HUMAN RESEARCH ETHICS COMMITTEE
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15 September 2017

Professor Elizabeth Armstrong
School of Medical and Health Sciences
JOONDALUP CAMPUS

Dear Elizabeth

ETHICS APPROVAL – MULTICENTRE RESEARCH PROJECT

Project Code:	**17291**	
Chief Investigator	**Professor Elizabeth Armstrong**	
Associate Investigators	**A/Prof Deborah Hersh, A/Prof Judith Katzenellenbogen, Prof Sandra Thompson, A/Prof Natalie Ciccone, Prof Leon Flicker, Prof Juli Coffin, A/Prof Tapan Rai, A/Prof Dominique Cadilhac, A/Prof Erin Godecke, Prof Graeme Hankey, Prof Neil Drew, Ms Deborah Woods, Prof Colleen Hayward, Dr Ivan Lin, Ms Meaghan McAllister**	
Project Title:	**Enhancing rehabilitation services for Aboriginal Australians after brain injury**	
Approval Dates:	*From:* 15 September 2017	*To:* 5 September 2020

Funding source: NHMRC
Grant: G1002749

Thank you for your recent application for ethics approval. This proposal has been reviewed by members of the ECU Human Research Ethics Committee (HREC). The Committee noted that this project has previously been approved by the Royal Perth Hospital Human Research Ethics Committee.

I am pleased to advise that the proposal complies with the provisions contained in the University's policy for the conduct of ethical human research and ethics approval has been granted. In granting approval, the HREC has determined that the research project meets the requirements of the National Statement on Ethical Conduct in Human Research.

All research projects are approved subject to general conditions of approval. Please see the attached document for details of these conditions, which include monitoring requirements, changes to the project and extension of ethics approval.

We wish you success with your research project.
Yours sincerely

Kim Gifkins
SENIOR RESEARCH ETHICS ADVISOR

Conditions of approval – multicentre research project

1. Monitoring of Approved Research Projects

Monitoring is the process of verifying that the conduct of research conforms to the approved ethics application. Compliance with monitoring requirements is a condition of approval.

The *National Statement on Ethical Conduct in Human Research* indicates that institutions are responsible for ensuring that research is reliably monitored. Monitoring of approved projects is to establish that a research project is being, or has been, conducted in the manner approved by the Ethics Committee. Researchers also have a significant responsibility in monitoring, as they are in the best position to observe any adverse events or unexpected outcomes. They should report such events or outcomes promptly to the Ethics Committee and take prompt steps to deal with any unexpected risks.

All projects approved by an Ethics Committee are approved subject to the following conditions of approval:

- If the research project is discontinued before the expected date of completion, researchers should inform the Ethics Committee as soon as possible, giving reasons.
- An annual report (for projects that are longer than one year) and a final report at the completion of the research will be provided to the Ethics Committee.
- Researchers must also immediately report anything that might warrant review of the ethical approval of the protocol, including:
  Any serious or unexpected adverse effects on participants
  Any unforeseen events that might affect continued ethical acceptability of the project.

This project is a multicentre research project previously approved by another institutional Ethics Committee.

The *National Statement* also indicates that wherever more than one institution has a responsibility to ensure that a human research project is subject to ethical review, each institution has the further responsibility to adopt a review process that eliminates any unnecessary duplication of ethical review. In addition, where an institution decides to rely on ethical review by a body it has not established, the roles for monitoring should be established.

Responsibility for monitoring this project is therefore delegated to the other institutional Ethics Committee that initially provided ethical review and approval for the project.

2. Changes and amendments

Compliance with the approved research protocol is a condition of approval, and any changes to the research design must be reported to the Ethics Committee. Amendments to the research design that may affect participants and/or that may have ethical implications must be reviewed and approved by the Ethics Committee before commencement.

Any changes to documents and other material used in recruiting potential research participants, including advertisements, letters of invitation, information sheets and consent forms, should be approved by the Ethics Committee.

In order to request approval for a change, please send an email to the Ethics Office outlining why the change is needed, describing the change (e.g. the new participants or new research procedures), attach a copy of any amended documents, and attach notification of approval for the change from the other institutional Ethics Committee.

3. Extension of ethics approval

All research projects are approved for a specified period of time – from the date of approval until the date of completion provided in the ethics application. If an extension of the approval period is required, a request must be submitted to the Ethics Committee. Please ensure that requests for extension of approval are submitted before the original approval expires.

In order to request an extension of ethics approval, please send an email to the Ethics Office providing a brief reason why the extension is needed and giving the new expected date of completion.