

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.

| Section 1: Issues that may require consent | Yes | No |
|---|--------------------------|--------------------------|
| 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"> • Are not part of the clinical care team OR • 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 | <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***

If the response to statement 15 is YES and the response to all other statements is NO then no ethical risks have been identified with this project and no further ethical review is required.

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