HUMAN RESEARCH ETHICS
ETHICS AND COMPLIANCE UNIT

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A GUIDE TO CONSENT CONSIDERATIONS

Section 2.2 of the National Statement provides detail on gaining consent to participate in research. The following information complements section 2.2 by responding to common issues raised by CSU researchers.

Failure to Obtain Consent

Failure to obtain consent of the research participant is a significant ethical issue relating especially to respect and justice.
There may also be:

- serious legal consequences for the researcher and the University. Lack of consent, or an ineffective consent, could result in civil actions for assault, negligence or breach of privacy and confidentiality.
- professional consequences, such as disciplinary proceedings by professional bodies or under the University's Code of Conduct for Research.
- Reputational consequences to the researchers and the institution

Criteria for Consent

A signed written consent form is only *prima facie* proof that the research participant has consented. Legally and ethically any consent must meet three criteria: it must be voluntarily given; it must be informed; and, the person must have the capacity to consent.

A voluntary consent must be freely given and the research participant must be under no coercion or compulsion. The Human Research Ethics Committee will examine closely cases where financial or other inducements are offered, particularly where the research participants are in institutional settings such as schools, hospitals, prisons.

Research Participants' Age

A research participant has the capacity to give consent when they understand what is being requested. The law generally presumes that an adult of sound mind and full age (over 18) has the capacity to consent, but researchers need to consider any special characteristics possessed by the research participant when seeking consent.

In NSW, a child over the age of 16 is deemed capable of consenting. Between the ages of 14 and 16, either the child or its parent or guardian can consent. The Human Research Ethics Committee would normally expect parents of children of this age to be informed even if they are not asked formally to consent.

You need to consider the age of participants in the context of your research and clearly explain and justify the particulars relevant to your project.

Mental Capacity

A person who is intellectually disabled may be capable of giving an informed consent (subject to age rules above). If there is any doubt about a person's capacity to understand the nature of the consent, the parent, guardian or caregiver should be asked to consent. Similar caution should also be exercised in the case of research participants with psychiatric conditions such as dementia.

Research Participants of non-English Speaking Background

Special care must be taken with persons of non-English speaking background. This may have implications for the information statement and possibly inclusion and exclusion criteria.

Data Collection

Where the data to be collected involves personal or biographical information about the research participant, the consent must consider issues of identification of the research participant, privacy and confidentiality, access to the data by persons other than the researcher, and publication of the data.

Data Management

The retention period for research data that involves human participants or products is governed by the State Records Act – General Retention and Disposal Authority – University Records (GDA23) and by the Australian Code for the Responsible Conduct of Research. There are different provisions for data retention based on the significance of the project, ranging from a minimum of 5 years to a maximum of permanent retention.

For further information regarding institutional requirements for data management please refer to the Research Office webpage at the following: https://research.csu.edu.au/research-support/data-methods-and-tools/data-management

Complaints

Research participants must be advised that any complaints or concerns about the conduct of the research can be lodged with the Executive Officer of the Human Research Ethics Committee. Wherever possible, written details about how to lodge any such complaint should be provided to research participants and left with them for reference.

Renegotiating consent

As data collection and research proceeds, researchers need to be aware that any intentional or unanticipated changes to such things as: hypothesis, research design, methodologies, outcomes may impact on the terns of previous consent given. If there is any doubt, researchers should obtain a fresh consent from the research participant that takes into account these changes.

Confirmation of understanding

Where possible, research participants should be given a verbal explanation of the research even if they are consenting in writing and the consent form contains the necessary information to ensure understanding.

Section 2.3 of the National Statement – Qualifying or Waiving conditions of consent
Some projects are not straight forward with respect to issues of consent. It is advised that if considering the following approaches you read the relevant section of the National Statement carefully:

- Limited disclosure
- Opt out
- Waiver