



Queensland
Government

Metro North
Hospital and Health Service

**Royal Brisbane & Women's Hospital
Human Research Ethics Committee**

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Coordinator
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File Ref: HREC/2020/QRBW/66058
Email: RBWH-Ethics@health.qld.gov.au

Dr Fatima Nasrallah
Queensland Brain Institute
University of Queensland
St Lucia Qld 4072

Dear Dr Nasrallah,

Re: Ref N^o: HREC/2020/QRBW/66058: Prediction and Diagnosis using Imaging and Clinical Biomarkers Trial in Traumatic Brain Injury

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 14 September 2020.

I am pleased to advise that this research project meets the requirements of the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)* and that the RBWH Human Research Ethics Committee has granted ethical approval of this research project.

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

The approved documents include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Appendix A – Outcome Measures	1.0 – August 2020	
Appendix B – Clinical Measures	1.0 – August 2020	
Predict-TBI Blood Sample Protocol	1.0 – July 2020	
Appendix E – Institutional Acknowledgement	1.0 – August 2020	
Appendix F – Patient Journey	1.0 – August 2020	

<i>Document</i>	<i>Version</i>	<i>Date</i>
Predict TBI Case Report Form (CRF)	1.0 – August 2020	
TBI PRED MRI Record	1.0 – July 2020	
NHMRC 2020 MRFF Traumatic Brain Injury Research Grant approval		
Curriculum Vitae of Christopher John Joyce		08 January 2020
Curriculum Vitae of Esther Jacobson		
Curriculum Vitae of Michael O'Sullivan		
Curriculum Vitae of Nathan Brown		26 June 2020
Curriculum Vitae of Prof Stephen Rose		
MRFF 2020 TBI – Grant Proposal Curriculum Vitae of Craig Winter		
MRFF 2020 TBI – Grant Proposal Curriculum Vitae of David Reutens		
MRFF 2020 TBI – Grant Proposal Curriculum Vitae of Fatima Nasrallah		
MRFF 2020 TBI – Grant Proposal Curriculum Vitae of J Walsham		
MRFF 2020 TBI – Grant Proposal Curriculum Vitae of JP Ross		
MRFF 2020 TBI – Grant Proposal Curriculum Vitae of Judith Bellapart		
MRFF 2020 TBI – Grant Proposal Curriculum Vitae of Sandeep Bhuta		
MRFF 2020 TBI – Grant Proposal Curriculum Vitae of Sekhar S Chandra		
MRFF 2020 TBI – Grant Proposal Curriculum Vitae of Siva Senthuran		
MRFF 2020 TBI – Grant Proposal Curriculum Vitae of Trevor Russell		
Response to request for further information		18 September 2020
HREA	Sep ver 3	18 September 2020
PREDICT- TBI Study Protocol	1.1	17 September 2020
Participant Information Sheet & Consent Form - Enrol or Continue	1.1 – September 2020	
Participant Information Sheet & Consent Form – Substitute Decision Maker	1.1 – September 2020	
Appendix A for PICF: Participant Journey	1.1 – September 2020	

<i>Document</i>	<i>Version</i>	<i>Date</i>
Appendix C: MRI Procedure Protocol	1.1 – September 2020	

Ongoing approval is for the duration of the project, conditional on:

1. In accordance with Section 5.5.6 (b) of the National Statement, the Principal Investigator will report to the HREC annually (**Due by 30 April each year**) in the specified format with a final report to be submitted on completion of the study.
<https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>
 2. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project, in the specified format, including:
 - a. Unforeseen events that might affect continued ethical acceptability of the project.
 - b. Serious Adverse Events that materially impact on the continued ethical acceptability of the project.
 3. Amendments to the research project are to be submitted to the HREC for review. Amendments should be reflected in a cover letter from the Principal Investigator, providing a description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Further advice on submitting amendments is available from:
<https://metronorth.health.qld.gov.au/research/ethics-and-governance/post-approval-reporting>
 4. The Principal Investigator will notify the HREC if the project is discontinued at the participating site(s) with reasons provided.
 5. If additional sites are engaged prior to the commencement of, or during the research project, the Principal Investigator is required to notify the HREC. Notification of the withdrawn sites should also be provided to the HREC in a timely fashion accompanying a close out report for that site.
- **Please advise the HREC of the date you commence the research project for the approved site(s) using the Notification of Commencement Form:**
<https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>
 - The HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from:

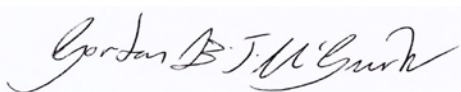
<https://www.health.qld.gov.au/metronorth/research/ethics-governance/hrec-approval/membership/default.asp>.

The nominated participating sites for this project are:

- Royal Brisbane & Women's Hospital
- Princess Alexandra Hospital
- Townsville University Hospital

The Royal Brisbane & Women's Hospital Human Research Ethics Committee wishes you every success in your research.

Yours sincerely,



Dr Gordon McGurk
Chairperson RBWH Human Research Ethics Committee
[Metro North Hospital and Health Service](#)
22 September 2020

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 multi-centre research proposals have been certified by the National Health and Medical Research Council.