Guidelines for negligible risk research

The *National Statement on Ethical Conduct in Human Research (2007)* (National Statement)**,** specifies come studies can be exempt from human ethics review and approval (National Statement 5.1.22). This includes:

1) Studies which pose negligible risk to participants. **Research is classed as 'negligible risk' where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience** [e.g. filling in a form or giving up time to participate in an anonymous survey of preferences]. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk (National Statement 2.1.7).
2) Research that involves the use of 'existing collections of data or records obtained by means of approved research studies that contain only non-identifiable data about human beings' (National Statement 5.1.22.b). Non-identifiable data is data which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and therefore no specific individual can be identified. Please avoid the term 'de-identified data', as it can also be used to refer to a record in which identifying information has been removed but the means still exist to re-identify the individual. (Note: research involving human biospecimens and data from Aboriginal and Torres Strait Islander peoples do not meet this criteria and require review).

Research which involves risk of discomforts (e.g. minor physiological side-effects like fatigue, measuring blood pressure or anxiety induced by an interview) or harms (e.g. physical, psychological, social, economic or legal), even if unlikely, which may be more serious than inconvenience **cannot** be regarded as involving negligible risk.

Whilst the National Statement allows for exemption of human ethics approval, the research must meet the requirements of the National Statement (National Statement 5.1.23). As such La Trobe University has the following expectations in regard to negligible risk research:

- Studies that may be considered as involving negligible risk and do not require human ethics approval, are required to submit to the relevant College Human Ethics Sub-Committee (CHESC) for assessment and acceptance by the Chair. Please note the Chair may refer projects to the relevant low risk CHESC or University Human Ethics Committee (UHEC).

- Researchers must maintain auditable records of negligible risk studies.

- Where information is to be obtained from individuals, researchers are expected to provide Participant Information Statements which comply with the requirements of the Participant Information and Consent form Guidelines**.**

- Negligible risk studies cannot be modified using the Modification form, minor changes to a project do not require review. Researchers are responsible for informing the CHESC of any major modifications that may mean the research no longer fits the requirements of a negligible risk project. The Chief Investigator should send an email to the relevant CHESC entitled "modification for negligible risk project" with the project reference number (e.g. S16-500). Researchers will be informed via email if they are required to submit an application for human ethics review and approval to the CHESC or UHEC or if the modification is acceptable.

Examples of negligible risk studies include:

1) **An anonymous online survey of adults** asking about pet ownership, which does not collect any personal or sensitive information that can in any way be linked with the data. Some survey platforms allow you to collect personal details for compensation purposes separately from the main data collected so that they are not linked together.

2) **Studies that relate to normal work activities** undertaken by a staff member that meet the definition of being negligible risk. These may be similar to quality assurance but defined as research. For quality assurance guidance, see details below.

3) **Studies of public behaviour that are purely observational** (non-invasive and non-interactive), such as standing in a public place and noting the actions of passers-by. If interaction with participants will occur, such as taking photographs or videorecording, human ethics approval is required.

Quality Assurance

Where researchers determine their project(s) to be a quality assurance/evaluation, researchers are asked to read the NHMRC guidelines on quality assurance and note that where one or more of the triggers for review apply, it should be sent to either the low risk or above low risk review. A letter to confirm the project is quality assurance can be provided if required, please contact the relevant CHESC human ethics officer.

SUBMISSION REQUIREMENTS

Please send an email with the subject heading, "Negligible risk application" with the following attachments:

1) Negligible risk application form
2) Risk assessment checklist
3) Participant Information Statement(s) (if applicable)
4) Questionnaires (if applicable)

Useful Links

National Statement on Ethical Conduct in Human Research (2007)
http://www.nhmrc.gov.au/guidelines-publications/e72

Ethical Considerations in Quality Assurance and Evaluation Activities
http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e111_ethical_considerations_in_quality_assurance_140326.pdf

Contact details

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