Informed Consent Procedures

Behavioural and Situational Research Group
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Amendment History

Version	Date	Author/s	Amendment Details
2	19/11/15	Gudrun Wells	Changes to point 1 of Procedure.
3	14/09/2017	Gudrun Wells	Reviewed

Purpose & Scope:

This SOP outlines protocols relating to obtaining informed consent from study participants.

Responsibility:

This standard applies to all staff, students, visiting professionals, consultants and volunteers working with the BSRG. The Chief Investigator is responsible for delegating and training staff in collecting informed consent (as recorded in the Delegation and Training Logs).

Materials:

- Informed Consent Form
- Study Information Sheet

Procedure:

Informed consent forms must be consistent with the guidelines outlined in *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA Comments, 2000*. Informed Consent Forms, and Study Information Sheets must be approved by the H&MREC for every BSRG study *before* the study commences. Once these documents have been approved by the H&MREC for a new study, changes cannot be made to the forms (or to the study) without updated approval by the H&MREC.

In order to gain informed consent from a new participant, the following steps should be followed:

1. **Explain the study:** The staff member should explain the study in detail, particularly how involvement in the study may affect the participant (possibly including, but not limited to: impacts on their health, expected time commitment, and reimbursement schedules) and how the information from the study will be used. Note the following:
    a. The staff member may not coerce or unduly influence a subject to participate or continue to participate in a study;
    b. None of the oral and written information concerning the study, including the written informed consent form, should contain any language that causes the subject or the subject's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence;
    c. The language used in the oral and written information about the study, including the written informed consent form, should be as nontechnical as practical and should be understandable both the subject or the subject's legally acceptable representative and impartial witness when applicable;
    d. If required by the study, an interpreter will be made available.
2. **Study information sheet:** Participants should be provided with the information sheet (where possible, both before and at the enrolment interview) and given ample time to read it;
3. **Questions:** Participants should be encouraged to ask questions to make sure that they understand the details of the study;
4. **Informed Consent Form:** The Informed Consent form should then be provided and explained to the participant (or their legal representative) before they are asked to sign the form;
5. **Obtain signatures:** The Informed Consent Form must be signed and dated by both the participant (or their legal representative) and the staff member conducting the informed consent interview who acts as a witness to the participant's signature.

Participants are to be given a signed copy of the Informed Consent Form for their records. Signed Informed Consent Forms are to be held in a secure location for as long as all other study related information.

Glossary:

Informed Consent A process by which a participant voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

International Conference on Harmonisation (ICH) International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use is a joint initiative involving both regulators and research-based industry focusing on the technical requirements for medicinal products containing new drugs.

Good Clinical Practice (GCP) A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

Human and Medical Research Ethics Committee (H&MREC) This committee has responsibility for the review of all health and medical research projects involving human participation that are undertaken by researchers of the University of Tasmania and through agreement, the Department of Health and Human Services and external researchers who are not affiliated with these organisations.

References:

International Conference on Harmonisation of Good Clinical Practice: http://ichgcp.net/

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

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with Therapeutic Goods Association Comments, 2000