

**Contact for this correspondence**

Research Ethics Office

Research Ethics Support Officer

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22 December 2021

Professor Jonathan Iredell  
Department of Infectious Diseases and Microbiology/Clinical School  
The Children's Hospital at Westmead

Dear Professor Iredell,

**HREC Reference: 2021/ETH11861**

**Project title: Standardised treatment and monitoring protocol for adult and paediatric patients receiving bacteriophage therapy**

**Sites:**

- Westmead Hospital**
- Sydney Children's Hospitals Network**
- The Alfred Hospital**
- Royal Melbourne Hospital**
- Central Adelaide Local Health Network**
- Royal Brisbane and Women's Hospital**
- Queensland Children's Hospital**
- Fiona Stanley Hospital, Murdoch**
- Perth Children's Hospital**
- Westmead Institute for Medical Research**
- Monash Centre to Impact Antimicrobial Resistance**
- Telethon Kid's Institute**
- The Doherty Institute**

Thank you for submitting the above project for single ethical and scientific review. This project was first considered by the Sydney Children's Hospitals Network (SCHN) Human Research Ethics Committee (HREC) ("the Committee") at its meeting held in November 2021 and subsequently by the Executive Officer on 20 December 2021 and 22 December 2021.

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The HREC has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review, and by the National Health and Medical Research Council as a certified committee in the review of multi-centre clinical research projects.

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research and CPMP/ICH Note for Guidance on Good Clinical Practice.

I am pleased to advise that the Committee has granted ethical approval of this research project. Your approval is valid for five (5) years, effective the date of this letter.

This application has been assessed in accordance with, and meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) (including all updates).

**Please note the following conditions of approval:**

1. The Coordinating Investigator will immediately report anything which may warrant review of ethical approval of the project in accordance with the NSW Health's monitoring and safety reporting requirements <https://www.medicalresearch.nsw.gov.au/clinical-trial-safety-monitoring/>.
2. All proposed changes to the research protocol, including the conduct of the research, changes to site or personnel, or an extension to HREC approval, are to be provided to the HREC or its delegate for review before those changes can take effect.
3. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
4. The co-ordinating investigator will provide an annual report to the HREC on the anniversary of this approval letter, and a final report on completion of the study.
5. Your approval is valid for five (5) years from the date of the final approval letter. If your project extends beyond that five year period and you are still actively recruiting you will be required to submit an application for renewal for up to 5 years of ethics approval incorporating any amendments prior to the approval expiry date, and within six (6) months of the expiry date. If your project is in follow up, or analysis, please submit an application for amendment to extend the approval period. Ethics approval can be extended for a period of twelve (12) months at a time.
6. In the event of a project **not having commenced** within 12 months of its approval, the approval will lapse and reapplication to the HREC will be required.

The documents reviewed and approved by the Committee are:

Document	Version	Date
HREA	4	20 December 2021

<b>Document</b>	<b>Version</b>	<b>Date</b>
2021ETH11861 Response to Committee Form	-	21 December 2021
STAMP protocol	1	20 December 2021
PHAGE STAMP Response to Committee Form	-	8 December 2021
Master Adult PICF STAMP	1	8 December 2021
Master Parent_Guardian PICF STAMP	1	8 December 2021
Master Person Responsible PICF STAMP	1	8 December 2021
Master Young Person PIS STAMP	1	8 December 2021
HREC cover letter	-	10 October 2021
EQ-5D-5L and EQ-5D-Y QOL questionnaires	1.2	Received 22 October 2021
STAMP Site Feasibility Survey	-	10 October 2021
Combined Lab SOPs Phage Therapy	-	Received 22 October 2021
STAMP DSMB charter 300921 with signatures	1	30 September 2021
eCRF 191021	-	Received 22 October 2021
Stream 3 ToR revised with signatures	-	30 September 2021
Combined emails from Liz Barnes x2 Julia Warning Tom Snelling Nettie Burke x2	-	Received 22 October 2021
Email Clarification re. peer review and stat endorsement	-	26 October 2021
Phage STAMP ethics checklist FINAL	-	22 October 2021
070286 Project Registration	-	Received 22 October 2021

The documents reviewed and noted by the Committee are:

<b>Document</b>	<b>Version</b>	<b>Date</b>
Extension of Scope to CHW - Prof Iredell	-	3 April 2020
ASID CRN Endorsement STAMP	-	25 October 2021

Should you have any queries about the HREC's consideration of your project please contact the Research Ethics Support Officer on (02) 9845 1253 or SCHN-Ethics@health.nsw.gov.au.

**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 Chief Executive or delegate of that site has been obtained. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.**

The SCHN HREC wishes you every success in your research.

Yours faithfully,



Associate Professor Sarah Garnett

**Chair, Sydney Children's Hospitals Network Human Research Ethics Committee  
Sydney Children's Hospitals Network Human Research Ethics Committee**

*NB: All clinical trials must now be registered on a publicly accessible registry such as the Australian New Zealand Clinical Trials Registry. For further information please go to [www.anzctr.org.au](http://www.anzctr.org.au). Please provide this office with a copy of your registration number for our records if you have not already done so.*

CC: Ameneh Khatami ([ameneh.khatami@health.nsw.gov.au](mailto:ameneh.khatami@health.nsw.gov.au)) and Lani Attwood ([lani.attwood@health.nsw.gov.au](mailto:lani.attwood@health.nsw.gov.au))