Documenting & Reporting Adverse Events

Behavioural and Situational Research Group
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Amendment History

Version	Date	Author/s	Amendment Details
2	19/11/15	Gudrun Wells	Edited reporting requirements in line with TGA recommendations.
3	25/5/2016	Gudrun Wells	Edited reporting requirements in line with changed NHMRC position statement.
4	14/09/2017	Gudrun Wells	Reviewed.

Purpose:

In the case of an adverse event (AE), serious adverse event (SAE) or suspected unexpected serious adverse reactions (SUSARs), the following operating procedure should be completed. This document outlines the procedure for reporting events to the University of Tasmania Health and Medical Human Research Ethics Committee (H&MHREC). Additional reporting (e.g., to the study sponsor) may be required for some studies; study specific protocol requirements will supersede those detailed here.

Responsibility:

All staff involved in collecting data from participants should be aware of the following protocol for documenting and reporting events. The CI is responsible for delegating and training staff in how to document and report AE/SAE/SUSAR's (as recorded in the Delegation Log and Training Log).

Scope:

This document outlines the protocol for documenting and reporting adverse events in study participants to the H&MHREC.

Materials:

- Study Specific Adverse Events Log

Procedure:

Once an AE has been identified, the first step is to determine the level of seriousness of the AE (see Glossary for definitions of AEs, SAEs and SUSARs). The determination of the seriousness of the event should be made by the Chief Investigator of the study, or an adequately trained study staff member to whom the Chief Investigator has delegated this responsibility (as recorded in the Delegation and Training Logs).

1. **Non-serious AEs**
    a. AEs should be noted and recorded in the Adverse Events Log specific to study. Information about the event will be elicited as per the study protocol. It may include:
        i. A patient identifier (such as initials, date of birth)
        ii. Contact details for the reporter (name, address, phone number)
        iii. A description of the event
        iv. Medicines suspected of causing the event
        v. Any other medicines the patient was taking
        vi. Date of onset of the adverse event
        vii. Date of starting and stopping the suspected medicines
        viii. Date of starting and stopping any other medicines
        ix. Details of how the adverse event was treated
        x. The outcome of the event, and the date of the outcome.
    b. AE reports should be collated and included in the study specific Annual Report to the H&MHREC.
    c. If the study has a Data Safety Monitoring Board (DSMB): AEs should be collated and reported at each meeting.
2. **SAEs and SUSARs**
    a. SAEs and SUSARs should be noted and recorded in the Adverse Events Log specific to study. Information about the event will be elicited as per the study protocol. It may include:
        i. A patient identifier (such as initials, date of birth)
        ii. Contact details for the reporter (name, address, phone number)
        iii. A description of the event
        iv. Medicines suspected of causing the event
        v. Any other medicines the patient was taking
        vi. Date of onset of the adverse event
        vii. Date of starting and stopping the suspected medicines
        viii. Date of starting and stopping any other medicines
        ix. Details of how the adverse event was treated
        x. The outcome of the event, and the date of the outcome.
    b. The Chief Investigator of the study should be notified immediately if an SAE or SUSAR is reported.
    c. <u>SAEs and SUSARs need to be reported to the study sponsor, if applicable, within 24hrs of becoming aware of the event</u>.

d. SAEs and SUSARs need to be reported to the Tasmanian Health and Medical HREC within 72hrs of the CI becoming aware of the event. To do this:
    i. Email the secretary of the H&MHREC (human.ethics@utas.edu.au) and request a SAE reporting form.
e. If the study has a DSMB: SAEs should be report to the chair of the DSMB immediately.

Glossary:

Adverse Event (AE): An AE is defined as an untoward medical occurrence in a study participant administered a medicinal product and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

Serious Adverse Event (SAE): A SAE is defined as any untoward medical occurrence in a study participant that at any dose:

1) results in death,
2) is life-threatening,
3) requires inpatient hospitalisation or causes prolongation of existing hospitalisation,
4) results in persistent or significant disability/incapacity,
5) is a congenital anomaly/birth defect, or
6) requires intervention to prevent permanent impairment or damage.

Suspected Unexpected Serious Adverse Reactions (SUSARs): A SUSAR is defined as an adverse reaction that is both serious and unexpected (the severity of the reaction was not consistence with the Reference Safety Information contained in the Investigators Brochure or Production Information).

Data Safety Management Board (DSMB): Larger trials often use a Data and Safety Monitoring Board (DSMB) that monitors the trial. While the trial is in progress the DSMB will meet regularly to monitor the progress of the trial and make recommendations about whether the trial should continue, continue with some changes or be stopped. Typically the DSMB will report to the project steering committee, but can also report directly to the study ethics committee for any important results.

TGA: Therapeutic Goods Administration.

References:

National Statement on Ethical Conduct in Human Research 2007 (Updated May 2015). The National Health and Medical Research Council, the Australian Research

Council and the Australian Vice-Chancellors' Committee. Commonwealth of Australia, Canberra

NHMRC Australian Health Ethics Committee (AHEC) Position Statement, Draft prepared for public consultation, April 2016.

https://www.tga.gov.au/reporting-medicine-and-vaccine-adverse-events
Reporting medicine and vaccine adverse events. Therapeutic Goods Administration's requirements for reporting adverse events. Accessed 19/11/15.