Government of **Western Australia**
**East Metropolitan Health Service**

**Royal Perth Hospital**
**Human Research Ethics Committee (EC00270)**

9 December 2016

Ms Simone Quartermaine
Continence Service
Bentley Hospital

Dear Ms Quartermaine

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| Project Title: | ***A containment strategy using anal plugs for the treatment of intractable faecal incontinence (FI) in stroke survivors versus standard FI care in a rehabilitation setting: a feasibility study*** |
| REG Number: | **2016-221** |
| HREC Meeting: | **23 November 2016** |

The ethics application for the project referenced above has been reviewed by the Royal Perth Hospital (RPH) Human Research Ethics Committee (HREC). In reviewing this project, the Committee has considered whether the protocol meets the requirements of the NHMRC's National Statement on Ethical Conduct in Human Research (National Statement).

The RPH HREC considers that the research meets the requirements of the National Statement and resolved at the meeting to approve the project.

This approval is valid to **9 December 2019** and on the basis of compliance with the 'Conditions of HREC Approval for a Research Project' (attached).

The nominated participating site(s) in this project is/are:

- **Bentley Health Service**

| **Documents** |
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| IFI study proposal plan Version 2.0 06Dec2016 |
| Bowel Chart |
| Bristol Stool Chart |
| Revised Faecal Incontinence Scale |
| Patient Satisfaction Survey - Incontinence Aids |
| Caregiver Self-Assessment Questionnaire |
| Caregiver Satisfaction Survey - Incontinence Aids |
| WA Master PICF Version 2.0 06Dec201 |
| WA Master PICF (Carer) Version 06Dec2016 |

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 Notification of withdrawn sites should also be provided to the HREC in a timely fashion.

**This letter constitutes ethical approval only**. This project cannot proceed at any site until separate site authorisation has been obtained from the CE, or delegate, of the site following Site Specific Assessment by a Research Governance Officer.

The RPH HREC is registered with the Australian Health Ethics Committee and operates according to the NHMRC National Statement on Ethical Conduct in Human Research and International Conference on Harmonisation – Good Clinical Practice.

**Research Ethics & Governance**
Level 3 Colonial House, Royal Perth Hospital, GPO Box X2213 Perth WA 6847
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Should you have any queries about the HREC's consideration of your project, please contact the HREC Administrative Officer on (08) 9224 2292. The HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the SIRO Research Ethics & Governance Unit or from the website: http://ww2.health.wa.gov.au/About-us/East-Metropolitan-Health-Service/About/Human-Research-Ethics-and-Governance

Yours sincerely

**DR RAMIN GHARBI**
**Chairman | Royal Perth Hospital Human Research Ethics Committee**

CC Caroline Bulsara

# CONDITIONS OF HREC 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 the approval will be deemed to be an acceptance of these conditions by all investigators involved in the research project:

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| 1. | The responsibility for the conduct of projects lies with the Coordinating Principal Investigator (CPI), all correspondence should be signed by CPI. |
| 2. | 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 stand. |
| 3. | The submission of an application for HREC approval will be deemed to indicate that the investigator/s and any sponsor recognises the approving HREC is registered with the National Health and Medical Research Council (NHMRC) and that it complies in all respects with the National Statement on Ethical Conduct in Human Research and all other national and international ethical requirements. **The HREC will not enter into further correspondence on this point.** |
| 4. | A list of attendance at a specific meeting is available on request, but no voting records will be provided. |
| 5. | 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 in the project being suspended or approval withdrawn. |
| 6. | The CPI will notify the HREC of any departures of named investigators. The CPI will also notify the HREC if any new investigators and/or sites join the project that will utilise the HREC's approval. |
| 7. | The CPI will inform the HREC about any changes to the project. The CPI is responsible for submitting any amendments to the approved documents listed on the approval letter, or any new documentation to be used in the project. Any new or amended documentation should be submitted in a timely manner and cannot be implemented at any participating site until they have received HREC approval. |
| 8. | The CPI is responsible for reporting adverse events, indicating whether or not the project should continue. Reporting requirements are as per the WA Health Research Governance and Single Ethical Review Standard Operating Procedures. Additional reports other than those outlined that are submitted to the HREC will be returned without acknowledgement. The HREC can request additional reporting requirements as a special condition of a research project. |
| 9. | Where a project requires a Data Safety Monitoring Board (DSMB) it is the CPI's responsibility to ensure this is in place before the commencement of the project and the HREC notified of this. All relevant reports from the DSMB should be submitted to HREC. |
| 10. | For projects where the site is acting as the sponsor (ie. investigator initiated project) it is the responsibility of the CPI to report serious and unexpected drug/device reactions, as well as other reactions/events to the Therapeutic Goods Administration (TGA). Please refer to TGA website for further information and the relevant forms (see http://www.tga.gov.au/pdf/clinical-trials-guidelines.pdf p71 for medications or p77 for devices). |
| 11. | If this project involves the use of an implantable device a properly monitored and up to date system for tracking participants is to be maintained for the life of the device in accordance with the National Statement section 3.3.22 (g). |
| 12. | The investigator is responsible for notifying the Therapeutic Drugs Administration of a device incident in accordance with the National Statement section 3.3.22 (g). |
| 13. | An annual report on an approved research project will be required on the anniversary date of the project's approval. HREC approvals are subject to the submission of these reports and approval may be suspended if the report is not submitted. |

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| 14. | The HREC has the authority to audit the conduct of any project without notice. Exercise of this authority will only be considered if there are grounds to believe that some irregularity has occurred, if a complaint is received from a third party or the HREC decides to undertake an audit for Quality Improvement purposes. |
| 15. | The HREC can 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 Office (RGO) at each site. |
| 16. | Complaints relating to the conduct of a project should be directed to the HREC Chair and will be promptly investigated according to the Committee's complaints procedures. |
| 17. | CPI are reminded that records of consent or authorisation for participation in a project form part of the Acute Hospital Patient Record and should be stored with that record in accordance with the WA *Health Patient Information Retention and Disposal Schedule (Version 2) 2000.* A copy of the 'Participant Information Sheet' should also be included in the medical records as part of informed consent documentation. |
| 18. | The duration of HREC approval for a project is 3 year (with the option of 5 years) from the date of approval. The date of approval expiry is stipulated in the HREC approval letter. |
| 19. | If the project is to continue beyond the stipulated approval expiry date a request for an extension should be submitted prior to that expiry date. One extension of 3 years can be granted but approval beyond this time period may necessitate further review by the HREC. |
| 20. | Once the approval period has expired, the CPI is required to submit a final report. If the report is not received within 30 days the project will be closed and archived. An outstanding final report could impact on the CPI's ability to apply for approval for future projects. |
| 21. | If a project is suspended or terminated by the CPI, or a project sponsor, the CPI must immediately inform the HREC and the RGO at each site of this and the circumstances necessitating the suspension or termination of the project. Such notification should include information as to what procedures are in place to safeguard participants. |
| 22. | If a project fails to meet these conditions the HREC will contact the investigator(s) to request they rectify the identified issues. If, after being contacted by the HREC, the issues are not addressed the HREC approval will be withdrawn. The HREC will notify the RGO at each site within WA Health that work may no longer be conducted in relation to the project other than that concerning the participants safety. |