20 December 2022

Professor Henry Woo
Australian Clinical Trials Suite 406
San Clinic
185 Fox Valley Road, Wahroonga NSW 2076
c/o Dr Anthony-Joe Nassour

Dear Professor Woo

AHCL Reference ID: 2022-036
Project Title: Salvage 177Lu PSMA for PSA Biochemical Failure After Radical Prostatectomy for High-Risk Prostate Cancer (SLAP; Authorised prescriber and Case Study)

ETHICAL REVIEW – this letter constitutes ethical approval only. A separate site specific assessment (governance review) is required at the study site.

Thank you for submitting the above project for ethical review. The project was last considered by the Adventist HealthCare Limited Human Research Ethics Sub-committee (HREC)[1] at its full board meeting on **23 November 2023**. Thank you for attending the meeting and presenting the study proposal to the HREC.

We have received your responses to the HREC's request for additional information/modification of the above study.

I am pleased to advise that the HREC chairs as delegated by the full-board HREC, have granted ethical approval out of session upon review of above response letters of the **greater than low risk research project** for one (1) year until **13 December 2023[2].**

[1] 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), Australian Code for the Responsible Conduct of Research (2018) and the CPMP/ICH Note for Guidance on Good Clinical Practice. No HREC members with a conflict of interest were present for review of this project

[2] The AHCL HREC made ethical approval contingent on the submission of a progress report within 1 month of the HREC approval anniversary each year. When the progress report has been approved, ethical approval will automatically extend by 12 months, up to a maximum of 5 years overall approval period. Please refer to the condition section of this letter for details.

The documents reviewed for use are:

Document type	Document title	Version	Action
Letters	final_ Endorsement of Authorised Prescriber 2022-036 SLAP Edwin Szeto	06-Dec-2022	**NOTED**
Email	Drug details - update after HREC meeting	02-Dec-2022	**NOTED**
Letter Of Support	Gavin Marx Letter of Support	8-Nov-2022	**NOTED**
Letter Of Support	Henry Woo Letter of Support	8-Nov-2022	**NOTED**
Letter Of Support	Lisa Tarlington Letter of Support	8-Nov-2022	**NOTED**
Application	20201028_Application-for-an-Authorised-Prescriber (3)	18-Nov-2022	**NOTED**
PIC supplementary	1361RAD1220_Lu-PSMA_safety_instructions_HR	1361RAD1220	**APPROVED**
PIC supplementary	1361RAD1220_Lu-PSMA_Therapy_prostate_cancer_HR	1361RAD1220	**APPROVED**
PIC supplementary	1361RAD1220_Lutetium-177 PSMA Therapy Procedure_HR	1361RAD1220	**APPROVED**
Letter Of Support	Readibility confirmation PISCF - nurse Saskia Hyman	13-Dec-2022	**NOTED**
Letter Of Support	Readability confirmation of PISCF - nurse Levina Saad	13-Dec-2022	**NOTED**
PICF - Site Specific (Patient Information and Consent Form)	PISCF - SLAP -approved - final clean v1.2	v1.2; dated 13-Dec-2022	**APPROVED**
Protocol	SLAP_V4_Protocol_Template_24.11.2022	24-Nov-2022	**APPROVED**
Letters	Submission SLAP Cover letter	10-Oct-2022	**NOTED**

The project is ethically approved to be conducted at

- **Sydney Adventist Hospital – campus wide**
- **Prof Henry Woo's private practice rooms**

In compliance with the *Guidelines for Good Clinical Research Practice (GCRP) in Australia* and the requirements of Adventist HealthCare Limited, the Principal Investigator is responsible to ensure that the following conditions are met:

- The HREC will be notified, giving reasons, if the project is discontinued before the expected date of completion.
- The Principal Investigator will provide an annual report to the HREC and a final report at completion of the study, in the specified format. Your annual review date is 13 December.
- The AHCL HREC made ethical approval contingent on the submission of a progress report **by** the anniversary date **(13 December)** each year. When the

progress report has been approved, ethical approval will automatically extend by 12 months, up to a maximum of 5 years overall approval period. Further extensions beyond the 5 years lifetime of a project need to be applied for in writing on an amendment form and send to the Research Governance Office the latest 3 months before the expiry of ethical approval. **Failure to submit reports will result in ethical approval being suspended without further notification.**

- It is the responsibility of the Principal Investigator to ensure a current certificate of insurance is maintained by this office **at all times**. Failure to provide evidence of current insurance will result in site authorisation being withdrawn.

- Where applicable, it is the responsibility of the Principal Investigator to ensure that the Manager, Medical Records is advised of the required retention period of AHCL medical records. The standard medical record destruction period of 7 years will apply if alternate arrangements are not made.

- Publications - Any publication resulting from research conducted at an Adventist HealthCare facility should acknowledge AHCL as providing the facilities and/or resources. Please forward a copy of all publications to the Research Office to keep add them to the AHCL Research Publication database.

- Amendments - If there is an event requiring amendment/s to the approved research you should submit a request in the specified format.

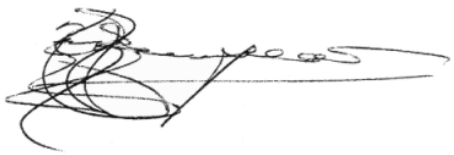
- You must comply with the Adventist HealthCare Limited Research Policy. A copy of the policy can be found on the ethics committee web page.

- For safety reporting please refer to **Appendix A**.

Should you have any queries about the Adventist HealthCare Limited Human Research Ethics Committee's consideration of your project please contact the Research Officer on (02) 9487 9604 or research@sah.org.au. We look forward to managing this application with you throughout the project lifecycle.

The Adventist HealthCare Limited Human Research Ethics Committee wishes you every success in your research.

Yours faithfully,



Professor Ray Roennfeldt
Chairperson, Adventist HealthCare Limited Human Research Ethics Committee

APPENDIX A

Safety reporting and monitoring (applicable to ethical approval and site specific authorisation)

*****Please note, despite this project being a case series and not a clinical trial, the below safety reporting requirements still apply due to the interventional character of the project and the off-label use of Lutetium *****

- The principal investigator will immediately report, in the specified format, anything which might warrant review of ethical approval of the project including any unforeseen events that might affect continued acceptability of the research and in accordance with NHMRC Guidance: Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (November 2016); https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods

- The AHCL HREC has adopted most of the NHMRC guidance and is therefore no longer reviewing single case AEs and SUSARs or device/non-therapeutic good trial equivalents or six monthly line listings. **However, the Committee has requested to review all SAEs. Please forward all SAEs to the AHCL Research Office for review by the AHCL HREC.**

- Please refer to the HREC approval terms in this letter for any additional reporting requirements.

- Please note the reporting timelines vary depending on whether the trial involves an IMP (Investigational Medicinal Product) or IMD (Investigation Medicinal Device). Please refer to the above link for guidance.