Guide for Researchers completing the Swinburne Human Research Ethics Application Form

General Instructions

- Download and use the most current version of the form available at https://www.swinburne.edu.au/intranet/research/research-integrity--ethics/forms/
- Familiarise yourself with the National Statement on Ethical Conduct in Human Research and the frequently asked questions (FAQs) before preparing your application.
- Where specific sections of the National Statement provide information relevant to the question, the initials will be given, NS, and the relevant chapter or section.
- Preparing an ethics application and seeking approval can take some time therefore plan ahead and submit your application well in advance of your proposed start date.
- Consult with a Research Ethics Advisor (REA) for advice and review of your application.
- Give plenty of time for the Head of Department, Unit or Centre (or above) to read and endorse your application.
- Pay attention to typographical and grammatical errors as these can make it difficult for the committee to understand and consequently clarifications will be sought. Plain language that is clear, consistent and succinct must be used.
- You are the person with the most information and knowledge of your research. The Ethics Officers can only offer advice and cannot tell you how to answer questions. The committee's job is to evaluate whether you have considered the rights and welfare of participants as well as compliance with the National Statement.
- Research that is regarded as negligible or low risk may be reviewed by a Swinburne Human Ethics Sub-Committee (SHESC). Research regarded as more than low risk or of a nature that cannot be reviewed by a sub-committee will be reviewed by the main committee, SUHREC. Application lodgement and meeting dates can be found here: https://www.swinburne.edu.au/intranet/research/research-integrity--ethics/human-research-ethics/lodgement-instructions-and-deadlines/. You will need your SIMS username and password to gain access.
- Attach all documentation as indicated throughout the application form. Make sure that you refer to each attachment in the body of the application form using Attachment 1, Attachment 2 etc.
- Number all of the pages in the final document sequentially.
- The boxes to add text will expand as required. If necessary you can also copy and paste the boxes for example when adding more co-investigators or students.
The Swinburne Human Research Ethics Application Form

The Swinburne Human Research Ethics Application Form is to be used for most types of research. For clinical trials please use the National Ethics Application Form, complete the Victorian Specific Module and any further required documentation such as a Research Protocol. Check with the Research Office if you have any queries.

The Swinburne form is made up of eight sections all of which must be completed:

- Section 1: Level of Research – low risk or more than low risk?
- Section 2: Administrative Details
- Section 3: Project Details
- Section 4: Participants and Recruitment
- Section 5: Ethical Considerations
- Section 6: Data Collection, Retention, Use and Disposal
- Section 7: Declarations and Signatures
- Section 8: Checklist

Section 1: Level of Risk

This section is designed to assist you in determining the level of risk in a project. Projects with negligible or low level of risks can usually be reviewed by one of the sub-committees. Any project with risks determined to be above low risk must be reviewed by the main committee. The risk factors could relate to a participant, researcher, the University or wider community. Other factors such as funding body rules could specify main committee review. NS 2

This section must be completed and the risk factors identified before completing the application form. All risk factors identified should be addressed in the application form in terms of negating, minimising and/or managing the risk.

If your project has been identified as more than low risk and therefore should be reviewed by the main committee but you consider that the project could be reviewed by a sub-committee then you can put forth an argument for the Research Office to consider. Equally, if you think your project has inappropriately been classified as a negligible or low risk project and should be reviewed by the main committee, you can put a case to the Research Office.
Section 2: Administrative Details

| 2.1 | Choose a title that is short, simple and self-explanatory that will identify for participants and ethics committee members the essential point of the project. The title should be the same as that used on all documentation provided to participants. Acronyms should not be used. |
| 2.2 | The start dates for the project must be at least 14 days post the meeting date at which the application is to be reviewed. Retrospective approval cannot be given. |
| 2.3 | The Chief Investigator (CI) must be a current Swinburne staff member and not a student. All fields must be completed. Even if the CI has previously completed an ethics application for a different project the ‘Qualifications and research expertise relevant to the project’ section must be completed as the information given here is required to be specific to this project. Do not simply answer with “CI” for the “Role in the project” question. What is required here are broad details of what the CI will actually be involved in, for example, co-ordinating the recruitment process or managing the data collection or analysis of data and publications. |
| 2.4 | Only complete this section if the person for communication is different to the CI. The CI must be copied into all communications with the Research Office. Modifications or reports will not be accepted by the Research Office unless the CI has been copied into the correspondence with the Research Office. |
| 2.5 | Check all the boxes that describe the type of activities involved in the project. |
| 2.6 | Check the box for the category that most applies to your project. |
| 2.7 | This question is only applicable for class projects involving multiple students. Supervisors/teachers must keep a list of those involved and provide this to the Ethics Office as required. The description provided must include the role or roles that the students will have, details of the training provided, including who will be providing it and the supervision of the students and the progress of the project. |
| 2.8 | Details of non-student co-investigators should be included here. All sections must be completed. Copy the table as many times as required in order to include each Co-CI. |
| 2.9 | Details of all student co-investigators should be included here. All sections must be completed. Copy the table as many times as required in order to include each student. |
| 2.10 | Provide the details of any related previously Swinburne-approved ethics projects. |
| 2.11 | Check any boxes that indicate what sort of peer review this project has had. Provide details of the outcome. |
| 2.12 | If this project will be submitted for approval to any government department or institution, or to a non-Swinburne business, such as: Department of Education, prisons, government institutions or businesses. Provide the details and attach any approvals or relevant documentation. |
2.13 If the project involves collaboration with non-Swinburne people or another organisation then indicate this here and provide any relevant documentation such as approvals, email communications or contracts.

2.14 Provision of financial details is important to assist the reviewing committee in considering the viability of the project. For example if a project is halted half the way through due to lack of funding then this could be considered not fair or unethical for those participants that have already agreed to participate on the basis of completion of the project. Make sure that you attach any relevant documentation or contracts to your application.

2.15 Swinburne usually provides insurance or indemnity to its employees (in some cases the project details might have to be provided to Swinburne Finance in order to ensure enough cover) but if there is non-Swinburne people or organisations involved additional insurance or indemnity might be required. Please indicate here if this is the case and attach any relevant documentation.

## Section 3  Project Details

**NS 5.2.6** Plain language must be used throughout the application. This is to ensure that each member of the committee can have a clear understanding of the research and approach to be taken. The language used must be able to be understood by those outside of your discipline or profession.

### 3.1. The summary should be in plain English as to what this project is about with reference to what the participants are being asked to do. Acronyms should be avoided. Maximum 200 words.

### 3.2. State clearly and simply the background and aims including why this project has merit. References should be cited and a full reference list provided. The ethics committee needs to form a clear understanding of the aims and value of the project.

### 3.3. State clearly the research design or methodologies to be used. Include all details regarding participants such as: inclusion/exclusion criteria, recruitment protocols, covert observations, use of placebos, sampling techniques, what data are to be collected, measures to be used, randomisation procedures, statistical methods, etc. A flow chart can be used for simplicity. In order to review the project the ethics committee needs to form a clear understanding of what is to happen in a project so that it can determine if the project meets the requirements of the National Statement and is ethically acceptable. The committee must be able to weigh the potential benefits of the project against the burden placed on participants involved.

### 3.4. Outline any anticipated direct or indirect benefits to the participant and any benefits more generally anticipated (knowledge, understanding, society, profession, etc). If there are no direct benefits for participants then state that.
3.5. If research is not an online survey nor located at Swinburne, provide the details and attach approvals or contracts. **NS 4.8** When you propose to conduct a project in another country, additional ethical considerations may arise. Regard for the beliefs, customs and cultural heritage of participants could require recognition of values in addition to those in the National Statement.

3.6. All research conducted overseas must comply with the National Statement. Attach all documentation or correspondence relating to conducting your research overseas and detail any local legislation, regulations, permissions or customs that need to be addressed before the research can commence.

### Section 4  Participants or their Data and Recruitment

**NS 1** Human research is research conducted with or about people, or their data or tissue. Different categories of participants can raise different issues in the design, conduct and consequently ethical review of a project. Specific details of participants are required to assess whether the principle of justice has been considered in the design of the project. For example an injustice could occur when the benefits and burdens are restricted to a particular group due to convenience for the researchers or recruitment of a particular group due to convenience.

If targeting children and young people as participants researchers must be particularly cognisant of **NS 4**. Participants under the age of 18 are normally required to have parental or guardian consent prior to them participating in a project. However, approval could be given for consent to be sought directly from a young person if that young person can be demonstrated to be mature enough to understand and consent, and not vulnerable through immaturity in ways that would warrant additional consent from a parent or guardian. **NS 4.2.8 and 4.2.9**

| 4.1 | Specific details of participants are required to test the principle of justice. There is a potential for injustice if the benefits or burden of participation are restricted to a particular age group or gender or group of people. If precise numbers of participants are not known then provide approximations and flag that the numbers are approximate. If an age range cannot be given, the broad categories of ‘age range’ should be used such as young adults or older adults. If a specific gender is not being targeted for recruitment then state ‘not applicable’. |
| 4.2 | Justification should consider sample size, statistical power and data analysis as well as why that particular group is being targeted. If there is any imbalance in respect to gender, age or other group you will need to justify this, that is, if you are only targeting females from 25-30 you will need to justify why you are not also recruiting males of similar age and furthermore you will need to justify why you are targeting this age group in particular. 
  - If you are targeting children or young people under the age of 18 then be cognisant of **NS 4.2** |

SUT Ethics Form Version 8 Jan 2016  Page 5 of 13
- If Aboriginal or Torres Strait Islander Peoples are to be targeted for involvement, give details and explain any culturally appropriate protocols to be followed, including community consultation(s), where appropriate, referring to NHMRC, AIATSIS or other relevant guidelines. Be cognisant also of NS4.7

4.3 All criteria that can include or exclude a potential participant need to be listed here. The inclusion and exclusion criteria must relate back to the aims of the project.

4.4 State where the participants will be recruited, such as via a website, club or clinic.

4.5 Provide details of any posters, flyers, participant information sheets, consent forms, advertisements, emails and letters that will be used. Include a listing of any online or physical sites the advertisements will be posted. Make sure that you attach all of the material to your application.

4.6 Specify who will make the first contact and how. Be sure to include all relevant details of any third parties involved.

4.7 Researchers must protect the privacy and confidentiality of participants at all times. Personal information cannot be accessed without consent.

4.8 A person's decision to participate in research must be based on sufficient information, an understanding of the research and the implications of participation. This is usually via a Participant Information Statement. For online surveys, the information statement may be incorporated into the survey preamble. These documents must be attached to the application. A template Participant Information Statement (PIS) covering the information (as required by the NS2.2) is available at https://www.swinburne.edu.au/intranet/research/research-integrity--ethics/human-research-ethics/how-to-apply-for-ethical-review/

People being asked to participate in a research project must be properly informed as to what they are being asked to do and the likely consequences for them if they do choose to participate. Information statements must be written in simple plain English and without technical terminology. The choice to participate must be made in absence of any coercion.

4.9 Indicate what type of consent will be sought. If consent is to be given by someone other than the participant, you must specify by whom. Written consent of participants is normally required. For this reason, investigators are usually required to prepare a written Participant Information Statement (PIS) and Consent Form. Exceptions to the requirement for a written PIS and Consent Form will be considered such as implied or oral consent. If you do not intend to provide a written PIS and Consent Form or where signed consent is not to be obtained, you are required to justify this. Along with a PIS and Consent Form, a Withdrawal of Consent Form should also be provided to potential participants at recruitment stage if appropriate for your study.

Participants must be provided with their own copy of the PIS and Consent Form to keep. An outline of the required components of a PIS and Consent Form is available on the human research ethics web site - see **Participant Information Statement Guidelines** available on that website. The title of the project and the names of the investigators,
including affiliations must appear at the top of both the PIS and the Consent form.

If the research is conducted in an **overseas country**, then written PIS and Consent Forms are usually expected to be translated into the language of that country or the most appropriate language for the participants being recruited. If the researcher is not a native speaker of the language, then translated copies should be verified as being equivalent to the English versions by either a Swinburne staff member or the translated copies should be professionally certified.

For projects involving participants who are **under 18 years of age**, it is the responsibility of the investigator, in all but exceptional circumstances, to ensure that each child or young person has parental/guardian consent prior to them participating in the project. In addition, it is the responsibility of the investigator to ensure that the child or young person is willing to participate. Investigators should not assume a child has agreed to participate just because their parent or guardian has given consent. Where signed consent is not to be obtained from parents or guardians for participants under 18, justification for this must be included in the application for ethics approval.

**Implied consent** The ethics committee accepts that a questionnaire completed and returned by a participant may constitute implied consent. A signed agreement to participate is not required if the project only necessitates the return of a questionnaire that does not contain information identifying the participant, for example, an anonymous survey. It may be sufficient to provide participants with a Participant Information Statement as a cover page to the questionnaire. In this case, the cover page must include all of the information required in a standard PIS and Consent Form with the exception of the signature block at the end of the form. Please note, however, that where an anonymous questionnaire is to be administered to children in schools, parental consent is normally required.

If the project includes any methodology other than an anonymous questionnaire, a signed agreement must be included, with provision for both participant and investigator to sign the form, unless the ethics committee has approved an alternative.

**Consent via VCAT** If a research project involves procedures for the purposes of medical research and the procedure is to be conducted on participants 18 years and over that have a disability and are incapable of giving consent to the procedure then the consent of the Victorian Civil and Administrative Tribunal (VCAT) may be required. For these purposes, a disability is defined as having an intellectual impairment, mental disorder, brain injury, physical disability or dementia. In this instance medical research includes clinical trials, observational studies, human tissue studies, human genetic research, physiotherapy studies, behavioural science projects and epidemiological studies.

However, an application to VCAT may be unnecessary where the project involves simple
forms of measurement of height, weight, blood pressure or vision; routine diagnostic measurements such as ECGs and MRIs; where there is minimal risk of harm to the patient; the collection of body tissue by non-invasive means, such as collection of urine samples, provided that the collection is not for the purposes of genetic or other controversial research; observation of a person's activities without significant compromise of privacy; gathering information in the course of routine medical treatment and talking to or questioning a person, whether by formal questionnaire, personal interview or focus group; and where the consequences of participation are not detrimental to the person's interests. In such cases, consent should be sought from the next-of-kin as for non-medical research projects.

**Research in schools** Researchers must ensure that parental consent is obtained for children or adolescents participating in research at their school.

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.10</td>
<td>If the information statement and consent documents are to be written in a language other than English, then both the English and the non-English version need to be submitted with the application. Researchers should take appropriate steps to ensure that the non-English version is appropriate.</td>
</tr>
</tbody>
</table>
| 4.11 | NS 4.3. This includes parent/child, guardian/ward, administrator/client, professional/client, teacher/student, doctor/patient, warder/prisoner, supervisor/subordinate, other power relationship etc. Special care must be exercised if any participants in a study are in a dependant or unequal power relationship with any of the researchers. Participants who might be considered to be in a dependent relationship with the researchers include:  
- People under the care of a health professional or carer who is also a researcher;  
- People under the care of a health professional or carer who will assist in recruiting participants;  
- People whose superiors in their place of employment will assist in recruiting participants;  
- University students whose teachers or supervisors will assist in recruiting participants;  
- School students whose teachers or school principal will assist in recruiting participants;  
- People who are clients of an investigator or of any professional who will assist in recruiting participants;  
- Prison authorities and prisoners.  
Projects involving the participation of people in dependent or unequal power relationships must satisfy the ethics committee that inclusion of people in this situation is justified, that the rights and welfare of participants will be protected, and that the person's consent is both adequately informed and voluntary. In addition, the applicants must give an assurance that refusal to participate in, or withdrawal from the research, will not result in any discrimination, reduction in the level of care, or other penalties for the participant. |
4.12.1 This question is designed to give the ethics committee an idea of how much time each activity in the project will be required of participants. It could be that a particular group of participants might only take part in some of the activities in the project. If there are multiple interviews per participant then add up all the hours a participant is required to participate. A range can also be given i.e. 2-3hrs. An explanation of this is required in 4.12.2.

4.12.2 All activities identified in 4.12.1 must be explained and any related documentation attached to the application. A flow chart can be used if it makes it easier to understand what participants or participant groups are doing and when.

Section 5 Data Collection, Retention, Use and Disposal

5.1 Identify the type of data you are collecting, using or disclosing. If you will be collecting more than one type of data, check all boxes that apply.

5.2 If you answered YES you will need to provide a proposal to the main committee as to why the public interest value of your research out-weighs the public interest in the protection of privacy.

The terms “health information”, “sensitive information” and “personal information” are defined under relevant legislation and can have some varying usage. This matter should be approached with the understanding that it concerns any information (whether health, sensitive or personal) from which an individual's identity can reasonably be determined and informed consent is not being obtained for its collection, use or disclosure. It is also important that you understand the terms “collection”, “use” and “disclosure”.

If the information you are planning to access is subject to the following Guidelines:

- Guidelines under Section 95 of the Privacy Act 1988 (Cth), available at: https://www.nhmrc.gov.au/guidelines/publications/pr1 and/or
- Guidelines under Section 95A of the Privacy Act 1988 (Cth), available at: https://www.nhmrc.gov.au/guidelines/publications/pr2 and/or

then you will also complete Section 3 of the Victorian Specific Module (VSM), available at: https://www2.health.vic.gov.au/about/publications/formsandtemplates/Victorian Specific Module

There is a Guide to completing the VSM, available at: https://www2.health.vic.gov.au/about/publications/formsandtemplates/Victorian%20Specific%20Module%20Guidelines

If the collection, use and/or disclosure of identifiable personal/sensitive/health information are subject to other jurisdictions, please contact the Swinburne Research Ethics Office.
Clarify how your data collection procedures will protect the participants' privacy and confidentiality. Confidentiality can be maintained by:

- not recording participant names or any other identifying information;
- using participant codes; or
- keeping and storing results separately from the lists of names and codes.

Particular care should be taken when conducting focus groups in which sensitive information may be revealed. At the beginning of a focus group, the facilitator should provide clear guidance about confidentiality practices that are to be observed by all group members. In addition, the facilitator should intervene whenever these practices are not followed by any group member, including the termination of the group discussion if necessary.

Re-identifiable data may require special attention in relation to privacy and confidentiality issues.

Participants must be informed if recordings of any form are to take place and how their confidentiality and privacy is to be ensured. If a participant is identifiable, then they must consent to this. This information should be in the Participant Information Statement and Consent Form.

Include in your answer what the form of the data will be, for example, de-identified, re-identifiable or non-identified. Data relating to research involving Aboriginal and Torres Strait Islander Peoples may be subject to cultural, regulatory or contractual requirements. Be sure to include details as to what consultation has taken place and what culturally appropriate arrangements have been made.

In many cases, it is appropriate to provide participants with a summary of the results of the research. If relevant, this information should be included in the Participant Information Statement and Consent Form.

Participants must be informed as to how their data are to be reported and this information should be in the Participant Information Statement and Consent Form. Outline if participants will have the option of being identified or referred to by a pseudonym. Where the sample size is very small, it may be impossible to guarantee anonymity/confidentiality of participant identity. Participants involved in such projects need to be clearly advised of this limitation in the information provided to participants. **NS 3.1.10**

If results of the study will appear in any publication (journals, conference papers, theses, reports) state this here. Include this information on the Participant Information Statement and Consent Form. If there no publically accessible outcomes explain why.


All records and materials should be stored in secure, lockable locations. Computer files should be password protected. Specify the precise location of the storage place and explain who will have access to the data. Give details such as the storage medium, for example a locked filing cabinet or password-protected computer files and include precise location details, such as the room number, department, faculty and campus of the University or department in a specified external institution. It is not usually acceptable for data to be stored in an investigator's home but where this is the case, researchers should explain how the data will be kept secure and
when it will be transferred to the University.

In virtually all cases, data must be stored at the University following completion of the study. Researchers are to specify the precise location of the storage place, as outlined above, and explain who will have access to the data. Note that it is not acceptable for original data to be stored in an investigator's home. Researchers are to also state the date and stage at which raw data, such as personal participant identifiers, interview notes, returned questionnaires and audio/video tapes will be disposed of and the method of disposal.

5.11 Note that the **minimum** period for retention of research data is 5 years from the date of any publication and varies depending on the specific type of research. For more information refer to Section 2 of the Australian Code at [http://www.nhmrc.gov.au/guidelines/publications/r39](http://www.nhmrc.gov.au/guidelines/publications/r39)

Data, de-identified where appropriate, and Consent Forms should normally be kept for a period consistent with the requirements of the Public Records Office of Victoria Standard (PROS02/01), normally at least 5 years for non-clinical trial data and 15 years for clinical trial data, following publication/completion of the project. Please note that for certain types of research and for projects conducted in association with external agencies such as hospitals, data and consent forms may be required to be kept for longer periods than normally required by the University.

Where the investigator plans to keep data, including samples and specimens collected for possible future use in another research project, the investigator must specify:

- the nature of the data to be kept
- when the data might be used in another project
- how that data might be used and for what purpose it might be used
- who might be given access to the data for another project

5.12 Describe how you intend to use the data in the future and how you have informed participants of this.

Data can only be used for the current project as described and approved. If you intend to use the data in future research projects then you must inform participants via the Participant Information Statement.

Any further use of the data is subject to a specific separate ethics approval at the time it is to be used. The intention to keep data for future use must be included in the Participant Information Statement and Consent Form. Note that if the specific names of personnel who will access the data in the future are included in the PIS and Consent Form, then access to these data will be restricted only to those named individuals.

---

**Section 6 Ethical Considerations**

6.1 **NS 2.1** Burden is the impact on the participant caused by, for example, filling in the form, questionnaire, having their blood pressure taken or anxiety induced by an interview.
Researchers need to carefully consider participant involvement from the point of view of the participant and list all potential burdens regardless of severity.

6.2 **NS 2.1** A risk is a potential for harm, discomfort or inconvenience. Risks can be emotional, social, legal, medical or physical and can include distress. Researchers need to carefully consider participant involvement from the point of view of the participant and list all potential risks regardless of severity.

6.3 **NS 1.7 and 2.1** Researchers need to identify strategies for the management and wellbeing of participants if any of the risks identified should occur no matter how minor they appear. This includes distress protocols, occupational health and safety practices (including possible exposure to electrical currents), first aid procedures etc.

6.4 **NS 1.6 and 2.1** Briefly and clearly justify your research proposal in terms of the benefits versus the burden and or risk of participation.

6.5 **NS 5.5 and 3.3.19-3.3.2** It is a condition of approval that researchers immediately report to the Ethics Office reportable adverse events.

Adverse events are any undesirable or unintended response or occurrence in a participant that can be related or not to the study. Serious adverse events (SAEs) are any untoward medical occurrence that:

- Results in death;
- Is life-threatening;
- Requires inpatient hospitalisation or prolongation of existing hospitalisation;
- Results in persistent or significant disability/incapacity;
- Is a congenital anomaly/birth defect; or
- Is a medically important event or reaction.

Serious unexpected suspected adverse reactions (SUSAR) are events for which there is some degree of probability that the event is an adverse reaction to the administered drug and the reaction is unexpected. Unexpected adverse drug reactions (UADR) are usually reactions that the nature or severity of which are not consistent with the applicable scientific information. SAEs, SUSARs and UADRs are all reportable adverse events.

6.6 **NS 2.2.10-2.2.11 and 3.3.18** Reimbursement or any other inducement for participation that would encourage participants to take risks is ethically unacceptable. It is however acceptable to reimburse costs involved with participation including travel, accommodation and parking.

If using the Psychology Research Experience Program (REP) you must provide details of the advertising, the debriefing statement and the amount of credit to be awarded. Ethics approval is required to access the REP.

6.7 **NS 2.3** Generally it is ethically unacceptable to conduct research that is covert or deceptive. However it is acknowledged that there may be experimental procedures which would not be possible if the participants knew in advance what the research aims and procedures were. In such cases, participants should not be subjected to any
procedure which is likely to result in harm or undue risks and participants must be fully informed at the close of the experiment, through a debriefing process, about the true nature and aims of the research. Where possible and appropriate, if a participant wishes to withdraw consent immediately following debriefing, investigators are required to destroy, in a secure manner, the participant's data arising from their participation. Research projects involving active concealment or planned deception are not considered low or negligible risk and can only be approved by the main committee.

| 6.8 | Carefully consider any risks to the researchers being involved in this project and outline how each will be managed. For example where interviews are to be held in participants’ homes as opposed to public places provide a rationale other than convenience for why this is necessary (and outline the personal safety protocol for the researchers involved). Australian Code 1.2. |
| 6.9 | Consider any risks to relatives of participants, bystanders, or the project sponsor including the University. Describe the possible risks and outline how they will be mitigated and managed. |
| 6.10 | Research in some instances may discover illegal activity by participants or others and researchers need to carefully consider the impact of their study and the possible need to act on their findings. Include in your explanation why there is no legal alternative. Consider the benefits of the research as opposed to the risks to the participants and if there is sufficient confidentiality arrangements in place. |
| 6.11 | For example are any of the researchers, employees, shareholders or promoters of the funding body? Will researcher(s) receive any additional or bonus payments or benefits related to the conduct of the research and outcomes? All perceived, potential or actual conflicts of interest must be declared. Further to this participants in the project should be informed via the PIS and any conflicts should also be disclosed in any reports. |

**Section 7 Declarations and Signatures**

| 7.1 | All listed investigators, including students (but not those involved in class projects) must sign the declaration here. |
| 7.2 | All supervisors of students involved in the project must sign this declaration. |
| 7.3 | This is to be signed by your Academic Head of unit or above. This person cannot be a named investigator on the project. If they are then the next level of management should endorse the project. |