SOP Number: 90

SOP Title: Participant Informed Consent Process and Documentation

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Amendment History

Version	Date	Author/s	Amendment Details
1.0	1 June 2010	Katrina Brosnan	New
2.0	December 2017	Roberta Lusa &Bernadette Morris-Smith,	All sections, incorporating ICH GCP E6 (R2) and teletrials: QH TELETRIAL PILOT VERSION 1.0
3.0	June 2018	Roberta Lusa	All sections, refinement after CRC input: PUBLIC RELEASE VERSION 3.0
4.0	April 2019	Roberta Lusa	Amendments post Round 1 Health Service Directive Consultatio.

1 Purpose

To describe procedures and documentation management relevant to the Informed Consent process, including consenting via telehealth.

2 Responsibility / Scope

This standard applies to all Queensland Health employees (including visiting health professionals, contractors, consultants and volunteers) who propose to undertake, administrate, review and/or govern human research involving Queensland Health patients and staff. All study personnel involved in the clinical study must operate within their scope of practice.

The use of e-signatures in the consent process in Queensland Health is currently being reviewed by the department. Therefore, until a final position is adopted by the department, the consent form must be signed by hand and in ink by both parties (wet signature).

3 Glossary

For an explanation of acronyms and the definition of terms used in these SOPs, please refer to Chapter Two: Glossary of the Australian ICH GCP (including Teletrials) Standard Operating Procedures (SOP) Compendium.

For the purposes of this SOP, the term ‘authorised substitute decision-maker ‘has the same meaning as the term ‘legally authorised representative’.

4 Procedure

4.1. Informed Consent Process

- In obtaining and documenting Informed Consent, the investigator must comply with the NHMRC National Statement, Chapter 2.2 and adhere to ICH GCP E6 (R2) 4.8
- The principles of the Declaration of Helsinki inform the ethical principles of the National Statement. However, the National Statement is the primary statement on ethical principles related to human research in Australia.

- Obtaining Informed Consent from any Participant is the responsibility of the Principal Investigator including consent from Participants from each site under the responsibility of the Principal Investigator.
- Obtaining Informed Consent maybe delegated to an appropriately qualified medical practitioner as described in SOP 30.
- The Investigator must be in possession of both, the written approval from the relevant HREC and written authorisation from the local research governance office/r for:

  a) the Informed Consent form

  b) any other information to be provided to the Participant, and

  c) the Informed Consent process

  before these documents may be used to obtain consent from any Participant.

- When changes have been made to a HREC approved Informed Consent, the Investigator must have the relevant HREC's written approval (and if needed the written authorisation from the local research governance office/r) of the amended Informed Consent before it may be used to obtain consent from any Participant.
- The Study Coordinator or other appropriately qualified person may initiate the process, and discuss the intricacies of the clinical trial. However, all medical questions must be answered by and final consent signing must be carried out by the Investigator. This final step cannot be undertaken by anyone who is not a medical practitioner (or dentist if applicable).
- The manner in which Informed Consent will be obtained i.e. in person or via telehealth, is to be clearly documented in the HREC application and the Participant Information and Consent Form (PICF) and clearly described to the Sponsor and in other documents where this information is pertinent to the conduct of the clinical trial e.g. Participant's medical record, Source document. With telehealth, all measures will be taken to ensure privacy and confidentiality of the Participant's identity, as described in the Teletrial Clinical Consultation Manual.
- A description of how study procedures, visits, assessments, collection of data and medical consultations will be undertaken e.g. they may be conducted in person or via telehealth or a combination of both, are to be clearly detailed in the

HREC application and the PICF and clearly described to the Participant during the consent process.

- If Informed Consent is obtained by telehealth consultation, all persons who are not known to each other must produce photographic identification to the other person to ensure verification of each person's identity and to confirm the identity of the Participant who is giving valid consent.
- If Informed Consent is obtained by telephone, this must be recorded on the Informed Consent form and in the Participant's medical record, and/or Source document, stating (as an example):

  "The protocol was discussed with [Participant's name] via telephone on [DD/MMM/YYYY]. I received the Participant's signed consent form on [DDMMMYYYY]."

  The Investigator must then sign the consent form on the date they **received** the consent form NOT the date they **obtained** consent from the Participant.

4.1.2 Research involving Participants who are unable to give consent

The investigator must ensure that, in addition to ICH GCP E6 (R2) 4.8.15 and NHMRC National Statement, Chapter 2.2. the following is taken into consideration in Queensland.

The Declaration of Helsinki states that research involving Participants who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving Informed Consent is a necessary characteristic of the research group. In other words, in these cases, the study must be relevant to the physical or mental condition of the Participant that prevents them from being able to consent to participate in the study.

Where an adult is unable to give consent to participate in a study, once the Investigator has received HREC approval, the Investigator may apply under the Guardianship and Administration Act 2000 (Qld) to the Queensland Civil and Administrative Tribunal (QCAT) to obtain consent for the adult to be a Participant in 'special medical research' or 'experimental health care' – provided the criteria described in section 72 of the *Guardianship and Administration Act 2000* apply.

The terms 'special medical research' and 'experimental health care' are defined in Schedule 2 of the *Guardianship and Administration Act 2000*. QCAT may also approve 'approved clinical research' to

be undertaken. ‘Approved clinical research’ is defined in Schedule 2 of the *Guardianship and Administration Act 2000.*

Research	Description	General Requirements
Special Medical Research or Experimental Health Care	This category of research involving a clinical intervention has the highest threshold for consent. This category covers all research projects involving a clinical intervention with the particular patient in relation to a particular condition or potential exposure to a particular condition and which does not fall within one of the other categories. Consequentially, this category often involves use of experimental therapies which have no proven benefit, such as a phase 1 clinical trial or use of a clinical intervention which is not recognised as an accepted form of medical treatment.	A patient may consent to this category of research by a prior Advance Health Directive.1 If there is no Advance Health Directive, QCAT may approve an individual patient's participation in this category of research.2 The circumstances where QCAT may approve this category of research is limited.3 All such QCAT approved research must have prior approval by a HREC. A statutory health attorney or person appointed under an enduring power of attorney cannot give consent for this category of research for a patient.4
Approved Clinical Research	This category of research relates to research projects which are the subject to prior Queensland Civil and Administrative Tribunal ("QCAT") or Supreme Court approvals.	A statutory health attorney or person appointed under an enduring power of attorney can may give Research Consent for this category of research in the same manner as providing Treatment Consent.5 All such research projects must be approved by a HREC.
Comparative Assessment Research	This category involves research comparing two or more existing methods of health care which have proven to be beneficial. For clarity, lack of inclusion on the Australian Therapeutic Goods	

	Register does not necessarily mean a therapy falls within this category if that therapy is in regular and accepted medical practice.6	
Psychological Research	This category involves research where the proposed intervention is limited to psychological study of the participant.	

An application may also be made to the Supreme Court to obtain consent for the person to participate in a trial. In these cases, a legally authorised representative cannot give consent on behalf of a Participant.

If a legally authorised representative is not available and if the study cannot be delayed, depending on the exceptional circumstances, in some cases the study may proceed without obtaining informed consent, if this is approved by the HREC, and is not contrary to any laws.

In all cases, consent to remain part of the study must be obtained as soon as possible from the Participant (if they become capable of giving consent), QCAT, or a legally authorised representative – depending on the circumstances.

For more information, refer to the Queensland Health Guidance "Research involving patients who are unable to give consent 2018" https://www.health.qld.gov.au/hiiro/html/regu/regu_home

[1] *Guardianship and Administration Act 2000* (Qld); s65(2).
[2] *Guardianship and Administration Act 2000* (Qld); s65(3).
[3] *Guardianship and Administration Act 2000* (Qld); s72.
[4] *Guardianship and Administration Act 2000* (Qld); s65.
[5] *Guardianship and Administration Act 2000* (Qld); Schedule 2, 12(2).
[6] *Re MP* [2006] QGAAT 86.

4.2 Informed Consent Documentation

Ensure the essential elements are present as described in the NHMRC National Statement, Chapter 2.2 (https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018) and ICH GCP E6 (R2) Section 4.8.10

- The Master PICF is supplied by the Sponsor. Any necessary national or local adaptation for the ethics review process will be made as required for submission to the reviewing HREC. An HREC may approve a Master PICF amended with preapproved local site PICF adaptations such as

    - *By signing this consent form, I give permission for the study investigator to obtain information from the following:*
        - *ambulance transportation,*
        - *any admission to any hospital,*
        - *Emergency Department visits,*
        - *stays in an observation unit,*
        - *information from my local doctor,*

      for the term of the study period. The information collected from these places / persons will only be requested if it is required for this study and will only be used for the purpose of this study

    - The appropriate pre-approved wording relating to the use of contraception where a site has a specific requirement.

- Where the Investigator has delegated obtaining Informed Consent to another appropriately qualified medical practitioner, this must be recorded on the Delegation Log
- Once the PICF is signed and dated by both Participant and the Investigator, the original PICF is kept in the Participant's medical record and a copy is given to the Participant.
- Storage of Informed Consent documents maybe at the satellite site, at the primary site or at both sites (refer to SOP 70).
- Where consent has been obtained by telehealth or telephone, once the PICF is signed and dated by both the Participant and the Investigator (and any other person present for example an interpreter), the Participant is to tick the statement identifying that consent was obtained by telehealth or telephone with the name of the Investigator. Similarly, the Investigator is to tick the statement identifying that consent

was obtained by telehealth or telephone with the name of the Participant. The Participant's original PICF is kept in the Participant's medical record (electronic or paper), a copy is given to the Participant and:

- where paper records are kept, a certified copy of the Participant's signed and dated PICF is sent to the Primary Site for filling in the Participant's medical record with the Investigator's signed and dated original. The investigator to add the date the Participant's PICF was received.
- where electronic records are kept, both signed PICFs are uploaded into the Participant's electronic medical record, a certified copy of the PICF is not required.
- If the Participant requests a copy of the PICF with the Investigator's signature, obtain a copy of the Investigator's signed PICF and give to the Participant.

- Examples of pre-approved statements that may be added to the PICF where consent is obtained by telehealth/telephone:

  - Consent was obtained using telehealth with "Name of Investigator", whose photographic identification was sighted by the Participant who observed the Investigator's signature being written
  - Consent was obtained using telehealth with "Name of Participant", whose photographic identification was sighted by the Investigator who observed the Participant's signature being written
  - Consent was obtained via telephone with "Name of Investigator", on [DD/MMM/YYYY].
  - Consent was obtained via telephone with "Name of Participant", on [DD/MMM/YYYY].
  - Participant's signed consent form received by the Investigator on [DDMMMYYYY].
  - Discussed with [Participant] via telephone on [insert date], and received signed consent form on [insert date]. Signed by [Investigator]

5 Guidance Documents

1. Queensland Health Research Ethics and Governance Health Service Directive # QH-HSD-035:2019
2. Queensland Health Guide to Informed Decision-making in Healthcare (2nd Edition January 2017)
3. Queensland Health Guidance "Research involving patients who are unable to give

consent 2018”

4. Queensland Health Research Management Policy QH-POL-013:2015 (23 June 2015)
5. Queensland Health Research Management Standard QH-IMP-013-1:2016
6. Queensland Civil and Administrative Tribunal (QCAT)
7. Guardianship and Administration Act 2000 (Qld)
8. Teletrial Clinical Consultation User Guide
9. AUSTRALIAN ICH GCP (including Teletrials) SOPs 30 and 70

6 Appendices

Appendix 1: NHMRC Standardised Patient Informed Consent Documents
Appendix 2: National Participant Information and Consent Form (PICF) Parts A, B and C