**Guide to Human Research Ethics Informed Consent Instruments**

# Requirement for Informed Consent Instruments

The process of informed consent has two aims: to provide sufficient information for a proper, informed decision to be made regarding participation, and to establish valid consent.

All Human Research Ethics applications require the applicant to attach a sample of the informed consent instruments that will be used to inform participants of the research project being undertaken and to gain their voluntary consent to participate in the project.

Two key documents are ordinarily used: an information statement and a consent form. Some projects will not require both documents. For example, a consent form is not needed when the return of a completed questionnaire is clearly understood to imply consent and a consent form is not needed. In other cases, projects may require informed consent statements for minors/dependents separate or additional to statements written for parents/guardians. Participation on line requires its own appropriate measures.

# General Points regarding Informed Consent Instruments

* Both the information statement and consent form(s) must be on Swinburne letterhead (or joint letterhead if a collaborative project)
* The consent information statement should be labelled as such and the consent form (if applicable) should closely and clearly correlate.

# Statements should be carefully and economically written for intended participants, not for ethics committee members. Most projects require a plain language statement about a page long.

* The informed consent instruments should not introduce any new information – all information given must correlate with detail given in the human research ethics application. Nor should the signed consent form introduce items not covered in the information statement.
* Language used should be clear, concise, invitational, culturally appropriate and logically set out. Appropriate subheadings can be used to aid reading (see the attached guide). Special terms used should be defined or explained using language appropriate to the participant(s)
* Format of the statement or detail can vary, but if the project is complex, consider formats which assist easy understanding such as attached tables, schedules, separate but linked summary and details, etc
* Statements must include contacts for further information and outline a standard complaints procedure
* Consent instruments should include version control details (version name, no, date, etc)
* Any request or proposal to vary or waive consent arrangements must be cleared by the Swinburne’s Human Research Ethics Committee (SUHREC)

# Detailed Guide to Consent Instruments and Sample Consent Forms

Below are downloadable documents which can be used as the bases of your proposed consent instruments. Note that these will not cover all situations and in all cases thought must be given to the particular project needs or relevance.

# Guide to a Consent Information Statement

Whilst a detailed guide and discussion for preparing a consent information statement, the format can be used as the basis for the statement. Some items on the detailed guide may not apply to a particular project.

# Informed Consent forms

**Sample A** For an individual adult having full capacity to give voluntary consent in his/her own right on the basis of sufficient information provided

**Sample B** For informed consent on behalf of a minor or dependent. In some cases a separate (additional) appropriately written consent form may be required for minors significantly able to give or withdraw consent

**Sample C** Authority to involve an agent or official of an organisation (representative participation).

**Guide to a Consent Information Statement**

[***Please Note****: This is a guide to the kind of information which should be included in a consent statement.* ***Please remember to attach proposed consent instruments to your ethics application.*** *Where possible, your final consent form needs to be on Swinburne letterhead (or joint letterhead if a collaborative project) and use version control (version name, no, date, etc). Inapplicable/bracketed information from this guide should be deleted from your final version, including this instruction*.]

The consent information statement should be clearly labelled as such (or quite similar) and contain key pieces of information as follows:

# Project Title

Give the project full title as used in the ethics application form unless the title has much specialist or complex language, in which case the short title from the ethics application form may be used.

# Investigators and Other Project Personnel

List clearly all researchers and their affiliations (Swinburne or otherwise), including student investigators as such, and any research project officer or research assistant who will be accessing sensitive identifiable information (including heath/personal information). Positions and roles of project personnel should be clear.

# Introduction to Project and Invitation to Participate

Both introduce the project and invite participation.

# What this project is about and why it is being undertaken

Sufficiently explain what the project is about, its aims, why it is being conducted, etc.

# Project and researcher interests

Researcher and project interests should be sufficiently disclosed as applicable, eg, project is partly, mainly or wholly to satisfy the requirements for a student’s academic qualification. If the project is being supported by an external source (cash and/or in-kind), state the source and extent of the support (eg, that the project is being partly funded by XYZ Pharmaceutical Enterprises.) Some conditions attached to such support may have ethical implications which need to be addressed in the ethics application and in consent instruments. In some cases, there may also need to be a disclaimer as to what Swinburne is or is not endorsing.

# What participation will involve – time, effort, resources, costs, compensatory payments, etc

Give sufficient clear detail as to what is being asked of participants – voluntary consent to their time, effort, supply of information/body tissue/records/personal effects, etc. Tabulated forms or attachments are useful if participation arrangements are long and complex. These should be properly cross-referenced. Avoid language which can be read as orders or directives (ie, not “You will do this or that”; but better as “We will ask you”, etc) and presumptuous language (eg, “Dear Participant”).

Any proposal to award prizes or gifts to participants using a form of lottery (any element of chance) may be subject to government regulations. Further information is available from the Research Ethics Office.

# Participant rights and interests – Risks & Benefits/Contingencies/Back-up Support

Outline realistically any potential risks (minimal or otherwise) and what preventive, minimisation or redress arrangements are in place. If some research questions or issues can be considered particularly sensitive,

give sample questions or topics as an indication of the information that will be discussed or requested. If there is to be any non-disclosure of information about the project, any withholding/substitution of treatment or services or use of placebo, this will need to be addressed appropriately, eg, a form of debriefing.

Describe any benefits pertaining to individual participation or more generally. Avoid grandiose claims.

As applicable, give clear information on support facilities that are freely available to Swinburne students (counselling/ medical/academic assistance/etc), listing these by campus (Hawthorn, Lilydale, Wantirna, etc). **If reasonably there is non-existent or negligible need for such back-up or referral, don’t list any.** If costs are to be borne by participants with respect to accessing back-up support, this should be clarified (eg, the Swinburne Psychology Clinic operates on a low-cost fee-for-service basis).

# Participant rights and interests – Free Consent/Withdrawal from Participation

Participation or not is to any extent to be voluntary, free from any coercion or perceived coercion. Detail on this matter should be clear – that an individual is free to participate or not and the circumstances. If, for example, the participants are students, patients or employees, it will help to clarify that their decision to participate or not in the project will have no bearing on their results, treatment or employment (in some cases this may need further explanation, such as details about recruitment).

A statement about the participant’s right to withdraw participation, data or material contributed, ordinarily without question or explanation, needs to be included. However, if there are consequences to withdrawal (eg, stopping a course of medication/therapy or a program), this needs sufficient clarification. Special care needs to be taken with minors or vulnerable participants.

Don’t forget to outline how valid consent is to be obtained (by signed consent form, by implied consent – completion and return of anonymous questionnaire, any witnessing procedure if applicable, etc). Often it helps to highlight or **embolden** this.

# Participant rights and interests – Privacy & Confidentiality

Give clear information about secure arrangements for data access, collection, use, retention and/or disposal. If an organisation has agreed to contact prospective participants on behalf of researchers, state this and whether any contact details have been made available to Swinburne researchers. This needs to comply with mandatory Privacy Principles (National/Health/Information Privacy Principles/etc), as with use of any pre-existing database to contact participants. (See also Swinburne’s Privacy Policy <http://www.swinburne.edu.au/privacy/>)

If signed consent forms are required, state whether they will be stored separately to any data collected and who will have access. But don’t specify room locations where data and consent forms are stored.

Follow-up contact arrangements with participants, eg, to ensure accuracy of data collected, need careful attention in relation to Privacy and consent requirements.

Remember, people are increasingly concerned about data access and data matching. Good detail will help allay concerns.

# Research output

Outline intended or anticipated publication or reporting of research findings, including anticipated student output (thesis, etc). If need be, reiterate or refer to privacy arrangements for confidentiality/anonymity. Offer to make available any report or article or summary, where appropriate, and indicate how this will occur. In some cases, such follow-up contact may be an issue in itself and the procedure should be carefully considered and outlined. Use of separate, unattached forms with follow-up contact details may be acceptable to prevent undue data matching.

# Further information about the project – who to contact

You will need to nominate at least one effective person to contact regarding further information about the research activity or participation in the project. A student project should include the Swinburne supervisor’s contact details. Eg: “If you would like further information about the project, please do not hesitate to contact:

Position Title(s) and Name(s) Swinburne Contact Address(es) (Swinburne) Tel No(s): (Swinburne) Email(s): “

Particularly with any health/personal information communicated, official Swinburne email and other contact details should be used (non-Swinburne email addresses and ISP-related servers, for example, should not be used; nor personal home telephone numbers).

# Concerns/complaints about the project – who to contact:

All Swinburne human research projects require contact details to which complaints can be directed. Avoid making the complaints information appear like contact details for further information about or communication in relation to the project. A preferred format is as follows:

|  |
| --- |
| This project has been approved by or on behalf of Swinburne’s Human Research Ethics Committee (SUHREC) in line with the *National Statement on Ethical Conduct in Human Research*. If you have any concerns or complaints about the conduct of this project, you can contact: Ethics & Integrity Officer, Swinburne University of Technology, Jalan Simpang Tiga93350 Kuching, Sarawak, MalaysiaTel 82 260 923 or +60 82 260 923 or ethics@swinburne.edu.my  |

**SAMPLE A:** Informed consent from an individual adult having full capacity to give voluntary consent in his/her own right on the basis of sufficient information provided.

[***Please Note****: This is not a prescribed form but an indication of the kind of information which should be included in a consent form.* ***Please remember to attach proposed consent instruments to your ethics application.*** *Your final consent form needs to be on Swinburne letterhead (or joint letterhead if a collaborative project) and use version control (version name, no, date, etc). Inapplicable/ bracketed information should be deleted from your final version, including this instruction*.]

# Swinburne University of Technology Project Title:

**Principal Investigator(s):**

1. I consent to participate in the project named above. I have been provided a copy of the project consent information statement to which this consent form relates and any questions I have asked have been answered to my satisfaction.

[*For 2/3 below, list as appropriate, delete inapplicable text and add to/renumber the list as necessary]*

|  |  |
| --- | --- |
| 2. ***In relation to this project, please circle your response to the following:*** |  |
| * I agree to be interviewed by the researcher
 | **Yes** | **No** |
| * I agree to allow the interview to be recorded by electronic device
 | **Yes** | **No** |
| * I agree to make myself available for further information if required
 | **Yes** | **No** |
| * I agree to complete questionnaires asking me about
 |  |  |
| [insert topic(s)] | **Yes** | **No** |

1. I acknowledge that:
	1. my participation is voluntary and that I am free to withdraw from the project at any time without explanation;
	2. the Swinburne project is for the purpose of research and not for profit;
	3. any identifiable information about me which is gathered in the course of and as the result of my participating in this project will be (i) collected and retained for the purpose of this project and (ii) accessed and analysed by the researcher(s) for the purpose of conducting this project;
	4. I understand the length of time researcher/s will have access to this information;
	5. my anonymity is preserved and I will not be identified in publications or otherwise without my express written consent.

By signing this document I agree to participate in this project.

**Name of Participant:** ……………………………………………………………………………

**Signature & Date:** ……………………………………………………………

**SAMPLE B:** Informed consent on behalf of a minor or dependent. Please note that, in *some* cases, a separate (additional) appropriately written consent form should be used or may be required for minors significantly able to give or withdraw consent.

[***Please Note****: This is not a prescribed form but an indication of the kind of information which should be included in a consent form.* ***Please remember to attach proposed consent instruments to your ethics application.*** *Your final consent form needs to be on Swinburne letterhead (or joint letterhead if a collaborative project) and use version control (version name, no, date, etc). Inapplicable/ bracketed information should be deleted from your final version, including this instruction*.]

# Swinburne University of Technology Project Title:

**Principal Investigator(s):**

1. I/We consent to my/our child/dependent here named to participate in the project named above. I have been provided a copy of the project consent information statement to which this consent form relates and any questions I have asked have been answered to my satisfaction.

Name of Child/Dependent: ………………………………………………………

[*For 2/3 below, list as appropriate, delete inapplicable text and add to/renumber the list as necessary]*

## In relation to this project, please circle your response to the following:

* + I/We agree that s/he can be interviewed by the researcher **Yes No**
	+ I/We agree that the interview can be recorded by electronic device **Yes No**
	+ I/We agree to allow completion of questionnaires asking her/him about

[insert topic] **Yes No**

* + I/We agree to make myself/ourselves available for further information if required **Yes No**
1. I/We acknowledge that:
2. my/our child’s/dependent’s participation is voluntary and that s/he is free to withdraw from the project at any time without explanation;
3. the Swinburne project is for the purpose of research and not for profit;
4. any identifiable information gathered in the course of and as the result of my/our child/dependent participating in this project will be (i) collected and retained for the purpose of this project and (ii) accessed and analysed by the researcher(s) for the purpose of conducting this project;
5. I understand the length of time researcher/s will have access to this information;
6. my/our child’s/dependent’s anonymity is preserved and s/he will not be identified in publications or otherwise without my express written consent.

By signing this document I/We agree to your child’s/dependent’s participation in this project. **Name of Parent(s)/Guardian:** ………………………………….……………………………… **Signature & Date:** ……………………………………………………….……

**[SAMPLE C:** Authority to involve an agent or official to provide a response on behalf of an organisation (representative participation). Request(s) for ‘gate-keeper’-type access/authority (eg, authority to enter premises, access personnel or resources in order to conduct research) should be separately detailed. A Sample A consent form should be separately used for individuals able to participate in their own right.]

[***Please Note****: This is not a prescribed form but an indication of the kind of information which should be included in a consent form.* ***Please remember to attach proposed consent instruments to your ethics application.*** *Your final consent form needs to be*

*on Swinburne letterhead (or joint letterhead if a collaborative project) and use version control (version name, no, date, etc). Inapplicable/ bracketed information should be deleted from your final version, including this instruction*.]

# Swinburne University of Technology Project Title:

**Principal Investigator(s):**

1. On behalf of: ………………………(Name of Organisation)………………………………

I hereby authorise the following official(s)/employee(s)/agent(s) to participate in the project in a representative capacity, the project’s particulars having been satisfactorily explained to me:

Name of representative(s): …………………………………………………..…………

[*For 2-4 below, list as appropriate, add to/renumber the list as necessary and delete those not applicable to your project; then delete this instruction*.]

## In relation to this project, please circle your response to the following:

* I agree that s/he can be interviewed by the researcher **Yes No**
* I agree that the interview can be recorded by electronic device **Yes No**
* I agree that s/he can complete questionnaires about

[insert topic] **Yes No**

* I would like to check any transcription / citation in respect of my organisation’s involvement for accuracy

# Yes No

## Please circle your response to the following:

* I give my permission for the organisation to be named in any publication arising from the research.

# Yes No

* I further give my permission for the named researcher(s) to access/analyse organisational records as requested. **Yes No**
* I understand the length of time researcher(s) will have access to data/records for analysis

# Yes No

* In permitting access to or use of organisational records, the following / attached condition(s) apply:

…………………………………………………………………………

1. I acknowledge that the data collected for the Swinburne project will be used for research purposes and not for direct profit; research purposes may include publishable / peer reviewed outcomes.

**Name of Person of Authority and Position:** …………………………………………………………………

**Signature & Date** ……………………………..……………………………