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| |  | | --- | | Clinical Trial Annual Safety Report Form Template | |

Clinical Trial

Annual Safety Report Form

*This form should be used to provide the HREC with an annual safety report to summarise of safety events occurring in clinical trial involving the use of therapeutic goods.*

*Please upload this notification into ERM by creating a sub-form under the Ethics Project Tree. Select Jurisdiction as ‘Queensland Health’, Select ‘Safety Report Form Qld’ or email* [GCHEthics@health.qld.gov.au](mailto:GCHEthics@health.qld.gov.au) *as the lead HREC.*

Section 1 – Clinical Trial Profile

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| --- | --- |
| **Date of Report** |  |
| **HREC Project Number:** |  |
| **HREC Committee:** |  |
| **Title:** |  |
| **Sponsor:** |  |
| **Name of Coordinating Principal Investigator:** |  |
| **Type of Investigational Product(s)/Category of Therapeutic Good** | ***Please list all Investigational Product(s), category of therapeutic good and indication:*** |
| **CTN Number:** |  |
| **Phase/Stage of Clinical Trial[[1]](#footnote-1):** |  |
| **NHMRC Clinical Trial Risk Category:** | **Type A:** Risks comparable to standard medical care.  **Type B:** Risks associated with modified use of an existing product  **Type C:** Risk associated with use of an unlicensed product (an unapproved therapeutic good) |
| **List all Sites and Locations** | 1. *Gold Coast University Hospital, Gold Coast QLD Australia* 2. *Robina Hospital, Gold Coast QLD Australia* |
| **Trial Status** | **Open to recruitment**  **Recruitment complete**  **Participant Follow-Up**  **Data Analysis/Publication** |
| **Total Number of patients** | * **Screened:** * **Recruited:** * **Early withdrawal:** * **Completed treatment:** * **Target:** |
| **Trial Conduct:** | **Summarise number and nature of Protocol deviations** |
| **Total number of Safety Events Reported:** | **Adverse Events/Adverse Reactions/Adverse Device Effects:**  **Serious Adverse Events/Serious Adverse Device Effects:**  **Unexpected/Unanticipated events (ARs/SUSARs/UADEs):**  **Significant Safety Issues (SSIs)/Urgent Safety Measures (USMs):** |
| **Primary Objectives/Outcome measure/Endpoint:**    **Secondary Objectives/Outcome measure/Endpoint:** | |

Section 2 – Clinical Trial Safety Events

*\*Can be attached as a excel sheet or supporting document with similar headings Indicates Adverse Reactions, italics indicates reclassification by DSMB*

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| ADVERSE EVENT(S)/ SERIOUS ADVERSE EVENT(s)/ADVERSE DEVICE EFFECT(S)\* | | | | | | | |
| Participant Number: | **AE Term** | **Severity** | **Start date** | **Stop date** | **Event Outcome** | **Serious?** | **Related** |
| *e.g., GCH001.* | *Coughing* | *Mild* | *03/01/2020* | *04/01/2020* | *Resolved* | *N* | *N* |
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| --- |
| DEVICE DEFICIENCIES/MALFUNCTIONS |
| List all devices deficiencies and malfunctions by Participant number and provide description: |
| Suspected Unexpected Serious Adverse Reactions (SUSAR)/Unexpected Serious Adverse Device Effects (USADE) |
| List all unexpected/unanticipated events by Participant number and provide description: |
| URGENT SAFETY MEASURES (USM)/SIGNIFICANT SAFETY ISSUE (SSI) |
| Provide descriptions of all significant safety issues or urgent safety measures: |

Section 3

Safety Profile of Investigational Products

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| Description and analysis of new/relevant developmental safety findings |
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| Implications of the safety findings on the risk and benefit of the project |
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| Describe any measures, taken or proposed to minimise risk |
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Section 4

Investigators Brochure (and Other Reference Safety Information)

*The reference safety information for a research project may be contained in an investigator’s brochure, product information, instructions for use or clinical investigational plan.*

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| Has the IB or reference safety infomation been reviewed in the last 12 months? |  |
| **Does the IB reference safety infomation require an update with new and relevant information?** |  |

Safety Monitoring Plan

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| Has the safety monitoring plan been implemented or changed in the last 12 months? |  |
| **Does the project have a DSMB or alternative safety oversight committee, such as a Safety Review Committee, Dose/Escalation Committee, Trial Management Group (TMG), Trial Streeting** **Committee (TSC), Medical Monitor, Clinical Events Committee?** |  |
| **Please list the number of time and dates the DSMB/safety oversight committee reviewed the clinical trial in the past 12 months?** |  |
| **Date and status from most recent DSMB/safety oversight committee decision:** | **Continue the clinical trial.**  **Modify the clinical trial.**  **Stop the clinical trial.** |
| **Comment(s):** | |

Section 4

**Signature Declaration:**

*To be completed by the Coordinating Principal Investigator (CPI) for a multi-site project, or the Principal Investigator (PI) for a single-site project.*

*The information provided in this report is complete and correct. The project is being conducted in accordance with the National Statement on Ethical Conduct in Human Research (NHMRC, 2007 updated 2018) and Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (NHMRC, 2016), or as amended.*

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| Coordinating Principal Investigator |  |
| Organisation |  |
| Email |  |
| Contact Number |  |

1. [Pg.43 – 54. Clinical Trials Phase and Stages. Australian Clinical Trial Handbook.](https://www.tga.gov.au/sites/default/files/australian-clinical-trial-handbook.pdf) [↑](#footnote-ref-1)