callaghan

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	Database	
<u>Summary description</u>		
The SAC HREC granted a waiver of consent for the investigators to access the medical records of potential participants to determine whether they are eligible to participate in this study.		
301.17	Characterization of glucose control and stress hyperglycaemia during cardiac surgery.	Mr Greg Roberts
<u>Summary description</u>		
The SAC HREC granted a waiver of consent for the investigators to access the medical records of potential participants to determine whether they are eligible to participate in this study.		
490.11	The PROGRESSA Study- Predicting Risk Of Glaucoma: Relevant SNPs with Strong Association	Professor Jamie Craig
<u>Summary description</u>		
The SAC HREC granted a waiver of consent for de-identified DNA samples and clinical data to be sent to Regeneron for the purpose of exome sequencing.		
86.067	Genetic Risk Factors in Complications of Diabetes	Professor Jamie Craig
<u>Summary description</u>		
The SAC HREC granted a waiver of consent for de-identified DNA samples and clinical data to be sent to Regeneron for the purpose of exome sequencing.		
281.18	Hepatitis B vaccination outcomes in a remote Indigenous population of South Australia	Associate Professor Alan Wigg
<u>Summary description</u>		
The SAC HREC granted a waiver of consent for the investigators to use the participant's data for the purpose of the study. There was no intervention to the participant.		
166.19	A Phase 1b randomised, double-blind, placebo-controlled study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and clinical activity of EQ001 in subjects with moderate-to-severe uncontrolled asthma (EQUILLIUM)	Dr Huw Davies
<u>Summary description</u>		

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The SAC HREC granted a waiver of consent for the investigators to access the medical records of potential participants to determine whether they are eligible to participate in this study.

443.16	Assessing quality of life and attitudes toward health self-management in people who have had a recent investigation of the bowel	Dr Erin Symonds
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### Summary description

The SAC HREC granted a waiver of consent for the investigators to access the medical records of potential participants to determine whether they are eligible to participate in this study.

258.14	Are vascular surgery patients a nutritionally vulnerable group and is there a cost effective nutritional screening tool to assist in identifying the nutritionally vulnerable?	Professor Michelle Miller
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### Summary description

The SAC HREC granted a waiver of consent for the investigators to access CT scan images of participants. Participants had already decided to participate in this study and this required no additional intervention as the CT scans had already be done as part of routine care.