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## GCHHS ETHICS COMMITTEE CERTIFICATE OF APPROVAL

26 May 2023

Dr Caroline Thng  
Principal Investigator  
[caroline.thng@health.qld.gov.au](mailto:caroline.thng@health.qld.gov.au)

**HREC Reference:** HREC/2023/QGC/94612  
**Project title:** VIRGo – Vaccine-induced Immune Responses against Gonorrhoea: A study to investigate immune response induced by the 4CMenB vaccine against gonorrhoea

Dear Dr Thng,

Thank you for submitting the above-named project for ethical and scientific review, which was undertaken by the Gold Coast Hospital and Health Service Human Research Ethics Committee (HREC).

This research project meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)-Updated May 2018*.

HREC approval is valid for **3 years**. Expiry 26 May 2026

### Sites Approved

Gold Coast Hospital and Health Service
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Please note the following conditions of approval:

1. **This letter constitutes ethical approval only and is not authorisation to commence.** Please submit this letter to the Research Governance Officer (RGO) at any HHS study sites along with a completed Site-Specific Assessment (SSA) Form and relevant documents, for authorisation.
2. **Reporting to HREC:** The following reports are required by the HREC. Failure to report may result in withdrawal or suspension of HREC approval:
  - i. **Annual Progress Reports:** Progress reports are due by **30 April each year**.
  - ii. **Clinical Trial Safety Reporting:** This HREC aligns with the guidance of the NHMRC – [Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods \(NHMRC 2016\)](#).
  - iii. **Other monitoring:** The GCHHS administration and/or HREC may inquire into the conduct of any research being conducted on GCHHS premises or claiming any association with GCHHS; or which the Committee has approved.

- **Amendments:** Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review. Please provide the rationale for the amendment and track changed documents where applicable. These must be submitted via a PAN form in ERM.

**3. Early termination/ routine completion of the project:**

- Please notify the HREC if the project is discontinued at any site prior to completion.
- For projects that are completed, submit a progress report with a copy of any research summaries or intended publications.

**APPROVED DOCUMENTS**

*It is the Coordinating Principal Investigator's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved:*

Document	Version	Date
HREA Application		15 May 2023
Cover Letter		16 March 2023
Response to the Committee		17 May 2023
Protocol	1.1	17 May 2023
Participant Information and Consent Form	1.1	17 May 2023
VIRGo Advertisement	1	03 April 2023
VIRGo Pre Screening Inclusion and Exclusion	1	15 April 2023
VIRGo Pre-vaccination checklist	1	13 April 2023
Australian Product Information – BEXSERO	12.0	16 December 2022
BEXSERO Final Update – Therapeutic Goods Administration		22 March 2016
Investigator CVs: <ul style="list-style-type: none"> <li>• Dr Caroline Thng (GCHHS)</li> <li>• Dr Ian Hughes (GCHHS)</li> <li>• Professor Kate Seib (Griffith University)</li> <li>• Mr Evgeny Semchenko (Griffith University)</li> <li>• Professor Michael Jennings</li> </ul>		

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)*, *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2018)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. The GCHHS HREC has been certified by the NHMRC to review multi centre research.

The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from [http://www.health.qld.gov.au/ohmr/html/regu/regu\\_home.asp](http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp)

The HREC wishes you and your colleagues every success in your research.

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Jenny Fraser  
Research Ethics and Governance Officer  
On behalf of

**Prof Justin Williams, Chairperson**

Gold Coast Hospital and Health Service Human Research Ethics Committee (EC00160)

Office for Research Governance & Development  
Level 2, PED Building

*Attached: HREC membership composition*