

Protocol Deviations Guidance Notes December 2010

It is the responsibility of the Chief Investigator to ensure that all research projects are conducted in accordance with the terms set out in the application approval letter, any subsequent amendment approval letters and in accordance with the *National Statement on the Ethical Conduct Human Research* (NHMRC 2007). Any activity that occurs that does not confirm to what has been approved by the Human Research Ethics Committee (Tasmania) Network (the 'Committee') should be reported. In particular protocol deviations should be reported as follows.

Definitions

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 your site, which does not conform to the procedures set out in the protocol. This includes but is not limited to the following:

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

Reporting requirements

It is the responsibility of the Chief Investigator to ensure that all protocol deviations that occur at your site are reported to the Committee as soon as is practicable using the [Protocol Deviation Report Form](#). We do not require protocol deviations that occur at other Australian or international sites to be reported to us, unless the deviation results in a change to the protocol, in which case we 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. A signed hard copy must be received before acknowledgment will be issued. Once the report has been received it will be submitted to the Tasmania Health and Medical Human Research Ethics Committee 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.

Please note

If any changes to the project/protocol are required following the protocol deviation, an [amendment](#) should be submitted.