

How to Write a Consent Form: Guidelines and Examples

These guidelines have been prepared in accordance with the *National Statement on Ethical Conduct in Research Involving Humans* available at <http://www7.health.gov.au/nhmrc/publications/synopses/e35syn.htm>

Establishing Consent

Participants in research must clearly consent to being involved in a study. The most suitable way for participants to demonstrate their consent will vary according to the nature of the research and the kind and level of risk involved. Whatever method is chosen, research should be designed so that each participant's voluntary participation is clearly established. Different methods include return of a signed form, returning an anonymous survey (providing tacit consent), and audio recording of verbal consent. Other means may be appropriate depending on the nature of the research.

Changing the Project

Where the research process is dynamic and continuous, consent may need to be renegotiated or confirmed, especially in the case of complex, long-running projects or with participants who are vulnerable. Research participants should be told if there are changes to the terms to which they originally agree, and given the opportunity to continue their participation or withdraw.

Writing a Consent Form

It should be written at the level of comprehension of the reader. Write it in the first person ie 'I have read the Participant Information Sheet and I have had the opportunity to ask the researcher any questions.' A Consent Form is read by the participant, signed and handed back to the researcher and should include the following features:

1. Use University of Wollongong/AHS letterhead.
2. Provide the title of the research project, the researcher(s) name, supervisor's name (for student research), the Unit in which the researcher is based and the name of the governing institution.
3. State that the PIS has been read and the participant has had the opportunity to ask questions of the researcher.
4. State exactly what the participant is consenting to including the research methods involved. If there are several aspects it may be appropriate to use tick boxes.
5. Briefly re-state the risks or inconveniences associated with the research.
6. If appropriate, include a statement that participants' anonymity and/or confidentiality will be maintained.
7. State that participation is voluntary and potential participants are free to refuse consent and to withdraw consent at any time.
8. A statement should be included stating that the participant is aware that they can contact the University of Wollongong Ethics Officer if they have any concerns or complaints regarding the way in which the research is or has been conducted.
9. A section should be provided in the consent form for the participant to indicate agreement to participate by signing and dating the form (It may be appropriate to provide for a witness to the signature such as a parent or guardian).

Seeking Alternative Ways of Gaining Consent in Social Science Research

Chapter 2 of the *National Statement* states that research participation should be “voluntary, based on sufficient information and adequate understanding of the purpose, methods, demands, risks and potential benefits of the research. This information must be presented in ways suitable to each participant” (p. 19). Sometimes it is challenging to do this by standard ways of communication e.g. in an overseas country with particular cultural standards or when the participants may be particularly vulnerable (eg homeless children who cannot read) so alternative procedures are sometimes needed.

Section 4 of the *National Statement* has chapters on special situations such as research involving children and young people, people in dependent relationships, people who are highly dependent on medical care, peoples with cognitive impairment, people involved in illegal activities, Aboriginal and Torres Strait Islander people and people in other countries. In these situations, it is especially important for researchers to demonstrate ethical capacity and integrity.

Some alternative ideas for consideration are:

1. Recruitment

- Researchers need to demonstrate cultural understanding in order to recruit in the most appropriate manner and be aware of the local context by accessing local government agencies, non-government organisations and support networks.
- Negotiate recruitment with networks, directly or word of mouth.
- A different process may be needed for recruiting vulnerable participants eg sometimes recruitment needs to be done through “liason” where a “trusted contact” might be used. eg in Pakistan, cultural and traditional norms do not appreciate direct approach with people who are not known to the participant or may not be trusted. When using an intermediary it is important that they are aware of ethical conventions and will respect the confidentiality and privacy of participants.

2. Negotiating Informed Consent

- An information sheet is preferred but if this is not possible (eg participants cannot read) then key aspects of the research still need to be communicated. In some cases this can be done by alternative means such as using culturally appropriate images of who approved the research and the data gathering methods including interview/focus group verbally, written, actions.
- Images can also be used to convey the methodology. Below are some sample images. There are samples only and should NOT be copied, as the nuances of each situation and participant group need to be taken into account.

- It is important for participants to also be aware of harm/discomfort/inconvenience and benefits
- It may also be culturally appropriate to encourage participants/informed others to identify risks involved in the research as well as identifying ways to minimise the risk.

3. Establishing Consent (see p. 19-24 of the National Statement, which required the researcher to establish that consent has taken place)

Establishing consent should meet three conditions: (i) sufficient information provided;
(ii) (ii) adequate understanding, and
(iii) (iii) be voluntary:

Recording consent can be done by by various methods including obtaining signatures, verbally, field notes, diary, web site
Please note that for long term projects consent may need to be renegotiated at different stages.

Examples (please note that these are not prescriptive but only a guide)

- [Example of general Consent Form](#)
- [Example of Consent Form for University Students](#)
- [Example of Consent Form for Children](#)

CONSENT FORM FOR (INSERT

NAME) RESEARCH TITLE:

RESEARCHER/S:

I have been given information about *research title* and discussed the research project with *researcher's name* who is conducting this research as part of a *degree name* supervised by *supervisor* in the department of *department* at the University of Wollongong.

I have been advised of the potential risks and burdens associated with this research, which include *identify the most significant risks or burdens*, and have had an opportunity to ask *researcher's name* any questions I may have about the research and my participation.

I understand that my participation in this research is voluntary, I am free to refuse to participate and I am free to withdraw from the research at any time. My refusal to participate or withdrawal of consent will not affect *my treatment in any way /my relationship with the Department of ... or my relationship with the University of Wollongong, (revise as appropriate given the research and the population participating in research)*.

If I have any enquiries about the research, I can contact *(insert names of researcher and supervisor (if student researcher) and their contact phone numbers)* or if I have any concerns or complaints regarding the way the research is or has been conducted, I can contact the Ethics Officer, Human Research Ethics Committee, Office of Research, University of Wollongong on 4221 3386 or email rso-ethics@uow.edu.au.

By signing below I am indicating my consent to (please tick):

brief account of how the research involves the participant
etc

I understand that the data collected from my participation will be used for *purpose (eg thesis, journal publication, etc)*, and I consent for it to be used in that manner.

Signed

Date

.....

...../...../.....

Name (please print)

.....

**Consent Form for University
Students**

**Promoting reflective thinking sin a distance education health services management subject: A
case study**

Researcher: John Peters

I have been given information about “*Promoting reflective thinking in a distance education health services management subject: A case study*”. I have discussed this research project with John Peters, the subject coordinator of HSM603 Perspectives on Health Care Systems offered by Wollongong University. This is part of a PhD degree supervised by Dr George Rolls from the Faculty of Education at the University of Wollongong.

I understand that if I consent to participate in this project I will be asked to allow copies of my print and electronic communications in HSM403 Perspectives on Health Care Systems, including my reflective journal and forum contributions to be used in the study. I also consent to participate in a survey and interview to be conducted by a research assistant after the academic session has concluded. I understand that my contribution will be confidential and that there will be no personal identification in the data that I agree to allow to be used in the study. I understand that there are no potential risks or burdens associated with this study.

I have agreed to provide an electronic copy of my reflective journal for retention for the purposes of the study, which will be stripped of personal identifiers and coded by the research assistant prior to any analysis. I have had an opportunity to ask John Peters any questions I may have about the research and my participation. I understand that my participation in this research is voluntary and I am free to refuse to participate and I am free to withdraw from the research at any time. My refusal to participate or withdrawal of consent will not affect my relationship with the Faculty of Education at the University of Wollongong in my course/program of study in health services management.

If I have any enquires about the research, I can contact John Peters (02 4238 4756 and/or Dr George Rolls 4221 4450. If I have any concerns or complaints regarding the way the research is or has been conducted, I can contact the Ethics Officer, Human Research Ethics Committee, University of Wollongong on 4221 3386 or email rso-ethics@uow.edu.au..

By signing below I am indicating my consent to participate in the research. I understand that the data collected from my participation will be used primarily for a PhD thesis, and will also be used in summary form for journal publication, and I consent for it to be used in that manner.

Signed

Date

.....
Name (please print)

...../...../.....

.....

Consent Form for Children

Research Title: The use of “Computer Animation” as a teaching strategy to assist primary school children in their understanding of fractions.

Researcher’s Name:

I have read the participation information sheet and have had the opportunity to ask the researcher any further questions I may have had. I understand that my participation in this research is voluntary and I may withdraw at any time from the study without affecting my treatment at school in any way.

I understand that the risks to me are minimal in this study and have read the information sheet and asked any questions I may have about the risks. I understand that I will be involved in three individual, 30 minute audio recorded interviews and that photographs will be taken of my work. My name will not be used to identify my comments or work in the study.

If I have any concerns or complaints regarding the way the research is or has been conducted I can contact the Ethics Officer, Human Research Ethics Committee, Office of Research, University of Wollongong on 4221 3386 or email rso-ethics@uow.edu.au.

By signing below I am consenting to (please tick):

Participating in a series of lessons using ‘computer animation’ in my classroom with my teacher.

Having three audio recorded interviews for 30 minutes each with the researcher asking me about my work and learning experiences.

Having copies and photos of my work taken for work samples demonstrating the use of ‘computer animation’ to teach a Mathematics concept. (The photographs will only be of my work and not of me.)

I understand that information from me will be used for a thesis and possibly other published studies and I consent for it to be used in this manner.

I give permission for my child _____ to participate in this research. (child’s name)

Parent/ Guardian Signature _____ Date__

Name (please print) _____

Child’s signature _____