Standard Operating Procedures

5.17 Adverse Event Reporting

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Introduction / Background

Good Clinical Practice clarifies the responsibilities of research sponsors and investigators with regards to research related adverse events in an attempt to forestall adverse events and to ensure when they occur that systems are in place to accurately report, record, and investigate them.

It is important to record adverse events for both Investigational drug and non-drug studies (such as trials that involve surgery, radiotherapy or are observational).

Objective

This SOP describes the procedure by which adverse and serious adverse events are recorded, reported and evaluated as required by Hospital Research Ethics Committees (HRECs) and the International Conference on Harmonisation of Good Clinical Practice (ICH GCP) guidelines.

Scope

This SOP is to be used for any study where adverse and serious adverse events are to be reported. It applies to all staff involved in clinical studies conducted by PaCCSC irrespective of individual organisational employment, role or position.

Ownership and Responsibility

All staff in contact with participants are responsible for noting adverse and serious adverse events that are reported by the participant or observed, and making them known to the study team caring for the participant in a particular study.

It is the responsibility of the Principal Investigator to ensure that all adverse and serious adverse events are accurately assessed and recorded. While this task can be delegated to other suitably trained study member and should be recorded in the Staff Signature and Delegation Log (*refer* SOP 4.2.4 Delegation of Duties), overall supervision and responsibility remains with the Principal Investigator.

Procedure

1. Identification of possible adverse events

- At each assessment and/or visit the participant should be assessed for the following:
  1) Have there been any problems since the last assessment?
  2) Have there been any new medications, or changes to other medications?
- If the answer is "yes" to either of those two questions, further assessment is needed to determine if the change constitutes an adverse event.
- In addition, each protocol may specify specific symptoms that need to be assessed.

2. Assessing the severity of adverse events

- All problems/symptoms that meet the criteria of an adverse event are to be assessed using the NCI CTCAE criteria.
- The severity is to be a grade between 1 and 5.
- All adverse events are to be discussed with the Principal Investigator.

3. Recording adverse events

- All adverse events are to be fully recorded in the patient clinical record and within the study specific Adverse Event Form or Case Report Form.
- All adverse events are to be followed to resolution.
- All adverse events are to be clearly recorded within the participant's medical record.

4. Assessing the seriousness of adverse events

- All adverse events must be assessed to determine if the event also meets the criteria of a serious adverse event.
- This will be a "yes" or "no" response on the Adverse Event Form or Case Report Form.

5. Recording serious adverse events

- If an adverse event is determined to be a Serious Adverse Event (SAE), the details are to be recorded on a Serious Adverse Event Form.
- The SAE is also to be entered into the database within 24 hours of becoming aware of the event.
  - Once entered, the PaCCSC Coordinating Centre will check the SAE report and seek clarification when required. The SAE will be reported to HREC if indicated by the initial assessment (as outlined above), and in accordance with the approving HREC requirements, and will also be reported to:
    - The Trials Management Committee and the Management Advisory Board
    - The Data Safety Monitoring Committee/Medical Monitor
    - The regulatory authorities when the adverse events are both **serious and unexpected drug reactions OR serious and expected drug reactions** or when the SAE may affect the conduct of the trial, the safety of the participants or their willingness to continue participation in the trial using the standard form for Adverse Drug Reactions Advisory Committee (ADRAC) by the PaCCSC National Manager only.

- The requirements of the approving HREC and local research governance office are to be followed **at all times**.

6. Follow-up of serious adverse events

- The serious adverse event is to be followed up to resolution, death, or where further information is no longer possible to obtain.

Other related SOPs

4.2.4 Delegation of Duties
5.5.5 Allocation of Participant ID Number
5.5.1 Electronic Data Handling
5.17.1 Medical Monitor
6.0 Protocol Development
8.0 Essential Documents

Other related documents

Template 14: Adverse Event Form

References

Australian guideline for pharmacovigilence responsibilities of sponsors of registered medicines regulated by drug safety and evaluation branch. 2003, Department of Health and Ageing, Therapeutic Goods Administration. Amended 31 Mar 2005.

Cancer Therapy Evaluation Program, Common Terminology Criteria for Adverse Events, V4.0, DCTD, NCI, NIH, DHHS, May 28, 2009.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). November 2016 (accessed 23/10/2017)
https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf

National Statement on Ethical Conduct in Human Research (2007) - Updated March 2014 - (accessed 19/10/2017) http://www.nhmrc.gov.au/guidelines-publications/e72

Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting. 2000 (accessed 12/11/2017)
https://www.tga.gov.au/sites/default/files/ich37795.pdf

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95). Annotated with TGA comments 2000 (accessed 17/10/2017)
https://www.tga.gov.au/sites/default/files/ich13595an.pdf

Acknowledgments

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History			
Version	Date	Author	Reason
1.1	10/01/2006	Contributing authors	New procedure
1.2	25/02/2007	S Whicker	Administrative update
1.3	11/07/2007	B Fazekas	Update prior to MAB review
1.4	18/08/2007	B Fazekas	Changes ratified by MAB and external review
1.5	16/10/2007	B Fazekas	Update after David Currow review
1.6	21/01/2008	B Fazekas	Administrative update following new reference material
1.7	9/09/2010	B Fazekas, T Shelby-James	Periodic review
2.0	3/02/2011	B Fazekas	Changes ratified by MAB
2.1	19/05/2015	C Hope	Periodic review
2.2	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)

Approval		
Version	Approval Name	Approval Signature
2.2	David Currow	