

## ALFRED HOSPITAL ETHICS COMMITTEE

### The Low Risk Guide

This guide is divided into 3 sections:

1. **An overview of the Low Risk ethics review process**
2. **How to determine whether your activity is suitable for Low Risk review**
3. **How to complete the Low Risk Application Form**

Section 1 provides information on what the definition of low risk review is and what the process is for submitting an application.

Section 2 provides information on the types of activities that can and cannot be considered for low risk review. It is essential to read this section prior to completing the application form.

Section 3 provides further information to assist in completing the application form.

#### SECTION 1: LOW RISK ETHICS REVIEW PROCESS

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 Statement and Ethics Committee rather than the clinical context, and that risks are not confined to just physical 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.

Before considering sending an application in for low risk review it is important that any planned activity that fits into the following three categories, should be directed to the relevant areas first.

- **Nursing related activities** (at The Alfred only), including those conducted by nurses, using nursing resources, or involving nurses as research subjects, must be presented to the Nursing Research and Access Committee prior to any submission to the Ethics committee:  
<http://www.alfredresearch.org/ethics/nursing.htm>
- Researchers solely using **discarded tissue** should use the discarded tissue application form:  
<http://www.alfredresearch.org/ethics/tissue.htm>
- **Activities generated by external organisations** (eg DHS) requiring: help in facilitation, use of multiple departments and/or Alfred Health authorisation, should contact the Clinical Governance Unit of the Alfred Hospital: <http://intranet.baysidehealth.org.au/Department.aspx?topicID=252>

#### The process:

1. Review the activities checklist to determine if your activity is excluded from review.
2. Complete the application form. This is located <http://www.alfredresearch.org/ethics/applicat.htm>  
It is the responsibility of the investigator designated as the 'Principal' investigator to:
  - ensure that the information provided on the form is accurate and detailed sufficiently to enable review.
  - approach the relevant departments for approval to access sources of information
  - approach supporting departments for approval to provide the necessary resources (including staff, time, and facilities)
  - inform all those involved in the activity of their responsibilities
  - meet all Alfred Health requirements such as checking the 'opt-out of research' list held by HIS prior to contacting patients for participation in research.

3. E-mail the completed form and any relevant documents to [research@alfred.org.au](mailto:research@alfred.org.au) In the subject field, type "Project for low risk ethical review", followed by your last name. Please send a hard copy of the signatures in Section G to the Ethics Office. There is no submission date as applications are reviewed on a continual basis.

4. When an application is received, the Ethics Office checks the application in order to identify any preliminary issues that need addressing in order to facilitate adequate review. E.g. Failure to attach data collection pages.

5. All approved low risk projects will be allocated a project number. Future correspondence in relation to the project should make reference to this project number.

6. The application is reviewed by delegated member/s of the Ethics Committee once the completed application has been submitted.

7. The Ethics Office sends an e-mail to the applicant, which either:

- i) approves the application; or
- ii) approves the application subject to conditions that need to be met before approval can be granted; or
- iii) defers the application for further consideration; or
- iv) declines the application and explains why a full application to the ethics committee is required.

A requirement of approval is completing a [Low Risk Final Report](#) once the project is finished. This is a short form. For projects with a greater-than 12-month duration, an annual summary of progress is required on the anniversary date of approval.

## SECTION 2: DETERMINING SUITABILITY FOR LOW RISK REVIEW

To assist in determining whether the activity is Low Risk read through the various types of activities listed below.

### 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** <http://www.alfredresearch.org/ethics/applicat.htm>

*It is important to note that:*

*-low risk is not defined by what is lower clinical risk in a given medical specialty but by the National Statement and the Ethics Committee.*

*-risk is not just physical but may incorporate social, psychological, financial or cultural risks, or risks such as breach to privacy.*

<b>1. ACTIVITIES REQUIRING A FULL ETHICS APPLICATION (not suitable for Low Risk review)</b>
<input type="checkbox"/> Interventions. The research involves providing an intervention. Examples include testing; drugs, surgical procedures, therapeutic procedures, therapeutic devices, preventative procedures, diagnostic devices or diagnostic procedures.
<input type="checkbox"/> 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, cognitively or intellectually impaired persons and the elderly.
<input type="checkbox"/> Genetic research. The project involves genetic research where information may be discovered or generated that is of potential importance to the future health of the individual or generates sensitivities for the individual, their family or their community.
<input type="checkbox"/> Human Stem Cells. The research involves studying stem cells or using stem cells or their products to develop new therapies.
<input type="checkbox"/> 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.
<input type="checkbox"/> 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.
<input type="checkbox"/> 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.
<input type="checkbox"/> 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 <u>identifying</u> information.
<input type="checkbox"/> Student researchers. The project involves a student, not on placement at Alfred Health, accessing identifiable information.
<input type="checkbox"/> External sites. The research involves sites that are not part of Alfred Health, do not have their own Ethics oversight and for which Alfred Health would be required to provide research governance. Examples include private practitioners and their patients.
<input type="checkbox"/> 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.
<input type="checkbox"/> Illegal Activities. The research intends to study or is likely to discover illegal activity. Examples include questioning about illicit drug use.

## CHECKLIST 2

If the project involves one or more of the activities below, justification will be required in the Low Risk Application (Section B, Question 2) as to why this should be considered low risk.

<b>2. ACTIVITIES REQUIRING JUSTIFICATION (may or may not be suitable for low risk review )</b>
<input type="checkbox"/> Externally funded research where there is a commercial interest.
<input type="checkbox"/> A multi-centre study originating from Alfred Health with Alfred Health as the coordinating centre
<input type="checkbox"/> Data access, collection or use of identifiable information that is not secondary use and is without consent
<input type="checkbox"/> Use of already collected tissue and blood samples without the prior consent of the patient
<input type="checkbox"/> Transfer of tissue and blood samples without consent to external researchers
<input type="checkbox"/> Access/collection/use of sensitive information
<input type="checkbox"/> Access/collection/use of information that has regulatory and/or legal reporting requirements
<input type="checkbox"/> Personally intrusive/confronting or quite inconvenient/embarrassing questioning
<input type="checkbox"/> Providing, or potential to provide, individual health/medical/psychiatric diagnosis
<input type="checkbox"/> Screening for healthy participant inclusion/exclusion
<input type="checkbox"/> Change or withdrawal of services
<input type="checkbox"/> Conflicts of interest or dual researcher-professional roles
<input type="checkbox"/> Research conducted overseas
<input type="checkbox"/> Deception (participants will receive limited or no information about the research at time of recruitment)
<input type="checkbox"/> Participant recruitment/selection via a third party
<input type="checkbox"/> Qualitative research without experience
<input type="checkbox"/> 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,
<input type="checkbox"/> 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
<input type="checkbox"/> Participation incentives, prizes or significant payments
<input type="checkbox"/> Research placing researchers/assistants at risk

## **SECTION 3: COMPLETING THE LOW RISK FORM**

All sections of the application must be completed with sufficient detail to allow a clear picture of what the project involves. The principal investigator is responsible for ensuring the accuracy of the information.

### **Section A**

#### **Proposed period of ethics approval**

The proposed period of ethics approval covers the duration of the activity, including the data gathering, write up and submission for publication. For those completing a retrospective review, this is not to be confused with the time period of data collection.

### **Section B**

#### **4. Selection and Recruitment**

- i) This seeks to find out whether the number is based on convenience, anticipated numbers, the maximum available or a sample size determined by statistical means.
- ii) If the number of participants/samples in each group being studied is less than the maximum number available, explain how participants and/or their samples will be selected (eg. randomly, consecutively, etc.).
- iii) This seeks to find out whether the participants and/or their samples are identified from a database search, attendance at clinics or from previous research.
- iv) This part is only applicable for projects that intend to make contact with participants. In this instance the question seeks to determine if participants will be sent a letter, telephoned, approached at a clinic appointment etc.

#### **5. Risks**

Risks should include all actual and potential risks. Risks should not be limited to physical risks to participants, but should include where applicable, risks to a participant's emotional, social, financial, cultural, vocational and professional wellbeing. Risks can also be direct or indirect and encompass broader topics such as risks of civil liability, infringement on people's rights, employability and professional reputation. Risks are not just to the participant but may also be to others such as carers, health providers and institutions.

#### **7. Likely Impact**

This relates to the degree of significance of the findings; whether the impact is at a personal/departmental/hospital/professional-peer level and what that impact may be (E.g. further review of processes, changes to guidelines, educational requirements, treatment changes, development of larger research project).

### **Section C**

#### **What is meant by identifiability of health information?**

A key issue concerning health information is whether the individual concerned is "identifiable" from the information. Data used for projects can be identifiable, re-identifiable or coded, or non-identified or anonymous.

Identifiable data is 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.

Coded or re-identifiable Information. Coding is the technique of separating personally identified data from substantive data, but maintaining a potential link by assigning an arbitrary code number to each data - identifier pair before splitting them.

It is important to note that data can still be potentially 'identifiable' if it is possible to infer an individual's identity from it (eg asking a hospital employee for work discipline or grade if they are the only ones working in that area).

Data coded with abbreviated identifiers (for example, combination of initials, date of birth, sex) are sometimes used for reporting particular conditions. This allows re-identification by the clinician reporting, but is anonymous to the recipient, although duplicates can be linked.

Non-identified data (not re-identifiable, anonymised, anonymous, unlinked): Data that have been collected without personal identifiers and from which no personal identifier can be inferred.

It should be recognised that the term “de-identified” is used frequently in other documents and processes to refer to sets of data from which only names or partial identifiers have been removed; (such data may remain “potentially identifiable” and is not non-identified data).

It is possible that projects may involve more than one of these. 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 and then provide only the coded data set to a student on clinical placement so the student only has non-identifiable data to work with.

Linking of data sources requires identification.

Human tissues are considered identifiable or potentially identifiable.

Web-based surveys may collect ‘identifiable’ data if recording the IP address.

#### **a), b) and c)**

These questions relate to accessing information. Some projects may need to access a database to identify potential participants and then access health information from records kept in the database. Some projects may require accessing patient information kept by the patient’s bedside or in their medical history. All sources of information must be listed in b).

#### **d) and e).**

These questions relate to collecting information and this is different to accessing information. Collecting may occur after accessing, as in the case of gathering information from a medical record/database to put into a spreadsheet, however it might also occur without any access, such as collecting information from a satisfaction survey or questionnaire handed out to participants.

#### **f)**

The question relates to the process of transference. When transference is from Alfred Health, is the information/sample coded? At which site is it coded? If there are samples, will they be transferred according to guidelines? Where the transference is to Alfred Health, in what format is it being sent?

### **SECTION D**

When considering whether a project involves ‘secondary use’ of information there are two key requirements that must be addressed in keeping with the Privacy Act (1988):

1. The secondary purpose, (the project), must be related to the primary purpose of collection (usually for diagnosis and treatment, but could include information that has been collected on tasks such as program evaluation) and, if the personal information is sensitive information, directly related to the primary purpose of collection.
2. The individual, whose information is being used, would reasonably expect the organisation to use or disclose the information for the secondary purpose (the project).

If a project meets ‘secondary use’ then consent for use of the information is not required.

A comment explaining how the project meets these two requirements must be provided.

A waiver of the requirement to obtain consent may be requested and granted if certain conditions exist. The granting of a ‘privacy waiver’ is based on provisions in the Health Records Act 2001 (Vic), Privacy Act (1988), and the National Statement of Ethical Conduct in Human Research (2007).

The following items must be addressed when requesting a waiver.

- involvement in the research carries no more than low risk to participants;
- the benefits from the research justify any risks of harm associated with not seeking consent;
- it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records);
- there is no known or likely reason for thinking that participants would not have consented if they had been asked;
- there is sufficient protection of their privacy;
- there is an adequate plan to protect the confidentiality of data;
- in case the results have significance for the participants’ welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media);
- the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled;
- the waiver is not prohibited by State, federal, or international law.

## **SECTION E**

**1a).** The response must include all forms of data; electronic, multi-media and paper based information. 'Where' should cover aspects such as locked rooms, locked filing cabinets and password protected drives and also include the physical location eg particular unit's office.

**1e).** Alfred Health requires most low risk project data to be stored for 7 years. There may be instances where data is kept for a different time period and if this is the case, then an explanation for the difference should be provided.

## **SECTION G**

**A proper review can only be done if researchers provide complete and accurate information. Researchers, when signing their declaration, attest, amongst other things, that this is the case.**

**The Head of Department, in signing the Statement, attests that the research project and its conduct conform to the relevant ethical and research standards.**

**In addition, the Head of Department is required to make a comment on the points on which he/she has signed off.**