



Queensland
Government

Metro North
Hospital and Health Service

Royal Brisbane & Women's Hospital
Human Research Ethics Committee

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File Ref: HREC/18/QRBW/105
Email: RBWH-Ethics@health.qld.gov.au

Professor Paul Cumming
QIMR Berghofer Medical Research Institute
300 Herston Road
Herston Qld 4006

Dear Professor Cumming,

Re: Ref N^o: HREC/18/QRBW/105: Neuroinflammation in Boxing: Quantification of translocator protein (TSPO) expression using the tracer [18F]-PBR111 in a PET/MRI setting

Thank you for submitting the above research project for single ethical review. This project was considered by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (RBWH HREC) (**EC00172**) at its meeting held on 12 March 2018. The research project meets the requirements of the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*.

I am pleased to advise that the RBWH Human Research Ethics Committee has granted ethical approval of this research project.

The nominated participating site for this project is:

- Royal Brisbane & Women's Hospital, including Herston Imaging Research Facility (HIRF)

This letter constitutes ethical approval only. This project cannot proceed until separate research governance authorisation has been obtained from the CEO or Delegate of the Royal Brisbane & Women's Hospital under whose auspices the research will be conducted.

The approved documents include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		25 February 2018
Human Research Ethics Application (HREA) (<i>Submission Code: AU/1/D434313</i>)	1	18 February 2018
P2357 Protocol	2.2	18 February 2018
[¹⁸ F]PBR111 Investigator's Brochure	1	August 2017

<i>Document</i>	<i>Version</i>	<i>Date</i>
Radiation Dose Assessment		31 January 2018
MRI Safety Questionnaire	1.0	July 2016
ANIB Inclusion/Exclusion Criteria	1.0	17 February 2018
ANIB Participant Identification Sheet	1.0	23 February 2018
QIMR Berghofer HREC letter of approval		01 December 2017
QUT Office of Research Ethics and Integrity (OREI) Administrative Approval		21 December 2017
Curriculum Vitae of Bjorn Burgher	1.0	19 February 2018
Curriculum Vitae of Karen Sullivan	1.0	
Curriculum Vitae of Michael Paul Pender	1.0	21 February 2018
Curriculum Vitae of Louise Clare Campbell	1.0	23 February 2018
Curriculum Vitae of Omkar Laxman Patkar	1.0	23 February 2018
Curriculum Vitae of Nanette Douglas	1.0	21 July 2017
Curriculum Vitae of Fatima A Nasrallah	1.0	23 February 2018
Curriculum Vitae of Paul Thomas	1.0	26 February 2018
Curriculum Vitae of Paul Cumming	1.0	23 February 2018
Response to Request for Further Information		22 April 2018
Initial Contact (Phone Script)	2.0	22 April 2018
Advertisement Flyer: 'Imaging Brain Health in Boxers'	2.0	22 April 2018
Advertisement - Media	2.0	16 April 2018
Participant Information Sheet & Consent Form for MS Patients	2.2	06 April 2018
Participant Information Sheet & Consent Form for Healthy Adult with no boxing experience	2.2	06 April 2018
Participant Information Sheet & Consent Form for Boxers	2.2	06 April 2018

Approval of this project from the RBWH HREC is valid from **08.05.2018** to **08.05.2021** subject to the following conditions being met:

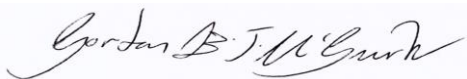
- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the RBWH HREC of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found at <https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/default.asp>.
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with the RBWH HREC policy and procedures. These instructions can be found at <https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>.
- In accordance with Section 3.3.22 (b) of the National Statement the Coordinating Principal Investigator will report to the RBWH HREC annually in the specified format, the first report being

due on **08.05.2019** and a final report is to be submitted on completion of the study. These instructions can be found at <https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>.

- The Coordinating Principal Investigator will notify the RBWH HREC if the project is discontinued before the expected completion date, with reasons provided.
- The Coordinating Principal Investigator will notify the RBWH HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found at <https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/default.asp>.
- The Coordinating Principal Investigator will notify the RBWH HREC of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.
- A copy of this ethical approval letter together with completed Site Specific Assessment (SSA) and any other requirements must be submitted by the Coordinating Principal Investigator to the Research Governance Office at the Royal Brisbane & Women's Hospital in a timely manner to enable the institution to authorise the commencement of the project at its site.
- Should you have any queries about the RBWH HREC's consideration of your project please contact the [HREC Coordinator on 07 3646 5490](mailto:rbwh.hrec@health.qld.gov.au). The RBWH HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from <https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/membership/default.asp>.

The RBWH HREC wishes you every success in your research.

Yours sincerely,



Dr Gordon McGurk
Chairperson RBWH Human Research Ethics Committee
[Metro North Hospital and Health Service](#)
08.05.2018

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)*. The processes used by this HREC to review research proposals have been certified by the National Health and Medical Research Council.