ADDRESS FOR ALL CORRESPONDENCE
RESEARCH ETHICS AND GOVERNANCE OFFICE
ROYAL PRINCE ALFRED HOSPITAL
CAMPERDOWN NSW 2050
TELEPHONE: (02) 9515 6766
EMAIL: SLHD-RPAEthics@health.nsw.gov.au
REFERENCE: **X21-0118 & 2021/ETH00732**
10.8/JUN21

16 June 2021

This letter constitutes ethical approval only. You must NOT commence this research project at ANY site until you have submitted a Site Specific Assessment Form to the Research Governance Officer and received separate authorisation from the Chief Executive or delegate of that site.

Dear Dr Nguyen,

Re: Protocol No X21-0118 & 2021/ETH00732 - "Indocyanine green angiography for preventing postoperative mastectomy skin flap necrosis in breast reconstruction: The ICGA FLAP randomized controlled trial"

The Executive of the Ethics Review Committee, at its meeting of 16 June 2021 considered your correspondence of 8 and 16 June 2021. In accordance with the decision made by the Ethics Review Committee at its meeting of 12 May 2021, ethical approval is granted.

- The research project meets the requirements of the *National Statement on Ethical Conduct in Human Research*.

This approval includes the following:

- HREA (Version 3, 11 June 2021)
- Protocol (Version 7, 15 June 2021)
- Product Information – IC-GREEN™ (NDA 11-525-S-017)
- Executive Summary of the PIS (Master Version 1, 30 March 2021)
- Participant Information Sheet and Consent Form (Master Version 2, 15 June 2021)
- Participant Information Sheet and Consent Form – Person Responsible (Master Version 2, 15 June 2021)
- Master Code Sheet (Version 1, 20 April 2021)
- Data Collection Form (Version 1, 20 April 2021)
- SLHD Research Data Management Plan (Version 2, 20 May 2021)
- Victorian Specific Module (21 March 2021)

You are asked to note the following:

- **This study requires notification to the Therapeutic Goods Administration (TGA) under the Clinical Trials Notification (CTN) Scheme.**

The Committee noted that authorisation will be sought to conduct the study at the following sites:

- Chris O'Brien Lifehouse (NSW)
- Royal Melbourne Hospital (VIC)
- Westmead Hospital (NSW)

- It is a requirement of ethics approval that, before its commencement, this clinical trial is registered on a publicly accessible register, such as the Australian New Zealand Clinical Trials Registry or another appropriate international register. The Committee therefore sought details of the Register in which the study has been included and its registration number.

- This approval is valid for **five** years, and the Committee requires that you furnish it with annual reports on the study's progress beginning in **June 2022.** If recruitment is ongoing at the conclusion of the five year approval period, a full re-submission will be required. Ethics approval will continue during the re-approval process.

- This human research ethics committee (HREC) has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review and is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

- You must immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project.

- You must notify the HREC of proposed changes to the research protocol or conduct of the research in the specified format.

- You must notify the HREC and other participating sites, giving reasons, if the project is discontinued at a site before the expected date of completion.

- If you or any of your co-investigators are University of Sydney employees or have a conjoint appointment, you are responsible for informing the University's Risk Management Office of this approval, so that you can be appropriately indemnified.

- Where appropriate, the Committee recommends that you consult with your Medical Defence Union to ensure that you are adequately covered for the purposes of conducting this study.

Should you have any queries about the Committee's consideration of your project, please contact me. The Committee's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Sydney Local Health District website.

The Ethics Review Committee wishes you every success in your research.

Regards,

S. Thomas

Sanaa Thomas
Executive Officer
Clinical Trials Sub-committee (RPAH Zone)

for:
Merela Ghazal
A/Executive Officer
Ethics Review Committee (RPAH Zone)