Government of Western Australia
Department of Health

Royal Perth Hospital Human Research Ethics Committee

24 August 2021

Dr Stephanie Babic
Albany Hospital
Warden Avenue
ALBANY WA 6330

Dear Dr Babic

PRN:	RGS0000004752
Project Title:	Efficacy and safety of intra-articular Botulinum Toxin A versus corticosteroid injections in knee osteoarthritis: A randomised control trial

Note: This project cannot commence until site governance approval has been obtained.

I am pleased to advise you that the Royal Perth Hospital (RPH) Human Research Ethics Committee (HREC) has granted **ethical approval** of this research project.

The nominated participating site(s) for this project is/are:
Royal Perth Hospital

If additional sites are recruited prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the HREC. Notification of withdrawn sites should also be provided to the HREC in a timely fashion.

The approved documents include:

Document	Version	Version Date
EQ-5D-5L (Sample Only)	1.2	2009
Oxford Knee Score (Sample Only)		1998
PICF - RCT on intra-articular Botox injections for knee OA	1	22/08/2021
RPH HREC Response Letter *(Noted)*		12/08/2021
Study Protocol - RCT on intra-articular Botox injections for knee OA	1	22/08/2021
Visual Analogue Scale (Sample Only)		

This ethical approval is valid to **24 August 2024** subject to compliance with the 'Conditions of Ethics Approval for a Research Project' (Below).

A copy of this ethical approval letter must be submitted by all site Principal Investigators to the Research Governance Office or equivalent body or individual at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.

This letter constitutes ethical approval only. This project **cannot proceed at any site until separate site authorisation has been obtained** from the Chief Executive or Delegate of the site under whose auspices the research will be conducted at that site.

Should you have any queries about the HREC's consideration of your project, please contact the Ethics Office at EMHS.REG@health.wa.gov.au or on 08 9224 3799. The HREC's Terms of Reference, Standard Operating Procedures and membership are available from the Ethics Office or from http://ww2.health.wa.gov.au/About-us/East-Metropolitan-Health-Service/About/Human-Research-Ethics-and-Governance.

The HREC wishes you every success with this project.

Yours sincerely

Adj Prof FRANK van BOCKXMEER
Chairman | Royal Perth Hospital Human Research Ethics Committee

CONDITIONS OF ETHICS APPROVAL FOR A RESEARCH PROJECT

The following general conditions apply to the research project approved by the Human Research Ethics Committee (HREC) and acceptance of ethical approval will be deemed to be an acceptance of these conditions by all project investigators:

1. The responsibility for the conduct of this project lies with the Coordinating Principal Investigator (CPI).
2. The investigators recognise the reviewing HREC is registered with the National Health and Medical Research Council and that it complies with the current version of the National Statement on Ethical Conduct in Human Research.
3. A list of HREC member attendance at a specific meeting is available on request, but no voting records will be provided.
4. The CPI will immediately report anything that might warrant review of ethical approval of the project.
5. The CPI will notify the HREC of any event that requires a modification to the protocol or other project documents and submit any required amendments to approved documents, or any new documents, for ethics approval. Amendments cannot be implemented at any participating site until ethics approval is given.
6. The CPI will submit any necessary reports related to the safety of research participants in accordance with the WA Health Research Governance Standard Operating Procedures.
7. Where a project requires a Data Safety Monitoring Board (DSMB), the CPI's will ensure this is in place before the commencement of the project and notify the HREC. All relevant reports from the DSMB should be submitted to HREC.
8. For investigator-initiated and collaborative research group projects the CPI may take on the role of the sponsor. In this case, the CPI is responsible for reporting to the Therapeutic Goods Administration (TGA) any unexpected serious drug or device adverse reactions, and significant safety issues in accordance with the TGA guidelines.
9. If the project involves the use of an implantable device, the CPI will ensure a properly monitored and up to date system for tracking participants is maintained for the life of the device.
10. The CPI will submit a progress report to the HREC annually from the ethics approval date and notify the HREC when the project is completed at all sites. The HREC can request additional reporting requirements as a special condition of a research project. Ethics approvals are subject to the receipt of these reports and approval may be suspended if the report is not received.
11. The CPI will notify the HREC of his or her inability to continue as CPI and will provide the name and contact information of their replacement. Failure to notify the HREC can result approval for the project being suspended or withdrawn.
12. The CPI will notify the HREC of any changes in investigators and/or new sites that will utilise the ethics approval.
13. The HREC has the authority to audit the conduct of any project without notice if some irregularity has occurred, a complaint is received from a third party or the HREC decides to undertake an audit for quality improvement purposes.
14. The HREC may conduct random monitoring of any project. The CPI will be notified if their project has been selected. The CPI will be given a copy of the monitor's report along with the HREC and Research Governance (RG) Office at the site/s.
15. Complaints relating to the conduct of a project should be directed to the HREC Chair and will be promptly investigated according to the WA Health's complaints procedures.
16. The CPI should ensure participant information and consent forms are stored within the participant's medical record in accordance with the WA Health's RecordKeeping Plan.
17. The CPI will notify the HREC of any plan to extend the duration of the project past the expiry date listed above and will submit any associated required documentation. A request for an extension should be submitted prior to the expiry date. One extension of 5 years may be granted but approval beyond this time period may necessitate further review by the HREC.
18. Once the approval period has expired or the project is closed, the CPI will submit a final report. If the report is not received within 30 days the project will be closed and archived.
19. Projects that do not commence within 12 months of the approval date may have their approval withdrawn and the project closed. The CPI must outline why the project approval should remain.
20. The CPI will notify the HREC if the project is temporarily halted or prematurely terminated at a participating site before the expected completion date, with reasons provided. Such notification should include information as to what procedures are in place to safeguard participants.
21. If a project fails to meet these conditions the HREC will contact the CPI to address the identified issues. If, after being contacted by the HREC, the issues are not addressed, the ethics approval will be withdrawn. The HREC will notify the RG Office at each site within WA Health that the project procedures must discontinue, except for those directly related to participant's safety.