ALFRED HOSPITAL ETHICS COMMITTEE

The Low Risk Guide

This guide contains

Overview

A low risk activity is defined by the National Statement on Ethical Conduct in Human Research (2007) as one where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.

It is important to note that:

- Risks include potential risks and not just actual risks
- Risk is defined by the National Statement and Ethics Committee rather than the clinical context
- Risks are not confined to just physical risks and can include psychological, social, financial and cultural risks

Low risk review is a process whereby activities that are low risk are reviewed to ensure that issues of an ethical nature are addressed before commencement of the activity.

Submitting an application for review

1. Applicants must review checklists 1 and 2 to determine if the activity is suitable for low risk review.

2. If the activity is to be conducted at multiple sites and reviewed under a multi-site streamlined ethical review scheme the information on the multi-site streamlined webpage along with the streamlined ethical review guide should be followed.

3. Applicants should be familiar with and understand privacy and identifiable health information as outlined in Table 1.

4. Activities in the following categories need initial review prior to submission of an ethics application for ethics review

- Nursing research and/or research involving nurses needs review by Nursing Research
- Activities involving the resources, staff or patients of the Rehabilitation, Aged & Community Care (RACC) Program at Caulfield Hospital, require a signed Notice of Intention
- Activities instigated by the Department of Health and Human Services requiring facilitation across numerous departments or activities seeking to use Alfred Health policies and guidelines should consult the Clinical Governance Unit.

5. If the activity is to be conducted at Alfred Health, an appropriately qualified Alfred Site Principal Investigator will be required. A student cannot be the Site Principal Investigator but may be a 'student Co-Site Principal Investigator' along with aresearch-experienced member of staff.

6. Applications are made using either:
   I. The Alfred Hospital Ethics Committee Low Risk Application form for single site review or
   II. The Human Research Ethics Application Form (HREA) for multi-site Low Risk applications

A separate protocol commensurate with the nature of the application is mandatory.

Other submission documents will vary on a project by project basis.

7. Follow the submission and review processes outlined on the website.
Low risk applications may be submitted at any time to research@alfred.org.au. In the subject field, type "Project for low risk ethical review", followed by your last name.

Checklist 1

If the project fits into one or more of these categories, **it cannot be reviewed through the Low Risk Process and requires a full application.**

1. ACTIVITIES REQUIRING A FULL ETHICS APPLICATION (not suitable for Low Risk review)
☐ Interventions. The research involves providing an intervention. Examples include testing, drugs, surgical procedures, therapeutic procedures, therapeutic devices, preventative procedures, collection of fresh biospecimens from donors where risks associated with collection are more serious than discomfort, diagnostic devices or diagnostic procedures.
☐ Vulnerable participants. The project requires obtaining consent from vulnerable people, where competence to provide consent is diminished. Examples include children, ventilated patients, those dependent on care, those with a mental health condition, and cognitively or intellectually impaired persons.
☐ Biospecimen (including genetic) research. The project involves research using an individual's biospecimens where information may be discovered or generated that is of potential importance to the health of the individual, their blood relatives or their community; and/or generates sensitivities for the individual, their family or their community.
☐ Human Stem Cells. The research involves studying stem cells or using stem cells or their products to develop new therapies.
☐ Pregnancy and the foetus. The research involves the foetus or foetal tissue or has the potential to impact on the wellbeing of the foetus through involvement with a woman/ women who is/are pregnant.
☐ External registries. The project involves establishing an external registry where external is defined as one or more of the following: non-Alfred Health custodian, data contribution by other institutions to an Alfred Health registry, data access and use granted to researchers from outside Alfred Health.
☐ External researchers. The research is being conducted by a person not associated with the institution and there is no one on the research team from Alfred Health.
☐ External researchers. The research is being conducted by a person not associated with the institution and there is minimal supervision by Alfred Health staff and there is a request for waiving the requirement of obtaining consent to access/collect/use or disclose identifying information and/or biospecimens.
☐ Student researchers. The project involves a student, not on placement at Alfred Health, accessing identifiable information and/or biospecimens.
☐ External sites. The research involves sites that are not part of Alfred Health, do not have their own Ethics Committee and for which Alfred Health would be required to provide research governance. Examples include private practitioners and their patients.
☐ External sites. The research involves external sites with Alfred Health as the coordinating centre, where the external sites require full HREC committee approval. Examples are where cross approval at other institutions will be sought.
☐ Illegal Activities. The research intends to study or is likely to discover illegal activity. Examples include questioning about illicit drug use.
☐ Complex and lengthy protocols. Projects deemed to have a level of complexity that will therefore benefit from full ethical review. For example, multiple sites, various participant groups, consent processes etc.

Checklist 2

If the project involves one or more of the activities below, justification may be as to why the research should be considered low risk.

2. ACTIVITIES REQUIRING JUSTIFICATION (may or may not be suitable for low risk review)
☐ Externally funded research where there is a commercial interest
☐ Data access, collection, use and/or disclosure of identifiable information without participant consent
☐ The collection of fresh tissue directly from participants (i.e. risk level of collection procedure/s)
☐ Use of already collected biospecimens without the prior donor consent for research use
☐ Transfer of biospecimens to external researchers without donor consent
☐ Access/collection/use of sensitive information
☐ Access/collection/use of information that has regulatory and/or legal reporting requirements
☐ Personally intrusive/confronting or quite inconvenient/embarrassing questioning
☐ Providing, or potential to provide, individual health/medical/psychiatric diagnosis
☐ Screening for healthy participant inclusion/exclusion
☐ Change or withdrawal of services
☐ Conflicts of interest or dual researcher-professional roles
☐ Research conducted overseas
☐ Deception (participants will receive limited or no information about the research at time of recruitment)
☐ Participant recruitment/selection via a third party
☐ Qualitative research without experience
☐ Research involving family members of the patient where participants will recruit family members or where family members may need to help the participant to take part and/or provide extra info, etc.
☐ Research involving staff where (a) staff may be identifiable in findings, (b) there is a potential to damage or infringe on the rights of staff, (c) there is the potential to cause distress
☐ Participation incentives, prizes or significant payments
☐ Research placing researchers/assistants at risk

Table 1 What is meant by 'identifiability' of health information?

<table>
<tr><td colspan="2">Data used for projects can be identifiable, re-identifiable (coded), non-identifiable or anonymous.

It is possible that projects may involve more than one of the above. For example, a clinician may access identifiable medical records, collect re-identifiable data by using a study code for each patient and keeping a separate log of the study code against the UR number and then provide only the coded data set to a student on clinical placement, so the student only has re-identifiable data to work with.

Please note:
• Linking of data sources requires identification.
• Human biospecimens are considered identifiable or potentially identifiable.
• Web-based surveys may collect 'identifiable' data if recording the IP address.</td></tr>
<tr><td>Identifiable data:</td><td>Data that allows a specific individual to be identified. Identifiers may include the individual's name, date of birth, UR or HRN number. An example is a hospital medical record. In particularly small sets of data, even information such as a postcode may be an identifier.</td></tr>
<tr><td>Coded or re-identifiable Information:</td><td>Coding is replacing identifiable data with an arbitrary code number. For example: Names & UR numbers can be replaced with a study code and the Principal Investigator could keep a separate document which has the identifying information along with the study codes. If re-identification is required – to check something at a later date – then it can be done. Dates of birth can be replaced with age at a particular cut-off point such as time of diagnosis or admission. It is important to note that data can still be potentially 'identifiable' if it is possible to infer an individual's identity from the information (e.g. asking a hospital employee about their work if they are the only person working in that role).</td></tr>
<tr><td>Non-identified data (anonymised, anonymous, unlinked, not re-identifiable):</td><td>Data that have been collected without personal identifiers and from which no individual can be identified. It should be pointed out that the term 'de-identified' is used frequently to refer to sets of data from which only names or partial identifiers have been removed; (such data may remain 'potentially identifiable' and is therefore not non-identified data).</td></tr>
</table>