

POLICY ON RESEARCH

1. POLICY

- 1.1. Sydney Adventist Hospital is committed to providing a research environment that will promote the highest standards of professional conduct on the part of its researchers and a culture of research practice that is ethical, competent, safe, accountable and respectful of research participants.
- 1.2. To this end, all research conducted at Sydney Adventist Hospital, whether by employees, Accredited Medical Officers, volunteers or students, must comply with existing laws, regulations and national guidelines governing research, including the National Health & Medical Research Council's National Statement on Ethical Conduct in Research Involving Humans (2007) ("the National Statement") and the Australian Code for the Responsible Conduct of Research (2007) ("the Australian Research Code").
- 1.3. Researchers must also comply with this protocol and the Human Research Ethics Committee's Standard Operating Procedures.

2. SCOPE

This policy applies to all research being undertaken at Sydney Adventist Hospital Limited.

3. DEFINITIONS

Definitions are included in the protocol

4. RESPONSIBILITIES

All staff, Volunteers and Accredited Medical Officers and Health Care Workers of Sydney Adventist Hospital Limited undertaking research must comply with this policy

5. RATIONALE

This policy has been developed to provide governance to research at Sydney Adventist Hospital Limited

6. PROCEDURE/ PROTOCOL FOR RESEARCH PRACTICE

This protocol sets out procedures to be followed by all those involved in research at Sydney Adventist Hospital, consistent with the National Statement and the Australian Research Code. It addresses the following:

- 6.1. What is "research" for the purposes of this protocol?
- 6.2. Who is a "researcher"?
- 6.3. Researcher's responsibilities
- 6.4. How the ARI can assist researchers
- 6.5. How is approval to conduct research granted?
- 6.6. Maintaining a safe and ethical research environment
- 6.7. Conduct of research by employees and volunteers
- 6.8. Conduct of research by Accredited Medical officers
- 6.9. Conduct of research by students
- 6.10. Conduct of research in another country

- 6.11. Conduct of research under commercial and contractual arrangements
- 6.12. Conflicts of interest
- 6.13. Maintenance of records and retention and storage of research data
- 6.14. Privacy and Confidentiality relating to research
- 6.15. Authorship and publication
- 6.16. Ownership of research: Intellectual property resulting from research
- 6.17. Payment for research
- 6.18. Research Grants
- 6.19. Research misconduct and fraud
- 6.20. Compliance with this policy and protocol
- 6.21. Review of this policy and protocol
- 6.22. Flowchart: Review of Research – Using the research checklist
- 6.23. Flowchart: Governance & Ethical Review of Research

7. WHAT IS “RESEARCH” FOR THE PURPOSES OF THIS PROTOCOL?

Under the Australian Research Code, “research” is defined as any original investigation undertaken to gain knowledge, understanding or insight. Within Sydney Adventist Hospital, this could include a wide range of activities, such as:

- 7.1. Conducting surveys, interviews or focus groups;
- 7.2. Trialling new medical procedures or techniques;
- 7.3. Extracting and analysing data from medical records;
- 7.4. Participation in company-sponsored clinical trials;
- 7.5. Developing and testing administrative processes and procedures;
- 7.6. Collection of body organs, tissue or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and biopsy specimens) or exhaled breath for scientific analysis.

Some of these activities do not involve human experimentation. However, researchers should nonetheless ensure that all relevant aspects of this protocol are complied with. In the case of research involving humans, it is imperative that the interests of research participants are protected in accordance with the National Statement, the Australian Research Code and this protocol. Ethical review is required for all such research.

Activities undertaken as part of routine quality assurance or clinical audit are sometimes considered not to constitute research. However, for the purposes of this protocol, all such activities should be regarded as falling within the meaning of research and are subject to the requirements of this protocol.

8. WHO IS A “RESEARCHER”?

For the purposes of this protocol, a researcher is any employee, volunteer, Accredited Medical Officer or student affiliated with Sydney Adventist Hospital who conducts research (as described above) at the Hospital.

9. RESEARCHER’S RESPONSIBILITIES

All researchers at Sydney Adventist Hospital must comply with the responsibilities of researchers set out in the Australian Research Code. These responsibilities include:

- 9.1. Researchers must foster and maintain a research environment of intellectual honesty and integrity, and scholarly and scientific rigour. Researchers must:
 - 9.1.1. Respect the truth and the rights of those affected by their research
 - 9.1.2. Manage conflicts of interest so that ambition and personal advantage do not compromise ethical or scholarly considerations
 - 9.1.3. Adopt methods appropriate for achieving the aims of each research proposal
 - 9.1.4. Follow proper practices for safety and security
 - 9.1.5. Cite awards, degrees and research publications accurately, including the status of any publication.
- 9.2. Researchers should ensure that research findings are disseminated responsibly.
- 9.3. Researchers must comply with ethical principles of integrity, respect for persons, justice and beneficence.
- 9.4. Researchers should conduct their research so as to minimise adverse effects on the wider community and the environment.
- 9.5. A researcher who considers that research misconduct may have occurred must act in a timely manner, having regard to the policy of the institution where the research is being undertaken.

In addition, researchers at Sydney Adventist Hospital must adhere to the following principles:

- 9.6. Research must be conducted or supervised only by those persons with experience, qualifications and competence appropriate to the intended research.
- 9.7. Researchers must demonstrate that a research proposal is justifiable in terms of the contribution to knowledge, the researcher's skill and experience and the likelihood that the research will achieve its intended objective.
- 9.8. Researchers must demonstrate regard for the welfare, rights, beliefs, perceptions, customs and cultural heritage of persons involved in research.
- 9.9. Researchers must maximise possible benefits and minimise possible harms to participants in research whether physical, psychological, emotional, spiritual, economic, cultural or social.
- 9.10. Researchers must avoid imposing an unfair burden of participation in research on particular groups who are likely to be subject to over-researching.
- 9.11. Researchers must not discriminate in the selection and recruitment of human research participants by including or excluding them on the grounds of race, age, gender, disability or religious or spiritual belief except where the exclusion or inclusion of particular groups is essential to the purpose of the research.
- 9.12. Researchers have an obligation to ensure the safety of all persons associated with research by only conducting the research in appropriate facilities and where there are appropriate skills and

procedures for dealing with any contingencies that may affect research participants.

- 9.13. The consent of each participant and interested parties in research must be obtained before any research is undertaken and researchers must respect any individual or collectivities' refusal to participate in research.
- 9.14. Researchers must suspend or modify any research in which risks to participants are found to be disproportionate to the benefits and stop any involvement of any participant if continuation of the research may be harmful to that person.
- 9.15. In the event of a serious or unexpected adverse effect on participants in research approved by the Hospital's Human Research Ethics Committee, the researcher must immediately report this to the Committee

Research involving children and young people should only be conducted in accordance with the principles set out in the National Statement.

Research involving a person with an intellectual or mental impairment should only be conducted in accordance with the principles set out in the National Statement.

Research involving persons in dependent or unequal relationships, or persons highly dependent on medical care, should only be conducted in accordance with the principles set out in the [National Statement](#).

10. HOW THE ARI CAN ASSIST RESEARCHERS

- 10.1. The ARI conducts, facilitates and promotes research within its member organisations which include Sydney Adventist Hospital Ltd, Avondale College, Australian Health and Nutrition Association Ltd and South Pacific Division.
- 10.2. The Sydney Adventist Hospital strongly supports researcher's consultation with the ARI regarding development of a research proposal prior to submitting a research proposal for review. The ARI may provide assistance with developing the research plan, design and/or methodology.

11. HOW IS APPROVAL TO CONDUCT RESEARCH GRANTED?

- 11.1. All research conducted at Sydney Adventist Hospital must be reviewed and authorised in accordance with this protocol, prior to commencement. Retrospective authorisation will not be granted.
- 11.2. Research activities that require review include, but are not limited to, the following:
 - 11.2.1. Interview
 - 11.2.2. Survey
 - 11.2.3. Focus Group
 - 11.2.4. Audit
 - 11.2.5. Observation for research purposes
 - 11.2.6. Testing or treatment for research purposes

11.2.7. Peer Review

11.2.8. Clinical trial

- 11.3. For research which is recurrent, e.g. audits / surveys, authorisation must be obtained by the researcher prior to initial commencement and on each occasion that the assessment tool and/or methodology is changed.
- 11.4. For all research undertaken at Sydney Adventist Hospital, the following procedure must be followed:
- 11.5. The researcher obtains their supervisor's approval for a proposed research study;
- 11.6. The researcher submits the proposed research to the relevant Director or Executive Officer;
- 11.7. The Director or Executive Officer completes the Research Checklist which identifies ethical risks associated with the proposed research;
- 11.8. Where the Research Checklist does not identify any ethical risks, the Director or Executive Officer authorises the commencement of the research, by signing the Research Authorisation, and monitors the conduct of the research;
- 11.9. Where the Research Checklist identifies possible ethical risks, the Director or Executive Officer authorises the research, subject to the research proposal being submitted to the Human Research Ethics Committee for further review. Researchers are advised to liaise with the Human Research Ethics Committee regarding the appropriate review process.
- 11.10. Research proposals requiring Human Research Ethics Committee review will be subject to the following types of review:
 - 11.10.1. Expedited Review
 - 11.10.2. Full ReviewThe type of review is determined by the level of ethical risk identified on the Research Checklist. Refer to Flowchart Review of Research Requiring Review by [Human Research Ethics Committee](#).
- 11.11. Expedited Review is applied to research which presents no more than negligible risk such as the inconvenience of filling in a form or uses existing data or records that contain only non-identifiable data. Submission of the Research Proposal: Risk Assessment receives Expedited Review by the Chair of the Human Research Ethics Committee.
- 11.12. Full Review is applied to research which presents ethical risks which are more than negligible. Submission of the National Ethics Application Form (NEAF) and Site Specific Assessment Form (SSA) is required. Governance review of the SSA is conducted prior to ethical review by the Human Research Ethics Committee.

Although the approval of the Human Research Ethics Committee is only required for research that involves possible ethical risks, the Human

Research Ethics Committee (which incorporates the Research Governance Office) retains the responsibility for overseeing all research involving humans conducted at Sydney Adventist Hospital. This includes responsibility for conducting audits of research, reviewing policy and procedures relating to research and monitoring compliance with this policy and protocol.

12. MAINTAINING A SAFE AND ETHICAL RESEARCH ENVIRONMENT

- 12.1. All research which the Research Checklist identifies as involving possible ethical risks, including research involving human interaction, access to human tissue and/or identified personal information that is not already on public record, must undergo ethical review by the Human Research Ethics Committee prior to commencement. Retrospective ethical approval will not be granted.
- 12.2. The ethical review process is to be conducted in accordance with the principles set out in the National Statement and must incorporate all aspects of research governance to ensure that human research at Sydney Adventist Hospital meets appropriate standards of quality, safety, privacy, risk management, financial management and ethical acceptability. *Refer to Flowchart: Governance & Ethical Review of Research; and Appendix 1: Interpreting Research Evidence.*
- 12.3. Research activities approved by the Human Research Ethics Committee will be subject to the terms and conditions of approval imposed by the Committee including monitoring of the research through to its conclusion. Researchers will be required to submit progress reports, requests for amendments to approved protocols, immediate reporting of sudden adverse events and suspected, unexpected, serious adverse reactions and may be subject to audits of the research site by or on behalf of the Human Research Ethics Committee.

13. CONDUCT OF RESEARCH BY EMPLOYEES AND VOLUNTEERS

Employees and volunteers conducting research at Sydney Adventist Hospital must comply with this policy and protocol.

14. CONDUCT OF RESEARCH BY ACCREDITED MEDICAL OFFICERS

Accredited Medical Officers conducting research at Sydney Adventist Hospital and/or other sites approved by the Human Research Ethics Committee, must comply with this policy and protocol.

15. CONDUCT OF RESEARCH BY STUDENTS

- 15.1. All students conducting research at Sydney Adventist Hospital must comply with this policy and protocol. Where a student is conducting the research, the primary supervisor should be named as the Principal Investigator. The student may be listed as the Contact Person on an Application for Ethical Review, which means they will be the main correspondent for the research. The student should be named as a member of the research team and as such has shared responsibility

for the ethical conduct of the research, but it is the primary supervisor who has primary responsibility for the ethical conduct of the research.

- 15.2. The primary supervisor of a student conducting research will be responsible for providing guidance to the student on all matters of research practice and ensuring that the student is informed of relevant Hospital policies and procedures that affect the conduct of the student's research.
- 15.3. The supervisor will be entitled to have access to research data and other relevant information about the research of a student for the purposes of undertaking normal supervisory responsibilities and ensuring compliance with this protocol and other Hospital policies and procedures.
- 15.4. The primary supervisor must:
Ensure that the research is conducted in an ethical manner including:
 - 15.4.1. That the Application for Ethical Review is of an appropriate standard
 - 15.4.2. That any matters relating to ethical review are resolved in a timely manner
 - 15.4.3. That the research is conducted as approved by the Ethics Committee
 - 15.4.4. That the Committee is notified of any changes to the research
 - 15.4.5. That reporting requirements are complied with
- 15.5. Advise the student about the need to maintain confidentiality in respect of the student's research data, methodology or findings
- 15.6. Ensure the integrity of the student's research data is preserved
- 15.7. Where the student is part of a research team, inform the student at the commencement of the research of any protocols or operating conditions that may apply in respect of the conduct of the research; the use and storage of research data; publication of research findings; confidentiality or agreements that may apply to the research.
- 15.8. Take steps as are practicable to ensure the validity of a student's data and research methodology

16. CONDUCT OF RESEARCH IN ANOTHER COUNTRY

Where research is to be conducted in an overseas country by a person affiliated with the Hospital, the research must comply with the requirements of the National Statement as well as all applicable laws and guidelines of that country. The proposed research must be submitted to the Sydney Adventist Hospital Human Research Ethics Committee for ethical review.

17. CONDUCT OF RESEARCH UNDER CONTRACTUAL AND CONTRACTUAL ARRANGEMENTS

Research may be conducted under contractual arrangements or agreements with third parties. Researchers must ensure that all such research is carried out in compliance with relevant Sydney Adventist Hospital policies and procedures with particular reference to the Policy on Intellectual Property.

18. CONFLICTS OF INTEREST

Research activities are to be conducted in an objective manner, free from any potential for undue influence arising from the interests of those responsible for the conduct of the research. Where there is a divergence between the individual interests of researchers and their professional responsibilities as a researcher, such that the conduct of the research may be influenced by the researcher's own interests, a conflict of interest exists.

- 18.1. Researchers are required to disclose to the Human Research Ethics Committee any conflict of interest regarding affiliation with, or financial involvement in, any organisation or entity with direct interest in the subject matter or materials of the research. This includes disclosure of:
 - 18.1.1. Direct benefits such as sponsorship of the research
 - 18.1.2. Indirect benefits which may include provision of materials or facilities.
- 18.2. Researchers must disclose to any relevant outside parties, including editors of journals, readers of published work and external bodies from which funds are sought, any potential conflict of interest that could be seen to influence the research and investigations, publication and media reports and grant applications.
- 18.3. Any other interest which has the potential to influence the conduct of research, publication, grant applications or other research-related matters must be disclosed to the Human Research Ethics Committee as a potential conflict of interest immediately it is identified.
- 18.4. Researchers must maintain records of activities that may lead to conflicts of interest, for example consultancies, membership of committees or boards, or receipt of cash, services or equipment from outside bodies to support research activities.

19. MAINTENANCE of records, retention and storage of research data

Research data means the data, records, files or any other information or documents that form the basis of the inferences, observations, findings, conclusions, outcomes or elements of a research project or publication irrespective of the form in which it exists (e.g. print, electronic, physical, multi-media or other forms)

- 19.1. Research records and data must be retained and stored appropriately to enable the accuracy, veracity and basis of research findings and research methods to be tested, established and scrutinised.
- 19.2. Personal information generated for research purposes is to have identifiers removed at the earliest possible time, is to be stored securely and is to be retained only as long as is reasonably necessary for the proper conduct of the research. It must be disposed of in a secure manner once it is no longer needed for this purpose.
- 19.3. Aggregate data that are to be used for publication are to be kept for a minimum of five years from the date of publication, or longer where reasonably required.

- 19.4. During the conduct of the research, personal information is to be stored in a secure environment with access limited to those directly involved in the research.
- 19.5. Where there is more than one researcher involved in a research project, one researcher must be nominated as the research record-keeper and executive author of any research output and will have responsibility for all research data record-keeping, retention, storage, security and access. The original data should be retained and stored in the organisational unit and should not be retained by an individual researcher.
- 19.6. Data must be stored in a durable format. Magnetic media are not stable and data should not be stored on computer discs or hard drives. CDs are an acceptable alternative. Audio or video tapes should be transcribed and the transcript retained as an additional method of safeguarding their contents.

20. PRIVACY AND CONFIDENTIALITY RELATING TO RESEARCH

Researchers must be mindful of privacy and confidentiality obligations in relation to research data and the conduct of research. These obligations may arise from the need to protect the privacy interests of research participants or from other confidentiality requirements relating to intellectual property rights or commercial arrangements with a third party, such as a pharmaceutical company trial sponsor.

Researchers must comply with the requirements of applicable State and Commonwealth privacy legislation. These include the following:

- 20.1. Before collecting personal information, researchers must inform research participants what personal information about them will be collected, how it will be used and stored, to whom it will be disclosed, the length of time for which it will be stored and the fact that it will be disposed of thereafter. Research participants must provide consent for their personal information to be dealt with in this way.
- 20.2. Personal information that is collected must be relevant to the research purpose, up-to-date and complete. The collection of the information must not unreasonably intrude on the personal affairs of the individual.
- 20.3. Records containing personal information are to be stored securely and protected against loss and unauthorised access, use, modification or disclosure.
- 20.4. Individuals are entitled to access a research record containing their personal information, and can request that any errors in the records be corrected. If such a request is made, researchers should note the request in the record but should not alter the original research data.
- 20.5. Personal information must be securely disposed of once it is no longer required for the purpose for which it was collected.
- 20.6. Research data and records should, where possible, be maintained in a way that permits a third party to have access to them without revealing the identity of individual research participants. Where

appropriate, the records should have identifying details removed at the earliest possible time.

- 20.7. Researchers must ensure that any commercial or contractual arrangements they enter into, for example with a trial sponsor, are consistent with their privacy and confidentiality obligations to research participants.

AUTHORSHIP AND PUBLICATION

21. AUTHORSHIP

- 21.1. The minimum criterion for authorship is participation in the conceptualisation, execution or interpretation of part of the research. Participation must be sufficient to enable each person named as an author to take public responsibility for any publication.
- 21.2. A researcher who meets the minimum criterion for authorship may only be excluded as a named author with his or her written permission.
- 21.3. A person who has not participated in the conceptualisation, execution or interpretation of research does not meet the conditions for authorship and must not be identified as an author, for publication.
- 21.4. Where students are involved in contributing to research which may be published, they must be advised in advance of their participation of the criteria for authorship.
- 21.5. All co-authors of a publication must sign a statement of authorship verifying that they meet the criteria for authorship and stating that they have seen the version submitted for publication.
- 21.6. The written statement of authorship must be retained by the person nominated as executive author.
- 21.7. Authors must acknowledge in any publication, all other individuals or organisations who, while not meeting the criteria for authorship, have contributed to the research, including individuals and organisations providing facilities used in the research.

22. PUBLICATION

- 22.1. The results of research and the methods used should normally be published in ways which permit scrutiny and contribute to public knowledge.
- 22.2. Researchers must take reasonable steps to ensure published reports, statistics and statements about research activities are complete, accurate and unambiguous.
- 22.3. All researchers must consult the Marketing, Public Relations and Business Development Unit before reporting research findings in the public media or submitting an article for publication. Researchers must refer to the Hospital's Media Policy.

- 22.4. All publications must include information on all sources of financial support for the research.
- 22.5. Publication of multiple papers based on the same set or subsets of research data is only permissible where there are full cross-references within the papers.
- 22.6. An author who submits substantially similar work to more than one publisher must disclose this to the publishers at the time of submission.
- 22.7. Deliberate inclusion of inaccurate or misleading information or omission of relevant information constitutes research misconduct.
- 22.8. Research results should normally be made available to research participants.
- 22.9. Any publication resulting from research at Sydney Adventist Hospital must acknowledge the Hospital as providing the facilities and/or resources.
- 22.10. Any publication resulting from research must be forwarded to the Human Research Ethics Committee.

23. OWNERSHIP OF RESEARCH: INTELLECTUAL PROPERTY RESULTING FROM RESEARCH

It is the policy of Sydney Adventist Hospital to hold all intellectual property and data created in connection with the activities of the Hospital on trust for Australasian Conference Association Ltd (ACAL). This includes any and all data and other information (tangible and intangible) resulting from and/or generated or made in the performance of research at the Hospital. Examples of data and information are:

- 23.1. writings (irrespective of whether in written, oral or electronic form);
- 23.2. original clinical study files;
- 23.3. electronic final databases;
- 23.4. procedural contents of databases; and
- 23.5. final study reports.

A research database is a collection of related information organised in a useful manner that provides a foundation for procedures such as retrieving information, drawing conclusions and making decisions. Consistent with the above policy position, ACAL shall own all research databases for research in which Sydney Adventist Hospital is an interested party, whether as an employer, the researcher's institution, a party to a contract, memorandum of understanding, or similar arrangement.

Researchers must negotiate, clarify and document the ownership of the research work product before commencing any research with interested parties. Refer to the [SAH Policy on Intellectual Property](#).

On rare occasions, it may be necessary for researchers to consider departures from the above policy position, as where a research project is to be conducted

with an external party which insists upon owning some or all of the work product arising from the research. However, any departure from the above position must be approved by the Executive Committee (EXCOM) and set out in a written agreement.

24. PAYMENT FOR RESEARCH

Unless otherwise specified by EXCOM, payment for research will be deposited to the Hospital's bank account and allocated to specific trust accounts, where applicable.

24.1. Research Grants

Unless otherwise specified by EXCOM, all research grants must be submitted to EXCOM for prior approval.

25. RESEARCH MISCONDUCT AND FRAUD

Research misconduct is a serious offence. It includes, but is not limited to:

- 25.1. Fabrication of data; claiming results where none has been obtained
- 25.2. Falsification of data including changing records
- 25.3. Plagiarism including direct copying of textual material without adequate attribution
- 25.4. Misleading ascription of authorship including the listing of authors without their permission, attributing work to others who have not contributed to the research and the lack of appropriate acknowledgement of the work of a student or associate
- 25.5. Misuse of funds
- 25.6. Unethical conduct of research involving humans
- 25.7. Infringement of this protocol or other research related policies that is either intentional or caused by negligence
- 25.8. Other practices which seriously deviate from those commonly accepted within the research community
- 25.9. Negligence or failure to uphold commonly accepted standards in the conduct of research within the relevant field.

Misconduct does not generally include inadvertent errors or honest differences of opinion in the interpretation of or judgements about data.

A complaint alleging research misconduct may be made to the Research Governance & Ethics Officer of the Human Research Ethics Committee or Hospital's Chief Executive Officer and may be made in writing or orally. Once a complaint has been received the following steps will be taken:

- 25.10. The CEO (or nominee) will inform the Research Governance & Ethics Officer as soon as possible of any complaints received.
- 25.11. The Research Governance & Ethics Officer will advise the Principal Investigator of the research of the complaint. Further information may be sought and in some instances the investigator may be required to attend a Human Research Ethics Committee meeting to explain the situation. The Committee is required to respond urgently where there is a risk of harm to participants, researchers or other persons.

- 25.12. The Research Governance & Ethics Officer will investigate the matter and refer the results of the investigation to the Human Research Ethics Committee for consideration.
- 25.13. Following consideration of the complaint, the Human Research Ethics Committee will make a recommendation to the Board of Directors, Sydney Adventist Hospital Ltd on the appropriate course of action, which may include:
- 25.13.1. Determining that the allegations have no substance and dismiss the complaint
 - 25.13.2. Determining that there is no evidence of misconduct or fraud but issue a caution
 - 25.13.3. Initiating increased monitoring by the Committee
 - 25.13.4. Requesting an amendment to the research plan / protocol
 - 25.13.5. Suspending ethical approval
 - 25.13.6. Withdrawing ethical approval
- 25.14. The Board will consider the recommendation of the Human Research Ethics Committee at its next meeting (or earlier if required) and decide what action should be taken in relation to the complaint.
- 25.15. Where an allegation of misconduct is upheld by the Board, the Research Governance & Ethics Officer will:
- 25.15.1. Advise the Principal Investigator in writing of the outcome of the investigation
 - 25.15.2. Inform grant funding bodies and/or other parties with a direct interest in the matter, the Hospital's Chief Executive Officer, Director of Medical Services, Director of Risk Management and Chair of Ethics Committee.
 - 25.15.3. Take other action as may be necessary to protect the interests of the Hospital and exercise a duty of care towards staff members, students, the public or any other parties involved in the matter.
 - 25.15.4. The Hospital may also exercise its right to take legal or other action against the researcher or a third party
- 25.16. In the event that a matter may be the subject of an investigation or action under more than one process, such as complaints resolution or disciplinary processes specified in other Hospital policies, the matter should be considered in a manner that will minimise duplication of processes.

26. COMPLIANCE WITH THIS POLICY AND PROTOCOL

Compliance with this policy and protocol will be subject to monitoring as outlined in the Hospital's Compliance Policy. Non-compliance with this protocol may constitute research misconduct. Refer to section: [Research Misconduct and Fraud](#).

27. ACCREDITATION STANDARDS

ACHS Equip 4 Standard 2.5.1
ISO 9001:2000 Standard 4.2.3 and 5.5
JCI 2008 LD 04.01.07

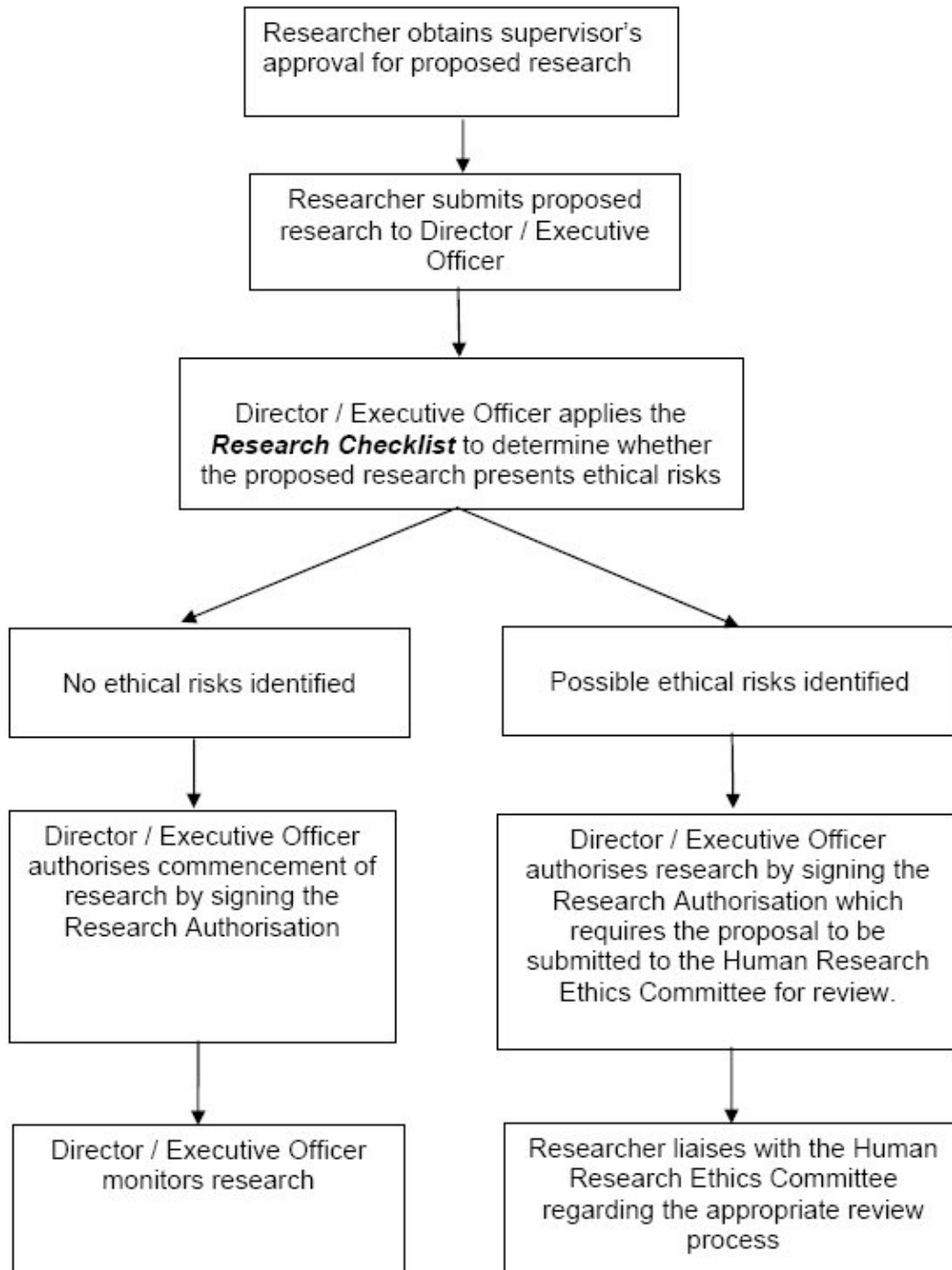
28. POLICY CATEGORY

Category One – Approved by Excom on 15 October 2009.

29. REVIEW OF THIS POLICY AND PROTOCOL

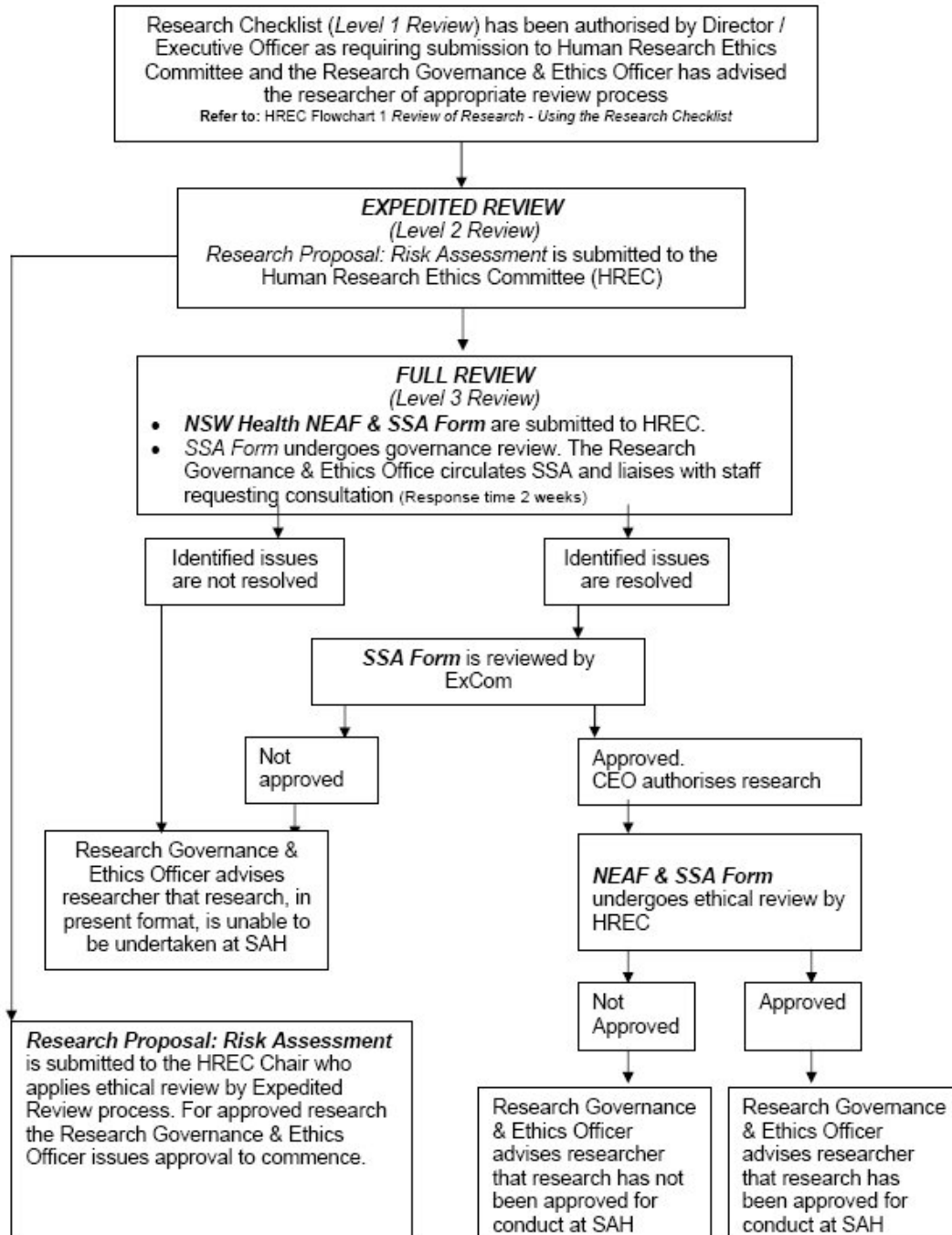
It is acknowledged that this policy and protocol is a developing area. Consultation will continue after publication and reviewed every six (6) months and amended as necessary. Proposed amendments should be submitted in writing to the Research Governance & Ethics Officer of the Human Research Ethics Committee ethics@sah.org.au

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



REVIEW OF RESEARCH REQUIRING REVIEW BY THE HUMAN RESEARCH ETHICS COMMITTEE

Sydney Adventist Hospital
Human Research Ethics Committee



Acknowledgements:

Policy on Research Practice. Flinders University

<http://www.flinders.edu.au/ppmanual/research/resprac.htm> printed 23/7/08

Research Management Policy. Curtin University of Technology

Code of Conduct for Research. University of the Sunshine Coast

www.usc.edu.au/University/AbouttheUniversity/Governance/Policies/Research/Code.htm

printed 23/7/08

Useful Links:

Australasian Research Institute

<http://www.australasianresearch.org/>

NHMRC National Statement

http://www.nhmrc.gov.au/publications/synopses/_files/e72.pdf

NHMRC Australian Code for the Responsible Conduct of Research

NHMRC Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research

NHMRC Guidelines Under section 95 of the Privacy Act 1988

NHMRC additional levels of evidence and grades of recommendations for developers of guidelines. Stage 2 Consultation

http://www.nhmrc.gov.au/guidelines/_files/Stage%20%20Consultation%20Levels%20and%20Grades.pdf

APPENDIX 1

Interpreting research evidence

Applying research evidence in real, clinical situations is not usually straightforward. It is helpful to consider research evidence in the following ways:

Classifying levels of research evidence: Research evidence is classified within a hierarchy according to the potential for the type of research to adequately answer a research question. For example: A randomised controlled trial (Level II) is more likely to answer a research question than a cohort study (Level III)

Grading the evidence recommendations: Grading the evidence recommendations indicates the strength of a body of evidence and assists in making appropriate and informed clinical judgements. For example: Grade A evidence is directly applicable to Australian healthcare while Grade D evidence is not.

Research Evidence Hierarchy			
Strength of Evidence		Body of Evidence	
Levels of Evidence	Type of Intervention	Grades of Recommendation	Description
I	A systematic review of Level II studies	A	Body of evidence can be trusted to guide practice
II	A randomised controlled trial	B	Body of evidence can be trusted to guide practice in most situations
III	A pseudo-randomised controlled trial OR A comparative study with concurrent controls such as a cohort study OR A comparative study without concurrent controls such as an interrupted time series without control group	C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
IV	Case series with post-test or pre-test/post-test outcomes	D	Body of evidence is weak and recommendation must be applied with caution

When interpreting what research evidence means for healthcare at Sydney Adventist Hospital Limited, and to assist in making conscientious, explicit and judicious use of the evidence in everyday practice, the National Health & Medical Council's Evidence Statement form should be completed.