**Clinical Trial Annual Progress & Safety / Final Report**

**All clinical trials:** In keeping withthe *NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods (2016)*, it is a requirement to provide the reviewing HREC an annual safety report. Please ensure you include a description and analysis of all new/relevant safety issues. The report should also include a statement from the Principal Investigator advising whether, or not, there may be any impact on study participants.

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| 1.0 TRIAL DETAILS | |
| HREC Reference Number | <<INSERT approval number>> |
| Reviewing HREC | <<INSERT name of reviewing HREC>> |
| Site/Local Reference Number  *(if different from reviewing HREC reference number)* | <<INSERT site approval number>> |
| Trial Title | <<INSERT trial title>> |
| Coordinating Principal Investigator or Site Principal Investigator | **Name:** <<INSERT PI name>>  **Email:** <<INSERT PI email>>  **Telephone:** <<INSERT PI telephone>> |
| Sponsor Details | **Name:** <<INSERT Sponsor name>>  **Email:** <<INSERT Sponsor email>> **Telephone:** <<INSERT Sponsor telephone>> |
| Date of this report | <<INSERT DAY MONTH YEAR>> |

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| **2.0 Status of Project (only check boxes that apply) *(double click to ‘check’ each box)*** | |
| **Not yet commenced** | *\*If checked, please provide reasons for delayed start*  [INSERT explanation] |
| **In progress/continuing** |  |
| **Completed/Early Termination** |  |

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| **3.0 Compliance** | | |
| * 1. **For this calendar year, has the project been conducted in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research (2018, or as amended)?*** | Yes | No\* |
| *\* If NO, please explain*  [INSERT explanation] | | |
| * 1. **For this calendar year, has the project been conducted in accordance with the approved project description/protocol and approval conditions?** | Yes | No\* |
| *\* If NO, please explain*  [INSERT explanation] | | |

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| **4.0 Confidentiality and Storage of Data (only check boxes that apply) *(double click to ‘check’ each box)*** | | | | | |
| **4.1 Has the storage of your data changed?** | | | | Yes\*  Please complete the following | No (go to section 5) |
| **Data Type** | **Campus/Location** | **Building/Server Name** | **How is data stored securely** | **How is access restricted** | **Estimated date of data destruction** |
| **Physical**  (add additional rows for multiple locations) |  |  |  |  |  |
| **Digital**  (add additional rows for multiple locations) |  |  |  |  |  |
| **Audio/Visual/Photographs**  (add additional rows for multiple locations) |  |  |  |  |  |
| **Biospecimens**  (e.g. blood/tissue/saliva), other physical specimens, artefacts or archival material)  (add additional rows for multiple locations) |  |  |  |  |  |

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| 5.0 SAFETY PROFILE |
| Description and analysis of new/relevant safety findings (please discuss adverse events/reactions/effects, serious adverse events/reactions/effects (including SUSARs and USADEs), significant safety issues that occurred over the past 12 months) |
| <<INSERT text here>> |
| Describe any anticipated impact on study participants (if any) |
| <<INSERT text here>> |
| Implications of the safety findings on the risk and benefit of the trial |
| <<INSERT text here>> |
| Describe any measures, taken or proposed, to minimise risk |
| <<INSERT text here>> |

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| 6.0 SAFETY MONITORING |
| Has the safety monitoring plan been reviewed or adapted in the past 12 months? |
| Yes  No  N/A  *If changes are required to any documents approved by the HREC, complete a Modification for review by the HREC* |
| Has the safety monitoring plan been implemented? |
| Yes  No (if no, explain why the safety monitoring plan has not been implemented)  N/A |
| Does the trial have a Data and Safety Monitoring Board (DSMB) or a designated safety monitor? |
| No  Yes  If yes, how many times has the DSMB or safety monitor reviewed the trial in the past 12 months?  <<INSERT how many times the DSMB or safety monitor reviewed the trial >> |

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| 7.0 REFERENCE SAFETY INFORMATION  *The reference safety information for a trial may be contained in an investigator’s brochure, product information, instructions for use or clinical investigational plan* |
| Has the investigator’s brochure (or other reference safety information) been reviewed? |
| Yes  No  N/A |
| Does the investigator’s brochure (or other reference safety information) require an update with new and relevant information? |
| Yes  No  N/A  *If changes are required to any documents approved by the HREC, complete a Modification for review by the HREC* |

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| 8.0 FINAL REPORT  *Principal Investigators are required to submit a final report when a study has been terminated early or completed.*  *For commercially/industry sponsored clinical trials: a study is considered complete once the closeout visit has been completed.*  *For La Trobe Sponsored clinical trials: a study is considered complete once the last participant has completed all follow-up and the data has been analysed.* |
| Was the Clinical Trial Completed? |
| Yes  No |
| Was the Clinical Trial terminated early due to safety issues and reported to lead HREC? |
| Yes  No |
| Will participants receive a written plain language explanation of the results? *(Please ensure you adhere to your approval protocol in terms of dissemination of results)* |
| Yes  No  N/A |

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| 9.0 DECLARATION  The Clinical Trial Annual Progress, Safety and Final report can be completed by the Sponsor, Site Principal Investigator or Coordinating Principal Investigator |
| By submitting this Clinical Trial Annual Progress, Safety and Final report, I the Sponsor/Site Principal Investigator/Coordinating Principal Investigator declare that:   * The information contained in this report is true and accurate; * This trial is being conducted in keeping with the conditions of reviewing HREC approval. |

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| 10.0 HOW TO SUBMIT THIS REPORT |
| Log in to  [PRIME Researcher portal](https://prime.latrobe.edu.au/portal/) to lodge Clinical Trial Annual Progress, Safety and Final report:   1. To find your ethics project click on “My Ethics Approvals” tile and select the Ethics Approval Number you wish to submit a Clinical Trial Annual Progress, Safety and Final report for 2. At the top of the screen click the “down” blue arrow dropdown menu and click “Create Annual Report” 3. Click the 'Post Approval Documents' tab and upload the completed Clinical Trial Annual Progress, Safety and Final report 4. In the progress bar at the top of the page, select "Review by Research Office" and then click "Mark as Current Status" to the right |