

UWA Human Research Ethics Application - Risk Assessment Checklist

PLEASE ANSWER ALL QUESTIONS

Ethics Approval for Research Involving Humans

Protocol number

TRIM Number
(Office Use Only)

Project Title:

Project Summary (Plain language explanation)

Chief Investigator or Supervisor (if Student Research)

Address 1

Address 2

Address 3

Email

Phone

Employee Id

Department

CI Position

Qualifications

Organisation
(if not UWA)

Mailing Address

Yes No Are Other UWA Investigators Involved in this Protocol?

Yes No Are External Investigators Involved in this Protocol?

SECTION 1

Exemption from ethics review is requested on the basis that the activity should NOT be classified as "human research".

Yes No B1 Is your proposed activity a quality assurance, an audit or a teaching & learning activity that is conducted as part of the usual business in which you are engaged, rather than "human research"? (E.g. Quality assurance studies, or audits, in health care delivery, or in other professional fields; or surveys, tests, interviews or observations for teaching & learning purposes may not be classified as "research" and, therefore, may not require human research ethics approval.)

SECTION 2

Exemption from ethics review is requested as the activity, although classifiable as "human research", meets National Statement criteria for exemption.

Yes No B2 Does your research involve anything more than access to, and use of, existing data or records that contain only non-identifiable information about people?

Yes No B3 Does your research involve anything more than "**negligible risk**"? For a definition of negligible risk refer to paragraph 2.1.7 on page 18 of the *National Statement on Ethical Conduct in Human Research* located at: http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/e72-jul09.pdf

PART C - CHECK FOR MANDATORY L3 ETHICS REVIEW BY A HREC

Yes No C0 Is this a Biomedical Project?

Yes No C1 Does the research involve any physically invasive procedures or the collection, extraction or use of human tissue (including cell lines), blood or other body fluids?

Does your research involve the following?

- Yes No C2 Active concealment of information from participants and/or planned deception of participants. (National Statement NS 2.3.4)
- Yes No C3 A focus on illegal activity or highly likely to discover illegal activity (NS 2.3.4 and NS 4.6)
- Yes No C4 A focus on people with a cognitive impairment, an intellectual disability or a mental illness. (NS4.5)
- Yes No C5 A focus on Aboriginal and Torres Strait Islander (ATSI) peoples, groups, communities or issues. (NS4.7)
- Yes No C6 Provision of data or linkage between one or more databases that will require further approval of the Department of Health of Western Australian Human Research Ethics Committee?
- Yes No C7 Use of personal (identifiable) information in medical research, or personal health information, including tissue samples, without specific consent from the individuals to whom the information relates. *This includes cell lines other than those acquired commercially* (NS2.3.5)
- Yes No C8 Clinical research, an innovation in clinical practice, a clinical trial or the application of randomised trial methods in other fields of human research (NS3.3)
- Yes No C9 Human genetic studies (NS 3.5)
- Yes No C10 Human stem cells (NS3.6)
- Yes No C11 A focus on women who are pregnant and/or research involving the human foetus. (NS4.1)
- Yes No C12 People highly dependant on medical care who may be unable to give consent, e.g. unconscious or too ill. (NS4.4)

PART D - CHECK FOR ELIGIBILITY FOR EXPEDITED L1 ETHICS REVIEW

- Yes No D1 Will participants be quoted or be identifiable, either directly or indirectly, in reporting of the research?
- Yes No D2 Is it planned to recruit any adult participants who will not have sufficient competence to provide valid consent. (NS2.2.12)
- Yes No D3 Will the research involve children or young people aged <18 years who may lack the maturity to provide their own consent? (NS4.2)
- Yes No D4 Are the research participants in an unequal relationship (either now, or possibly in the future) that may influence their choice of whether to participate or not participate in the research, e.g. are the participants the students, patients, or employees of any of the researchers OR are the research participants prisoners, in custody, on remand, on parole, or, as members of the armed forces, employees of a company, or members of a police force, might they be in a position to experience or perceive pressure to participate in the research? (NS4.3)
- Yes No D5 Will data that can identify an individual (or be used to re-identify an individual) be obtained from databanks, databases, tissue banks or other similar data sources? (NS3.2)
- Yes No D6 Is there any risk of physical injury to participants? (NS2.1)
- Yes No D7 Could the research procedures cause substantial pain or physical discomfort to participants? (NS2.1)
- Yes No D8 Might the research procedures cause participants psychological or emotional distress? (NS2.1)
- Yes No D9 Could the research expose participants to civil, criminal or other proceedings? (NS2.1)
- Yes No D10 Does the research involve the collection of sensitive personal information? (NS2.1)
- Yes No D11 Could the research expose participants to economic loss, reduced employability or damage to their reputation? (NS2.1)
- Yes No D12 Could the research have a negative impact on personal relationships? (NS2.1)
- Yes No D13 Will potential participants be offered inducements that could be considered coercive to them? (NS2.2.10, NS3.3.5)
- Yes No D14 Does the research involve covert observation? (NS2.3.1)
- Yes No D15 Does the research involve limited disclosure to research participants? (NS2.3.1)

DECLARATION BY CHIEF INVESTIGATOR OR PROJECT SUPERVISOR

This application will be reviewed by the University's Human Research Ethics Committee.

By ticking the boxes below you are declaring that:

I am satisfied that an adequate peer review has been conducted and that the research proposal is ready for submission for ethics approval.

The resources required to undertake this project are available.

The researchers have the skill and expertise to undertake this project appropriately

Signed:
(type name)

Date:

List Internal Personnel (including students)

Researcher 2:

Category:

Department /
Institution:

Researcher 3:

Category:

Department /
Institution:

Researcher 4:

Category:

Department /
Institution:

Researcher 5:

Category:

Department /
Institution:

Researcher 6:

Category:

Department /
Institution:

Researcher 7:

Category:

Department /
Institution: