**Clinical Trial - Good Clinical Practice Serious or Suspected Breach /**

**Non-Serious Breach Report**

**WHEN TO USE THIS FORM**

* When La Trobe University is the reviewing HREC and/or the event happened at one of the La Trobe University Campuses and/or La Trobe University is the sponsor of the trial.
* A **serious breach** of **Good Clinical Practice (GCP) or the Protocol** is defined as a breach that is likely to affect to a significant degree the safety or rights of a research participant or the reliability and robustness of data generated in the research.
* A **suspected breach** is a report that is judged by the principal investigator as a possible serious breach but has yet to be formally confirmed as a serious breach by the sponsor.
* A **Non-serious breach (Deviation)** is a breach, divergence or departure from the requirements of GCP or the clinical trial protocol that does **not** have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the clinical trial

Information on reporting breaches is available in [Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods (NHMRC, 2018).](https://www.nhmrc.gov.au/sites/default/files/images/reporting-of-serious-breaches-of-good-clinical-practice.pdf)

Note: this definition is about breaches from the requirements of Good Clinical Practice or the trial protocol and differs from the definition in the *Australian Code for the Responsible Conduct of Research* (the Code). A failure to meet the principles and responsibilities set out in the Code is a breach of the Code.

|  |  |
| --- | --- |
| 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>> |
| Report Category | Serious or Suspect Breach  Non-Serious Breach |

|  |  |
| --- | --- |
| 2.0 GOOD CLINICAL PRACTICE / PROTOCOL BREACH DETAILS | |
| Date of GCP Breach/Protocol Deviation | <<INSERT DAY MONTH YEAR>> |
| Site where the GCP/Protocol Breach took place | <<INSERT site Institution>> |
| Who the GCP Breach/Protocol Deviation has been reported to | Site or Coordinating Principal Investigator/Other Site Investigators (*if applicable*)  Sponsor *(if applicable)*  Site Institution *(if applicable)*  TGA – under the CTX/CTN Scheme *(if applicable)*  HREC |
| Description of the GCP Breach/Protocol Deviation | <<INSERT describe and explain the breach, including reason/s why the breach occurred>> |
| Impact | Could the Breach significantly affect the safety or rights of participants, or the reliability and robustness of the data generated in the research trial?  Definitely  Possibly  No |
| Impact on participant safety or participant rights | <<INSERT a description of how participant safety and rights were impacted>> |
| Impact on conduct of the trial (e.g., reliability and robustness of data) | <<INSERT a description of how the breach impacts on the ethical acceptability of the trial>> |
| Impact on trial documentation | <<INSERT an explanation if the breach requires a change to the trial protocol and/or any of the approved trial documents>>>> |
| *If modifications to the approved trial documentation need to be made, submit a modification request to the HREC.*  *For immediate threats, modifications can be implemented prior to receiving written HREC approval.* | |

|  |
| --- |
| 3.0 ACTION TAKEN |
| Action  *Note the HREC may require the trial protocol to be modified as a result of the Breach.*  <<INSERT any action(s) that were taken to address the breach, including corrective and preventative steps taken to prevent the breach from occuring again>> |
| No action  <<INSERT explanation for taking no action>> |

|  |
| --- |
| 4.0 DECLARATION  The Protocol/GCP report must be completed by Principal Investigator |
| By submitting this Protocol/GCP Breach Report, I the 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; * The trial is being conducted in compliance with the NHMRC National Statement on Ethical Conduct in Human Research (2018) and Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods (2018). |

|  |
| --- |
| 5.0 HOW TO SUBMIT THIS REPORT |
| Log in to  [PRIME Researcher portal](https://prime.latrobe.edu.au/portal/) to lodge Protocol/GCP Breach report:   1. To find your ethics project click on “My Ethics Approvals” tile and select the Ethics Approval Number you wish to submit a Serious or Suspected Breach of GCP/Trial Protocol report for 2. At the top of the screen click the “down” blue arrow dropdown menu and click “Create UAE/Safety Report” 3. Click the 'Post Approval Documents' tab and upload the completed 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 |