

QCIDD RESEARCH CONSENT POLICY

Policy Statement

QCIDD seeks informed consent from participants in its research projects and conforms with the University's Code of Ethics for research, as set out in Section 4.20.1 of the Handbook of Policies and Procedures. Where the participant does not have the capacity for informed consent, this consent will be sought from their Statutory Health Attorney, guardian or attorney for personal matters.

Rationale

Research participants are entitled to be treated with respect and receive full information about the nature of any research project they participate in. If their ability to give informed consent is impaired, then a person authorised to make decisions on their behalf has these same entitlements. Under the terms of the Guardianship and Administration Act 2000 and the Power of Attorney Act 1998,¹ a person may be authorised to make decisions about consent requests for a person with impaired decision making capacity. The legislation lists these relationships in order of their suitability:

1. the person's spouse, if the relationship is close and continuing
2. the person's primary carer, so long as the carer is unpaid
3. a close adult friend or relation

Note: The term carer includes the parent of an adult with intellectual disability.

In cases where there is no one to act as Statutory Health Attorney, the next step would be to consult the Adult Guardian.

In summary, there will be some cases where adults with intellectual disability will be able to decide for themselves whether or not to take part in a research study. Where this is not the case, the role of providing consent or otherwise will fall to a Statutory Health Attorney, or the Adult Guardian.

Procedures

Any QCIDD research proposal needs to firstly have the endorsement of the QCIDD Director. If supported, the researchers are then required to seek ethical clearance from the Behavioural and Social Sciences Ethical Review Committee using any process

¹ For information on the Guardianship and Administration Act 2000 and the Power of Attorney Act 1998 and fact sheets on the Statutory Health Attorney and Making Health Care Decisions, the following web site link is suggested www.justice.qld.gov.au

determined by that committee from time to time. The ethical proposal should clearly identify the participant consent requirements entailed and set out how these will be dealt with.

Establishing Capacity to Consent

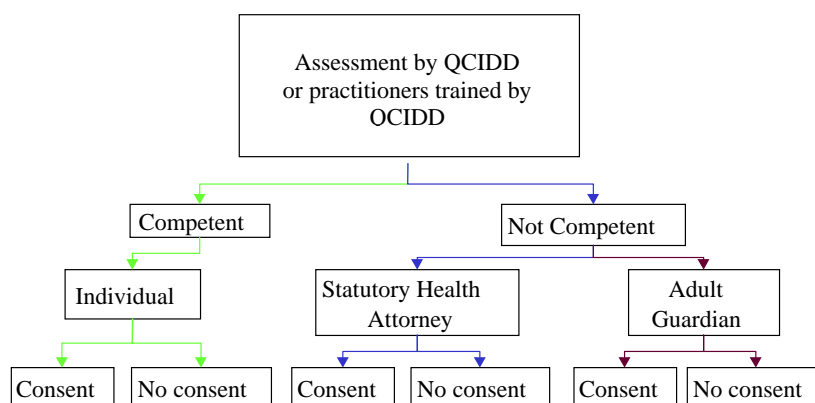
Adults with intellectual disabilities are often quite capable of providing consent. In particular, people with a mild disability are competent to make significant decisions, and their right to make these choices will be supported. However many people with an intellectual disability will be unable to provide informed consent.

QCIDD will assess capacity for informed consent using the Behavioural and Social Sciences Ethical Review Committee Guidelines (1996). As stated in Section 14.3.4, the process of assessing competence includes the following elements:

- the ability to understand the relevant options
- the ability to understand the relevant consequences for the subject's welfare
- the ability to evaluate the consequences of the various options by relating them to his/her own values.

As is usual in working with people with an intellectual disability, when informed consent cannot be obtained from the individual with intellectual disability, then consent may be sought through a Statutory Health Attorney, or the Adult Guardian if there is no Statutory Health Attorney. The issue of providing consent will be judged on an individual basis. The consenting process is depicted in Figure 1 below.

Figure 1 Flow Chart Depicting the Consenting Procedure



Obtaining consent

Contact details of any relevant Statutory Health Attorney or guardian will be noted as part of the initial meetings with proposed participants. This information will be filed securely or destroyed if the person does not proceed as a participant. Any change of these details will be recorded over the course of the research.

Each research project will develop an information sheet and consent form for participants, support agency workers and Statutory Health Attorneys or guardians. Informed, written consent must be obtained and securely stored.

Use, Storage and Disclosure of Sensitive Material

All electronic information will be kept in locked premises and will be accessed using computer security codes, or for hard copies, locked in filing cabinets. Participants with an intellectual disability will be identified by a number, linked to the person's name and kept separately. Only the research staff will have access to the name of the adult with intellectual disability.

Participant and Statutory Health Authorities or guardian contact details and consent forms will also be securely stored in locked filing cabinets.

QCIDD's research will be guided by the *Australian Code for the Responsible Conduct of Research (2007)* Ref <http://www.nhmrc.gov.au/publications/synopses/files/r39.pdf>

Australian Code for the Responsible Conduct of Research (2007) guides institutions, researchers and Human Research Ethics Committees (HRECs) in the ethical review and conduct of such research. The Behavioural and Social Sciences Ethical Review Committee from which QCIDD normally gains ethical approval to conduct research is a subcommittee of the University of Queensland HREC. Records will be generally kept for a period of five years. However, this period may vary dependent on the nature of the research project.

In order to conform to current guidelines, we will follow Section 2.1.1 of the *Australian Code for the Responsible Conduct of Research (2007)* which states that:

In general, the minimum recommended period for retention of research data is 5 years from the date of publication. However, in any particular case, the period for which data should be retained should be determined by the specific type of research. For example:

- for short-term research projects that are for assessment purposes only, such as research projects completed by students, retaining research data for 12 months after the completion of the project may be sufficient
- for most clinical trials, retaining research data for 15 years or more may be necessary
- for areas such as gene therapy, research data must be retained permanently (eg patient records)
- if the work has community or heritage value, research data should be kept permanently at this stage, preferably within a national collection.

Where advice needs to be sought about the secure and safe storage and/or disposal of research data, QCIDD will contact the Research Officer, Research and Research Training, University of Queensland.