**WEST MORETON HOSPITAL AND HEALTH SERVICE**

**HUMAN RESEARCH ETHICS COMMITTEE**

Choose an item. ***Report***

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| **HREC Reference Number:** |   |
| **Protocol Title:** |   |
| **Principal Investigator:** |   |
| **Reporting Period:** | From: Click or tap to enter a date. |
|  | To: Click or tap to enter a date. |

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| **Information Required** | **Response** | **Comments / Additional Details** |
| ***Study Status*** |
| Please advise of study status.\*If status is discontinued/abandoned; not yet commenced or on hold, please provide an explanation in the Comments. | Choose an item.If Other, please detail:  |  |
| Was a Public Health Application (PHA) required for this study? If yes, provide expiry date of the PHA | Choose an item.Expiry Date: |  |
| ***Progress to Date*** |
| Number of participants to be recruited as outlined in the protocol? |  |  |
| Number of participants recruited to date? |  |  |
| Have you encountered any difficulties? e.g. recruiting | Choose an item.If Yes, please detail: |  |
| Please provide details of any results to date.\*Including publications, presentations, posters, meetings |  |  |
| ***Study Documentation*** |
| Please provide version number and dates of study documents currently in use: |
| Protocol: | Version number: | Date: |
| PICF: | Version number: | Date: |
| Other (please specify): | Version number: | Date: |
| Other (please specify): | Version number: | Date: |
| Other (please specify): | Version number: | Date: |
| Is all study-related data being stored according to the protocol for non-clinical trial studies and GCP for clinical trials? | Choose an item.If No, please detail: |  |
| ***Changes to the Approved Study*** |
| Have there been any amendments to the approved study (eg. changes to the research team) since the original submission or last progress report? | Choose an item.If Yes, please detail: |  |
| ***Risks and Safety*** |
| Have there been any complaints regarding the conduct of the study since approval of the study or last progress report? | Choose an item.If Yes, please detail: |  |
| Have any issues regarding safety occurred since submission of the last progress report? | Choose an item.If Yes, please detail: |  |
| Have all urgent safety measures including amendments, temporary halt, or early termination of the study for safety reasons been submitted to the HREC? | Choose an item.If No, please detail: |  |
| Have all Serious Adverse Events been reported to the study sponsor within 24 hours of becoming aware of the event? | Choose an item.If No, please detail: |  |
| Have all significant safety issues and suspected unexpected serious adverse reactions (SUSARS) been reported to the HREC? | Choose an item.If No, please detail: |  |
| Is a Data Safety Monitoring Committee[[1]](#footnote-1) (DSMC) or independent safety monitoring required for this study? | Choose an item.If Yes, please provide details of last meeting and any recommendations: |  |
| ***Other Considerations*** |
| Are there sufficient resources (eg. funding, staff etc) to complete the study in the manner as approved by the HREC? | Choose an item.If No, please detail: |  |
| Have any concerns arisen from the study that you wish to draw to the attention of the HREC? | Choose an item.If Yes, please detail: |  |

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| **Signature of Principal Investigator** |  |  **Date** |

***Please submit the completed and signed report via ERM.***

***Ongoing ethical approval is contingent on receiving an annual report by 30 April each year.***

***A final report is due on completion of the research.***

1. An independent and multidisciplinary group established by the trial sponsor to review, at intervals, accumulating trial data, in order to monitor the progress of a trial and to make recommendations on whether to continue, modify or stop the trial for safety or ethical reasons.

*See NHMRC Guidance on Data Safety Monitoring Boards (DSMBs) for more information* [*here.*](https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods) [↑](#footnote-ref-1)