Office for Research

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Government of South Australia | Health Southern Adelaide Local Health Network

Final Authorisation for Governance

A/Professor Morton Burt
Endocrinology
Southern Adelaide Local Health Network

Email Contact: Morton.burt@sa.gov.au
Faran.khalili@sa.gov.au

Dear A/Professor Burt

OFR Number:	55.21
HREC reference number:	2021/HRE00191
SSA reference number:	2021/SSA00356
Project title:	Optimum diagnostic testing for prednisolone-induced hyperglycaemia
Principal Investigator:	Morton Burt
Associate Investigators	Faran Khalili Michael Shanahan Kellie Fusco Richard Woodman Sophie Drake
Governance Authorisation Date:	16/08/2021

On the basis of the information provided in your Site Specific Assessment submission, I am pleased to inform you the SALHN Chief Executive Officer or delegate has granted authorisation for this study to commence at **Flinders Medical Centre, Noarlunga Health Service and Marion GP Plus, SALHN.**

Please ensure this study meets current SA Health COVID-19 regulations before recruitment commences.

Please note that only those investigators listed above are authorised for this study based on the nature of duties performed; types of clients/patients; and the ability to access certain work locations[#].

The below documents have been reviewed and approved **subject to the terms and conditions** set out on the reverse of this page:

Document	Version	Date
Site Specific Assessment Form	2021/SSA00356	26/07/2021
SAC HREC Approval Letter**	2021/HRE00191	26/07/2021
Clinical Study Protocol	1	2021
FMC Participant Information Sheet/Consent form	2	14/05/2021

Should you have any queries about this authorisation, please contact the Office for Research on 8204 6453 or via email: Health.SALHNOfficeforResearch@sa.gov.au quoting the OFR reference number.

Yours sincerely

Simon Windsor
Manager, Research Governance & Ethics

Date 16/08/2021

TERMS AND CONDITIONS OF ETHICS AND GOVERNANCE APPROVAL

The Principal Investigator must ensure this research complies with the National Statement on Ethical Conduct in Human Research (2018) & the Australian Code for the Responsible Conduct of Research (2007 updated 2018) by immediately reporting to the Office for Research (OFR) anything that may change the ethics or scientific integrity of the project. Final approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. Confidentiality of research participants MUST be maintained at all times.
2. If the research involves the recruitment of participants, a signed copy of the 'Consent Form' must be given to the participant. Any changes to the Participant Information Sheet/Consent Form must be approved by the lead HREC prior to being used.
3. No promotion of a study can commence until final ethics and SALHN executive approval has been obtained. All advertisements/flyers need to be approved by the committee and media contact should be coordinated through the FMC media unit.
4. Non-SA Health researchers viewing confidential SALHN data are required to complete and sign a SALHN Confidentiality Disclosure Deed
5. All approved requests for access to medical records at any SALHN site must be accompanied by this approval letter.
6. If your study involves a tertiary institution, contact the University to ensure compliance with University requirements prior to commencement of this study. This includes any insurance and indemnification.
7. The PI must adhere to Monitoring and Reporting requirements for both ethics and governance which are available on the SALHN Research Website.
8. The PI must immediately report to SAC HREC anything that may change the ethics or scientific integrity of the project
9. An annual report must be submitted to the SAC HREC and SALHN governance on each anniversary of the date of final approval. Please visit the Office for Research website for the current template.
10. Non-SA Health researchers coming onsite at SALHN must provide evidence of a recent (<3 years) screening check. It is the responsibility of the Principal Investigator to ensure any non-SA Health personnel who conducts or monitors research meets SA Health screening requirements as per the SA Health Criminal & Relevant History Screening Policy Directive before they access any SA Health site. The cost of any such screening is the responsibility of the individual accessing the site or their employer.
11. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
12. Once the research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable). Please refer to the relevant committee link on the SALHN intranet for further information.
13. SALHN site-monitoring of authorised studies - this approval/authorisation is subject to participation in this monitoring process. You will be notified in advance if your site has been selected for an inspection.

Please visit the SALHN Research website regularly and comply with all submission requirements as they may change from time to time.

****HREC reviewed documents listed on the approval letter are accepted as part of the site authorisation.**