SDRN: Scottish Diabetes Research Network

Obtaining Informed Consent

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DOCUMENT HISTORY

Version number	Detail of purpose / change	Author / edited by	Date edited
1.0	New SOP	Gill Reekie	
2.0	Supplementary information included on Informed Consent.	Louise Greig	June 2012

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1. Introduction

ICH GCP states that "systems with procedures that assure the quality of every aspect of the trial should be implemented." This SOP details the procedure that should be used in obtaining informed consent during a clinical trial.

2. Background

ICH GCP (1997) guidelines 1.28 define informed consent as follows –
"A process by which a subject voluntary 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 subject's decision to participate. Informed consent is documented by means of a written, signed and dated consent form."

This SOP was developed to ensure that the process for gaining informed consent is standardised throughout all studies adopted by the SDRN and adheres to ICH GCP (1997) guidelines.

3. Procedures

- Potential study subjects are identified via various recruitment methods.
- These potential subjects are contacted/approached by the study doctor or research nurse.
- The study is discussed and the potential subject given a Patient Information Sheet and a screening or pre-screening appointment is made.
- This appointment should occur at least 3 days after the patient has received the Patient Information Sheet. This is to ensure that the patient has adequate time to consider his or her decision to participate in the study.
- At the screening/pre-screening visit the person taking the informed consent will fully review the patient information sheet with the patient or if he or she is not able to give informed consent his or her legally acceptable representative.
- Any questions will be answered fully.
- None of the trial staff should coerce or unduly influence the patient to take part in the trial.
- The informed consent form should be signed and personally dated be the patient or the patients legally acceptable representative and by the person conducting the informed consent discussion. This should occur before any trial procedures take place.

ICH GCP 4.8.5 state that "The investigator, or a person designated by the investigator should fully inform the subject ……..."

ICH GCP 4.8.9 state that "the consent form should be signed by the person who conducted the informed consent discussion……..."

- Most commercially sponsored trials have a protocol requirement that an investigator should take and sign for the informed consent. However, it is acceptable for another member of the study team to fully discuss the purpose and procedures of the research.

- Study participants should receive a copy of the informed consent form they signed. (Either ask the study participant to sign two copies of the consent form or photocopy the original and give the photocopied version to the participant)

- A copy of the signed informed consent form must be placed in the participant"s medical notes and the original kept by the study team.

- The informed consent process should not end once the informed consent form has been signed. The practice of giving information about the study to participants should be an ongoing process performed by all members of the research team. This is particularly important if protocol amendments are introduced, or if important new information that may be relevant to the participant"s willingness to continue taking part in the study is discovered. In these circumstances it may be necessary to re-consent the participant using an amended consent form, to continue their involvement in the study.

4. Special Cases

- When a clinical trial includes subjects who can only be enrolled with the consent of a legally acceptable representative (e.g. minors or patients with severe dementia) the subject should be informed about the trial to the extent compatible with the subjects understanding and, if possible the subject should sign and personally date the written informed consent.

- In emergency situations where prior consent of the subject is not possible, the consent of the subject's legally acceptable representative, it present, should be requested. If this is not possible enrollement is still possible if procedures are documented and approved by the IRB/IEC. The subject or his/her legally acceptable representative should be informed of the trial as soon as possible and consent to continue taken as appropriate.

5. Verification of informed consent

- The signed and dated informed consent forms must be available for review by the sponsor company representatives for data verification purposes or audit.

The above procedure will ensure that all subjects enrolled to clinical trials within the SDRN have given fully informed consent to their participation in the trial and thus satisfy the ICH GCP (1997) guidelines and that all documentation is stored correctly.