CONSENT FORM GUIDELINES

PLEASE NOTE – The consent form should be written specifically for your particular research project and must be printed on CSU Letterhead. **It must be a separate document from the information sheet so that it can be returned to the investigator.**

In many cases, written consent of research participants is required. Details on a consent form should **parallel the corresponding information statements**, which are given in writing to the research participant – with the consent being obtained at a reasonable time after the participant has had the opportunity to read the information statement. The consent form should, where possible, be printed on Charles Sturt University letterhead (students can obtain this from their supervisors).

There are a number of exceptions to requiring written consent from research participants:

- telephone surveys,
- very simple procedures (e.g. hearing tests),
- procedures where ignorance of the participants as to the intended research objective is essential,
- anonymous research,
- projects involving mass-distribution questionnaires. For some questionnaires, the return of the questionnaire is reasonably taken as an indication of voluntary consent to participate and this fact should be clearly stated on the questionnaire itself. Also, an information sheet **must** accompany the questionnaire when it is forwarded to research participants.

It is recommended that when preparing a consent form, the **consent form checklist** devised by the Committee is adapted as necessary and used by investigators. The consent form should ideally fit on one page and must not be longer than two pages.

NOTES ON CONSENT

1. Failure to Obtain Consent

Failure to obtain consent of the research participant is an ethical issue, which may have 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. There may also be professional consequences, such as disciplinary proceedings by professional bodies or under the University's Code of Conduct for Research.

Where your research involves obtaining human tissue samples, you will need to give thought as to whether you require the consent of the persons from whom the human tissue samples are derived and/or the organisation which has custody of the samples. You should also take into account any privacy considerations for the persons from whom the samples are derived.

2. Criteria for Consent

A signed written consent form is only *prima facie* proof that the research participant has consent. 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, etc.

3. 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.

4. 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.

5. Research Participants of non-English Speaking Background

Special care must be taken with persons of non-English speaking background. Assuming these persons are otherwise capable of consenting, consents that take no account of language difficulties may still be vitiated.

6. 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.

7. Data Storage

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 "data for research without potential long term effects," for example, the minimum requirement is to "retain for minimum of 5 years after project completed, then destroyed." For projects "with potential long term environmental effects" or "for research with human subjects and potential long term effects" the minimum requirement is to "retain for minimum of 20 years after project completed, or after research subjects have reached the age of 25 years, whichever is longer, then destroy." Details on these data retention provisions can be found at http://www.recordkeeping.unsw.edu.au/documents/Retentionperiodsforrecordsrelatingtoresearch.pdf

8. Physical and Psychological Well-being of Research Participants

Some types of research or data collection may have a direct or indirect impact on the physical or psychological well-being of the research participant, e.g. psychological tests, collection or removal of body fluids and tissues, the treatment or non-treatment of physical or psychological conditions, the use of drugs and chemicals, the use of mechanical devices using light, electricity or sound, and so on. In these cases, the research participant must be informed of such things as: the effects on the research participant including the degree of discomfort they may experience, any long term and short term side effects, any prognosis or outcome, the safeguards to protect them from any harm.

9. Right to Withdraw

All consents should advise the research participant that they have the right to withdraw from the research at any time, without penalty.

10. 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.

11. Deception

The Human Research Ethics Committee will examine carefully research proposals that might involve deception of the research participant. While informed consent does not imply that the research participant must have complete foreknowledge of everything that is to happen in the research - for example in "double blind" experiments, researchers must take all steps to minimise the extent of any deception or the possibility that the research participant has given a partially informed consent.

12. Changes to Research Proposals

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 etc may vitiate an earlier consent. If there is any doubt, researchers should obtain a fresh consent from the research participant that takes into account these changes.

13. Explanation of the Research

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.

CONSENT FORM CHECKLIST

The Consent form **must**:

1. be printed on CSU Letterhead
2. be written specifically for your particular research project in user friendly terms
3. include the name of the research project
4. the name of the investigator(s), and name and contact details of the supervisor(s), and identification of the investigator as a student (if applicable) **at the top of the document**
5. make provision for the consent of the parent/guardian or caregiver if the research participant is under the age of 14, or has a disability that may prevent a full understanding of what is being consented to
6. include a statement to the effect that “I understand that I am free to withdraw my participation in the research at any time, and that if I do I will not be subjected to any penalty or discriminatory treatment”.
7. include a statement to the effect that “the purpose of the research has been explained to me and (I have read and understood the information sheet given to me” ***or*** “I have been given the opportunity to ask questions about the research and received satisfactory answers”
8. include a statement to the effect that “the purpose of the research has been explained to me, including the (potential) risks/discomforts associated with the research” plus either “I have read and understood the written explanation given to me” ***or*** “I have been given the opportunity to ask questions about the research and received satisfactory answers”

9. include a statement to the effect that "I understand that any information or personal details gathered in the course of this research about me are confidential and that neither my name nor any other identifying information will be used or published without my written permission
10. where applicable include a statement to the effect that "I understand that interviews/focus groups will be audio taped"
11. include the following clause at the end of the document please choose from the following depending on approval process.

For applications submitted to the University Human Research Ethics Committee	***For Minimal Risk Review Applications submitted to the appropriate Faculty***
Charles Sturt University's Human Research Ethics Committee has approved this study. I understand that if I have any complaints or concerns about this research I can contact: **Executive Officer** **Human Research Ethics Committee** **Office of Academic Governance** **Charles Sturt University** **Panorama Avenue** **Bathurst NSW 2795** Phone: (02) 6338 4628 Email: ethics@csu.edu.au Any issues you raise will be treated in confidence and investigated fully and you will be informed of the outcome**.**	The Faculty Human Ethics Committee - XXX has approved this study. I understand that if I have any complaints or concerns about this research I can contact: **Executive Officer** *Insert appropriate***:** **Address** Phone: xxxx Email: xxxx Any issues you raise will be treated in confidence and investigated fully and you will be informed of the outcome**.**

12. include provision for the signed consent of the participant to the above, for example;

    Signed by: .....

    Date: .....