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**HUMAN RESEARCH ETHICS COMMITTEE**

**of NT Health and Menzies School of Health Research**

**ANNUAL PROGRESS REPORT / FINAL REPORT FORM**

***Instructions:***

* *Ethics approval for the research study will lapse if the progress report is not received by the specified report due date or if the report is deemed to be unsatisfactory by the Ethics Committee.*
* *All sections of this report, including signatures, must be completed otherwise the report will be considered invalid.*
* *Please email the completed* ***electronic*** *progress report and relevant attachments to* [*NTHREC@menzies.edu.au*](mailto:NTHREC@menzies.edu.au)

**Part A: Project Details**

|  |  |  |
| --- | --- | --- |
| **1** | **NT HREC File Reference No.** |  |
| **2** | **Project Title** |  |
| **3** | **Principal Investigator** |  |
| **4** | **Project Commencement Date** |  |
| **5** | **Project Completion Date** | **Currently approved completion date:**  **Do you wish to extend your completion date:  Yes  No**  **New expected completion date:**  **Please state your reasons for extension in your report summary at the end of this document.** |
| **6** | **Project Coordinator/Contact** | **Name:**  **Position:**  **Qualifications:**  **Organisation/Affiliation:**  **Postal Address:**  **Phone Number:**  **Email Address:** |
| **7** | **Research Team Members** | Have there been any changes to the investigators or project team members that have not yet been notified to and approved by this HREC?  **Yes**  **No**  **If yes, please detail:**    **Name:**  **Position:**  **Role in the project:**  **Qualifications:**  **Organisation/Affiliation:**  **Postal Address:**  **Phone Number:**  **Email Address:** |

**Part B: Status of Project**

Completed *(Note: Please attach a Final Report – refer to Part D of this document).*

**Please note that, if completed, relevant stakeholders from whom support was obtained should be informed of the FINAL outcomes of the research project.** *(Refer to Part D of this document)*

In Progress *(Note: Please attach a Progress Report – refer to Part D of this document).*

Abandoned prematurely *(Please attach an explanation).*

Reason:

Not yet commenced but it is appropriate to keep ethics approval current.

Reason:

Will not commence and it is appropriate to terminate ethics approval.

Reason:

**Part C: Research Conduct**

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| **1** | **Compliance** | Has the conduct of the project been in accordance with the general conditions stated in the NHMRC National Statement on Ethical Conduct in Human Research? | Yes  No |
|  |  | Is the project being conducted in compliance with the approved protocol of the ethics application?    If **NO**, please provide details of any protocol deviations or violations in your summary. | Yes  No |
|  |  | If **NO,** has approval for amendments to the protocol been previously sought from the Committee?  If **NO,** please attach relevant documentation and an explanation on why permission to amend the protocol was not sought from the Committee prior to the implementation of the changes. | Yes  No |
| **2** | **Amendments** | Have there been any amendments to the project in the last 12 months?  If **NO,** please go to question 3. | Yes  No |
| If **YES**, have you previously forwarded them to the Ethics Committee?  If **NO**, please submit a separate amendment request using the amendment request form.    If the study was approved under the **NMA** scheme, please include a summary of relevant amendments approved by the primary reviewing HREC in the report summary below. | Yes  No |
| **3** | **Participant Recruitment.**  **This question is not limited to clinical trials.**  ***(If not applicable, e.g. retrospective audit, please select N/A and go to Question 4)*** | Summary of participant recruitment for the sites approved by this HREC.  (If multiple sites have been approved, please provide more detail in the report summary.) | N/A |
| Target Recruitment Number : |  |
| Number of participants recruited to date: |  |
| Number of participants currently in study: |  |
| Number of participants withdrawn: |  |
| Number of participants who have completed study: |  |
| **4** | **Adverse Effects relating to any project.**  **This question is not limited to clinical trials.** | Has participation in the project resulted in any adverse effects on participants including either serious or minor effects?  If yes, were any of these adverse effects minor?  If Minor, please elaborate in your attached report summary.  If yes, were any of these adverse effects classified as Serious Adverse Events (SAE) or Sudden and Unexpected Serious Adverse Reactions (SUSAR)?    If **YES**:  Were they reported within 72 hours to the Ethics Administration?  Did the SAE (including SUSARs or significant events) have an impact on the study?    **PLEASE attach a list of any previously unreported SAEs or SUSARs to this report.** | Yes  No  Yes  No  Yes  No  Yes  No  Yes  No |
| Have any other unforeseen events or ethical problems or issues arisen to date?    If **YES**, please attach details with this report. | Yes  No |
| **5** | **CLINICAL TRIALS**  ***(If not applicable, please select N/A and go to Question 6)*** | **CLINICAL TRIALS**  Have line listings been received from the sponsor at least 12-monthly?  If **NO**, please provide a reason in your report summary:  If **YES,** has the Principal Investigator reviewed all listings and reported anything of significance to the Ethics Committee?   * No, the listings are not reviewed. * No, the listings are reviewed but significant events are not reported yet. * Yes, reviewed but nothing to report. * Yes, reviewed and reported. | N/A  Yes  No |
|  |  | **CLINICAL TRIALS**  Is the insurance certificate current?  If **NO,** please attach a current copy from the sponsor and forward with this document. | Yes  No |

|  |  |  |  |
| --- | --- | --- | --- |
| **6** | **Privacy and Confidentiality** | Do you consider the security of the data collected during the research and the conditions governing access to such data to be adequate?  If **NO,** please attach details with this report. | Yes  No |
| **7** | **Issues of Ethical Significance** | Have findings of ethical significance arisen at this site or elsewhere?  If **YES**, please attach details with this report.  Have study participants been informed of these events?  If **NO**, why not? Please comment in your summary. | Yes  No  Yes  No |

**Part D: ReportING**

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| **1** | **Publications** | Have any publications, either in refereed journals or non-refereed publications resulted from this research?  If **YES**, please cite full publication details in your summary. | Yes  No |
| **2** | **Stakeholder Feedback** | Have study participants, relevant communities and organizations been informed of the results or findings of the above research project?  Please note that relevant stakeholders from whom support was obtained should be informed of the FINAL outcomes following completion of the research. | Yes  No |
| If **YES,** how has feedback been provided?  Please provide details: |
| If **NO**, please provide an explanation and comment on why feedback has not been provided.  Please provide details: |
| **3** | **Activity Summary** | 1. Please attach a report in plain English of the project’s outcome or progress to date including all important findings/conclusions. 2. If the project is a multi-jurisdictional study, please also differentiate any Northern Territory specific information. 3. This should be no more than 1 page, please do not forward large reports. 4. If you wish to extend your project date please include your reasons in your summary |  |
| **4** | **Other attachments** | 1. As appropriate, any other documentation relating to any of the above questions |  |

**Report Activity Summary can be inserted here or attached separately:**

**Part E: Signatures and Declarations**

* I confirm that this project has been conducted as originally approved by the Human Research Ethics Committee of the NT Health and Menzies School of Health Research (and subject to any changes subsequently approved as amendments).
* I confirm that this project continues to be conducted in compliance with the NHMRC *National Statement on Ethical Conduct in Human Research* (NHMRC 2007).
* I confirm that this report accurately reflects the status of the above research project.

**Principal Investigator Name:**

**Signature:                                          Date:**

**Please forward an electronic copy to:** [**NTHREC@menzies.edu.au**](mailto:NTHREC@menzies.edu.au)