Informed Consent Procedures and Writing Participant Informed Consent Forms

Standard Operating Procedure

Office of Health and Medical Research

Queensland Health

SOP reference:	**006**
Version number:	1
Effective date:	01 June 2010
Review due:	May 2011
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Amendment History

Version	Date	Author/s	Amendment Details

1 Purpose

To describe the procedures related to informed consent procedures and writing Participant Informed Consent (PIC) forms.

2 Responsibility / Scope

This standard applies to all Queensland Health employees (including visiting medical officers, visiting health professionals, contractors, consultants and volunteers) who propose to undertake, administrate, review and/or govern human research involving Queensland Health patients and staff.

3 Applicability

Principal Investigator, Associate/Sub Investigator(s), Research Coordinators and other staff delegated trial-related activities by the Principal Investigator.

4 Procedure

4.1 Informed consent procedures

The investigator(s) should:

- Comply with local HREC requirements, NHMRC National Statement on Ethical Conduct in Human Research (2007) and other applicable regulatory requirement(s), and adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. **ICH GCP 4.8.1**
- Obtain the authorising HREC's written approval/favourable opinion of the written informed consent form and any other written information to be provided to research participants prior to the beginning of the trial.
- Ensure that the written informed consent form and any other written information to be provided to research participants is revised whenever important new information becomes available that may be relevant to the research participant's consent or willingness to continue participation in the project. The communication of this information should be documented. **ICH GCP 4.8.2**
- Determine, according to level of risk to participants, who of the study team is appropriate to lead the participant informed consent process. This should be documented on the "Delegation of Duties" log. **ICH GCP 5.7; QH RUG**
- The footer details to be updated with each modification of the Information Sheet and Consent form.
- Obtain the HREC's approval/favourable opinion in advance of use for any revised written informed consent form, and written information. **ICH GCP 4.8.2**
- Ensure that all currently enrolled study participants are re-consented when a new version of the informed consent form is approved. **ICH GCP 4.8.11**
- Ensure the person or persons taking the informed consent have an adequate understanding of the project and of the informed consent process. **ICH GCP 4.8.6**
- Not, nor permit, trial staff to coerce or unduly influence potential participants to enrol or to continue participation in a research project. **ICH GCP 4.8.3**
- Ensure that any of the oral and written information concerning the project, including the written informed consent form, is written in layman's terms, and generally, to the

level of comprehension of a thirteen (13) year old (grade 8 standard). **ICH GCP 4.8.6; QH RUG**

- Ensure that oral and written information concerning the project does not contain any language that causes the participant or the participant's legally authorised 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. **ICH GCP 4.8.4**
- (Or a person designated by the investigator), fully inform the participant or, if the participant is unable to provide informed consent, their legally authorised representative, of all pertinent aspects of the trial including the written information and the approval/ favourable opinion by the HREC. **ICH GCP 4.8.5**
- Ensure that before informed consent is obtained, they, or a person designated by the investigator, provide the participant or their legally authorised representative ample time and opportunity to inquire about details of the project and to decide whether or not to participate in the research. All questions about the study should be answered to the satisfaction of the participant or their legally authorised representative. **ICH GCP 4.8.7**
- Ensure prior to a person's participation in the project, that the written informed consent form is *personally signed and dated* by the participant or by their legally authorised representative, and by the person who conducted the informed consent discussion. **ICH GCP 4.8.8**
- Ensure if a participant is unable to read or if their legally authorised representative is unable to read, that an impartial witness be present during the entire informed consent discussion, and that discussion be held in an appropriate language. **ICH GCP 4.8.9**
- There is no requirement for a witness to the consent process, except as indicated in **GCP 4.8.9**.
- Ensure that after the written informed consent form and any other written information to be provided to participants, has been read and explained to the participant or their legally authorised representative, and after the participant (if deemed mentally competent) or their legally authorised representative has orally consented to the participant's participation in the trial and, if capable of doing so, has personally signed and dated the informed consent form, the witness (if required as per **GCP 4.8.9**) should personally sign and date the consent form. In this instance, the witness is confirming that the process of obtaining informed consent has been correctly followed.
- Ensure that the study participant or their legally authorised representative is given a copy of the signed informed consent form, and any other written information provided to the participants. **ICH GCP 4.8.11**

The investigator(s) should ensure:

- That when conducting trials in patients having a disease or condition for which the investigational product is intended, that the participants in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.
- That in emergency situations, when prior consent of the participant is not possible, the consent of the participant's legally authorised representative, is requested. In this instance, if the participant's legally authorised representative is not available, provided that the research project has been reviewed and approved by the HREC and authorisation to commence enrolment has been received at the site, consent for

enrolment should be sought from the Statutory Health Attorney at Queensland Civil and Administrative Tribunal (QCAT). **ICH GCP 4.8.15** http://www.qcat.qld.gov.au/.

- In the above instance, the participant or the participant's legally authorised representative is informed about the trial as soon as possible and consent to continue and other consent as appropriate must be sought.

Please refer to the ***National Statement on Ethical Conduct in Human Research, 2007*** for details on obtaining consent in special cases.

4.2 Writing Participant Informed Consent forms ICH GCP 4.8.10

The investigator(s) should:

- Ensure the written informed consent form and any other written information provided to project participants includes explanations of the following:
  a. That the trial involves research – which may include experimental treatments.
  b. The purpose of the project.
  c. If a clinical trial, the trial treatment(s) and the probability for random assignment to each treatment.
  d. The project procedures to be followed, including all invasive procedures.
  e. The participant's responsibilities.
  f. Those aspects of the project that are experimental (see dot point "a"_.
  g. The reasonably foreseeable risks or inconveniences to the participants and, when applicable, to an embryo, foetus, or nursing infant.
  h. The reasonably expected benefits. When there is no intended clinical benefit to the participants, they should be made aware of this.
  i. The alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks.
  j. The compensation and/or treatment available to participants in the event of project related injury.
  k. The anticipated prorated payment, or coverage of expenses, if any, to the participants for participating in the project.
  l. The anticipated expenses, if any, to participants for participating in the trial.
  m. That participation in the project is voluntary and that participants may refuse to participate or may withdraw from the project, at any time, without penalty or loss of benefits to which they would otherwise be entitled.
  n. That the monitor(s), the auditor(s), the HREC / Governance Office, and the regulatory authority(ies) will be granted direct access to the participant's original medical records for verification of project procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's legally authorised representative is authorizing such access.
  o. Those records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the study are published, the participant's identity will remain confidential.
  p. That the participant or the participant's legally authorised representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue involvement in the study.

q. The person(s) to contact for further information regarding the project and the rights of study participants, and whom to contact in the event of project-related injury.

r. The foreseeable circumstances and/or reasons under which the participant's involvement in the project may be terminated.

s. The expected duration of the participant's involvement in the project.

t. The approximate number of participants involved in the study.

4.3. Training Records

The investigator(s) should:

- Ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions. **ICH GCP 4.2.4**
- Should ensure that all study staff are aware of their professional scope of practice, and operate within that scope.
- Ensure that documentation of this training be kept current and available for review on request. **ICH GCP 8.2.10**

5 Glossary

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.

Governance Office/r

The Office or coordinated function within a Public Health Organisation which is responsible for assessing the site-specific aspects of research applications, make a recommendation to the District CEO / delegate as to whether a research project should be granted authorisation at that site, and overseeing that authorised research at the site meets appropriate standards (research governance).

Human Research Ethics Committee (HREC)

A body which reviews research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines.

The National Statement requires that all research proposals involving human participants be reviewed and approved by an HREC and sets out the requirements for the composition of an HREC.

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.

Investigator

An individual responsible for the conduct of a clinical trial at a trial site and ensures that it complies with GCP guidelines. If a trial is conducted by a team of individuals at a trial site, one investigator should be designated as the responsible leader of the team and should be called the site Principal Investigator. In this instance they may delegate tasks to other team members.

Protocol

A document that describes the objective(s), design, methodology, statistical considerations and organization of a trial.

QCAT

Queensland Civil and Administrative Tribunal (http://www.qcat.qld.gov.au/). An independent body established by the Guardianship and Administration Act 2000 to appoint decision makers to protect the rights of adults with impaired decision-making capacity. Impaired decision making capacity can be as a result of an intellectual or psychiatric disability, an acquired brain injury, an illness such as dementia or a combination of these.

Sub / Associate Investigator

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows, clinical research coordinators. The P.I. will designate who will be nominated as Associate Investigators for that site.

6 References

1. Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, July 2000, sections 4.
2. National Statement on Ethical Conduct in Human Research, (2007).