7 May 2019

Principal Researcher (as per the AHREC application form):	Prof. Gary Wittert
Organisation:	South Australian Health and Medical Research Institute (SAHMRI)
Via email to corresponding researchers:	Carolyn.Astley@sahmri.com

RE: Initiation of a novel in-hospital treatment for patients with Type 2 diabetes (REMIT-2D, stage 2)

AHREC Protocol #: 04-19-822

Dear Gary,

Thank you for your submission and requesting ethical review from the Aboriginal Health Research Ethics Committee (AHREC).

I am pleased to advise that the study was reviewed and granted final ethical approval by AHREC at its meeting held on 2/5/2019. We wish you well with the study and look forward to receiving your progress reports. Please be advised that, in accordance with the National Statement, AHREC requires researchers to submit reports for monitoring purposes on an annual basis. Regardless of the approval date, AHREC implements a streamlined annual reporting deadline for all studies and requires researchers to submit their annual reports every November. The first annual report or the final report of the study is due by 30 November 2019. Please plan for any subsequent reporting deadlines accordingly and be advised of the standard conditions of approval below.

If you require further information, please do not hesitate to contact the Executive Officer, Dr Gokhan Ayturk, from 08 8273 7200 or email Gokhan.Ayturk@ahcsa.org.au .

Sincerely yours,

On behalf of AHREC's Leadership,

Dr Gokhan Ayturk

Executive Officer, AHREC

Standard Conditions

1) The approvals are granted based on the documentation and scope outlined by the researcher at the time of the review. AHREC must be notified of, and, approve, any changes to the study including minor or major changes to the study parameters, personnel updates and extension requests.
2) Where applicable, the onus of following the appropriate procedure for obtaining informed consent and protecting the well-being of a participant lies solely with researcher(s).
3) AHREC approvals are valid for three years from the date of the approval letter unless up to a maximum of 5 year approval timeframe is specifically requested, for example, in case of longitudinal studies and research projects conducted under Centres of Research Excellence. AHREC does not grant approvals on an indefinite basis and requires the submission of an extension request before its approval expires.
4) Studies aiming to involve an Aboriginal organisation, e.g. an Aboriginal Community Controlled Health Service, should adapt a partnership approach and go through a meaningful engagement process evidenced by an in-principle support letter or appropriate agreement.
    a. This letter or agreement should clearly articulate the time, expertise and resources required to support the study.
    b. Study timeframes and tools should be implemented with respect to the characteristics of each context engaged without an adverse impact on the quality of care and capacity of service.
    c. The Committee recognises that this process may not always be possible to finalise ahead of the ethical review process and advises that its approval is conditional upon the consultation process occurring to the satisfaction of the Aboriginal organisations and people whose support is sought to achieve study goals.
5) Where studies are granted approvals on the basis of the need to source ongoing advice from an established Aboriginal governance structure (e.g. Aboriginal advisory group, steering committee) or, where researchers indicated that it will be established, studies should be implemented as such. Should the ongoing monitoring of a study find that the original approval parameters were not adhered to by researchers, AHREC may further deliberate on the continued ethical acceptability of the study.
6) All adverse events to participants or local organisations and communities must be reported to AHREC immediately. These may include any serious or unexpected effect, unforeseen events and information that may invalidate the ethical integrity of the study.
7) Where possible, research participants should be supported for their time attending research activities. If the researchers will provide gift cards to incentivise participation, these should be gift cards that cannot be utilised for the purchase of alcohol or tobacco.
8) Research participants should be offered support for transportation to the location where research activities will take place and/or reimbursed for costs incurred e.g. parking, travel costs. This support should ideally be provided to participants up-front.
9) AHREC requires researchers to submit their annual reports every ***November,*** by the end of the month, throughout the approval timeframe. Final reports can be submitted at any time. Please find the reporting template at: http://ahcsa.org.au/research-overview/ethical-review-ahrec/
10) As part of AHREC's monitoring function and in accordance with the NHMRC Guidelines, where the Committee identifies that a study is high risk due to its interest in issues that are highly sensitive to Aboriginal communities or has become high risk due to its overall code of conduct; it requires researchers to submit their manuscripts for review and approval before publication. The researchers are notified of this advice specifically during the approval timeframe.