Reporting Protocol Deviations

Behavioural and Situational Research Group
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Amendment History

Version	Date	Author/s	Amendment Details
2	14/09/2017	Gudrun Wells	Reviewed

Purpose:

To outline the steps to be taken should there be deviations from the approved study protocol, and to define what these might be.

Responsibility/Scope:

It is the responsibility of the Chief Investigator to ensure that all research projects follow the approved study protocol. If there are any deviations from this approved protocol, they must be reported to the H&M HREC as detailed below. This SOP details how to report protocol deviations.

Materials:

- Protocol Deviation Form (to be obtained from human.ethics@utas.edu.au)

Procedure:

It is the responsibility of the Chief Investigator to ensure that all protocol deviations that occur at sites for which UTAS is responsible are reported to the Tasmanian Health and Medical HREC as soon is as practicable using the Protocol Deviation Report Form obtained from the Tasmanian Health and Medical HREC. Protocol deviations from other sites do not need to be reported, unless the deviation results in a change to the protocol. In this case the Tasmanian Health and Medical HREC would be expected to be notified via the submission of an amendment. The protocol deviation report form can be completed electronically and submitted via email to human.ethics@utas.edu.au or the named recipient on the Protocol Deviation Form. This form needs to be signed by the Chief Investigator. Once the report has been received it will be submitted to the Tasmania Health and Medical HREC for review. Following this an acknowledgment of receipt will

be issued. If applicable, this receipt and a copy of the report should be submitted to the study sponsor.

The Chief Investigator is to keep a log of all protocol deviations, and report these to the trial sponsor, if required by study specific trial protocols.

Glossary:

Protocol: Means the document submitted that outlines the research procedures. This may be the version submitted with the original application or subsequent versions as approved by the Committee. This includes the protocol summary, any summary of changes documents, participant information sheet and consent forms, any recruitment materials, questionnaires and any other information/documents relating to the project.

Protocol Deviation: Means any activity that occurs, at a BSRG site, which does not conform to the procedures set out in the protocol. This includes but is not limited to the following:

1. Use of unapproved recruitment procedures;
2. Randomisation of an ineligible participant;
3. Use of an unapproved version of the patient information sheet and consent form;
4. Visit non-compliance (for example a study visit is conducted outside of the required timeframe or a participant monitoring visit is missed);
5. Incorrect execution of the consent form (for example consent form was signed by a person other than the Chief Investigator or Co-Investigator or the participant).

References:

University of Tasmania Protocol Deviations Guidance Notes:
http://www.utas.edu.au/__data/assets/pdf_file/0018/113535/Protocol-Deviations-Guidance-Notes.pdf