

Ethics approval and SSA Authorisation of HREC/88598/Austin-2022 dated 29.09.2022

Austin Health Research Office <Research@austin.org.au>

Thu 29/09/2022 13:47

To: HALL, Kat <Kat.HALL@austin.org.au>

Cc: David Liu <liu.davidsh@gmail.com>;BIGARAN, Ashley <Ashley.BIGARAN@austin.org.au>

Office for Research		Austin HEALTH
THIS EMAIL CONSTITUTES HUMAN RESEARCH ETHICS PROJECT APPROVAL AND AUSTIN HEALTH SITE SPECIFIC AUTHORISATION (if Austin Health is listed as a site)		
To Coordinating PI	Mr David Liu and Ms Ashley Bigaran	
Austin Site PI	Mr David Liu and Ms Ashley Bigaran	
From	Austin Health Human Research Ethics Committee	
Project HREC Number	HREC/88598/Austin-2022	
Austin Health SSA Reference Number (if applicable)	N/A	
Protocol Number / Short Title (if applicable)	1 / SOCS	
Project Title	Strong for Oesophago-gastric Cancer Surgery (SOCS) - A personalised multidisciplinary enhanced prehabilitation program for patients undergoing oesophagectomy and gastrectomy: A single centre retrospective and prospective cohort study	
LEX ID (for agreements)	N/A	
Sites	<ul style="list-style-type: none"> • Austin Health, VIC 	
Submission Type	<ul style="list-style-type: none"> • Approval of New Project <ul style="list-style-type: none"> ○ HREA – 334377(v2) 	
Approval Date	29.09.2022	
Approved Documents	<ul style="list-style-type: none"> • VSM • Study Protocol - SOCS_V1.1 Clean • SOCS_PICF_SOCS_v1.2_Clean • SOCS Posters Version 1.3 	

Austin Site Specific Authorised Documents	N/A	<ul style="list-style-type: none"> • SOCS Questionnaires v3.0
Acknowledged Document		<ul style="list-style-type: none"> • MPR exemption letter • Funding Project Budget_SOCS Version 2.0

Thank you for submitting the above for Human Research Ethics Approval and Austin Health Site Specific Assessment Authorisation (if Austin Health is listed as a site). This submission has been reviewed and approved by the Austin Health Human Research Ethics Committee (HREC), subject to the following conditions being met.

You are required to submit to the HREC:

- An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report, due within one month of the approval anniversary. Failure to comply with this requirement may result in suspension of the project by the HREC.
- A Final Report upon completion of the project.
- Submit to the reviewing HREC for approval of any proposed amendments to the project including any changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: Safety monitoring and reporting in clinical trials involving therapeutic goods November 2016.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters, which may affect the conduct of the project.
- If your project involves radiation, you are legally obliged to conduct your research in accordance with the Australian Radiation Protection and Nuclear Safety Agency Code of Practice 'Exposure of Humans to Ionizing Radiation for Research Purposes' Radiation Protection series Publication No.8 (May 2005) (ARPANSA Code).

The HREC may conduct an audit of the project at any time.

If you have any questions or concerns, please contact the Office for Research on:

- research@austin.org.au
- +61 3 9496 4090

Kind Regards,

Mark

Yuhui (Mark) Li

Ethics, Integrity and Governance Operations Team Leader

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