Far North Queensland HREC *(EC00157)*

# HREC / RGO Research Annual Progress Report / Final Report

This report must be submitted to the approving HREC and site RGO’s at least annually (minimum) by April 30th and at the completion of the project.

Please refer to [National Statement on Ethical Conduct in Human Research Section 5.4](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023#block-views-block-file-attachments-content-block-1) for more information. Complete all sections in this form. Incomplete forms will be returned for completion.

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| SECTION 1: | PROJECT INFORMATION | |
| **HREC Reference No:** | HREC / | |
| **Project Title:** |  | |
| **Report Type:** | Annual Progress Report  Final Report | |
| **Reporting Period:** | From: Click or tap to enter a date. | To: Click or tap to enter a date. |
| **Principal Investigator Name:** |  | |
| **Contact / Coordinator Name & Email:** |  | |
| **Sponsor Name** *(if applicable):* |  | |
| **Sites Approved** *(only complete this question if changed since last report):* | Name of Site & SSA Ref #:  Commencement Date at Site:  Recruitment # to date at Site: | |

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| SECTION 2: | STUDY STATUS |
| Is the study in progress at all sites approved by the FNQ HREC? Yes  No \*  - *If no, list the sites that are active and those that are not active in the table below.*   |  |  | | --- | --- | | Site Name: | Status (Inactive/Active): | |  |  | |  |  | |  |  |   Date of Commencement: Click or tap to enter a date.  In progress, but closed to recruitment: Yes  No  Discontinued/Abandoned \*:  Not yet commenced \*:  On hold \*:  *\* If the study has been discontinued/abandoned, not yet commenced, or on hold, provide an explanation in the box below.*   |  |  | | --- | --- | | Explanation of Study Status: |  | |  | |   Study completed at all sites:  - *If ticked, this is a final report, provide a summary of results in Section 9 and attach all publications, presentations or dissemination of outcomes.*  HREC expiry date for the study: Click or tap to enter a date.  Is an extension to HREC approval required? Yes \*  No  - *If yes, submit an amendment in ERM to the HREC, including justification for the extension. Contact the HREC Coordinator for amendment submission requirements.* | |

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| SECTION 3: | HREC APPROVED DOCUMENTATION |
| Please provide the version numbers and dates of the FNQ HREC approved documents currently in use *(only fill out if they have changed since the last progress report).*   |  |  |  | | --- | --- | --- | | Study Document: | Version Number: | Date: | | Protocol |  |  | | Participant Information Sheet (if applicable) |  |  | | Consent Form (if applicable) |  |  | | Questionnaire/Survey (if applicable) |  |  | | Other (please specify) |  |  | | Other (please specify) |  |  | | |

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| SECTION 4: | CHANGES TO THE APPROVED STUDY |
| Have there been any amendments to the approved study (including changes to the research team) since submission of the last progress report?  Yes \*  - *If yes, and you have not submitted these amendments to the HREC & appropriate RGO, please do so as soon as possible. Contact the HREC Coordinator for submission requirements. If any amendments have been submitted and approved by the HREC since the last progress report, please list them in the box below.*  No  - *If no, go to section 5.*   |  | | --- | | Details of Submitted and Approved Amendments: | |  | | |

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| SECTION 5: | MANAGEMENT OF RISKS |
| Have there been any complaints regarding the conduct of the study since the approval of the study or last progress report?  Yes \*  - *If yes, provide additional details as an attachment and upload it in ERM.*  No | |

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| SECTION 6: | CLINICAL INTERVENTION (Including clinical trials) |
| Has the Principal Investigator reviewed any issues regarding safety concerns since the submission of the last progress report? Please provide details below, and if applicable, provide an attachment of how any safety concerns were addressed.  N/A   |  | | --- | | Details of Safety Concerns Reviewed: | |  |   Has the Principal Investigator reported any issues regarding safety since the submission of the last progress report?  Yes \*  - *If yes, provide additional details as an attachment and upload it in ERM.*  No  N/A  Have all urgent safety measures including amendments, temporary halt or early termination of the study for safety reasons been submitted to the HREC and authorising RGO?  Yes  No \*  - *If no, provide additional details as an attachment and upload it in ERM.*  N/A  Have all serious adverse events been reported to the study sponsor within 24 hours of becoming aware of the event?  Yes  No \*  - *If no, provide additional details as an attachment and upload it in ERM.*  N/A  Have all significant safety issues and suspected unexpected serious adverse reaction (SUSARS) arising from a site been reported to the relevant local institutional RGO within 72 hours of becoming aware of the event?  Yes  No \*  - *If no, provide additional details as an attachment and upload it in ERM.*  N/A  Is a Data Safety Monitoring Committee / Board (DSMC/B) or independent safety monitoring required for this study?  Yes \*  - *If yes, provide any Data Safety Monitoring Recommendations Letters / Reports or Executive Summary to HREC/RGO as an attachment and upload them in ERM.*  No | |

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| SECTION 7: | OTHER CONSIDERATIONS |
| Have any concerns arisen from the study that you wish to draw to the HREC and RGO attention? E.g., barriers and obstacles encountered in the research project, difficulties with recruitment/data collection, etc.  Yes \*  - *If yes, provide further details below and any recommendations/strategies implemented to overcome concerns for submission to HREC/RGO.*  No   |  | | --- | | Further Details: | |  |   Are there sufficient funds to complete the study in the manner as approved by the HREC and authorised by the relevant RGO?  Yes  No \*  - *If no, provide further details in the box below.*  N/A   |  | | --- | | Further Details: | |  | | |

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| SECTION 8: | SECURITY OF PROJECT-RELATED DATA AND INFORMATION |
| How is the security of project-related data/records being maintained? Briefly describe in the box below the steps taken to protect data/records below including location and duration of data storage.   |  | | --- | | Details of Data Security and Storage Measures: | |  |   Have there been any security breaches related to project data/records since your last progress report?  Yes \*  - *If yes, provide details and actions taken in the box below.*  No   |  | | --- | | Details of Security Breaches (If Any): | |  | | |

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| SECTION 9: | PROGRESS TO DATE AND FINAL REPORT INFORMATION |
| Please provide a brief statement in the box below that includes:   * A summary of findings to date * Details of any publications accepted or in press during this reporting period * Details of any presentations given during this reporting period   For the Final Report: Please summarise the results in the box below and attach any related publications, presentations, or dissemination materials. Include a description of how the results have been shared with the appropriate parties in accordance with the approved protocol.  Note: If the project has been published or presented, copies of all publications, presentations, reports, etc., must be included/uploaded with this report. Submission of these documents is mandatory.  *(continued on the next page)*   |  | | --- | | Summary of Progress or Final Report Details: | |  | | |

### DECLARATION BY PRINCIPAL INVESTIGATOR:

The information provided in this report is complete and correct. I certify that the above project was carried out / is being carried out in accordance with the approved protocol submitted to and approved by the HREC.

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**Name of Principal Investigator**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Principal Investigator**

**Date: \_\_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_**