

Our Reference: 51347\_Approved

7<sup>th</sup> May 2019

Dr Sachin Nayyar  
Department of Cardiology  
The Townsville Hospital

[Sachin.Nayyar@health.qld.gov.au](mailto:Sachin.Nayyar@health.qld.gov.au)

Dear Dr Nayyar,

**HREC Reference number: HREC/2019/QTHS/51347**

**Project title:** Tissue microarchitecture-information based ventricular tachycardia ablation

Thank you for submitting a response to the Townsville Hospital and Health Service Human Research Ethics Committee (HREC) on 23/04/2019.

The Townsville Hospital and Health Service HREC is constituted according to the National Health and Medical Research Council's '*National Statement on Ethical Conduct in Human Research*' (NHMRC, 2007, updated 2018). The Townsville Hospital and Health Service HREC operates in accordance with the '*Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders*' (NHMRC, 2018); and the '*National Statement on Ethical Conduct in Human Research*' (NHMRC, 2007, updated 2018). Attached is the HREC composition with membership category and affiliation with the Hospital (Attachment I).

The HREC has granted conditional approval of this research project. The HREC requires the investigators undertake an interim analysis when 50% of the sample size is reached, providing the interim results to the HREC for consideration prior to further recruitment.

The research proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007, updated 2018).

<b>Documents reviewed and approved:</b>	<b>Version</b>	<b>Date</b>
Response		13.04.19
Participant Information Sheet and Consent Form	1.1	13.04.19
Study Protocol	1.1	13.04.19
<b>Documents noted:</b>	<b>Version</b>	<b>Date</b>
Human Research Ethics Application Form ( <i>Apr Ver 2</i> )		20.04.19
Curriculum Vitae – S.Nayyar		
Curriculum Vitae – K.Nanthakumar		
Curriculum Vitae – K.Roberts-Thomson		

The research project has ethical approval for the following sites:  
Townsville Hospital and Health Service  
Royal Adelaide Hospital

Please note the following key dates for this study:

**HREC approval expiry: 01/05/2024**  
**Annual report due: 01/05/2020**

**You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the CEO or Delegate of that site has been obtained.**

If conducting this study in a Health Service, a copy of this approval must be submitted to the Health Service Research Governance Officer/Delegated Personnel with a completed Site Specific Assessment (SSA) Form and supporting study documents for authorisation from the CEO or Delegate to conduct this research at the approved sites. Refer to the local THHS website for further information on Site Specific Assessment: <https://www.health.qld.gov.au/townsville/tresa/index>

Please note the following conditions of approval:

1. The Principal Investigator or study sponsor will report anything to the Committee which might warrant review of ethical approval of the project, including:
  - a) Within 72 hours of becoming aware of the event:
    - i. All significant safety issues and urgent safety measures taken as a response to the significant safety issue.
  - b) Within 15 calendar days of a sponsor's decision:
    - i. Notification of temporary halt of a study for safety reasons,
    - ii. Early termination of a study for safety reasons.
  - c) Within 15 calendar days of becoming aware of the event or report:
    - i. Any unforeseen events that might affect the ethical acceptability of the project,
    - ii. Any protocol violations and deviations from the study protocol that implicate participant consent, participant safety or data integrity,
    - iii. If the project is discontinued at a site before the expected date of completion,
    - iv. Where applicable, all industry safety monitoring and or Data and Safety Monitoring Board (DSMB) reports.

**Do not** submit individual line listings or individual adverse event reports to the HREC.

2. The Principal Investigator will provide an **annual progress report** and a final report at the completion of the study in the specified format to the HREC. The final report should include a copy of the results and/or publication, if not available at the time of reporting these must be provided in a timely manner. For clinical trials the annual report must include a safety report including a clear summary of the evolving safety profile of the trial.
3. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing ethical acceptability of the project must be submitted first to the HREC for review, then to the relevant Research Governance Offices (RGO).

Proposed amendments to the research protocol or conduct of the research which only affects the ongoing site acceptability of the project are to be submitted to the relevant RGOs only.

Further advice on submitting amendments is available from

<https://www.health.qld.gov.au/townsville/tresa/index/human-research-ethics-committee-hrec/amendments>

4. The HREC may undertake active monitoring of this research at any time. This may include random inspections of research sites, data, or consent documentation; and or interviews with research participants or other forms of feedback from them.

Should you require any additional information, please contact the HREC Coordinator on (07) 4433 1440 or TSV-Ethics-Committee@health.qld.gov.au. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from <https://www.health.qld.gov.au/townsville/tresa/index/human-research-ethics-committee-hrec>.

Once site specific authorisation to conduct the research has been granted, please complete the Commencement Form (Attachment II) and return to the HREC Coordinator.

The HREC wishes you every success in your research.

Kind regards,



Dr Kelvin Robertson (FSHP)  
Chairperson  
Human Research Ethics Committee  
Townsville Hospital and Health Service

**Townsville Hospital and Health Service  
Human Research Ethics Committee EC00183**

The following is the current composition of the QH Townsville Hospital and Health Service Human Research Ethics Committee (HREC) as at 20/03/2019.

It is advised that the Townsville Hospital and Health Service HREC is constituted according to the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007, updated 2018)*. The Townsville Hospital and Health Service HREC operates in accordance with the '*Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (NHMRC, 2018)*'; and the '*National Statement on Ethical Conduct in Human Research (NHMRC, 2007, updated 2018)*'.

It is also advised that the investigator(s) for a study are not involved in the deliberations regarding HREC approval of a study.

Attendance at a HREC meeting is in accordance with guidance of the National Statement on Ethical Conduct in Human Research section 5.2.30.

<b>COMPOSITION OF HREC as per National Statement 5.1.30</b>	<b>MALE OR FEMALE</b>	<b>HOSPITAL AFFILIATION (Y/N)</b>
Category A: Chair	1x Male	Y
Category B: Layperson	4x Female 2x Male	N N
Category C: Person with knowledge of and current experience in professional care, counselling or treatment of people	3x Female 1x Female 1x Male 2x Male	Y N Y N
Category D: Person who performs a pastoral care role	2x Male	N
Category E: Lawyer	1x Female 4x Female	Y N
Category F: Person with current research experience	4x Female 2x Female 1x Male 2x Male	Y N Y N
Category G: Other	2x Male	N

Should you require any additional information, please do not hesitate to contact the HREC Coordinator on 4433 1440 or email: [TSV-Ethics-Committee@health.qld.gov.au](mailto:TSV-Ethics-Committee@health.qld.gov.au)

**Attachment II**

Townsville Hospital and Health Service	Phone:	07 4433 1440
Human Research Ethics Committee EC00183	E-mail	<a href="mailto:TSV-Ethics-Committee@health.qld.gov.au">TSV-Ethics-Committee@health.qld.gov.au</a>

**NOTIFICATION OF COMMENCEMENT OF RESEARCH**

**HREC Reference number:** HREC/            /QTHS/

**Project title:**

**The above research commenced on:**            /    /

**PRINCIPAL INVESTIGATOR:**

**Signature:** \_\_\_\_\_ **Date:**    /    /

*Principal Investigator*

Our Reference: 51347\_AM01

13<sup>th</sup> August 2019

Dr Sachin Nayyar  
Department of Cardiology  
The Townsville Hospital

[Sachin.Nayyar@health.qld.gov.au](mailto:Sachin.Nayyar@health.qld.gov.au)

Dear Dr Nayyar,

**HREC Reference number: HREC/2019/QTHS/51347**

**Project title:** Tissue microarchitecture-information based ventricular tachycardia ablation

Thank you for submitting an amendment for the above mentioned study on 12/08/2019. The correspondence was reviewed by the Townsville Hospital and Health Service Human Research Ethics Committee Coordinator on 13/08/2019.

The documents reviewed and approved were:

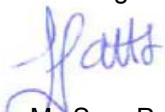
Document	Version	Date
<i>Notification of amendment:</i> Change in the primary affiliation of two co-investigators		12.08.19
Study Protocol	1.2	12.08.19

The Townsville Hospital and Health Service HREC is constituted according to the National Health and Medical Research Council's '*National Statement on Ethical Conduct in Human Research*' (NHMRC, 2007, updated 2018). The Townsville Hospital and Health Service HREC operates in accordance with the '*Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders*' (NHMRC, 2018); and the '*National Statement on Ethical Conduct in Human Research*' (NHMRC, 2007, updated 2018).

Please notify the Research Governance Office/r at each site of the amendment, by creating a Post Authorisation sub form under each SSA form in Ethical Review Manager (ERM), upload all the amended documents and submit online.

It should be noted that all requirements of the original approval still apply.

Kind regards,



Ms Sara Potts  
Coordinator  
Human Research Ethics Committee  
Townsville Hospital and Health Service