



## ETHICAL REVIEW OF RESEARCH - A PRACTICE GUIDE -

This **Practice Guide** provides the framework for ethical review of research and will assist health professionals at Sydney Adventist Hospital who wish to undertake research activities. This *Practice Guide* provides a *Research Checklist* and *Flowchart* to assist in this task.

### Preamble

At Sydney Adventist Hospital, all research that involves human interaction, access to human tissue and/or identified personal information that is not already on public record, must routinely undergo a simple review process prior to commencement. Research activities that require ethical review include, but are not limited to, the following:

- Interview
- Survey
- Focus Group
- Audit
- Observation
- Testing or treatment
- Peer Review
- Clinical trial
- Clinical intervention

A central purpose of ethical review is to identify whether a proposed research activity may impose ethical risks to patients and/or carers where these may occur other than through direct patient care. Some research activities are closely related to the treatment of the individual patients involved and will not pose additional ethical risks. When risks, suffering or inconvenience resulting from research activity may be present, patients need to be provided with sufficient information in an environment free of undue pressure to enable them to decide whether they wish to be involved. An important aim of ethical review is to protect patients' privacy and anonymity. Some research activities can be conducted using only re-identifiable or non-identifiable data. Some activities have the potential to generate information of a sensitive nature. Such information might be medical, such as HIV status or the identification of genetic disease, or it may be social, for example where a particular set of demographics, when applied in a small town or ethnic group, enable an individual or family to be identified.

### Considerations when reviewing research activities

The following sections are intended to clarify the questions posed in the *Research Checklist*. Comments are grouped according to the question numbers as they appear in the Checklist.

### Section 1: Issues that may require consent

Patients are routinely informed on hospital admission, or at another early point during their care, that their non-identifiable information might be used for quality improvement and other purposes, in a manner that respects privacy of health information. This is achieved through

the use of patient information leaflets that create a 'reasonable expectation' that a patient's health information may be used legally and for legitimate purposes.

Privacy legislation recognises that some research activities are permissible without explicit patient consent. Explicit consent is required when the activity requires direct contact with patients or relatives, if randomisation of interventions is required or where identifiable or sensitive personal data is collected. Consent may be demonstrated by various means including signed 'consent' forms, return of a self-administered survey, or recorded agreement for interview. Consent requires that sufficient information be provided for the person to make a decision, considering the risks and benefits, and that the decision is freely made. If there is any doubt about whether a research activity requires patient consent, it is prudent to seek guidance from the HREC.

Some cultural communities, such as Aboriginal and Torres Strait Islander, may require community consent, in addition to individual consent, for participation in research.

- Q 1 Direct contact with patients or families through phone calls or face-to-face interview may potentially create undue pressure or coercion, depending on how direct contact is planned. Patients or families may feel pressured firstly to participate, and secondly to respond in particular ways, depending on factors such as patient vulnerability or whether there is an ongoing treatment/care relationship. Patient surveys may legitimately ask about attitudes to aspects of care, but if these are not anonymous, may leave patients feeling compromised.
- Q 2 Additional harms or risks may be physical harm, psychological disturbance, risk of spiritual or social harm, or distress. Tests, blood samples, or medical interventions additional to the patient's routine clinical care will likely constitute burdens warranting express patient consent, as may persistent phone calls, additional visits to hospital or lengthy or intrusive questionnaires. Potential exploitation of cultural knowledge or property is considered another harm. There have been instances where such information has been damaging to some cultural minorities, such as contributing to discriminatory attitudes and stigmatisation.
- Q 3 A letter, fax or email sent to a patient that includes sensitive information could lead to a breach of confidentiality if such communication were to be read by another person. Examples of sensitive data include a diagnosis of HIV/AIDS or sexually transmitted disease, mental illness, sexual assault, domestic violence, drug and alcohol use, genetic testing or results, IVF or artificial insemination, or where a child is considered to be at risk.
- Q 4 Data that allows for identification of a specific individual is referred to as individually identifiable data. Examples of identifiers are the individual's name, date of birth, image, address, or diagnosis where the condition is rare. In very small data sets, even information such as a postcode may be an identifier.

## **Section 2: Privacy and Confidentiality**

Privacy legislation requires that patient information generated for research purposes has identifiers removed at the earliest possible time, is stored securely and is only retained for as long as is reasonably necessary for the proper conduct of the research. During conduct of the research, information is to be stored in a secure environment with access limited to those directly involved in the research. At the conclusion of the research the information is to be disposed of in a secure manner.

- Q 5 Re-identifiable data is data from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by using a code or linking different data sets.

Non-identifiable data is data that has never been labelled with individual identifiers or from which identifiers have been permanently removed by means of which no specific individual can be identified.

As a general principle, only re-identifiable data should be given to third parties who would not normally have access to it. Multi-centre research coordinated by an organization other than Sydney Adventist Hospital, will require ethical review by that organization, unless individual identifiers are removed from patient information before it is accessed by the external organization.

- Q 6 The 'clinical care team' refers to the group of health professionals involved in provision of a patient's clinical care and includes nursing, medical clinicians and allied health professionals.

Some research activities may involve an 'independent' third party assessment of provision of care using external observers and an audit tool. Interviews and observation give such parties direct contact with patients, often without their express consent and access to information as events occur. This may require ethical review by the HREC in order to safeguard patients' privacy and 'legitimise' the third party's presence while observing clinical care.

Student health professionals enrolled in recognised teaching institutions, which have formal agreements with Sydney Adventist Hospital, may have access to patient health records with the approval and direction of their supervisor, if that access is sought in respect of their education program at Sydney Adventist Hospital.

- Q 7 Where patient numbers are limited or the diagnosis is rare, this may inadvertently result in the patient being identified, even where the data has had identifiers removed in the usual manner. Activities that combine groups of similar patients from small units may assist in maintaining confidentiality, where this is feasible.
- Q 8 Activities amongst religious, ethnic or minority groups should be undertaken following appropriate consideration of cultural differences, as relevant to the activity. Some ethical issues associated with an activity may need to be considered in a broader context than the individual patient context, for example the notion of 'community privacy' often applies in Aboriginal communities.
- Q 9 No additional comment

### **Section 3: Other Implications**

- Q 10 Where research activities generate new knowledge and/or where new or alternate clinical interventions are undertaken, or new equipment is used, there is a potential risk of harm to patients. 'New' refers to interventions / protocols / equipment not previously approved for this purpose at Sydney Adventist Hospital.
- Q 11 Randomisation of patients to treatment groups to enable comparison of interventions will usually diminish treatment choice that may be unacceptable to the patient. Patients may choose not to participate in randomised activities. Interventional activities comparing one intervention with another should not involve provision of care inferior to the benchmark standard of care. Any project involving randomisation,

or other means of allocation to one of two or more treatment options, requires ethical review.

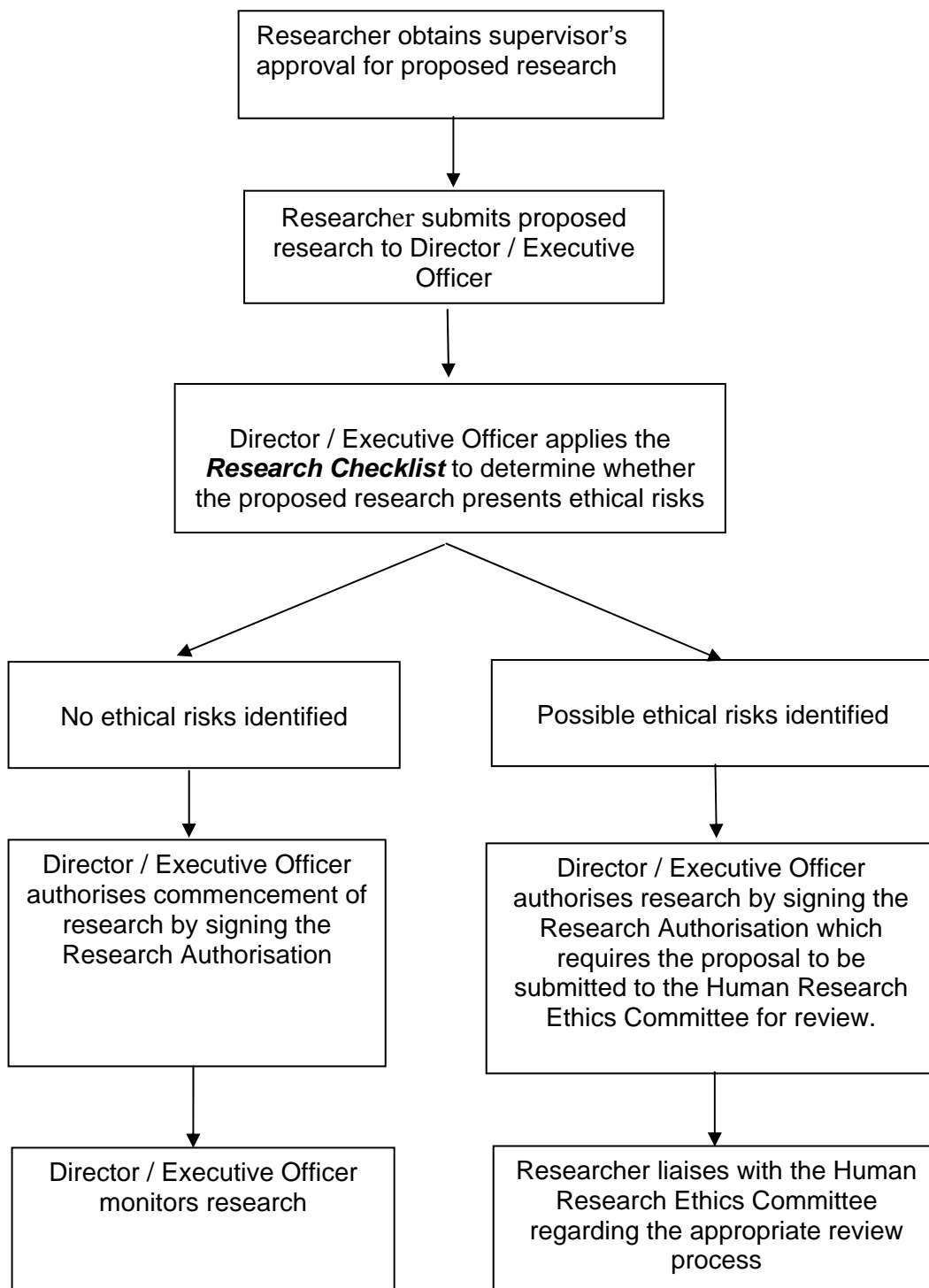
- Q 12 Genetic testing may have an impact on not only the individual being tested, but also other family members. Any activity involving genetic information needs informed consent, given the sensitive nature of the information and its potential implications.
- Q 13 There is increasing interest in comparison of patient outcomes or other performance indicators within, and more recently between units, departments or individual clinicians. These comparisons must be against agreed benchmark standards and with appropriate consideration of the variables impacting on outcomes and performance.

There is a general obligation to feedback results of research activities to health professionals who have been directly involved in the activity or affected by its results. There should also be consideration given to providing results of research activities to other participant groups.

- Q 14 Any project involving randomisation or other means of allocation to one of two or more treatment options and/or use of placebo requires ethical review.
- Q 15 Many professional journals require evidence of ethical review before results will be published, especially where identifiable or sensitive data are audited, or potential harm or burdens exist. This also applies where the results of the activity are for publication as a conference abstract or poster. If the *Research Checklist* identifies 'no ethical risks' and only intention to publish, then ethical review by the HREC is not required. Some international journals apply different standards for ethical review and intending authors should explore this on an individual basis. Presentation of non-identifiable data at conferences does not require ethics review by the HREC.

*Reference:*  
NSW Health Guideline. *Human Research Ethics Committees – Quality Improvement & Ethical Review: A Practice Guide for NSW*. Document No: GL2007\_020 Publication Date: 21 Nov 2007

**REVIEW of RESEARCH**  
**- Using the Research Checklist -**  
Sydney Adventist Hospital  
Human Research Ethics Committee



## ETHICAL REVIEW OF RESEARCH - RESEARCH CHECKLIST & AUTHORISATION -

Use of this checklist is required in identifying whether a proposed research activity involves 'ethical risks'. For detailed information related to each statement refer to **Considerations when reviewing research activities** in the **Practice Guide**. For recurrent research (audits/surveys) this checklist must be completed prior to initial commencement and each time the assessment tool and/or methodology is changed.

<b>Section 1: Issues that may require consent</b>	<b>Yes</b>	<b>No</b>
1. The project involves direct contact with patients, staff, consumers or members of the public	<input type="checkbox"/>	<input type="checkbox"/>
2. The project poses additional risks or burdens to the patient beyond their routine care	<input type="checkbox"/>	<input type="checkbox"/>
3. The data to be collected is of a sensitive nature or application	<input type="checkbox"/>	<input type="checkbox"/>
4. The data will be used, or made available, in such a way that may identify individuals	<input type="checkbox"/>	<input type="checkbox"/>

*If the response to any of statements 1-4 is YES informed consent is required. You should complete the **Research Proposal: Risk Assessment** and submit with the **Research Checklist & Authorisation** to the HREC. It is advisable to first consult the ARI regarding the research plan, design and/or methodology. Ph: 9487 9602.*

### Section 2: Privacy and Confidentiality

5. Re-identifiable data will be available to other than the researcher/s	<input type="checkbox"/>	<input type="checkbox"/>
6. Identifiable information will be available to people who: <ul style="list-style-type: none"> <li>• Are not part of the clinical care team OR</li> <li>• Do not normally have access to the patient's record or other data unless organisational responsibility requires access for the purpose of quality or safety as described in the privacy policy</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
7. The project involves rare conditions or a small community	<input type="checkbox"/>	<input type="checkbox"/>
8. Data will be selected or identified by Aboriginal, Torres Strait Islander status or ethnic, religious or minority group	<input type="checkbox"/>	<input type="checkbox"/>
9. Data will be collected beyond that which is normally collected in routine care	<input type="checkbox"/>	<input type="checkbox"/>

*If the response to any of statements 5-7 is YES informed consent is required. You should complete the **Research Proposal: Risk Assessment** and submit with the **Research Checklist & Authorisation** to the HREC. It is advisable to first consult the ARI regarding the research plan, design and/or methodology. Ph: 9487 9602.*

### Section 3: Other Implications

10. The project uses 'new' interventions, protocols or equipment not already approved by the Medical Procedures, Prosthetics and Disposables Committee	<input type="checkbox"/>	<input type="checkbox"/>
11. The project will involve randomisation of patients to treatment groups	<input type="checkbox"/>	<input type="checkbox"/>
12. The project will involve a genetic test / testing	<input type="checkbox"/>	<input type="checkbox"/>
13. The project may potentially infringe the rights, privacy or professional reputation of carers, health professionals or the Hospital	<input type="checkbox"/>	<input type="checkbox"/>
14. The project involves use of placebo	<input type="checkbox"/>	<input type="checkbox"/>
15. The project is likely to generate data that may lead to publication	<input type="checkbox"/>	<input type="checkbox"/>

*If the response to any of statements 10-14 is YES you will need to submit a full **Application for Ethical Review** to the HREC. You do not need to submit the **Research Proposal: Risk Assessment**. Contact the HREC by phone (m) 0417 042 300 or [ethics@sah.org.au](mailto:ethics@sah.org.au)*

*If the response to statements 1-15 is NO then no ethical risks have been identified with this activity and no further ethical review is required.*

**The authorisation on the next page must be completed.**

**ETHICAL REVIEW OF RESEARCH  
- RESEARCH AUTHORISATION -**

Name of Researcher:

Name of Research Activity:

The Research Checklist indicates:

- No ethical risks identified. Publication supported.
- No ethical risks identified. Research activity and commencement supported. Research will be monitored by the person authorising this research.
- Research activity supported. Must be submitted to the Ethics Committee.
- Research activity not supported.

***Authorised by:***

Name:

Position:                    Director / Executive Officer / ARI CEO / HREC delegate *Circle One*

Signature:

Date:

**A copy of the completed Research Checklist and Authorisation must be forwarded to Quality Management and the Ethics Committee**