Research involving patients who are unable to give consent

2018

Human medical research involves consideration of both legal and ethical principles. Amongst these principles is the consent relationship with patients who participate in research actvitiy. Research involving clinical intervention of a research participant requires consideration of consent or waiver of consent to the proposed clinical intervention ("Treatment Consent") and to participation in the research project ("Research Consent").

Generally, research participants should only be enrolled to a research project where the procotol includes a clinical intervention if they have given both Treatment Consent and Research Consent. However, there are limited circumstances where research may occur with patients who are unable to give consent arising from time critical intervention or a temporary or permanent impairment to their capacity. This document is provided to give an overview of legal and ethical issues involved in research involving adult patients who are unable to give consent. This document does not deal with research involving children.

Irrespective of this document, any person undertaking human medical research is required and expected to comply with relevant laws, policies and guidelines governing human medical research, including:

- Local laws governing capacity and consent requirements[1];
- National Statement on Ethical Conduct in Human Research (National Statement)[2]
- Queensland Health Research Ethics and Governance Health Service Directive[3] and Research Management Policy[4]
- Queensland Health's Guide to Informed Decision-making in Healthcare[5]

Research involving patients who are unable to give consent may fall within various categories which will affect the requirements of Research Consent. Appendix A to this document provides background on general categories of research projects involving patients who are unable to give consent.

It is essential that anyone conducting research involving humans obtains informed consent from the patient (or authorised substitute decision-maker[6]) before enrolling that patient in a research study. However, in specific circumstances, Human Research Ethics Committees (HREC) can grant a waiver of the requirement for Research Consent to use the patient's personal information, including personal health information, in research, including medical research.[7]

---

[1] *Guardianship and Administration Act 2000* (Qld); s72, Schedule 2; *Hospital and Health Boards Act 2011* (Qld); part 7; *Public Health Act 2005* (Qld); part [x].
[2] National Health and Medical Research Council, *National Statement on Ethical Conduct in Human Research 2007* (May 2015) <https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_may_2015_150514_a.pdf>.
[3] QHEPS, Research Ethics and Governance Health Service Directive # QH-HSD-035:2016 https://www.health.qld.gov.au/__data/assets/pdf_file/0025/494008/qh-hsd-035.pdf
[4] QHEPS, *Research Management Policy QH-POL-013:2015* (23 June 2015) https://www.health.qld.gov.au/system-governance/policies-standards/doh-policy/policy/qh-pol-013.pdf.
[5] QHEPS, *Queensland Health Guide to Informed Decision-making in Healthcare* (February 2012) <https://www.health.qld.gov.au/consent/documents/ic-guide.pdf>.
[6] For information regarding who can legally provide consent on behalf of patients who lack capacity to make decisions about a person's healthcare, consult the *Queensland Health Guide to Informed Decision-making in Healthcare*, available on QHEPS here: https://www.health.qld.gov.au/consent/documents/ic-guide.pdf.
[7] For information regarding when it may be appropriate for an HREC to waive the requirement for informed consent to participate in a research study, consult clause 2.3.9 of the *National Statement on Ethical Conduct in Human Research.*

'Deferred' or 'delayed' consent is not supported by the National Statement or by Queensland Health

The terms deferred or delayed consent are confusing. They do not exist in the National Statement and do not constitute any form of consent. This is because it is not possible to obtain a person's consent to something after that thing has already happened. Accordingly, the concepts of deferred or delayed consent are not recognised or supported by Queensland Health, and Queensland Health requires that the terms must not be used by researchers or HRECs operating in Queensland Health.

'Deferred' or 'delayed' consent is often confused with the process of opportunity to consent to continue in a research project. It is common for HRECs or Queensland Civil and Administrative Tribunal (QCAT) to require notification of enrolment into a research project be given to an authorised substitute decision maker or patient who regains capacity and that an opportunity be given to that person for withdrawal from the research project. This process should be termed as the 'consent to continue" and not 'deferred' or 'delayed' consent. It is Queensland Health's policy that the use of data and tissue in accordance with the research protocol may continue up until the point of withdrawal.

Human Research Ethics Committee waiver of Research Consent and impact on Treatment Consent

Where an HREC has waived the requirement for researchers to obtain a patient's Research Consent, this does not mean that legal requirements regarding obtaining a patient's informed Treatment Consent have been waived. Regardless of whether a HREC waiver has been granted to obtaining Research Consent, treating health practitioners must always discharge their legal duties to the patient, which include:

- to provide treatment only when a patient (or authorised substitute decision-maker) consents to that treatment, or where Treatment Consent is not required;
- to warn patients of the material risks attaching to the treatment; and
- to exercise reasonable skill and care in the provision of services, including examination, diagnosis and treatment.

Research Consent in circumstances where Treatment Consent is not required

There are certain limited circumstances where Treatment Consent is not required for the provision of health care. This may include in relation to urgent health care[8] or minor, uncontroversial health care[9]. In such settings, a HREC may, having taken account of relevant jurisdictional laws, approve a waiver of the requirement for Research Consent if the requirements of clause 4.4.13 of the National Statement are satisfied. If these requirements are satisfied, it may be open for health practitioners to decide (using reasonable professional judgement in the circumstances) to enrol a patient into a clinical research study without Research Consent. However, it is Queensland Health policy that this may only occur where:

- the study is Approved Clinical Research, Comparative Assessment Research or Psychological Research as defined in this document; and,
- the health practitioner has satisfied their legal duties to the patient, which includes having exercised reasonable skill and care in the provision of the treatments being studied.

More information: For more information, please contact the Health Innovation, Investment and Research Office, Department of Health on 3199 2973.

[8] *Guardianship and Administration Act 2000* (Qld); s63.
[9] *Guardianship and Administration Act 2000* (Qld); s64.

Appendix A: Categories of Research and Research Consent

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.[10] If there is no Advance Health Directive, QCAT may approve an individual patient's participation in this category of research.[11] The circumstances where QCAT may approve this category of research is limited.[12] 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 **can not** give consent for this category of research for a patient.[13]
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.[14] 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.[15]	
Psychological Research	This category involves research where the proposed intervention is limited to psychological study of the participant.	

[10] *Guardianship and Administration Act 2000* (Qld); s65(2).
[11] *Guardianship and Administration Act 2000* (Qld); s65(3).
[12] *Guardianship and Administration Act 2000* (Qld); s72.
[13] *Guardianship and Administration Act 2000* (Qld); s65.
[14] *Guardianship and Administration Act 2000* (Qld); Schedule 2, 12(2).
[15] *Re MP* [2006] QGAAT 86.