# Research Policy

Approved 7 Feb 2022

This document will be reviewed and updated periodically by AHCL.
The latest version is accessible on SanDocs.

Authors:
Daniela von Hieber, Manager Research Ethics & Governance
Shari Emerton, Research Ethics and Governance Officer

# Research Policy

## Contents

## 1. POLICY

1.1. Adventist HealthCare 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 Adventist HealthCare, whether by employees, Accredited Medical Officers, volunteers, students or external researchers, must comply with the following:

1.2.1. law and regulations - Human research is governed by Australian law that establishes rights for participants and imposes general and specific responsibilities on researchers. Some human research is subject to specific statutory regulation at Commonwealth and State and Territory levels [1];

1.2.2. the National Health & Medical Research Council's National Statement on Ethical Conduct in Research Involving Humans (2007) (Updated 2018) ("the National Statement") [2];

1.2.3. the Australian Code for the Responsible Conduct of Research (2018) ("the Australian Research Code") [3].

## 2. SCOPE

2.1. This policy applies to all research being undertaken at Adventist HealthCare Limited.

## 3. RATIONALE

3.1. This policy has been developed to provide governance to research at Adventist HealthCare Limited.

## 4. DEFINITIONS

4.1. Definitions are included in the policy

| Term | Definition |
|---|---|
| Acceptable Clinical Trial Register | Australian Clinical Trials Registry or another clinical trial register that meets the requirements of the International Committee of Journal Editors. |
| Adventist HealthCare | Adventist HealthCare Limited |
| Adverse Event | For Medicines. Includes any untoward medical occurrence in a participant who has been administered a pharmaceutical product which does not necessarily have a causal relationship with the treatment. An adverse event can be any unfavourable and unintended sign, symptom or disease temporally associated with the use of an investigational product, whether or not relation to the investigational product. For devices. Includes any undesirable clinical occurrence in a participant whether it is considered to be related to the investigational device or not, that includes a clinical sign, |

| | |
|---|---|
| | symptom or condition and/or an observation of an unintended technical performance or performance outcome of the device. |
| AHCL | Adventist HealthCare Limited |
| Application for Ethical Review | An application submitted to the Committee for review of a human research proposal that:<br><br>(a) Is to be conducted at sites under the direction and control of Adventist HealthCare Limited and /or<br><br>(b) Involves Adventist HealthCare Limited patients, clients, staff, volunteers, students or their information in the research and/or<br><br>(c) Uses the resources or staff of Adventist HealthCare Limited including accredited medical officers, volunteers, students and independent contractors of Adventist HealthCare Limited acting in that capacity |
| Application Form | Any application form for ethical review accepted by the Committee. |
| Approved Research Project | Any human research project described in an Application for Ethical Review submitted to the Committee and which has been given ethical approval by the Committee. |
| ARI | The Australasian Research Institute |
| Australian Privacy Principles | The Australian Privacy Principles are principles-based law. They are based on the privacy protection framework in the Privacy Act 1988. They give an organisation or agency flexibility to tailor their personal information handling practices to their business models and the diverse needs of individuals. Source: https://www.oaic.gov.au/privacy/australian-privacy-principles |
| Australian Research Code | Australian Code for the Responsible Conduct of Research, 2018 |
| Clinical Health Research | A systematic investigation undertaken for the purpose of adding to the body of knowledge pertaining to human health. |
| Clinical Investigation Research Agreement (CIRA) | A suite of research agreement templates developed by the Medical Technology Association of Australia for human research involving experimental medical devices |

| | |
|---|---|
| Clinical Trial | Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational product(s) and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy [Ref: Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95): Annotated with TGA comments] |
| Clinical Trial Research Agreement (CTRA) | A suite of research agreement templates developed by Medicines Australia for human research involving experimental pharmaceuticals |
| Committee | The Adventist HealthCare Limited Human Research Ethics Committee which is appointed and administered by Sydney Adventist Hospital Ltd |
| Co-ordinating Investigator | The individual who takes overall responsibility for the research study and submits the project for ethical and scientific review. They are responsible for ongoing communication with the HREC and passing on any outcomes from this to the Principal Investigators. For single-centre research, Co-ordinating Investigator and Principal Investigator are synonymous. |
| CTA | Clinical Trial Approval; Supply of Unapproved Therapeutic Goods under the Clinical Trial Approval Scheme published by the Therapeutic Goods Administration. |
| CTN | Clinical Trial Notification; Notification of Intent to Supply Unapproved Therapeutic Goods under the Clinical Trial Notification (CTN) Scheme published by the Therapeutic Goods Administration |
| DSMB | Data Safety Monitoring Board which is an independent monitoring board established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy points and to recommend to the sponsor whether to continue, modify or stop a clinical trial. [Ref: Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95): Annotated with TGA comments] |
| Epidemiological research | Is the study of the distribution and determinants of health-related states or events in specified populations and the application of this study to the control of health problems. |
| Ethical Review | Processes that have been established to safeguard those who participate in, and are potentially impacted by research, and the individuals as well as organisations who conduct human research |
| Executive Officer | In the context of this policy this means the Manager, Research Governance and Ethics |

| | |
|---|---|
| External Researchers | Researchers who are not employed by AHCL or currently accredited with AHCL |
| GCP Training | Good Clinical Practice training aims to ensure that research is conducted in compliance with the internationally accepted standard IHC GCP for the design and conduct of human research. These standards have their root in the World Medical Association's Declaration of Helsinki and are freely available online. |
| Governance Review | See: Site Specific Assessment |
| Group | Adventist HealthCare Limited |
| Health Privacy Principles | These principles are a guide for Health Service Providers to understand their obligations under the *Health Records Information Privacy Act 2002* (HRIP Act) and embed good privacy in their practice. Link: https://www.oaic.gov.au/privacy/guidance-and-advice/guide-to-health-privacy |
| HREC | Human Research Ethics Committee which is a committee constituted in accordance with the National Statement on Ethical Conduct in Research Involving Humans (2007) to review and where appropriate approve and monitor the ethical and scientific aspects of human research conducted at sites under its control |
| Human research | Research conducted with or about people, or their data or tissue as described in the National Statement on Ethical Conduct in Research Involving Humans (2007). |
| IB | see: Investigator's Brochure |
| Identifiable information | Any information that makes identification of an individual a reasonable possibility and usually contains some elements of name, residential address and/or date of birth. In a small data set, a postcode may be an identifier. |
| Institution Investigator Agreement | A supplement to the CTRA and CIRA which has been specifically developed for AHCL where investigators are not employees of the organisation where they intend to conduct the research. It outlines the rights and responsibilities of the Investigators and AHCL. |
| Intellectual Property Policy | The AHCL policy regulating Intellectual Property matters. |
| Investigator's Brochure | A compilation of clinical and non-clinical data on the investigational product(s) relevant to the study of investigational product(s) in human subjects. [Ref: Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95): Annotated with TGA comments] |

| | |
|---|---|
| Lead HREC | This HREC is accredited by the Director-General of the NSW Department of Health to conduct ethical and scientific review of human research on behalf of the NSW public health system in the categories of: (a) clinical trials/interventional clinical research and/or (b) general research. |
| Low risk research | Research where the only foreseeable risk to the participant is one of discomfort (minor side effects of medication, discomfort relating to measuring blood pressure or anxiety induced by an interview) or collects new data or data that is identifiable. [Ref: National Statement on Ethical Conduct in Human Research (2007)] |
| Matters of ethical approval | Any information that makes identification of an individual a reasonable possibility and usually contains some elements of name, residential address and/or date of birth. In a small data set, a postcode may be an identifier. |
| Matters of research governance | Matters excluding Matters of Ethical Approval, which must be considered by Adventist HealthCare HREC to determine whether it is a suitable site at which an Approved Research Project should be conducted, including, but not limited to: the proposed cost of the project; the proposed budget; the availability of appropriate equipment, drugs and other resources; and the skills and availability of clinical and non-clinical personnel. |
| Multi-centre research | Research conducted at more than one site within the jurisdiction of more than one HREC. |
| National Mutual Acceptance Scheme (NMA) | A explained by NSW Health, Australian state and territory health departments have signed a Memorandum of Understanding for the mutual acceptance of ethical and scientific review of multi-centre human research projects undertaken in public health organisations. The scope of National Mutual Acceptance includes any form of human research as defined in the latest version of the National Statement on Ethical Conduct in Human Research (National Health and Medical Research Council) for which an application must be made to a Human Research Ethics Committee for the purpose of being conducted at a public health organisation. |
| National Mutual Acceptance Standard Principles of Operation | A document outlining the operating principles for the NMA scheme |

| | |
|---|---|
| National Statement | National Statement on Ethical Conduct in Human Research (2007) - Updated 2018. The National Statement is developed jointly by the National Health and Medical Research Council, the Australian Research Council and Universities Australia. It outlined the ethical principles that apply to human research in Australia. |
| Negligible Risk Research | Research where the only foreseeable risk to the participant is one of inconvenience (filling in a questionnaire or form, participating in a survey or giving up time) uses existing data or records that contain only non-identifiable data. [Ref: National Statement on Ethical Conduct in Human Research (2007)-updated 2018] |
| NHMRC | National Health and Medical Research Council |
| Principal Investigator | The individual who takes responsibility for the overall conduct, management, monitoring and reporting of research conducted at a site and submits the research for governance review. |
| Privacy Legislation | The Privacy and Personal Information Protection Act 1998 (NSW), the Health Records and Information Privacy Act 2002 (NSW) and the Privacy Act 1988 (C'th) and any statutory instruments made pursuant thereto. |
| Quality Improvement or Assurance Projects | A systematic approach for improving efficiency, reliability, and performance of a health service or product where the aim of the project is not to contribute to generalisable knowledge. |
| Re-identifiable information | Data from which identifiable information has been removed and replaced by a code. In such cases it is possible to use the code or other means to re-identify the individual. Cross-tabulation of data can produce small data sets from which it may be possible to identify individuals to whom the data relates thus making the data identifiable. |
| Research activities | Within AHCL this includes all activities which involve human interaction (e.g. interview, survey, observation, audit, testing) or access to identified personal information that is not already on public record. |
| Research involving humans | Includes all forms of research which either involve humans directly or impact upon them directly or indirectly and may include, but is not limited to, research using pharmaceuticals, medical devices, medical radiation and imaging, surgical procedures, biological samples, access to health information as well as epidemiological, social and psychological investigations. |
| Review Body | |

| | |
|---|---|
| SAEs | Serious Adverse Events; For medicines: May also be referred to as a serious adverse drug reaction, is any untoward medical occurrence that at any dose –<br>• Results in death<br>• Is life-threatening where the participant was at risk of death at the time of the event<br>• Requires in-patient hospitalisation or prolongation of existing hospitalisation<br>• Results in persistent or significant disability/incapacity<br>• Is a congenital anomaly/birth defect<br>• Is a medically important event or reaction<br>For devices: Is any adverse medical occurrence that –<br>• Led to death<br>• Led to a serious deterioration in health of the participant or related personnel including:<br>o A life-threatening illness or injury<br>o Permanent impairment of body function or permanent damage to a body structure<br>o A condition requiring hospitalisation or increased length of existing hospitalisation<br>o A condition requiring unnecessary medical or surgical intervention<br>o Foetal distress, foetal death or a congenital abnormality/birth defect<br>• Might have led to death or a serious deterioration in health had suitable action or intervention not taken place including:<br>o A malfunction of a device such that is has to be modified or temporarily/permanently taken out of service<br>o A factor found on examination of the device such as a deterioration in the characteristics or performance |
| Site | A facility, location or service where research will be conducted. |
| Site authorisation | An authorisation granted by the Group CEO, or delegate, for the commencement of a research project. |
| Site Specific Assessment (SSA) | Also referred to as Research Governance Approval or Site Specific Authorisation. This authorisation is required before research may commence at AHCL and is conducted via the the AHCL Research Office (research@sah.org.au) |
| Site Specific Authorisation | See: Site Specific Assessment |
| Sponsor | of a clinical trial is the company, institution or organisation, body or individual that takes overall responsibility for the conduct of the trial and usually initiates, organises and supports the clinical trial |
| Standard Medicines Australia Indemnity | means the current Medicines Australia Form of Indemnity for Clinical Trials – Standard as published by Medicines Australia |
| Standard Medicines Australia Indemnity – HREC Review | means the current Medicines Australia Form of Indemnity for Clinical Trials – HREC Review Only as published by Medicines Australia. |

| | |
|---|---|
| Suspected, Unexpected, Serious Adverse Event (SUSAR) | An event to which there is some degree of probability that the event is an adverse reaction to the administered drug and it is unexpected. |
| Therapeutic good | broadly defined as a good which is represented in any way to be for therapeutic use.[Ref: Section 7 of the Therapeutic Goods Act (1989)] |
| Therapeutic Goods Administration (TGA) legislation | The Therapeutic Goods Act 1989 (C'th) and any statutory instruments made pursuant thereto. The legislation is applied by the Therapeutic Goods Administration |
| Waiver of Consent | An Australian HREC can grant an exception to the requirement of consent and may permit the use of personal information for research without consent from the person this information relates to, if the conditions outlined in the National Statement 2.3.10 and 2.3.11 are met. |

## 5. RESPONSIBILITIES

5.1. All staff, volunteers, students, Accredited Medical Officers, external researchers and Health Care Workers of Adventist HealthCare Limited undertaking research must comply with this policy.

## 6. PROCEDURE FOR RESEARCH PRACTICE

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

## 7. DEFINITION OF "RESEARCH" FOR THE PURPOSES OF THIS POLICY

7.1. Under the Australian Research Code [3], "research" is defined as follows:

*The creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.*

7.2. Within Adventist HealthCare, this could include a wide range of activities, such as:

- Conducting surveys, interviews or focus groups;
- Trialing new medical procedures or techniques;
- Extracting and analysing data from medical records;
- Conducting commercially-sponsored clinical trials;
- Developing and testing administrative processes and procedures, including Quality Improvement or Assurance Projects.
- Collection of body organs, tissue or fluids (e.g. skin, blood, urine, saliva, hair, bones, tumour and biopsy specimens) or exhaled breath for scientific analysis.

7.3. Some of these activities do not involve human experimentation. However, researchers should nonetheless ensure that all research conducted at

AHCL is in line with the values and principles of ethical conduct contained in the National Statement as well as this policy [2]. 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 policy. Ethical review is required for all such research.

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

## 8. DEFINITION OF A RESEARCHER

8.1. For the purposes of this policy, a researcher is any employee, volunteer, Accredited Medical Officer, a person external to AHCL who would like to conduct a research project at AHCL, or student affiliated with Adventist HealthCare who conducts research (as described above) at one of AHCL's facilities under the supervision of an AHCL accredited clinician or Research Affiliate.

## 9. RESEARCHER'S RESPONSIBILITIES

9.1. All researchers conducting research at AHCL must comply with the responsibilities of researchers set out in the *Australian Research Code* (see R14 to R29) [3] and the National Statement (5.2.5 to 5.2.22) [2] as well as institutional policies related to responsible research conduct. These responsibilities include, but are not limited to:

9.2. Researchers must foster and maintain a research environment of intellectual honesty and integrity, and scholarly and scientific rigour;

9.3. Respect the truth and the rights of those affected by their research and present information to participants in ways that help them make good choices about their participation;

9.4. Ensure the research addresses and reflects the values and principles of ethical conduct namely merit and integrity, justice and beneficence;

9.5. Demonstrate that the research is clear and comprehensive, and written in lay language;

9.6. Adopt methods appropriate for achieving the aims of each research proposal and ensure that conclusions are justified by the results;

9.7. Follow proper practices for safety and security in accordance with AHCL policies and operational manuals;

9.8. A researcher should disclose to the review body the amount and sources or potential sources of funding for the research;

9.9. A researcher developing or designing a research proposal involving two or more institutions should inform them all at an early stage in this process;

9.10. Manage conflicts of interest so that ambition and personal advantage do not compromise ethical or scholarly considerations;

9.11. Reference awards, degrees and research publications accurately, including the status of any publication;

9.12. Researchers should ensure that research findings are disseminated accurately and broadly;

9.13. Researchers must comply with ethical principles of integrity, respect for persons, justice and beneficence;

9.14. Researchers should conduct their research so as to minimise adverse effects on the wider community and the environment;

9.15. 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.

9.16. Research must be conducted or supervised only by those persons with experience, qualifications and competence appropriate to the intended research.

9.17. Researchers must demonstrate regard for the welfare, rights, beliefs, perceptions, customs, and cultural heritage of persons involved in research.

9.18. Researchers must maximise possible benefits and minimise possible harms to participants in research whether physical, psychological, emotional, spiritual, economic, cultural or social.

9.19. Researchers must avoid imposing an unfair burden of participation in research on particular groups who are likely to be subject to over-researching.

9.20. 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 or particular groups is essential to the purpose of the research.

9.21. 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.

9.22. 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. Where obtaining participant consent is not possible then the following pathways should be considered:

9.22.1. whether the research can be conducted using de-identified data;

9.22.2. where using de-identified data is not possible, provided the research fulfils the criteria for a Waiver of Consent (see sections

2.3.10(a) to (i) of the National Statement) [2] and the guidelines approved under s95A of the *Privacy Act 1988* [4] whether a HREC can grant a Waiver of Consent;

9.22.3. if the researcher can demonstrate that the research can be exempted from ethical review under clause 5.1.22 and 5.1.23 of the National Statement.

9.23. Researchers must suspend or modify any research in which risks to participants are found to be disproportionate to the benefits and stop the involvement of any participant if continuation of the research may be harmful to that person;

9.24. In the event of a serious or unexpected adverse effect on participants in research approved by the AHCL Human Research Ethics Committee, the researcher must immediately report this to the Committee. If the research is a clinical trial, safety reporting must follow the NHMRC guidelines on *Safety monitoring and reporting in clinical trials involving therapeutic goods* (2016) [5];

9.25. Researchers must acknowledge AHCL and collaborating research institutes in any publication arising out of the research project;

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

9.27. Research involving pregnant women and their fetuses may only be conducted in accordance with the principles set out in the National Statement;

9.28. Research involving a person with a cognitive impairment, intellectual disability or mental illness may only be conducted in accordance with the principles set out in the National Statement;

9.29. Research involving persons in dependent or unequal relationships, or persons highly dependent on medical care, may only be conducted in accordance with the principles set out in the National Statement;

9.30. Research involving persons who may be involved in illegal activities may only be conducted in accordance with the principles set out in the National Statement;

9.31. Research involving Aboriginal or Torres Strait Islander people, or people in other countries, may only be conducted in accordance with the principles set out in the National Statement;

9.32. Research that is not in line with the beliefs and values of the Seventh Day Adventist Church may require approval from the church headquarters before site authorization may be granted.

## 10. OBTAINING ETHICAL APPROVAL FOR RESEARCH CONDUCTED AT AHCL

10.1. All research conducted at Adventist HealthCare must be reviewed, approved and authorised in accordance with this policy prior to commencement. Retrospective HREC approval will not be granted.

10.2. In accordance with the National Statement, all research that poses ethical risks to humans must be reviewed and approved by a Human Research Ethics Committee. AHCL accepts ethical review from the AHCL HREC, an external NSW Health Lead HREC, NHMRC certified or registered HREC. In this context, AHCL also accepts HREC decisions made as part of the single ethical review scheme of multi-centre human research projects (National Mutual Acceptance Scheme; NMA) following the 'NHMRC National Mutual Acceptance Standard Principles of Operation' (2018) [6].

10.3. Research activities that could be subject to ethical review, include, but are not limited to:

- Interview
- Survey
- Focus Group
- Audit
- Observation for research purposes
- Testing or treatment for research purposes
- Peer Review
- Retrospective review of medical records
- Quality Assurance projects
- Clinical trial

10.4. 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.

10.5. The AHCL HREC can conduct ethical reviews of research outside AHCL. The researcher should ensure that the research site is willing to accept the ethical approval of a registered HREC.

## 11. OBTAINING A WAIVER OF CONSENT

11.1. Waivers of Consent can be applied for as part of an application for ethical review of research. A waiver of consent is not to be seen as an alternative to HREC review.

## 12. OBTAINING SITE SPECIFIC AUTHORITY TO COMMENCE RESEARCH AT AHCL

12.1. All research conducted at AHCL must receive site approval.

12.2. The Research checklist must be completed for each Research Proposal.

12.3. Site approval can only be granted after ethical approval is granted.

12.4. A submission of documentation to the Research Office in line with the AHCL Site Specific Assessment (SSA) Form [7] is required.

12.5. Clinicians who have private rooms at AHCL and whose research is solely contained within those rooms, may not require site approval. However, it is

a requirement that the research proposal is submitted to the AHCL Research Office to obtain confirmation. The Research Office will confirm whether an SSA is required.

12.6. The site-specific authorisation process is conducted by the AHCL Research Office, Director of Research, and various committees depending on the study design.

12.7. Site approval will be granted by the AHCL CEO or delegate upon completion of the internal review to assess the following aspects of the research:

12.7.1. budget and the financial risk to the organisation i.e. how is the research funded and is there sufficient funding;

12.7.2. insurance and indemnity matters to ensure that there is a sufficient level of insurance cover available should that be required;

12.7.3. contractual arrangements clearly outlining the responsibilities of the organization, the researcher and the funding or sponsoring body, for example Clinical Trial Research Agreements;

12.7.4. the composition of the research team and their skills, experience and expertise in conducting the project in relation to their roles in the project;

12.7.5. intellectual property that may result from the research and its ownership;

12.7.6. data security to ensure organisational compliance with relevant law and guidelines, including Health Privacy Principles and Australian Privacy Principles;

12.7.7. proof of an adequate level of ethical review;

12.7.8. confirmation of departmental support of the research for example Pathology Department, Pharmacy and Medical Records;

12.7.9. confirmation of sufficient resources and access to facilities to conduct the study without the interference of clinical care of AHCL patients;

12.7.10. confirmation of organisational approval to use medical procedures and prostheses.

## 13. MAINTAINING A SAFE AND ETHICAL RESEARCH ENVIRONMENT

13.1. The ethical review process is to be conducted in accordance with the values and principles set out in the National Statement and must incorporate all aspects of research governance to ensure that human research at Adventist HealthCare meets appropriate standards of quality, safety, privacy, risk management, financial management and ethical acceptability.

13.2. Research activities approved by the AHCL 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 any events whereby the participant safety and organizational reputation could be at risk. Researchers may be subject to audits of the research site by or on behalf of the Human Research Ethics Committee.

## 14. CONDUCT OF RESEARCH BY EMPLOYEES AND VOLUNTEERS

14.1. Employees and volunteers conducting research at Adventist HealthCare must comply with this policy.

14.2. The Principal Investigator must be an employee of AHCL, an Accredited Medical Officer or staff and affiliates of AHCL's tertiary education partner.

14.3. In research where a Medicines Australia or MTAA Clinical Trial Research Agreement (CTRA) or Clinical Investigation Research Agreement (CIRA) is used, an Institution Investigator Agreement must be entered into between AHCL and the Principal Investigator.

14.4. All investigators intending to conduct research at an ACHL site must be accredited for conducting research by the AHCL Accreditation Office. Research accreditation is a separate process to obtaining ethical and/or research governance approvals for a specific research proposal. Before a research project may commence at AHCL, all investigators must have obtained research accreditation through the Accreditation Office and site-specific authorisation for the project through the Research Governance Office.

14.5. All Principal Investigators, regardless of being an AHCL employee or a volunteer, conducting research at AHCL are required to provide proof of GCP training. The validity of the training must be within 3 years and the completion certificate is to be forwarded to the Accreditation Office to Accreditation@sah.org.au and the Research Governance Office to research@sah.org.au as part of becoming accredited to conduct research at AHCL.

14.6. All investigators on a study that have contact with participants, or access to participant data, must provide proof of professional insurance cover to the Accreditation Office to Accreditation@sah.org.au and the Research Governance Office to research@sah.org.au as part of becoming accredited to conduct research at AHCL.

## 15. CONDUCT OF RESEARCH BY ACCREDITED MEDICAL OFFICERS AND EXTERNAL RESEARCHERS

15.1. Accredited Medical Officers and external researchers conducting research at Adventist HealthCare and/or other sites approved by the Human Research Ethics Committee, must comply with this policy.

15.2. The Principal Investigator must be an employee of AHCL, an AMO or staff and affiliates of AHCL's tertiary education partner.

15.3. In research where a Medicines Australia or MTAA Clinical Trial Research Agreement (CTRA) or Clinical Investigation Research Agreement (CIRA)

is used, an Institution Investigator Agreement must be entered into between AHCL and the Principal Investigator.

15.4. For research solely conducted in an Accredited Medical Officer's private rooms on the AHCL campus, it is possible that an SSA may not be required. However, confirmation must be provided to the researcher by the AHCL Research Office following its review of the research proposal.

15.5. All investigators intending to conduct research at an ACHL site must be accredited for conducting research by the AHCL Accreditation Office. Research accreditation is a separate process to obtaining ethical and/or research governance approvals for a specific research proposal. Before a research project may commence at AHCL, all investigators must have obtained research accreditation through the Accreditation Office and site-specific authorisation for the project through the Research Governance Office.

15.6. All Principal Investigators, regardless of being an accredited medical officer of external researcher, conducting research at AHCL are required to provide proof of GCP training. The validity of the training must be within 3 years and the completion certificate is to be forwarded to the Accreditation Office to Accreditation@sah.org.au and the Research Governance Office to research@sah.org.au as part of becoming accredited to conduct research at AHCL.

15.7. All investigators on a study that have contact with participants, or access to participant data, must provide proof of professional insurance cover to the Accreditation Office to Accreditation@sah.org.au and the Research Governance Office to research@sah.org.au as part of becoming accredited to conduct research at AHCL.

## 16. CONDUCT OF RESEARCH BY STUDENTS

16.1. All students conducting research at AHCL must comply with this policy. Where a student is conducting the research, the primary supervisor should be named as the Principal Investigator. The Principal Investigator must be an employee of AHCL, an Accredited Medical Officer or staff or affiliate of AHCL's tertiary education partner.

16.2. 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 must 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 Principal Investigator who has primary responsibility for the ethical conduct of the research.

16.3. The Principal Investigator 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 AHCL policies and procedures that affect the conduct of the student's research.

16.4. The Principal Investigator 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 policy and other AHCL policies and procedures.

16.5. The Principal Investigator must ensure:

16.5.1. that the research is conducted in an ethical manner.

16.5.2. that the research proposal is of an appropriate standard.

16.5.3. that any matters relating to ethical review are resolved in a timely manner.

16.5.4. that the research is conducted as approved by a HREC.

16.5.5. that the HREC is notified of any changes to the research.

16.5.6. that reporting requirements are complied with.

16.5.7. the student about the need to maintain confidentiality in respect of the student's research data, methodology or findings.

16.5.8. the integrity of the student's research data is preserved.

16.5.9. the student is part of a research team, inform the student at the commencement of the research of any policies 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.

16.5.10. ensure the validity of a student's data and research methodology.

16.5.11. that adequate proof of insurance for the research has been provided to the Research Office or Clinical Trials Unit.

## 17. CONDUCT OF RESEARCH IN ANOTHER COUNTRY

17.1. Where research is to be conducted in an overseas country by AHCL employees, or by Accredited Medical Officers (if AHCL facilities or resources are required), 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 Adventist HealthCare Human Research Ethics Committee for ethical review.

## 18. CONDUCT OF RESEARCH UNDER COMMERCIAL AND CONTRACTUAL ARRANGEMENTS

18.1. 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 Adventist HealthCare policies and procedures with particular reference to the Policy on Intellectual Property. For all commercially sponsored research projects, AHCL must be listed on contractual agreements as a party to the contract, or requires a separate agreement with the sponsor. This is applicable to research activities taking place at AHCL facilities or with the support of AHCL resources. It is the Principal Investigator's responsibility to initiate the contractual agreements between the sponsor and AHCL.

## 19. CONFLICTS OF INTEREST

19.1. 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.

19.2. Researchers are required to disclose to the Human Research Ethics Committee any conflict of interest regarding affiliation with, or financial involvement in, any organization or entity with direct interest in the subject matter or materials of the research. This includes disclosure of:

19.2.1. Direct benefits such as sponsorship of the research;

19.2.2. Indirect benefits which may include provision of materials or facilities.

19.3. 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.

19.4. 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.

19.5. 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.

## 20. MAINTENANCE of records, retention and storage of research data

20.1. 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).

20.2. 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 scrutinized.

20.3. Personal information generated for research purposes is to have identifiers removed at the earliest possible time, is to be stored securely in an access restricted area and protected by encryption and passwords, 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. Researchers are to comply with the applicable minimum retention periods for research documentation.

20.4. Aggregate data that is to be used for publication are to be kept for a minimum of five years from the date of publication, or longer where required by law.

20.5. During the conduct of the research, personal information is to be stored in a secure environment password protected or in a lockable cabinet with access limited to those directly involved in the research.

20.6. 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. If no such person is nominated, it will be assumed that the Principal Investigator assumes this role. The original data needs to be retained and stored in the organizational environment and may not be retained by an individual researcher on their personal computers, personal storage devices or places of residence.

20.7. 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 outside an organizational IT department. Cloud storage solutions designed for save data retention are acceptable alternatives. Audio or video tapes should be transcribed and the transcript retained as an additional method of safeguarding their contents.

## 21. MONITORING

21.1. Monitoring research is the responsibility of the reviewing HREC and AHCL.

21.2. Researchers also have responsibility with regard to ensuring the integrity and ethical appropriateness of the individual project that they conduct.

21.3. They must also ensure that they are fulfilling reporting responsibilities, including SAEs where relevant), annual reports and final reports.

21.4. AHCL, sponsors and regulatory agencies may conduct random audits on researchers to ensure compliance with the rules and guidelines and also applicable law and regulations.

## 22. PRIVACY AND CONFIDENTIALITY RELATING TO RESEARCH

22.1. 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.

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

22.2.1. 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.

22.2.2. 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.

22.2.3. Records containing personal information are to be stored securely and protected against loss and unauthorised access, use, modification or disclosure as per section 21 of this policy.

22.2.4. 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.

22.2.5. Personal information must be securely disposed of once it is no longer required for the purpose for which it was collected.

22.2.6. 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.

22.3. It is the researcher's obligation to 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.

## 23. AUTHORSHIP AND PUBLICATION

23.1. 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.

23.2. A researcher who meets the minimum criterion for authorship may only be excluded as a named author with his or her written permission.

23.3. 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.

23.4. 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.

23.5. 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.

23.6. The written statement of authorship must be retained by the person nominated as executive author.

23.7. Authors must acknowledge in any publication, all other individuals or organizations who, while not meeting the criteria for authorship, have contributed to the research, including individuals and organizations providing facilities used in the research.

23.8. The results of research and the methods used should be published in ways which permit scrutiny and contribute to public knowledge.

23.9. Researchers must take reasonable steps to ensure published reports, statistics and statements about research activities are complete, accurate and unambiguous.

23.10. If the research poses potential reputational risks to AHCL, the Research Office or Director of Research may deem it necessary to have the research paper reviewed by the AHCL Public Relations office prior to its publication. AHCL reserves its rights to be removed any research papers or publications.

23.11. All publications must include information on all sources of financial support for the research.

23.12. 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.

23.13. An author who submits substantially similar work to more than one publisher must disclose this to the publishers at the time of submission.

23.14. Deliberate inclusion of inaccurate or misleading information or omission of relevant information constitutes research misconduct.

23.15. Research results should normally be made available to research participants.

23.16. Any publication resulting from research at Adventist HealthCare must acknowledge AHCL and/or Sydney Adventist Hospital providing the facilities and/or resources.

23.17. Any publication resulting from research approved by the AHCL HREC must be forwarded to the AHCL Human Research Ethics Committee.

## 24. OWNERSHIP OF RESEARCH: INTELLECTUAL PROPERTY RESULTING FROM RESEARCH

24.1. It is the policy of Adventist HealthCare to hold all intellectual property and data created in connection with the activities of AHCL on trust for Australasian Conference Association Ltd (ACAL). AHCL's position in relation to IP is set out in the Intellectual Property Policy. This applies to researchers employed by AHCL or where that researcher may collaborate with external parties to create data and other information (tangible and intangible) resulting from and/or generated or made in the performance of research. The terms set out in the Intellectual Property Policy will prevail unless otherwise agreed by AHCL in writing, for example a research

agreement between a commercial sponsor and AHCL, signed by the AHCL CEO or delegate.

24.2. Examples of data and information are:

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

24.3. 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 Adventist HealthCare is an interested party, whether as an employer, the researcher's institution, a party to a contract, memorandum of understanding, or similar arrangement, unless otherwise agreed by AHCL in writing.

24.4. Researchers must negotiate, clarify and document the ownership of the research work product before commencing any research with interested parties. Refer to the AHCL Policy on Intellectual Property Policy SAH-CGM-S02-D010.

24.5. 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, for example commercially funded research. However, any departure from the above position must be approved by the Executive Committee (EOC) unless set out in a written agreement signed by the AHCL CEO or delegate.

## 25. PAYMENT FOR RESEARCH

25.1. Unless otherwise specified by EOC, payment for research will be deposited to the Hospital's bank account and allocated to specific trust accounts, where applicable. Research Governance and Ethics fees are payable in accordance with the published Schedule of Fees upon receipt of an Application for Ethical Review, an Amendment to an approved research project and/or a Site Specific Assessment Form. Fees are non-refundable, even if a submission is unsuccessful or is withdrawn prior to consideration or determination.

## 26. RESEARCH GRANTS

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

## 27. RESEARCH MISCONDUCT AND FRAUD

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

27.1.1. Fabrication of data; claiming results where none has been obtained;

27.1.2. Falsification of data including changing records;

27.1.3. Plagiarism including direct copying of textual material without adequate attribution;

27.1.4. 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;

27.1.5. Misuse of funds;

27.1.6. Unethical conduct of research involving humans;

27.1.7. Infringement of this protocol or other research related policies that is either intentional or caused by negligence;

27.1.8. Other practices which seriously deviate from those commonly accepted within the research community;

27.1.9. Negligence or failure to uphold commonly accepted standards in the conduct of research within the relevant field.

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

27.3. A complaint alleging research misconduct may be made to the Manager, AHCL Research Office. For further details refer to the complaints section on the Research Office website.

27.4. 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.

## 28. COMPLIANCE WITH THIS POLICY

28.1. Compliance with this policy will be subject to monitoring as outlined in the Hospital's Compliance Policy. Non-compliance with this policy may constitute research misconduct. Refer to section Research Misconduct and Fraud.

## 29. ACCREDITATION STANDARDS

29.1. ISO 9001:2008 Standard 4.2.3 and 5.5.

29.2. JCI 2008 LD 04.01.07.

## 30. POLICY CATEGORY

30.1. Category One.

## 31. REVIEW OF THIS POLICY

31.1. It is acknowledged that this policy is a developing area. Consultation will continue after publication and reviewed every twelve (12) months and

amended as necessary. Proposed amendments should be submitted in writing to the Research Office: research@sah.org.au.

## 32. ACKNOWLEDGEMENTS


32.1. Policy on Research Practice. Flinders University http://www.flinders.edu.au/ppmanual/research/resprac.htm printed 23/7/08.

32.2. Research Management Policy. Curtin University of Technology.

32.3. Code of Conduct for Research. University of the Sunshine Coast.

32.4. www.usc.edu.au/University/AbouttheUniversity/Governance/Policies/Research/Code.htmprinted 23/7/08.


## 33. USEFUL LINKS


33.1. NHMRC National Statement.

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

33.3. NHMRC Australian Code for the Responsible Conduct of Research.

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

33.5. NHMRC Guidelines Under section 95 of the Privacy Act 1988.

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

33.7. http://www.nhmrc.gov.au/guidelines/_files/Stage%202%20Consultation%20Levels%20and%20Grades.pdf.

33.8. National Health and Medical Research Council (NHMRC), “Applicable laws and obligations,” 26 July 2021. [Online]. Available: https://www.nhmrc.gov.au/applicable-laws-and-obligations#4.

## 34. REFERENCES

[1] National Health and Medical Research Council (NHMRC), “Applicable laws and obligations,” 26 July 2021. [Online]. Available: https://www.nhmrc.gov.au/applicable-laws-and-obligations#4.

[2] National Health and Medical Research Council (NHMRC) , “National Statement on Ethical Conduct in Human Research (2007) - Updated 2018,” 26 July 2021. [Online]. Available: https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018.

[3] National Health and Medical Research Council (NHMRC), “Australian Code for the Responsible Conduct of Research, 2018,” 26 July 2021. [Online]. Available: https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018.

[4] National Health and Medical Research Council (NHMRC), “Guidelines approved under Section 95A of the Privacy Act 1988,” 26 Jul 2021. [Online]. Available: https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988.

[5] National Medical and Research Council (NHMRC), “Safety monitoring and reporting in clinical trials involving therapeutic goods,” 26 Jul 2021. [Online]. Available: https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods.

[6] National Health and Medical Research Council (NHMRC), “National Certification Scheme for the ethics review of multi-centre research,” 26 July 2021. [Online]. Available: https://www.nhmrc.gov.au/research-policy/ethics/national-certification-scheme-ethics-review-multi-centre-research.

[7] Sydney Adventist Hospital, “Our Services - Research Governance Forms & Guidelines,” 26 Jul 2021. [Online]. Available: https://www.sah.org.au/research-governance-forms.