POLICYI004 ADVERSE EVENT AND SAFETY REPORTS

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PURPOSE

To outline the requirements for adverse event and safety reporting.

POLICY

Bellberry follows the requirements of the National Statement on Ethical Conduct in Human Research (2007 incorporating all updates) and the NHMRC Guidance on safety monitoring and reporting in clinical trials involving therapeutic goods (November 2016), in relation to adverse event reporting for clinical trials.

In line with ICH GCP and ISO 14155 the NHMRC guidelines place the responsibility for the ongoing safety evaluation of the investigational product with the sponsor. To ensure that there is appropriate independent oversight of safety within a clinical trial, sponsors should generally utilise an independent committee or independent individuals to review accruing safety data.

It is the outcome of these reviews that are required to be provided to the HRECs, investigators, institutions and the Therapeutic Goods Administration (TGA).

Sponsors evaluate all safety information from the investigators and other sources, and are responsible for generating the safety communications. The communication of the safety information to investigators and HRECs also needs to include any clarification of the impact of each report on participant safety, trial conduct or trial documentation.

The reporting requirements for the HREC are as follows:

- Individual serious adverse events/reactions, suspected unexpected serious adverse reactions, or unanticipated serious adverse device reactions that occur at a Bellberry approved site, and are considered to be related to the study, are required to be submitted to the Bellberry HREC.
  A report of the action taken by the Investigator for the welfare of the affected participant(s), along with outcomes of the sponsor's analysis should be provided.
- Any other individual adverse events, serious adverse events, suspected unexpected serious adverse reactions, or unanticipated serious adverse device reactions occurring at a non-Bellberry site are not required to be submitted to the HREC. An outcome of the sponsor's analysis should be provided.
- Any Significant Safety Issue is required to be reported to the TGA, Investigator and HREC in accordance with the NHMRC Guidance.
- Six monthly line listings are not required to be submitted to the HREC, but an outcome of the sponsor's analysis provided.
- Annual Reports are required to be submitted to the HREC including a clear summary of the evolving safety profile of the trial.
- Outcomes of the sponsor's analysis can be provided in the annual report.

Sponsors report directly to the HREC and Investigators, but also have the flexibility to delegate reporting responsibilities. Sponsors need to ensure that responsibilities for safety monitoring and reporting are appropriately allocated and delegated.

Bellberry requires that all applications, including safety reporting, be submitted through eProtocol by the Investigator (or delegate). This will continue to meet the reporting requirements, and also ensure that all study related documents are recorded, reviewed, and acknowledged within the eProtocol system to maintain the full history of the study. This will also allow any communication required from the HREC to be directed to the Investigator in line with the National Statement.

The responsible organisation must develop clear guidance for investigators, detailing the requirements for safety reporting and monitoring clinical trials.

Please refer to the NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods https://www.nhmrc.gov.au/ for further information.

FLOW CHART FOR ADVERSE EVENT REPORTING TO BELLBERRY HREC

For Human Research Ethics Committees to be able to protect the safety of clinical trial participants, sufficient information about adverse events must be provided in context.

Supplying this information is a condition of ethical approval.

Adverse Event (AE)	Any untoward medical occurrence in a patient or clinical trial participant administered a medicinal product and that does not necessarily have a causal relationship with the treatment. These may be expected (defined in the Investigator Brochure).
Adverse Reaction (AR)	Any untoward and unintended response to an investigational medicinal product related to any dose administered.
Serious Adverse Event (SAE) Serious Adverse Reaction (SAR)	An event/reaction that: ❖ results in death ❖ is life threatening ❖ requires hospitalisation/prolongation of existing hospitalisation ❖ results in persistent or significant disability or incapacity ❖ is a congenital anomaly or birth defect.
Unexpected Adverse Reaction (UAR)	An adverse reaction, the nature or severity of which is not consistent with the Reference Safety Information (as contained in the current Investigator Brochure/Product Information)
Serious, Unexpected, Suspected Adverse Reaction (SUSAR)	An adverse reaction that is both serious and unexpected.
Unanticipated Serious Adverse Device Effect (USADE)	Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

Acknowledgment to: NHMRC Safety Monitoring and reporting in clinical trials involving therapeutic goods guidance

- Sponsors are responsible for evaluating all safety information.
- Those reports to be submitted must be via eProtocol using the Adverse Event/Safety Report form available through the Bellberry website (individual event or summary of events). Reports must be submitted by the Principal Investigator (or delegate), not by the Sponsor directly.
- Any questions or requests for clarification will be sent back to the Principal Investigator.

The Adverse Events Flowchart summarises the reporting requirements.