



Research Guidelines

MercyCare Ethics Committee

MercyCare Ethics Committee
C/- Administration
Mercy Hospital Mount Lawley
Thirlmere Road
Mount Lawley WA 6050

Telephone: (08) 9370-9290
Facsimile: (08) 9272-1229

Research applicants must read these Guidelines in their entirety and complete the Application Form in its current format and submit the entire document. No content may be deleted; if any areas are not relevant, they should be marked N/A.

This document is subject to update and amendment as required by the MercyCare Ethics Committee. Copies of the most recent version are available by email: soddy@mercycare.com.au

MercyCare would like to acknowledge St John of God Health Care Ethics Committee for the availability of their Ethics Handbook.

Date Issued: 20.05.2003
Date Revised: 01.06.2005
Date Revised: 05.02.2007
Date Revised: 19.05.2007
Date Revised: 04.07.2007
Date Revised: 05.09.2007 Final Board Approval
Date Revised: 24.04.2009 Final Board Approval

Index

	Page No.
MercyCare Mission Statement.....	4
Health Care in the Catholic Tradition – Seven Basic Principles	5
MercyCare Ethics Committee Terms of Reference	7
Meeting and Submission Dates.....	10
Submission to MercyCare Ethics Committee	10
Useful References	11
MercyCare Research Guidelines.....	13
Guidelines for Researchers – Human Research Proposals	16
Proforma: Participant Information and Consent Form (for General Studies).....	18
Protocol to Access Mercy Hospital Mount Lawley Medical Records	21
Monitoring of Approved Research – Serious Adverse Event (SAE) Process and Form	22
Annual Reports and Final Study Reports.....	24
Clinical Trial Agreements – Legal and Insurance Guidelines	25
Checklist for Researchers Making New Submissions	28
Request to Undertake Research within MercyCare Flowchart	29
Application Form	30
Declaration of Confidentiality	46

MercyCare Vision

Our vision is for a world where God's abundant love and mercy is celebrated by all and where every person has access to justice, equity and opportunities for wellbeing.

We realise this vision by working together in the spirit of the Gospels and with the ideals of Catherine McAuley. We cherish our vision as an inspiration for our decision making and as a motivation for our service.

MercyCare Mission

Our mission is to bring compassion to life.

We align ourselves with the life-giving mission of Christ through practical acts of mercy and by responding energetically to the changing needs of people in our community.
Through quality, caring services and through advocacy, we work for justice and we support people to enrich their lives.
Our core commitment is to those who are vulnerable and distressed in times of disadvantage.

MercyCare Values

We hold the values of respect, justice, compassion, integrity and excellence to be central to our culture and to the achievement of our vision and mission.

We demonstrate these values in our creative responsiveness to social need: our persistence in the face of challenge:
our commitment to human dignity and our hospitality to all.
Appreciating our diversity, we work together to create a climate of trust and collegiality so that in our relationships with each other and with those we serve, we honour each person's gifts and work.

Health Care in the Catholic Tradition

The following Statement and Principles are taken from the Code of Ethical Standards for Catholic Health and Aged Care Services in Australia. Mercy Hospital Mount Lawley supports this Code which was approved for publication by the Australian Catholic Bishops' Conference, 2001.

Life is a gift from God and health care is integral to the mission of the church. Catholic Health Australia is committed to developing a culture which affirms life and healing, a culture which promotes the common good through just and compassionate health, aged, disability and community services. Our concern for others is motivated by the belief that proper respect for human beings entails respect for their dignity as people created and loved by God. The sanctity of their lives is an inevitable consequence of this.

Seven Basic Principles

- 1. Respect for persons within the culture of life**
Our care for people who are sick, aged or disabled is founded on love and respect.
- 2. Health Care and the Mission of the Church**
Catholic health and aged care is called to respond to a person's health care needs with compassion and in fidelity to the healing ministry of Jesus Christ
- 3. The Goals of health care**
 - *To promote health and prevent disease;*
 - *To deepen our understanding of the causes of disease and to develop new forms of treatment;*
 - *To save lives, cure illness or slow progress of disease;*
 - *To relieve suffering and disability;*
 - *To care for people when they are sick, disabled, frail or elderly; and finally*
 - *To assist a person in his or her transition from this life in hope of the resurrection, while also caring for those who grieve that person's passing.*
- 4. Justice in health care**
Everyone has the right to receive essential health and aged care services. These services should be allocated justly across a society, with special provision for the most disadvantaged or most vulnerable to neglect.
- 5. Collaboration in health and aged care**
In the provision of health and aged care, patients, residents, practitioners, family and carers become a small community united in working for a person's good. The relationship which unites them is best understood as one of trusting collaboration in a common purpose.
- 6. Respect for personal embodiment**
Because the human person is a unity of body and spirit, a person's body is not an instrument to be manipulated in isolation from the authentic good of the person. Human sexuality and procreation in particular are personal, not just biological, realities.
- 7. Solidarity and the mystery of suffering and death:**
Illness, disability and suffering are never good in themselves: health care properly seeks to relieve them. There are, however, limits to what health care can achieve. Even when suffering and death cannot be eliminated, they can nonetheless acquire a positive, life-giving and redemptive value, especially from the perspective of religious faith.



Seven Basic Principles {contd}

Research conducted on Catholic healthcare premises is expected to follow these principles, and permission will not be granted to pursue any research which plainly contradicts any of these principles. Researchers may be required to amend research proposals and protocols accordingly.

Terms of Reference

TERMS OF REFERENCE

MERCYCARE ETHICS COMMITTEE

ORGANISATIONAL LINE: The Ethics Committee reports to the MercyCare Board of Governance.

PURPOSE: The purpose of the Ethics Committee is to review, assess, advise and provide recommendations to the MercyCare Board on the ethical aspects of clinical and research activities of MercyCare.

The Ethics Committee will conduct all its activities within the Code of Ethical Standards for Catholic Health and Aged Care Services in Australia and within the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct and other relevant regulatory bodies.

MEMBERSHIP: As per NHMRC minimum membership requirements of the Ethics Committee will comprise:

1. :
 - Chairperson
 - Two lay people (one man and one woman)
 - Person/s with knowledge of, and current experience in, the professional care, counselling or treatment of people
 - Two people with relevant current research experience
 - Person/s who performs a Pastoral Care role in the community
 - Lawyer

2. Additional members to be appointed at the discretion of the MercyCare Board:
 - CEO of MercyCare
 - Director of Nursing of Mercy Hospital Mount Lawley
 - A representative from Mercy Aged Care
 - A representative from Mercy Community Services
 - Mission Leader

Members of the Ethics Committee will be appointed by the MercyCare Board for a term of three (3) years and must receive formal notice of appointment and legal indemnity.

Terms of Reference {contd}

The Ethics Committee is empowered to co-opt expert advice or refer Research Projects to other Ethics Committee for advice as required.

The MercyCare Board will appoint the chairperson of the Ethics Committee.

All Members shall undertake to support the MercyCare Catholic Ethos.

ACCOUNTABLE FOR:

The Ethics Committee will be accountable for:

- Reviewing all human experimentation and health research proposals to be conducted at MercyCare, making recommendations to the Board and being responsible for ongoing monitoring of approved proposals;
- Supporting MercyCare management in the education of all MercyCare staff on ethical and related issues;
- Providing ethical advice to MercyCare on clinical issues, policies and procedures as requested;
- Preparing and / or articulating an ethical stance on issues with a view to making submissions to appropriate persons and bodies as delegated by the MercyCare Board.

RESPONSIBLE TO:

The Ethics Committee is responsible to the MercyCare Board and will report to the NHMRC as required.

The Governing Board of MercyCare will confirm in writing its decisions regarding all recommendations made to it by the Ethics Committee.

RECEIVES REPORTS:

The Ethics Committee will receive reports from other Ethics Committees and regulatory bodies as required.

MEETINGS:

Minutes will record the Ethics Committee meeting proceedings. These Minutes will be forwarded to the MercyCare Board and will be held in the central MercyCare archives and by the Committee Chairperson.

An opportunity for reflection will be made available at the commencement of each meeting.

Meetings will be held bi-monthly and more frequently, if required. Members may be called to meet on urgent matters only with reasonable notice.

The Minutes from the previous Meeting and Agenda will be distributed at least one (1) week prior to the next Meeting.

Terms of Reference {contd}

No member of the Committee can adjudicate on research in which he / she may be personally involved.

Decisions of the Committee shall not be reached unless a quorum is present and they have received all relevant papers and had the opportunity to contribute their views, as prescribed by the NHMRC guidelines.

The Ethics Committee may agree to an expedited review procedure on a case by case basis.

EVALUATION:

In September of every second year the Ethics Committee will review its Terms of Reference. Any recommendations to change the Terms of Reference will be forwarded to the Board of MercyCare for approval.

In October of that year, the MercyCare Board will conduct an annual evaluation of the role and performance of the Ethics Committee. In addition, the Ethics Committee will provide information from its records to the NHMRC on request.

To meet the requirements of Hospital accreditation, an annual outcome audit will be made by the Chairperson of the Ethics Committee.

Meeting and Submission Dates

2010 Meeting Dates	2010 Submission Close Dates
Wednesday – 10.02.2010	Tuesday – 26.01.2010
Wednesday – 14.04.2010	Tuesday – 30.03.2010
Wednesday – 09.06.2010	Tuesday – 25.05.2010
Wednesday – 11.08.2010	Tuesday – 27.07.2010
Wednesday – 13.10.2010	Tuesday – 28.09.2010
Wednesday – 08.12.2010	Tuesday – 30.11.2010

Submission to MercyCare Ethics Committee

Ms Sharon Oddy
MercyCare Ethics Committee Secretary
C/- Administration
Mercy Hospital Mount Lawley
Thirlmere Road
Mount Lawley WA 6050

Telephone: (08) 9370-9290
Facsimile: (08) 9272-1229
Email: soddy@mercyare.com.au

Useful References

National Ethics Application Form (NEAF)

- NEAF is a web-based tool that has been developed to assist Researchers of all disciplines to complete research ethics proposals for submission to Human Research Ethics Committees (HREC).
- AusInfo Government Information Bookshops, Toll Free: 132 447
- www.nhmrc.health.gov.au/publicat/pdf/e35.pdf

National Health and Medical Research Council (NHMRC) Statement on Ethical Conduct in Research Involving Humans (1999) and Supplementary Notes

This provides guidelines to Researchers making submissions to Human Research Ethics Committees throughout Australia. It is available from:

- AusInfo Government Information Bookshops, Toll Free: 132 447
- www.nhmrc.health.gov.au/publicat/pdf/e35.pdf

International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use Guidelines

Available from:

- www.ifpma.org/ich1.html

Therapeutics Goods Administration (TGA) provides a national framework for the regulation of therapeutic goods in Australia to ensure their quality, safety and efficacy. Access to unapproved therapeutic goods is available through the clinical trials schemes and the special access scheme (SAS). Guidelines on accessing both schemes are available from:

- www.health.gov.au/tga

The “Note for Guidance on Good Clinical Practice” is an internationally accepted standard for the designing, conducting, recording and reporting on clinical trials. It is available from:

- www.health.gov.au/tga/docs/pdf/euguide/ich/ich13595.pdf

The TGA also has a document entitled, “Human Research Ethics Committees and the Therapeutic Goods Administration” available from:

- www.health.gov.au/tga/docs/html/hrec.htm

Medicines Australia is a national association representing the prescription medicines industry in Australia. It has information targeted at consumers on the clinical trials process and prescription medicines.

- www.medicinesaustralia.com.au

The Australian Society for Medical Research (ASMR) aims to foster excellence in Australian health and medical research, and to promote community understanding and support for health and medical research in Australia. On this website you can find information about ASMR, access their newsletter, keep up-to-date with the latest news and up-coming events. There is also general information for students and access to related links.

- www.asmr.org.au

Database of Cancer Research in Australia (The CARA Database) has been developed by the Melbourne Branch of the Ludwig Institute for Cancer Research. CARA aims to provide access to information about Cancer Research in Australia. You can search the website by five (5) categories, being: Researcher name, tumour types, institute, keywords describing the research as well as by funding agency.

- cornhill.ludwig.edu.au/cara2/index2.html

Useful References {contd}

Research Australia is a national body of Australian organisations and companies that are committed to making health and medical research a higher national priority. It provides up to date information on the latest health research being conducted throughout Australia.

- www.researchaustralia.com.au

Code of Ethical Standards for Catholic Health and Aged Care Services in Australia

As a Catholic Health Care Provider, MercyCare follows a Code of Ethics as outlined in “Code of Ethical Standards for Catholic Health and Aged Care Services in Australia (2001)”, published by Catholic Health Australia. It can also be ordered through their website:

- www.cha.org.au/publications/index.html

Cooperative Research Centre for Discovery of Genes for Common Human Diseases (Gene CRC)

For further information on ethical issues in genetic research, guidelines on privacy and confidentiality, consent, and the content of participant information and consent forms, refer to the publication of the Cooperative Research Centre for Discovery of Genes for Common Human Diseases (Gene CRC), “Ethical Issues in Genetic Research – an introduction for members of the Australian Human Research Ethics Committees”. This, and other information is also available on the Gene CRC website:

- www.genecrc.org/

MercyCare Research Guidelines

1. Research Policy

Research proposed to be carried out within MercyCare or involving consumers of MercyCare services may only be undertaken with the approval of the MercyCare Ethics Committee (the Committee). Some Quality Assurance can be approved by the Divisional Heads.

2. Research Proposals

Research within MercyCare may only be undertaken with the agreement of the relevant Heads of Divisions in the first instance, and Ethics Committee approval in the second.

Staff within MercyCare wishing to undertake research will receive preference over external applicants. However, requests will be considered from external applicants who are:

- Post-Graduate students enrolled in Honours, Masters or Doctoral programs
- University Research Advisers on behalf of Under-Graduate students; and
- Suitably qualified and appropriate independent Researchers.

3. Procedure for Submission of Research Proposals

In order to obtain permission to undertake research within MercyCare, the following must be submitted:

- 3.1** A completed "MercyCare Research Proposal" Application Form.
- 3.2** Post-Graduate students will require a letter of endorsement from the Faculty Adviser / Research Supervisor indicating that the student is qualified to conduct the research, that the proposal has scientific merit and that relevant approval has been obtained from the Institution's Research Ethics Committee.
- 3.3** Graduate research proposals will be accompanied by a letter from the Faculty Adviser / Research Supervisor acknowledging responsibility and accountability for the quality of the study and that relevant approval has been obtained from the Institution's Research Ethics Committee.
- 3.4** Independent Researchers should attach a resume indicating research qualifications and credentials, previous research experience and publications and ethics approval from a relevant Institutional Research Ethics Committee.
- 3.5** Thirteen (13) typed copies of the research proposal, and Protocol if relevant, as per the Checklist for Researchers in Application Form.
- 3.6** All Researchers will identify funding sources and potential conflict of interest.

4. The Review Process

Once reviewed by the Divisional Head the proposal will be reviewed by the Committee.

A letter stating the outcome of the review process will be sent to the applicant as soon as possible after completion of the review.

The following conditions apply subsequent to proposal acceptance:

- 4.1** The Committee will nominate a liaison person who will facilitate the Investigator's access to MercyCare to implement the research.

MercyCare Research Guidelines {contd}

- 4.2 Progress Reports will be required at least annually or at other intervals determined by the Investigator and the Committee.
- 4.3 Any difficulties which may threaten the project will be discussed with the nominated liaison person.
- 4.4 Investigators will consider it their responsibility to inform the liaison person once data collection is complete.
- 4.5 The Committee must be notified of any variations to the project protocol, including Adverse Events in the case of clinical trials.
- 4.6 The Committee will also receive a copy of all published articles arising from the research.
- 4.7 At the conclusion of the study, a written research report will be submitted by the Investigator to the Committee at an agreed time.

5. Research Proposal Guidelines

A research proposal is a written summary of what the Researcher intends to do, how and why. It is forward looking and describes the anticipated plan of action for approval by the Committee.

A Research Proposal comprises of the following:

5.1 Project Title

5.2 Names of the Investigators including contact details of Chief Investigator or other nominated contact person

5.3 Introduction

- 5.3.1 Statement of the proposal in bold and underlined plain language
- 5.3.2 Background and significance of the proposal
- 5.3.3 Statement of the purpose
- 5.3.4 Anticipated time frame
- 5.3.5 Identification of funding sources
- 5.3.6 Statement identifying any actual, or potential, conflict of interest
- 5.3.7 Statement identifying other bodies having oversight

5.4 Review of Related Literature

(Not part of the proposal in some qualitative studies)

- 5.4.1 Review of relevant research
- 5.4.2 Review of relevant theoretical literature
- 5.4.3 Summary

5.5 Frame of Reference

- 5.5.1 Study Aim or Objectives
- 5.5.2 Hypotheses
- 5.5.3 Definition of Terms

5.6 Methodology

- 5.6.1 Identification of Study Design
- 5.6.2 Identification of Population / Sample Subjects
- 5.6.3 Study Setting
- 5.6.4 Methods of Data Collection

MercyCare Research Guidelines {contd}

5.6 Methodology {contd}

5.6.5 Data Analysis Procedures

5.6.6 Sample Size / Power Calculation

5.7 Ethical Considerations

Human participants are those who are interviewed, surveyed or observed, or whose data will be accessed for the purpose of the proposed study.

5.7.1 Consent

The Research Proposal must include:

- a) provision to participants, at their level of comprehension, of information about the purpose, methods, demands, risks, inconveniences, discomforts and possible outcomes of the research (including the likelihood and form of publication of research results), and
- b) Evidence of the exercise of a voluntary choice to participate.

5.7.2 In addition to this information, participants will be informed of their right to participate, or not, or withdraw from the project without prejudice. A research participant's information and consent form must also be included.

5.7.3 Provide a description of procedures used to obtain consent: to protect anonymity and confidentiality: to store data securely and to dispose of name identifying data.

5.8. Limitations of the Study

5.9. Proposed communication of the findings

5.10. References

5.11. Appendices

5.12 Research Proposal should not exceed 2000 words

Guidelines For Researchers – Human Research Proposals

- 1.** All Human Research projects undertaken within MercyCare must be approved and registered by the Ethics Committee prior to commencement. These projects may involve patients, residents, staff or other participants.
- 2.** Proposals for research must be submitted using the MercyCare Research Application Form as attached. The proposal must be accompanied by attached information as specified on the application form.
- 3.** The Ethics Committee meets bi-monthly. Applications must be received by the Chairperson of the Committee at least ten (10) working days prior to the scheduled meeting.
- 4.** The Committee’s approval of a project is valid for a maximum of three (3) years unless a shorter time is specified. An extension must be sought in writing and must be approved before any project proceeds beyond three (3) years. An Annual Progress Report is also required (refer below to “Time Limits on Research”).
- 5.** Proposals must indicate all Departments involved in the project and must be sufficiently detailed to allow for appraisal of resources. Where projects are funded by Commercial Organisations or Manufacturers, the relevant Heads of Divisions should be asked to indicate what group resources would be required.
- 6.** In order to help the Committee with its decisions, a brief non-technical description of the project is required with your application.
- 7.** Issues relating to consent and privacy must meet the NHMRC Guidelines, the CHA Code of Ethical Standards Guidelines and those of Section 95A of the Privacy Act 2001.
- 8.** Copies of research questions, information to be supplied to participants and consent form (where relevant) should be included with submission.
- 9.** Procedure for the storage and destruction of name identifying data should be explained.
- 10.** Annual Progress Reports are required and on completion of the study, a Final Report.

Time Limits on Research

A patient cannot give indefinite consent to access personal data eg – from Medical Records.

When they consent to participate in a study, patients must be made aware of, and consent to, a specified time period for which their health data will be available to the Researcher.

The following Protocol is a requirement for Ethics Committee approval.

Guidelines For Researchers – Human Research Proposals {contd}

PROTOCOL

a) Specific Time Periods

1. For each new research application submitted for review to the Committee, the Researchers must specify:
 - 1.1 the time period for which access is required to a patient's health data / Medical Records ("data collection phase"). The precedent for the data collection is no longer than three (3) years.
 - 1.2 the time period for the study as a whole ("study time period"). The study time period will normally be longer than the data collection phase, and will vary with the complexity of the research.
2. Both the data collection phase and the study time period must be defined in the Research Application, and in the Patient / Participant Information and Consent Form, by specific commencement and completion dates.
3. Researchers may not access data after the data collection phase has expired, unless an extension has been granted by the Committee.

b) Extensions

4. Researchers wishing to extend the specified time periods (either the data collection phase or the study time period), are required to make application to the Committee. The relevant periods are noted 1.1 and 1.2 above.
 - 4.1 If this application is made before the expiry of the relevant period, the Researcher need seek only an amendment to the existing approved study.
 - 4.2 If this application is made after the expiry of the relevant period, the Committee will deem this to constitute an entirely new study, for which a new research proposal must be lodged.
5. Researchers wishing to extend the range of data collected are also required to make application the Committee.
 - 5.1 The Committee will first determine whether a proposed extension substantially alters the aim or scope of the original study.
 - 5.2 If this application is made before the expiry of the relevant period, and does not substantially alter the aim or scope of the original study, the research need seek only the amendment to the existing approved study.
 - 5.3 If this application is made after the expiry of the relevant period, or substantially alters the aim or scope of the original proposal, the Committee will deem this to constitute and entirely new study for which the Researcher must lodge a new research proposal.

Proforma: Participant Information and Consent Form (for General Studies)

The following are guidelines for Researchers to assist in writing Patient / Participant Information and Consent Forms (for general studies). Potential recruits to your research study must be given sufficient information to allow them to decide whether or not they want to take part. Secondly, it is important that forms be written in simple language with explanation of medical / scientific / technical terms so as to be easily understood by a lay person. Thirdly, Participant Information and Consent Forms must be dated and given a version number. This makes it easier to keep track of approval of any subsequent and superseding amendments / updates to the forms that may occur.

Where applicable, information under the headings below should be included in a Participant Information and Consent Form.

- 1. Study Title**
Simplify title.
- 2. Invitation**
Explain participants are being asked to take part in study.
- 3. What is the purpose of the study?**
- 4. What is the drug or procedure being tested?**
Explain briefly.
- 5. Do I have to take part?**
Explain that taking part in the study is voluntary. Explain what the alternatives for diagnosis or treatment are if participant does not take part in the study. Explain that withdrawal will not affect any care you are receiving and that you will be free to withdraw at anytime.
- 6. What will happen to me if I take part?**
Explain, for example in simple terms study design / research methodology.
Explain procedures:
 - How long participants will be involved in study.
 - Any requirements of participants over and above their usual treatment eg – visits to clinic, interviews, give blood samples, x-rays etc.
 - Responsibilities of participants eg – self-administered medication, maintenance of a diary etc.
 - What costs will be covered by study eg – study medication, travelling expenses associated with attending study visits etc.
- 7. What do I have to do?**
For example: any lifestyle or dietary restrictions eg – avoid pregnancy due to unknown effects of study drug, avoid taking certain other medication etc. See Point 9.
- 8. What are the side effects of participation?**
For example: explain possible side effects of study drug / treatment and whether there are any unknown effects.
- 9. What are the possible risks and disadvantages of participating?**
For example: Any harm to the participant or an unborn child. Requirements for pregnancy test before entering study.

Proforma: Participant Information and Consent Form (for General Studies) {contd}

- 10. What are the possible benefits of taking part?**
- 11. What if new information becomes available?**
Explain that any information which becomes available during course of the study will be made known to participants.
- 12. What happens when the research is completed?**
- 13. Will my taking part in this study be kept confidential?**
Explain how privacy and confidentiality will be protected. Participants have a right to privacy. Participant name and personal information collected in course of study will be kept strictly confidential.
- 14. What will happen to the results of the study?**
- 15. Who is organising and funding the study?**
- 16. How is the research being funded?**
- 17. How will research results be disseminated and / or published?**
- 18. What if something goes wrong?**
Explain what redress may be available to participants should something go wrong during the study.
 - Legal redress available.
 - *eg - Compensation for any injury caused by taking part in this study will be in accordance with the guidelines of the Australian Pharmaceutical Manufacturers Association (APMA).*
 - *Broadly speaking, the APMA guidelines recommend that “the study sponsor”, without legal commitment, should compensate you without you having to prove that it is at fault. This applies in cases where it is likely that such an injury results from giving any new drug or any other procedure carried out in accordance with the protocol for the study. Copies of these guidelines are available on request.*
 - Researcher contact details for any questions or concerns about study.
 - Ethics Committee contact details for any complaints about study.
- 19. Who has reviewed the study?**
Ethics Committee name.
- 20. Contact details for further information and any other issues**
 - Researcher contact details for any questions or concerns about study.
 - Ethics Committee contact details for any complaints about study.
- 21. Consent Form Signatures and Thank You Notation**
 - Example:

Consent Form

Title of Study:

Name of Researcher:

Proforma: Participant Information and Consent Form (for General Studies) {contd}

1. I confirm that I have read and understand the Participant Information and Consent Form dated [date]...version [version number] for the above study and have had the opportunity to ask questions and all of these have been answered in a way I understand.
2. I understand that my participation is voluntary. I may refuse to take part in this study and I am free to withdraw from the study at any time, without my medical care or legal rights being affected. There is no penalty. My decisions do not affect my continuing medical care including my relationship with my Doctor or other Clinical Staff.
3. I understand that sections of any of my Medical Record may be looked at by responsible individuals from [company name] or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.
4. I agree to take part in the above study.

Name of Participant Date Signature

Name of Witness Date Signature

I, the undersigned have discussed the nature and purpose of the study and the possible risks and benefits of participation with the participant and / or legally authorised representative. I believe that the participant and / or his / her representative has been fully informed, using language which is understandable and appropriate, and has understood this explanation.

Name of Researcher / Date Signature
Person Obtaining Consent

Revocation of Consent

I hereby WITHDRAW my consent to participate in the research project described above and understand that such withdrawal will not make any difference to my medical care or my relationship with my Doctor or other Clinical Staff.

Name of Participant Date Signature

This Revocation of Consent should be forwarded to the Researcher: [name of Researcher].

Source: “Guidelines for Researchers: Patient Information and Consent Form” Bulletin of Medical Ethics May 1999; pp 8 – 12

Protocol to Access Mercy Hospital Mount Lawley Medical Records

A Researcher wishing to access Medical records at Mercy Hospital Mount Lawley for the purposes of medical research shall submit a completed Mercy Ethics Committee (MEC) Ethics Application Form, accompanied by a full research protocol (including current version number and date), for consideration by the MEC. The application shall:

- a) State whether the research requires extraction of data from Medical Records, Researcher access to Medical Records, or release of Medical Records.
- b) State what information (data fields) will be accessed from each Medical Record.
- c) State whether information accessed will be identified, de-identified, or re-identifiable, and provide details of methods of de-identification, record linkage, and nature and provenance of other data to be linked.
- d) State whether individual patient consent is to be obtained prior to access, and:
 - i) if consent from individual patients is to be obtained, submit one (1) Patient Information Sheet, and a signed “Consent to Access Medical Records” for each patient, or
 - ii) if consent from individual patients is not to be obtained, provide evidence that the research satisfies the provisions of S95A or NPP2.1 (d) of the Privacy Act 1988.
- e) State whether patients are to be contacted at any time during the research, and if so:
 - i) State how and by whom contact will be initiated, and for what reason, and
 - ii) State whether and how it will be disclosed to patients that their Medical Records have been or will be accessed during the research.
- f) If possible, provide a copy of at least one (1) other current Ethics Approval applying to the same version of the research protocol.
- g) For each member of the Research Team having access to Mercy Hospital Mount Lawley Medical Records, or having access to identified or re-identifiable information derived from Mercy Hospital Mount Lawley Medical Records, provide an appropriate signed agreement to maintain absolute confidentiality
- h) Describe security measures to be used in order to maintain confidentiality of all information removed from Mercy Hospital Mount Lawley.
- i) Reach an agreement with Mercy Hospital Mount Lawley Administration on who will physically access Medical Records or extract data from them. Access to Medical Records and charges associated with record access shall be in accordance with the Hospital Policy MGT MR 182 – Medical Record Access.

If necessary, after MEC has formally considered the research proposal, an expedited approval process may be implemented in order to facilitate the research.

Monitoring of Approved Research

Serious Adverse Event (SAE) Process and Form

As required by the National Statement on Ethical Conduct in Research Involving Humans (2007), an HREC must be advised by Researchers immediately on anything which might warrant review of ethical approval of the protocol, including Serious Adverse Events (SAEs) or unexpected adverse events on study participants.

The following Protocol is a requirement for MercyCare Ethics Committee approval. Researchers who do not meet the following requirements may have MercyCare Ethics Committee approval withdrawn.

PROTOCOL

- a) **SAEs or Unexpected Adverse Events occurring on a MercyCare Site eg – Mercy Aged Care, Mercy Education, Mercy Employment and Training, Mercy Family and Community Services, Mercy Hospital Mount Lawley**
1. Researcher is required to report these events immediately by completing the designated MercyCare SAE / Unexpected Adverse Events Form. This should be submitted to the MercyCare Ethics Committee for review, along with any other documentation detailing the event(s).
 2. To allow the MercyCare Ethics Committee to monitor SAE / Unexpected Adverse Events with perspective, the Researcher is also required to:
 - 2.1 submit to the MercyCare Ethics Committee copies of reports from the Independent Safety Monitoring Committee (or equivalent Committee), as and when these are received; and
- b) **SAEs or Unexpected Adverse Events occurring in All Other Sites**
3. The Researcher is **NOT** required to complete the designated MercyCare SAE/Unexpected Adverse Events Forms.
 4. To allow the MercyCare Ethics Committee to monitor SAE / Unexpected Adverse Events with perspective, the Researcher is required to:
 - 4.1 submit to the MercyCare Ethics Committee copies of reports from the Independent Safety Monitoring Committee (or equivalent Committee), as and when these are received; and
 5. All SAEs and unexpected adverse events will be reviewed by the MercyCare Ethics Committee.

MercyCare Ethics Committee

Serious Adverse Event and Unexpected Adverse Event Report

This form is to be completed for ALL EVENTS occurring at MercyCare Sites

Protocol Title: _____

Our Ref No: _____

Investigator(s): _____

Drug(s) Study Drug(s) _____ Drug(s) Dosage _____
 Intervention(s) eg – *Surgical Procedure* _____
 Device(s) Study Device(s) _____

No. of Study Participants on Study to date: _____

Date of Event: _____ Event/Report No: _____

Study Participant Gender: F M Study Participant Age: _____

Event Description and Management *

Event Outcome:

- Fatal
- Life Threatening
- Hospitalisation required / prolonged
- Permanent or significant disability/incapacity
- Other, please state: _____

Event Relationship to Study Drug(s) / Intervention(s) / Device(s):

- Related**
- Probably Related**
- Possibly Related**
- Not Related

Documented Side Effect ie – specified in Patient Information Sheet

How often has this same event occurred to date in the present study? _____

Any amendments required to Protocol and / or Patient Information and Consent Form? Yes No

Any implications for continued conduct of the study? Yes No
 If Yes, please describe: _____

 Signature Principal Investigator or Representative

 Date

** Please attach supporting documentation to this form, including reports from the Independent Safety Monitoring Committee, as and when these are received.*

Annual Reports and Final Study Reports

The MercyCare Ethics Committee requires that Researchers answer the following questions in their Annual Reports and Final Study Reports:

1. How many MercyCare patients have been recruited into the study thus far (if a multicentre trial, how many MercyCare patients have been recruited into the study thus far as a proportion of the total trial recruitment)?
2. What changes (if any) have there been made to the research protocol and / or information and consent form (that have not been previously reported to the MercyCare Ethics Committee)?
3. Any change of personnel on Research Team. Signed Confidentiality Agreements are required for all new team members.
4. Summary of SAEs that have occurred to date, including the significance of these.
5. Is the project completed / abandoned? What is the expected completion date? (please provide dates).
6. **(If Final Study Report)** What are the main study results / findings (in brief)?
7. **(If Final Study Report)** Please provide a copy of subsequent publication of results / findings.
8. Reports (Progress and Final) are to be submitted to the MercyCare Ethics Committee by January 20 of each calendar year.

Clinical Trial Agreements – Legal and Insurance Guidelines

PURPOSE

These guidelines are to assist with the preliminary review of Clinical Trial Agreements at a Divisional and Ethics Committee level. The guidelines set out the legal and insurance prerequisites for MercyCare to be a party to the clinical trial. Clinical Trial Agreements which do not accord with the requirements will take significantly more time to review and may not be accepted.

ALL Clinical Trial Agreements must be reviewed by MercyCare’s Legal Counsel for legal and insurance requirements prior to execution.

SCOPE OF MERCYCARE’S INVOLVEMENT IN CLINICAL TRIALS

Due to the limits of our Insurance Policy, MercyCare’s obligations under Clinical Trial Agreements must be specifically limited to the following services:

- The use of premises, equipment and nursing care under the direction of the Doctor accredited to Mercy Hospital who is conducting the trial; and
- MercyCare Ethics Committee approval of the trial.

MercyCare must not be contractually bound to organize the trial, obtain consent from patients or evaluate the results of the trial. Any such obligations will be outside the scope of our insurance cover.

ACCREDITED DOCTORS

The Clinical Trial Agreement must accurately reflect the relationship between MercyCare and its accredited Doctors. Usually we would expect the accredited Doctor to be a party to the Agreement so that each parties’ role and responsibilities in relation to the trial is clearly reflected in the Agreement.

In any event, the following clause must be included in the Agreement:

“The Company acknowledges that the Doctor is not an employee of MercyCare and that any obligation which MercyCare has under this Agreement in respect of the Doctor is limited to doing or procuring that which is within MercyCare’s reasonable control”.

INDEMNITY

MercyCare **will not** provide any indemnity under the Agreement. MercyCare’s insurance will not provide cover in respect of any liability incurred by MercyCare under an indemnity.

Correspondingly, MercyCare will not seek an indemnity from either the Clinical Trial Co-Ordinator or the drug company. This is clearly a fair commercial position which should be readily acceptable to all parties.

INSURANCE

The Clinical Trial Co-Ordinator must include the following clause in the Agreement:

“1. The Company will effect and maintain, for the duration of the Trial, at its expense:

1.1 a No Fault Compensation Insurance for Clinical Trials policy which:

- a) is held specifically for the [insert clinical trial number and name];*
- b) has a limit of liability of \$AUD10,000,000 for any one claim and in the aggregate;*
- c) has an excess of no more than \$AUD10,000;*
- d) names of the relevant MercyCare entity/ies and its Ethics Committee as insured/s under the policy;*

Clinical Trial Agreements – Legal and Insurance Guidelines {contd}

- e) *is on terms and conditions no less favourable than those generally obtained for conduct of clinical trials in Australia, and which are acceptable to MercyCare, acting reasonably;*
 - f) *complies with Medicines Australia Guidelines for Compensation for Clinical Trial Volunteers Participating in Clinical Trials; and*
 - g) *is placed with a reputable, financially secure insurer with a S&P rating of A- or above;*
- 1.2 *a Workers' Compensation policy in accordance with the statutory requirements of the State in which the clinical trial is occurring, which is extended to note MercyCare as a named principal.*
- 1.3 *The Company will provide a copy of the policies required by this clause, together with evidence of currency, to MercyCare prior to the commencement of, and at any time on request during, the agreement.*
- 1.4 *It is a condition of this agreement that the No Fault Compensation Insurance for Clinical Trials policy will either be renewed for seven (7) years after the expiration of the Trial or alternatively seven (7) years runoff cover will be purchased by the Company.*
- 1.5 *MercyCare will effect and maintain, for the duration of the Trial, at its expense:*
- a) *a Combined Liability and Professional Indemnity policy covering legal liability for death or bodily injury arising out of a negligent act, error or omission in the course of carrying out this Trial with a limit of liability of not less than \$AUD10,000,000 for any one occurrence; and*
 - b) *either a Workers' Compensation and Employer's Liability policy OR a licence as a Workers' Compensation self insurer in accordance with the Workers' Compensation and Injury Management Act 1981.*
- 1.6 *MercyCare will, on request, provide evidence of currency of the policies referred to clause 1.5 to the Company prior to the commencement of, and at any time during, the agreement."*

The Certificate of Currency provided by the Clinical Trial Co-Ordinator must:

- have a description of the clinical trial covered by the policy;
- name the insured parties, including the relevant MercyCare entity/ies;
- state the limit of liability;
- state the deductible amount;
- state the insurer; and
- state the period of currency.

The Certificate of Currency must be reviewed and approved in writing by MercyCare's Legal Counsel prior to the trial beginning.