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HUMAN RESEARCH ETHICS COMMITTEE POLICIES AND GUIDELINES

National Statement

The *National Statement on Ethical Conduct in Human Research* (2007) is University policy.

Application forms

The committee's policy is only to accept the most recently updated application form. Allowance will be made for the time-lag between downloading and submitting forms.

Duration of approval

Ethics approval is ordinarily given for up to 3 years. Researchers are able to seek an extension of up to a 1 year, making a total of up to 4 years approval.

- a. Ethics approval should be sought for the anticipated duration of work which involves human participants.
- b. Up to 3 years is considered a normal time frame for research projects, and initial ethics approval is normally given in line with this.
- c. The HREC will consider individual requests for longer terms of approval, such as for longitudinal studies or from part time students. In such instances, researchers should apply for entire anticipated duration of the study. Justification should be provided as part of the application for the extended time frame.
- d. The HREC may, at its discretion, approve all or only part of the time frame being applied for.
- e. The duration of approval is always contingent on the provision of an annual report.
- f. A formal request for all extensions must be made as this will not be automatic.
- g. Where an extension is sought beyond a total of 4 years the HREC will require a more extensive report, including justification that the project continues to meet ongoing ethical standards.

Approval beyond 4 years

Where an extension of approval is sought beyond 4 years, the HREC will conduct a review of the project no less than required by the National Statement (NS 5.5).

To facilitate this, the researcher will

- a) Provide an updated application form which incorporates all amendments or changes that have been made to the project, a summary of progress to date and information about any publications or outcomes of the research. The researcher should demonstrate how the project meets current ethical standards.

Alternately, where the HREC initially agreed to a time frame greater than 4 years, the researcher will

- b) Provide a statement outlining any changes that have been made to the project, a summary of progress to date and information about any publications or outcomes of the research. The researcher should demonstrate how the project meets current ethical standards.

Failure to provide the additional documentation may lead to suspension or closure of the project.

The review documents will be given a 'low risk' review in the first instance. The full HREC will review only those projects where the risks to participants have increased. Researchers need to be aware that this process, like any ethics review, can lead to additional or new conditions being placed on a project or more information being asked.

The HREC may also conduct further discussions with the researcher and / or undertake a site visit.

Time frame for response to conditions

The HREC expects researchers to respond to conditions in a timely manner. If no response to conditions has been received within 4 months from the date of sending the HREC's conditions letter, the conditional approval lapses and a fresh application will be required.

Repeating studies

If a study has been previously approved, or is based largely on a previously approved project, then the application will usually be reviewed as part of the low risk process in the first instance. To facilitate this, researchers must indicate on the Application Form which previous study the current application relates to and outline clearly any differences or diversions from the previously approved study.

Attachments to applications

Applicants are responsible for ensuring that all information relevant to the research project is incorporated into the application form. Applicants should attach standard documents such as Information Letters, Consent Forms, and copies of surveys, questionnaires or indicative interview questions.

Attachments or appendices related to rationale or procedures, e.g. project methodologies or program of study outlines, will not be read. This is material which should be summarised within the application. Unnecessary attachments will not normally be printed or distributed to the committee. Applicants need to be aware that attaching material in this way without providing an appropriate summary in the Application Form can delay approval of a project

Reimbursement for participating in a study

Appropriate reimbursement to cover the cost (to a participant) of participating in a study is acceptable. As a general guide, movie tickets, vouchers, the provision of meals or the opportunity to participate in a raffle are acceptable. Participation must at all times remain entirely voluntary and reimbursement must not be sufficient to be coercive.

Prizes

The Committee will make case-by-case decisions where applications include prizes as a form of inducement or reward. In considering the issue of prizes, the committee will take into account the extent to which this could coerce or pressure someone into participating in a study. Participation must at all times remain entirely voluntary.

Advertising for participants

Any form of advertising designed to attract participants to a study should be clear about the purpose and procedures of the study and must be presented in a form that does not pressure people to participate in the study.

Personal interest or conflict of interest

Researchers and HREC members must declare any personal interest or conflicts of interest, as required by the National Statement and by university policy.

It is usual for a member of the HREC to absent themselves from the meeting for the deliberation on an application where that person is named as an investigator. Where a member of the HREC has given significant advice towards the preparation of an application, that member must declare the potential for a conflict of interest at the time the application is discussed.

Project closure

The chief investigator is responsible for ensuring that a Project Closure form is completed at the end of the project. This should be done once contact with participants has been finalised. The closure form should be accompanied by a copy of the feedback given to participants.

Storage and destruction of data

The university's *Code of Conduct for Research* (1999) states:

"3.2 Data must be held for sufficient time to allow reference. For data that are published this may be for as long as interest and discussion persists following publication. It is in the interests of all researchers to ensure that original data are safely held for periods of at least five years."

Data includes audio tapes, video tapes, digital records and other records. In some cases participants may request or agree for tapes to be destroyed after they have been transcribed; in such cases usually only the transcript is retained. Investigators must detail in their applications how and where data will be stored both during and after the project, the level of security of the data storage and ongoing the accessibility of the data at least to the School or Department where it was generated.

Information for Participants

Research information is not legally privileged, it can be required to be submitted e.g. through a subpoena. Hence, researchers cannot give participants an (implicit or stated) absolute guarantee of confidentiality. Therefore, as statement along the following lines should be included in all participant information letters:

"...all information provided is treated as confidential and will not be released by the researcher to a third party unless required to do so by law."

Completion or discontinuation of a project

A standing condition of HREC approval is that researchers complete a Project Closure form once the project has been completed. If the project is discontinued prior to its expected date of completion, a Project closure form must be submitted as soon as possible.

Participant consent

Questionnaires that are strictly anonymous - where participants cannot be identified - generally do not require separate written consent from participants. Researchers must provide adequate description of the project so that participants can make give informed consent. It is usual to include a statement on such surveys to indicate that consent is assumed when the participant submits the survey.

Amending research protocols

Researchers may amend their research protocols or procedures. It is a requirement of the *National Statement* that the HREC is informed of changes to a research project. This is achieved by submitting an Amendment form. If the change is considerable and represents a significant deviation from the protocols presented in the original approval, a new application may be required.

Amendments are usually reviewed through the low risk review process. Applicants can generally expect to receive a response within a few working days.

Participant withdrawal

If a participant decides that s/he no longer wants to take part in the research, all data collected from that participant ceases immediately. If the participant asks to have any data collection from them destroyed or returned to them, that request must be honoured. However, if the data that has been collected is non-identifiable, then the participant must be told that their data cannot be extracted, but that no further data will be collected.

Consent of children

Children taking part in research shall be asked to provide consent whenever they are likely to have sufficient competence to do this. Children should be asked to give their consent in addition to that of a parent / guardian. This may be done by inviting the parent / guardian to discuss a project with their child and for the child to co-sign the consent form. If the consent form is signed in advance of the investigation (eg it is signed at home and mailed to the researcher) then a child's withdrawal of consent at the time of the research investigation must be respected regardless of the signed Consent Form.

Security Clearances

Where there are risks to researchers and / or participants an appropriate security clearance will usually be required. This includes research conducted in private homes or in some institutions, researching with children as participants or with some culturally identifiable groups.

For research in private homes a National Police Certificate is required.

For research with children, registered teachers will need to provide evidence of a Western Australian College of Teaching (WACOT) Criminal Record Check. All other researchers will need a Working With Children check. Copies of these should be provided as part of the Ethics Application.

Working with children

Does any part of the research focus on children under the age of 18?

Will you be in the presence of children and unsupervised by other adults?

Will you have access to personal information about children (e.g. home address, phone number, club memberships etc)?

Are the staff and / or volunteers in the organisation you will be attending ordinarily required to apply for a Working with Children Check?

Further information can be found at www.checkwwc.wa.gov.au

If the answer is 'yes' to two or more of these questions, then it is likely that a Working With Children check will be required.

National Police Certificate

Will the research involve interaction with people in their home or in a private setting? (This includes 'doorknocking' and entry onto private property.)

If 'yes', a National Police Certificate is required.

Will there be access to confidential, restricted or commercially sensitive material during the conduct of the research?

If 'yes', check with the organisation/s where the research is taking place whether or not they require a National Police Certificate.

National Police Certificate applications must be lodged at participating Australia Post outlets. For further information see www.police.wa.gov.au/OurServices/PoliceChecks/NationalPoliceCertificates/tabid/1339/Default.aspx

Other security clearances

Some other kinds of security clearance exist. These can be negotiated on a case by case basis. In each instance the researcher needs to demonstrate that they have at least the same standing as the more commonly required clearances.

Clearances are normally considered valid for up to three years from date of issue. Following this a new clearance will usually be required.

Ethics approval can sometimes be given to researchers whose security clearances indicate offences or convictions so long as the type of offence or conviction does not impact directly on the research being undertaken. Each application will be considered by the HREC on its merits.

Chief Investigator

The Chief Investigator for a project must be a Murdoch member of staff able to take ultimate responsibility for the project. For a student project this will usually be the supervisor. Students will be listed as Student Investigators. The reason for this is related to wider issues of risk management, professional indemnity insurance and University responsibility.

Support for participants

In instances where it is likely that participants could have an adverse reaction to the research e.g. an emotional, physical, or psychological reaction, a researcher should provide for the possibility of appropriate support to participants. This might be access to counselling, medical referral, or other professional support. In cases where the HREC might reasonably see a need for additional support, researchers should provide details of what kind/s of support are offered and how participants can access the support.

Aboriginal and Torres Strait Islander participants

Research conducted with Aboriginal and/or Torres Strait Islander participants must include a separate statement demonstrating how the issues in the relevant section of the *National Statement* and the *Murdoch University guidelines on Aboriginal and Torres Strait Islanders* are addressed. Research with Aboriginal and Torres Strait Islander participants cannot be expedited.

Door knocking

Entering private property usually requires that a researcher has a National Police Certificate. It is recommended that when door knocking a researcher be accompanied by a second person for their own personal protection. Researchers (and anyone accompanying them) must wear Murdoch University identification.

Low-Risk Review Committees

Low risk review committees function formally as sub-committees of the HREC (NS 5.1.18-21). These committees are usually chaired by members of the HREC. The HREC has the right to re-examine any application reviewed through the low risk process and can add further conditions, suspend or withdraw approval even if work has already started.

Journalism and media studies

All journalistic and media activities must be undertaken in accordance with the appropriate professional codes of conduct.

It is normal practice for staff and students in journalism and media studies to conduct interviews. Where undergraduate students conduct normal journalistic activities ethics approval is not expected. Where students are working towards an honours or postgraduate award, ethics approval is expected. It is accepted that written consent from participants can be impractical in this field. Staff and students must ensure that the standards of voluntary informed consent are maintained at all times. Interviewees must be fully informed about the context and purpose of an interview and the voluntary nature of their participation. The wishes of interviewees, regarding the use of written, audio or video material collected, should be upheld.

In film and television production both HREC approval and written consent from participants are required. If a participants' consent is withdrawn after video or audio material has been obtained, researchers should endeavour, as far as is practically possible, to accord with participants' wishes regarding the use of that material. Consideration should also be given in cases where the duty to respect the rights and wishes of participants conflicts with a duty to disclose information of major public interest.

Multi-Centre applications – minimising duplication

Applications being considered by another HREC, where the other institution is the lead institution should

- Provide a copy of the application that was submitted to the other institution.
- Complete the first 11 questions of Murdoch's ethics application form.
- Nominate, as chief investigator, the responsible Murdoch researcher.
- At question 11 of the Murdoch application form, outline the specific contribution of the Murdoch researcher/s to the project.
- Attach copies of letters of approval from the other institution(s), including details of any conditions placed on the research.

Provision of this complete documentation will usually enable a low risk review at Murdoch.

Once approval is granted the nominated Murdoch researcher must ensure that all standard reports and forms are completed and submitted to the Murdoch Research Ethics Office, and that any adverse events (regardless of where they occur) are promptly reported, in writing, to the Murdoch HREC.

Complaints procedure

Formal complaints about the decisions or processes of the HREC must be in writing.

1. In the case of students, the supervisor is the first contact point for lodging a formal written complaint. The supervisor should lodge the complaint with the chair of the HREC.
2. In the case of staff the chair of the school research committee or Head of School (HOS) is the first contact point for lodging a formal written complaint. The chair of the school research committee should lodge the complaint with the chair of the HREC.
3. The chair of the HREC will determine how a complaint is to be handled and will ensure procedural fairness.
