



## **MERCYCARE RESEARCH POLICIES AND PROCEDURES MANUAL**

**Researchers should read this document before completing the National Ethics Application Form (NEAF) or MercyCare Application Forms.**

**NEAF applicants must complete the Checklist and Declaration forms and attach them to the Proposal as a cover sheet. These documents are able to be accessed at: [www.mercycare.com.au/ethics](http://www.mercycare.com.au/ethics)**

**MercyCare Application Form may be used for “Low Risk” Research or for “Research requiring Access to Medical Records” from Mercy Hospital Mt. Lawley.**

**For further information and Meeting Schedule see Page 38**

November, 2011

## **Preamble**

This Handbook has been compiled to facilitate and streamline the process of conducting human research within MercyCare

All research applications submitted to MercyCare are reviewed by St. John of God Health Care Ethics Committee (SJGHCEC) and monitored by both SJGHC Ethics Committee and MercyCare. This handbook therefore provides information to researchers on the review process from initial approval through to completion.

The Handbook contains details, guidelines, policies and other reference material associated with the research process and also includes advice on how to obtain access to all required documentation

Research applicants should read this document before completing the National Ethics Application Form (NEAF) or MercyCare Application Forms.

NEAF and MercyCare application forms can be found at: [www.mercycare.com.au/ethics](http://www.mercycare.com.au/ethics)

**The MercyCare application form is used for Accessing Medical Records and Low Risk research only.** No content may be deleted from the MercyCare Application form. If any areas are not relevant, they should be marked N/A.

**For all NEAF applications**, the Researcher **must** complete the Checklist and Declaration forms and attach them to the Proposal as a cover sheet. These forms are contained within the handbook and/or maybe accessed on the MercyCare website: [www.mercycare.com.au/ethics](http://www.mercycare.com.au/ethics)

Researchers should familiarise themselves with the following key documents:

1. National Statement on Ethical Conduct in Human Research (NHMRC, 2007)
2. Code of Ethical Standards for Catholic Health and Aged Care Services in Australia (CHA, 2001).
3. Section 95(A) of Privacy Act 1988
4. Australian Code for the Responsible Conduct of Research, NHMRC, 2007

For a hard copy of this Manual please email: [ethics@mercycare.com.au](mailto:ethics@mercycare.com.au)

This document is subject to update and amendment as required by MercyCare

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

**Date of writing: November 2011**  
**Date for Review: November 2012**  
**Person responsible: Exec. Dir Mission & Culture**

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## 1 The MercyCare Environment

### 1.1 Mission Statement

# Our Vision, Mission and Values

## Our Vision

To achieve wellbeing, dignity and justice for all

## Our Mission

To bring compassion and justice to life

## Our Values

Respect

Justice

Compassion

Integrity

Excellence



## 1.2 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. MercyCare 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*

## 1.3 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
  - a. To promote health and prevent disease;
  - b. To deepen our understanding of the causes of disease and to develop new forms of treatment;
  - c. To save lives, cure illness or slow progress of disease;
  - d. To relieve suffering and disability;
  - e. To care for people when they are sick, disabled, frail or elderly; and finally
  - f. 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

## 2 The Research Policy Environment

Research conducted on Catholic healthcare premises is expected to follow the **Seven Basic Principles** (as outlined on page 5), 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

### 2.1. Approvals Policy

All Human Research projects proposed to be carried out within MercyCare, or involving consumers of MercyCare services, may only be undertaken with the agreement of the relevant Executive Director in the first instance, and with the approval of the St. John of God Health Care legal counsel and Human Research Ethics Committee (The Committee) in the second, prior to commencement. These projects may involve patients, residents, staff or other participants. Some Quality Assurance can be approved by the Divisional Heads.

### 2.2 Policy on Avoiding Pregnancy while Involved in Research

This should be written in plain, everyday language free from jargon, ambiguities and misleading statements. There should be no reference made to “artificial contraception/birth control”. Where applicable, the following wording should be used in accordance with the teachings of the Catholic Church:

*“Because of the (known/unknown) effects of the (study medication), women should avoid becoming pregnant (and/or breastfeeding) during the course of this trial.*

*“Because of the (known/unknown) effects of the (study medication), men should avoid fathering a child during the course of this trial (and should inform their partner about this requirement).*

### 2.3 Time Limits Policy

The SJGHCEC will approve each project for the time period (of the study as a whole), as defined in the Research Application and Patient Consent Forms, by specific commencement and completion dates. An extension must be sought in writing and must be approved before any project proceeds beyond the specified time period.

### 2.4 Accessing Medical Records and Associated Fees Policy

A researcher wishing to access Medical records at Mercy Hospital Mount Lawley for the purposes of medical research **shall submit, in electronic and hard copy form, a completed MercyCare or NEAF Research Application Form**, accompanied by a full research protocol (including current version number and date), for consideration by the St John of God Health Care Ethics Committee (SJGHCEC)

**Accessing Mercy Hospital Records** carries a small charge.

## 2.5 ADMINISTRATIVE FEE SCHEDULE

Significant funding is required to support formal ethical review and research governance activities including record retention and archiving, as required under the recommendations of the National Health and Medical Research Council (NHMRC) and Therapeutic Goods Administration (TGA). In order to alleviate this high resource commitment and achieve some cost recovery, an administrative fee applies to all **new research submissions** to the SJGHC Ethics Committee.\*\*

The administrative fee is a one-off fee to be paid at the time of initial submission of a research proposal to the SJGHC Ethics Committee, and covers any and all future amendments and extensions made to that research. The administrative fee schedule is as follows:

<p><b>COMMERCIALY SPONSORED EXTERNAL STUDIES</b> eg. Pharmaceutical companies, commercial device companies</p>	<p>\$4,000 + GST</p>
<p><b>NOT-FOR-PROFIT EXTERNAL STUDIES (excludes University applications)</b></p>	<p>\$700 + GST (charged on a discretionary basis)</p>
<p><b>UNIVERSITY STUDIES</b> eg. Student-initiated</p>	<p>\$100 + GST</p>
<p><b>INTERNAL STUDIES</b> eg. MercyCare staff initiated studies,</p>	<p>\$50 + GST</p>

\*\*In addition to the above, MercyCare also reserves the right to charge researchers, at its discretion, recovery costs for any significant direct or indirect MercyCare infrastructure costs involved in a research study (eg. MercyCare staff time, equipment use, facility/room use, etc),

### **EXEMPT FROM FEES:**

Studies conducted under the auspices of competitive state or national research funding bodies (eg NHMRC grant-based studies) are exempt from fees. Not-for-profit external studies will be reviewed individually and charged on a discretionary basis. The intention of this administrative fee schedule is NOT to hinder research but to offset SJGHC's costs associated with the review and ongoing monitoring of approved research.

### **Process to be followed by Researcher:**

On receipt of the formal letter of acceptance from MercyCare Ethics Executive Assistant and at the time of initial submission of a research proposal to SJGHCEC, the researcher should provide the following details to the Executive Officer, SJGHC Ethics Committee:

1. Full title of the study
2. Sponsor/researcher's name and postal address details
3. Sponsor/researcher's ABN (if applicable, for GST purposes)
4. Contact person's details (ie name, address & telephone) to direct tax invoice to.

SJGHC Finance will then forward a tax invoice directly to the sponsor/investigator for payment. Alternatively, researchers can make a cheque out to "St John of God Health Care" clearly stating that it is for administrative fee for study [state full study title] and forward it to the Executive Officer, SJGHC Ethics Committee.

## **2.6 Protocol Deviations and Violations Policy**

**Protocol violation:** is a failure to comply with the study protocol as approved by the Ethics Committee. A violation is a serious non-compliance with the protocol that can result in the exclusion of a participant or their results in the study, participant refusal to be part of the study, and in some cases a charge of research misconduct.

**Protocol deviation:** is a less serious non-compliance with the approved study protocol, and in some cases may be considered as a "breach of the Code"- the Australian Code for the Responsible Conduct of Research, NHMRC, 2007.

### **Reporting Protocol Deviations & Violations to SJGHCEC and MercyCare :**

*"Researchers have a significant responsibility in monitoring as they are in the best position to observe any adverse events or unexpected outcomes. They should report such events or outcomes promptly to the relevant institution/s and ethical review body/ies, and take prompt steps to deal with any unexpected risks (section 5.5.3, National Statement on Ethical Conduct in Human Research, NHMRC, 2007).*

*"An HREC must receive from any investigator(s), in an expedited manner, any deviations from the trial protocol that were undertaken by investigators to prevent imminent harm to subjects; any change significantly affecting the risk/benefit of the trial..." (pg 19 of Australian Clinical Trial Handbook, March 2006, TGA)*

Researchers should provide written reports to the SJGHCEC and MercyCare, of all significant protocol violations and deviations occurring at any MercyCare participating site as soon as practicable. Minor protocol violations/deviations as well as any occurring at other Australian or overseas sites, do not require reporting to the above Committees.

**Significance** is to be determined by the researcher, *but* for sponsored trials this does ALSO include any protocol deviations/violations which the Study Sponsor may require to be reported to the Committee. **Significance** refers principally to the degree to which the protocol deviation/violation produces imminent harm to research participants and/or alters the risk/benefit ratio of the study – thus potentially affecting the continued ethical acceptability of the research. ie

1. There are substantive safety or ethical implications for the participant(s)
2. The scientific integrity of the study is compromised (ie. completeness, accuracy and reliability of study data is affected)

Also, consideration should be given to the degree to which the following are contributing factors:

3. Researcher misconduct (or “breaches of the Code”)
4. Non-compliance with legislative requirements (eg. privacy legislation)
5. Major flaws in the study design/methodology (eg. exclusion criteria too strict)

Researchers should report the following to the Committee:

- Nature of the deviation/violation and reason(s) for occurrence
- Impact of the deviation/violation on patient safety and/or scientific integrity
- Any recommended action (eg participant withdrawal). *Note:* If any changes to the study are required as a result of the deviation/violation, an *amendment* should be submitted.
- Include documentation of the contact with the Study Sponsor regarding the deviation/violation and any recommended action (where applicable)
- What steps/safeguards have been/are to be taken to avoid a recurrence

## **2.7 Serious Adverse Event (SAE) Policy**

As required by the NHMRC’s National Statement on Ethical Conduct in Research Involving Humans (2007), SJGHCEC and MercyCare must be advised by Researchers immediately on anything which might warrant review of ethical approval of the protocol, including Serious Adverse Events (SAEs), Serious Adverse Drug Reaction (SADR), Serious Unexpected Suspected Adverse Reactions (SUSAR) and Serious Adverse Device Events (SADE) on study participants.

Section 4.8 outlines the exact protocol to be followed in the event of an unexpected or serious adverse event.

## **2.8 Clinical Trial Agreements Policy**

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 clinical care under the direction of the Doctor accredited to Mercy Hospital who is conducting the trial; and
- SJGHC 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.

All Clinical Trial Agreements must be registered with the Australian New Zealand Clinical Trial Registry (ANZCTR) or in a publicly accessible trials registry and reviewed by SJGHC Legal Counsel for legal and insurance requirements prior to execution. Clinical Trial Agreements which do not accord with the requirements will take significantly more time to review and may not be accepted.

**CTA form available at :[www.mercycare.com.au/ethics](http://www.mercycare.com.au/ethics)**

## **2.9 Researcher Conflict of Interest Policy**

A conflict of interest (actual or potential) may compromise the research process itself and/or the institutional processes governing research.

All Researchers using the **MercyCare Application** form shall sign the MercyCare "Conflict of Interest and Confidentiality Declaration" form which is contained within the MercyCare Application form.

**NEAF applicants** shall sign the "Conflict of Interest and Confidentiality Declaration" form provided with the Checklist on the MercyCare website and attach these as the cover page to the Research Application form.

## **2.10 Institutional policy for Monitoring of All Approved Research**

Monitoring of research refers to the process of verifying that the conduct of research conforms to the approved proposal. Responsibility for assuring that research is reliably monitored lies ultimately with MercyCare, under which the research is conducted, via its research governance arrangements.

In the case of Serious Adverse Events (SAEs), Serious Adverse Drug Reactions (SADR), Serious Unexpected Suspected Adverse Events (SUSAEs) and Serious Adverse Device Events (SADE) on study participants, the SJGHC and MercyCare must be advised by Researchers immediately on anything which might warrant review of ethical approval of the protocol. Research Sponsors also have such reporting responsibilities.

### **2.11 Institutional Policy on Withdrawal of Ethical Approval**

If the SJGHCEC and/or MercyCare finds reason to believe that continuance of the project will compromise participants' welfare, it will immediately seek to establish whether ethical approval should be withdrawn. This process should ensure that researchers and others involved in the project are treated fairly and with respect.

### **2.12 Institutional Policy Supporting HREC Engagement with Researchers**

Research Proposals submitted to MercyCare, and therefore to SJGHCEC, require good ethical review between the Committee and Researchers with a shared commitment to the review process. MercyCare encourages all research, including Multi Centre research.

### 3 The Research Procedure Environment

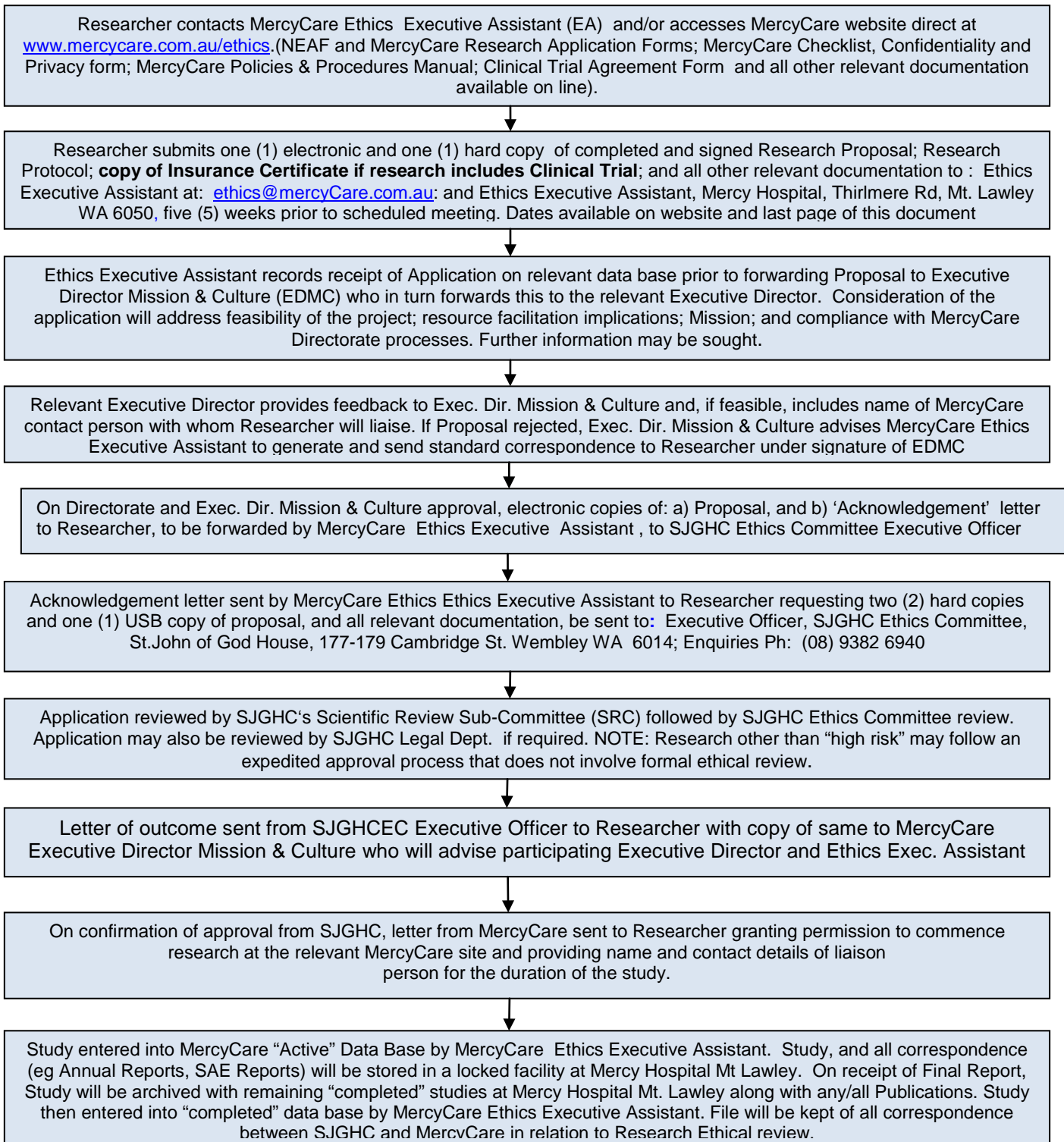
#### 3.1 Standard Operating Procedure for Ethical Review of all Research Proposals

MercyCare encourages all research, including multi-centre research. To that end, the following administrative procedure will be followed on receipt of a Research Proposal presented to MercyCare for Ethical review by the SJGHC Ethics Committee:

1. MercyCare Ethics Executive Assistant (EA) to receive one hard copy and one electronic copy of completed Research Application at least five (5) weeks prior to scheduled meeting of SJGHCEC. This will include the Research Protocol, **Copy of Insurance certificate if Clinical Trial**; and all other relevant documents (where possible). MercyCare Ethics EA to notify Executive Director Mission and Culture (EDMC). Mailing address for hard copies: Ethics Executive Assistant, Mercy Hospital, Thirlmere Rd. Mt. Lawley WA 6050
2. Research proposal forwarded to relevant Executive Director, by EA on instruction of EDMC. Consideration of the Application will address feasibility; resource implications; Mission; and Compliance with MercyCare Directorate processes.
3. If Research Application **not** considered feasible by relevant Executive Director, Researcher to be notified by MercyCare Ethics EA following consultation with EDMC
4. On notification of Executive Director **approval** the following will occur:
  - a) Research Proposal, and copy of 'Acknowledgement letter' to Researcher, to be forwarded electronically to SJGHC Ethics Committee Executive Officer, by MercyCare Ethics EA
  - b) acknowledgement letter sent by MercyCare Ethics EA to Researcher requesting one (1) electronic copy on USB and two (2) hard copies of Research Proposal, Research Protocol and all other relevant documents be mailed to;  
**Executive Officer, SJGHC Ethics Committee St John of God House  
Level 3, 177-179 Cambridge Street Wembley WA 6014**
5. Following Scientific and Ethical review, SJGHCEC confirms outcome with Researcher in formal letter, with copy of same sent to MercyCare EDMC. Note: Application may also be reviewed by SJGHC Legal Dept. if required
6. On receipt of the SJGHC Ethics Committee approval letter, formal letter from MercyCare confirms, in writing, approval to commence study at relevant MercyCare Directorate and informs researcher of name and contact details of Liaison person.
7. Proposal entered into MercyCare Research data base.

### 3.2 Flowchart -

#### Procedure to be followed for Ethical Review of all Research Proposals within MercyCare Facilities (Mercy Hospital Mt. Lawley, Mercy Aged Care and Mercy Family and Community Services).



### 3.3 Standard Operating Procedure Supporting HREC Engagement with Researchers

MercyCare encourages all research, including multi-centre research.

In order to encourage effective engagement with Researchers, communication between the parties will be non adversarial at all times. Promotion of friendly, co-operative engagement by promoting awareness of the NHMRC's National Statement and by providing ready accessibility to SJGHC review bodies, and MercyCare staff, will be encouraged.

### 3.4 Standard Operating Procedure for Managing Conflicts of Interest

A conflict of interest (actual or potential) may compromise the research process itself and/or the institutional processes governing research.

The following procedure for managing conflict of interest should be followed:

- a) Researchers are obliged to declare any actual or potential conflicts of interest in a particular research study. A "Conflict of Interest" form must be completed, signed and forwarded with the Study Application. (Accessible : [www.mercycare.com.au/ethics](http://www.mercycare.com.au/ethics))
- b) Where there are conflicts of interest involving researchers, the SJGHC Ethics Committee **may** adopt some of the following measures to manage these:
  1. information may be required to be disclosed to research participants
  2. a person other than the researcher may be required to make the initial approach to participants
  3. information may be required to be disclosed in any report of the research
  4. research may be required to be conducted by another researcher
  5. approval may be withheld

*Sometimes, a researcher who discloses the fact that he or she has a conflict of interest may have an ethically acceptable reason for not disclosing what that conflict is (for example that this might breach another person's privacy). If the review body is satisfied that the conflict can be managed without its nature being disclosed the researcher may then remain involved in the research.*
- c) An institution with a conflict of interest bearing on research should inform the SJGHCEC (the review committee), **and** MercyCare, about the conflict. Where another ethical review body becomes aware of a possible conflict of interest involving MercyCare, that review body should notify the SJGHC Ethics Committee **and** MercyCare
- d) Communication between a research sponsor and a review body should be avoided where it may, or may be perceived to, influence the ethical review and approval of the project
- e) Where the research proposal is a Multi-Centre proposal, the researcher should inform SJGHCEC of the names of the other institutions involved and whether or not there are any specific Conflicts of Interest with any of those institutions.

### **3.4 Standard operating procedure for Withdrawal of Ethical Approval**

- Where Ethical approval for a research project is withdrawn, the researcher/s, institution/s and participants will be informed of the withdrawal.
- MercyCare will ensure that the researcher promptly suspends the research and makes arrangements to meet the needs of the participants.
- The research may not be resumed unless either the researcher subsequently establishes that continuance will not compromise participants' welfare; the research is modified to provide sufficient protection for participants; the modification is ethically reviewed and approved by the SJGHCEC
- If the SJGHCEC considers that urgent suspension is necessary prior to the above process being undertaken, the instruction to stop will come via the management of MercyCare.

### **3.5 Standard operating procedure for Monitoring of Approved Research**

In order to encourage sound monitoring of research being conducted within MercyCare, the following should be adhered to:

- The frequency and type of monitoring should reflect the degree and risk to research participants.
- At regular periods, and at least annually, researchers will provide reports to the SJGHCEC **and** MercyCare. Progress report 'reminder letters' may be sent to researchers in December each year. These progress reports will include:
  - a) Progress to date
  - b) Maintenance and security of records
  - c) Compliance with the approved proposal
  - d) Compliance with any conditions of approval;
  - e) notification of any Adverse Events (SAEs, SUSARs, SADEs, and SADR);
  - f) notification of discontinuance of project
  - g) If a large multicentre trial, assurance that a Data Safety Monitoring Board (DSMB) is used and a mechanism for informing the HREC of any relevant emerging data from the DSMB is in place: and
  - h) If a local trial, that an identified person/s or committee with suitable expertise to assist and advise the HREC about reports of any serious adverse events, should be available.
- Feedback from participant (if any) including complaints, concerns or suggestions
- Any unanticipated ethical issues
- Researcher/Institutional Conflict of Interest arisen not previously reported to SJGHCEC and MercyCare
- If study is commercially sponsored, state whether Insurance Certificate is current
- In the case of a Final Report, the researcher must provide a report on the final outcome of the project and information/copy of any published documents associated with the project.

### **3.6 Standard Operating Procedure for Accessing Medical Records**

A researcher wishing to access Medical records at Mercy Hospital Mount Lawley for the purposes of medical research shall submit a completed NEAF or MercyCare Application Form, accompanied by a full research protocol (including current version number and date), for consideration by the SJGHCEC.

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.
- 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 Committee 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 (see – **Appendix A**)
- 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. See section 2.4 Accessing Medical Records and Associated Fees Policy
- j) If necessary, after SJGHC Ethics Committee has formally considered the research proposal, an expedited approval process may be implemented in order to facilitate the research.

## **4 Procedures, Protocols and Guidelines for Researchers**

### **4.1 Application Procedures**

In order to obtain permission to undertake research within MercyCare, this MercyCare “Research Policies and Procedures Manual” should be read and the following adhered to:

1. Proposals for research should be submitted on a National Ethics Application Form (NEAF), available on the MercyCare website; [www.mercycare.com.au/ethics](http://www.mercycare.com.au/ethics). The proposal must be accompanied by all relevant documentation information as specified on the application form and checklist. Researcher “Declaration” and “Checklist” must be completed, signed and attached as cover page to application. *All Researchers will identify funding sources; potential conflict of interest; and copy of Insurance certificate if a Clinical Trial.*
2. Proposals must indicate all MercyCare Directorates 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 Executive Director should be asked to indicate what group resources would be required.
3. **If “Low Risk” or accessing Mercy Hospital Medical Records only, researcher may use the MercyCare Application Form**
4. One electronic and one hard copy of the research proposal and Research Protocol completed and signed, with all relevant papers attached, should be received by the MercyCare Ethics Executive Assistant at least five (5) weeks prior to the next scheduled meeting of the SJGHCEC. Hard copies should be mailed to: **Ethics Executive Assistant, Mercy Hospital, Thirlmere Rd Mt. Lawley, WA 6050.**
5. Following acceptance of the study by MercyCare’s relevant Executive Director Mission and Culture, an acknowledgement letter will be sent to the Researcher requesting:
  - two (2) hard copies of the Research Proposal and Research Protocol; and
  - one (1) USB copy of the Research Proposal and Research Protocol.These should be mailed to the **:Executive Officer, SJGHC Ethics Committee; Level 3 St John of God House 175 Cambridge st Wembley WA 6940.**
6. The SJGHCEC meets bi-monthly. Meeting dates available on page 38 of this document; on the MercyCare website; or by phoning MercyCare Ethics Executive Assistant on: (08)9370 9290. A SJGHC Ethics review fee will apply. See Page 7, item 2.5
7. 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.

8. Graduate research proposals will be accompanied by a letter from the Faculty Adviser / Research Supervisor acknowledging responsibility & accountability for the quality of the study and that relevant approval has been obtained from the Institution's Research Ethics Committee
9. 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.
10. In order to help the Committee with its decisions, a brief non-technical lay description of the project is required with your application.
11. Issues relating to consent & privacy must meet the requirements of the NHMRC's National Statement, the CHA Code of Ethical Standards & those of Section 95A of the Privacy Act. (available at: [www.mercycare.com.au/ethics](http://www.mercycare.com.au/ethics))
12. Copies of research questions, brochures, advertisements, surveys questionnaires, information to be supplied to participants and consent form (where relevant), Insurance Certificates, where relevant should be included with submission.
13. Procedure for the storage and destruction of name identifying data should be explained.
14. Annual Progress Reports are required and on completion of the study, a Final Report.

#### **4.2 The Review Process**

Once approved by MercyCare's Executive Director (and SJGHC Legal Counsel where required), the proposal will be reviewed by the SJGHC Scientific Review Committee followed by the SJGHCEC. A letter stating the outcome of the review process will be sent to the applicant as soon as possible after completion of the review. A letter confirming approval and giving permission to commence the Study will be forwarded by MercyCare to the applicant.

The following conditions apply subsequent to proposal acceptance:

1. MercyCare will nominate a liaison person who will facilitate the Investigator's access to MercyCare to implement the research.
2. Progress Reports will be required at least annually or at other intervals determined by the Investigator and the SJGHCEC. Copies should go to SJGHCEC **and** MercyCare Ethics Executive Assistant, Mercy Hospital, Thirlmere Rd Mt. Lawley WA 6050
3. Any difficulties which may threaten the project will be discussed with the nominated liaison person.
4. Investigators will consider it their responsibility to inform the liaison person once data collection is complete.
5. The SJGHCEC **and** MercyCare Ethics Executive Assistant must be notified of any variations to the project protocol, including Adverse Events in the case of clinical trials.
6. The SJGHCEC **and** MercyCare Ethics Executive Assistant must be notified immediately of the discontinuance of the research project, including the reasons for this.
7. At the conclusion of the study, a final written research report will be submitted by the Investigator to the SJGHCEC **and** MercyCare at an agreed time.
8. SJGHCEC **and** MercyCare will also receive a copy of all published articles arising from the research.

### 4.3 Time Limits Protocol

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.

#### 4.3.1 Specific Time Periods

- a) For each new research application submitted to MercyCare for review by the SJGHCEC, the Researchers must specify:
  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.
  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.
- b) 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 Forms, by specific commencement and completion dates.
- c) Researchers may not access data after the data collection phase has expired, unless an extension has been granted by the Committee.

#### 4.3.2 Extensions

- a) Researchers wishing to extend the specified time periods (either the data collection phase or the study time period), are required to make a written application to the Committee. The relevant periods are noted above.
  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.
  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.
- b) Researchers wishing to extend the range of data collected are also required to make a formal application, in writing, to the Committee.
  1. The SJGHCEC will first determine whether a proposed extension substantially alters the aim or scope of the original study.
  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 researcher need seek only the amendment to the existing approved study.
  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 an entirely new study for which the Researcher must lodge a new research proposal.

#### **4.4 Data Management and Storage Protocol**

*The Australian Code for the Responsible Conduct of Research (2007)* ('the Code') describes the role and responsibilities of researchers and institutions in the appropriate collection, use, disclosure, storage and destruction of research data, and the important contribution this makes towards the responsible conduct of research.

During the course of a study, researchers are responsible for ensuring their research data is held in a secure place with access limited to only those involved in the study.

To protect privacy and confidentiality, once information is collected, any identifying records of individual persons should be held separately from the research data. The minimum period of research data retention is determined by the specific type of research (refer to Section 2.1.1 of the Code).

The MercyCare and SJGHC Ethics Offices will maintain a central database of all research applications made to the organisation on their respective computer networks. These will have secure and limited access available to both Ethics Offices and SJGHC Legal Services personnel only and will record summary details about each research study including when the study has been completed/published and the retention period/archival period. The databases will also act as a management tool to track each component of the approval process (ie ethical, legal operational, final approval) and the progress of studies from initial submission, to the final destruction of the research data record OR the permanent archival of the research data.

The MercyCare and SJGHC Ethics Offices will also maintain a complete record, in electronic form) of every research study application including all correspondence relating to the study approval process. The computer backup will be password protected so as to prevent unauthorised access, and only accessible by the respective MercyCare and SJGHC Ethics Office personnel. This computer back-up will also ensure that research records are never tampered with or lost.

Both MercyCare and SJGHC Ethics Offices ensure all archived studies are protected under lock and key in the respective Ethics Office or at a suitable secure and retrievable off-site location, only accessible by the MercyCare or SJGHC Ethics Office personnel.

#### **4.5 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 should not exceed 2000 words. *The Researcher should obtain a copy of the NHMRC's National Statement on Ethical Conduct in Human Research and refer to this at all times.*

A Research Proposal comprises of the following:

1. Project Title
2. Names of the Investigators including contact details of Chief Investigator or other nominated contact person
3. Introduction:
  - a. Statement of the proposal in bold and everyday plain language
  - b. Background and significance of the proposal
  - c. Statement of the purpose
  - d. Anticipated time frame
  - e. Identification of funding sources
  - f. Statement identifying any actual, or potential, conflict of interest
  - g. Statement identifying other bodies having oversight
4. Review of Related Literature (Not part of the proposal in some qualitative studies)
  - a. Review of relevant research
  - b. Review of relevant theoretical literature
  - c. Summary
5. Frame of Reference
  - a. Study Aim or Objectives
  - b. Hypotheses
  - c. Definition of Terms
6. Methodology
  - a. Identification of Study Design
  - b. Identification of Population / Sample Subjects
  - c. Study Setting
  - d. Methods of Data Collection
  - e. Data Analysis Procedures
  - f. Sample Size / Power Calculations

## **Research Proposal Guidelines continued...**

### 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

#### **a. Participant Information and Consent**

The research proposal must include:

- i. provision of information to participants, at their level of comprehension, 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
  - ii. Evidence of the exercise of a voluntary choice to participate.
- b. 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.
  - c. 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.
  - d. Researcher and Ethics Committee contact details for any questions, concerns or complaints or any other issues related to the study must be provided.

### 8. Limitations of the study.

### 9. Proposed communications of the findings.

### 10. References.

### 11. Appendices.

#### **4.6 Participant Information and Consent Form Guidelines**

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 wish 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 in simple language that participants are being asked to take part in study.
3. **What is the purpose of the study?** Short description in plain everyday language
4. **What is the drug or procedure being tested?** Explain briefly and simply.
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 the participant is receiving and that he/she will be free to withdraw at anytime.
6. **What will happen to me if I take part?** Explain, in simple terms, the 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 e.g. – self-administered medication, maintenance of a diary etc.
  - What costs will be covered by study e.g. – 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 becoming pregnant (and/or breastfeeding) during the course of the trial because of the (known/unknown) effects of the study; avoid taking certain other medication; diary keeping, 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. See page 6. (2.2) for wording re Policy on Avoiding Pregnancy.
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 the APMA 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, complaints 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 of Consent form follows:

## 4.7 Participant Consent Form Proforma

I confirm that I have read and understand the Participant Information and Consent Forms 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.

1. 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.
2. 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.
3. 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 / Person Obtaining Consent	_____ Date	_____ Signature
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### ***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

**Contact details of Researcher and HREC to be included on this form**

#### 4.8 Serious Adverse Events Protocol

The SJGHCEC and the MercyCare Ethics Executive Assistant must be advised by Researchers immediately on anything which might warrant review of ethical approval of the protocol, including Serious Adverse Events (SAEs), Serious Adverse Drug Reactions (SADR), Serious Unexpected Suspected Adverse Events (SUSAEs) and Serious Adverse Device Events (SADE) on study participants. Research Sponsors also have such responsibilities.

The following Protocol is a requirement for SJGHCEC approval and Researchers who do not meet these requirements may have Ethics Committee approval withdrawn:

- a) Researchers are required to report immediately, all SAEs, SADR, SUSAEs, SADR and/or SADEs occurring on a MercyCare Site (eg – Mercy Hospital Mount Lawley, Mercy Aged Care, Mercy Family and Community Services) by completing the designated MercyCare SAE/SUSAE, SADR, SADE form. (See page 28 ) This should be submitted to the SJGHCEC for review, **and a copy sent to MercyCare along with other documentation detailing the event(s).**
- b) To allow the SJGHCEC and MercyCare to monitor SAEs, SADR, SUSAEs, SADR and/or SADEs with perspective, and to ensure that any changes to the risk/benefit balance of a clinical trial are compatible with continued ethical approval, the Researcher is also required to:
  - i. offer their own opinion in regard to potential impact of SAE/ SUSAE/ SADR/ SADE on the need for action and continued ethical acceptability of a clinical trial.
  - ii. submit to the SJGHCEC **and** MercyCare, copies of reports from the Independent Safety Monitoring Committee (or equivalent Committee), as and when these are received; and

Events occurring in other Sites outside MercyCare do **NOT** require the designated MercyCare SAE/ SUSAE/ SADR/ SADE Forms to be completed.

- c) To allow the SJGHCEC and MercyCare to monitor SAE/ SUSAE/SADR/ SADE with perspective, the Researcher is required to:
  - i. submit to the SJGHCEC **and** MercyCare, copies of reports from the Independent Safety Monitoring Committee (or equivalent Committee), as and when these are received; and at least six monthly, a listing of all/any Suspected Unexpected Serious Adverse Reactions This should be accompanied by a covering letter with both the sponsor's and the researcher's own comments as to whether action is planned for the trial on the basis of these SUSARs.
  - ii. to provide, at least annually, a trial update that appropriately reviews safety information in the previous 12 months. Depending on whether the trial is commercially, investigator or collaborative group sponsored, the trial safety update may take one or more of the following formats:

- Updated investigator brochure
  - Current, approved product information
  - European Union Annual Safety report
  - Other trial update reports consistent with the NHMRC's National Statement
  - Good Clinical Practice as adopted by the Therapeutic Goods Administration
- d) All SAEs and unexpected adverse events will be reviewed by the SJGHCEC and monitored by MercyCare.

#### 4.9 Serious Adverse Event Reporting Form

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) \_\_\_\_\_

Where the participant has an implantable medical device, please confirm the existence, or establishment of a system for tracking that device for the lifetime of the device, proof of participant consent and whether or not any incidents have been reported to the TGA

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:

#### Intervention(s) / Device(s):

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

#### Event Relationship to Study Drug(s) /

- Related
- Probably Related
- Possibly Related
- Not Related

Documented Side Effect i.e. 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.

#### **4.10 Guidelines for Submission of an Annual Progress Report**

The following points must be addressed when submitting an Annual Progress Report. The report is to be submitted to the SJGHCEC and to MercyCare Ethics Executive Assistant by January 31<sup>st</sup> of each calendar year.

##### **STUDY DETAILS**

- Title of study
- Reporting period
- Our study Reference Number
- Registration Details:
  - Clinical Trials Registry and Trial Registration Number
  - Current Status of the study
  - Approved Duration of the Project
  - Name of approved Directorate (e.g. Mercy Hospital Mt. Lawley, MercyAged Care, Mercy Family and Community Services )
- How many MercyCare participants have been recruited into the trial (if multicentre, proportion of MercyCare participants)
- Have there been any participant withdrawal – state reasons
- Status of the study (e.g. in progress, not yet commenced, on hold, abandoned or complete)
- Outcomes of study so far. Please include an explanation of where and why study delays have occurred if applicable and if the delays have affected the outcome.
- Expected study outcomes
- Study changes (if any)
- Risk Management:
  - a) Compliance with specific conditions of approval (if any),
  - b) Action taken to ensure complete and accurate recording, secure storage and retention of data
  - c) Maintenance of Privacy and Confidentiality
  - d) Any Serious Adverse Events that may have occurred to date (SAEs)
  - e) Feedback from participants, if any. including complaints, concerns or suggestions – Please be specific
  - f) Any unanticipated ethical issues
  - g) Any Researcher/Institutional Conflict of Interest arisen not previously reported to MercyCare and SJGHCEC
  - h) If study is commercially sponsored, state whether Insurance Certificate is current
  - i) Name and Signature of Principal Investigator

#### **4.11 Guidelines for Submission of a Final Report**

The following points must be addressed when submitting a Final Report. The report is to be submitted to the SJGHCEC **and** MercyCare by January 31st of each calendar year.

##### **STUDY DETAILS**

- Title of study
- Reporting period
- Our study Reference Number
- Registration Details: Clinical Trials Registry and Trial Registration Number
- How many MercyCare participants were recruited (if multi centre trial, how many MercyCare participants as a proportion of total recruitment)?
- How many MercyCare participants withdrew or deceased– state reasons
- Were there any delays with the study? If so, how did these delays impact on the outcomes?
- Were there any changes made to the approved Research Protocol, Participant Information and Consent forms or research personnel? (ie that were not reported previously to the MercyCare and SJGHC Ethics Committee). NB Signed Confidentiality Agreements are required for all new team members
- Please provide a copy of subsequent publication of results / findings.
- Risk Management: please outline:
  - a) Compliance with specific conditions of approval (if any)
  - b) Action taken to ensure complete and accurate recording, secure storage and retention of data
  - c) Maintenance of Privacy and Confidentiality
  - d) Any Serious Adverse Events that may have occurred (SAEs) and what actions were taken in response to these
  - e) Feedback from participants, if any. including complaints, concerns or suggestions – Please provide details
  - f) IN PLAIN LANGUAGE what are the main study findings
  - g) Have the participants been informed of the study findings? (provide details of how this has occurred)
  - h) Have there been any publications/presentations of study results. If not, please explain why.
  - i) Name and Signature of Principal Investigator

#### 4.12 Clinical Trial Agreements – Legal and Insurance Guidelines

These guidelines are to assist with the preliminary review of Clinical Trial Agreements at a MercyCare Directorate and St John of God Health Care 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.

##### 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
- SJGHCEC 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 party’s role, and any 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;
  - 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 an 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 in 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 authorised Legal Counsel** prior to the trial beginning.

**Appendix A: CONFLICT OF INTEREST & PRIVACY FORM**

**This Declaration is to be signed by all Researchers using the National Ethics Application Form (NEAF) who are applying to undertake research at a MercyCare site, and/or applying to access medical records for research purposes**

Name of Researcher.....

Study Title.....

Organisation:.....

To the best of my knowledge I do not have a financial conflict of interest and declare that my particular circumstances are not likely to give rise to any potential conflicts of **any** nature. My interactions with all parties will be of the highest professional standard and there will be neither impropriety nor any indication that my objectivity has been impaired with respect to this project at MercyCare:

This declaration acknowledges, in relation to the research proposal detailed above, my obligations to:

- Declare any real, perceived or potential conflict of interest that currently exists, or may arise, in the course of my activities as a Researcher;
- Maintain strict and absolute confidentiality about any information concerning persons, processes and events that comes to my attention while conducting research within MercyCare. This includes information relating to internal MercyCare operations and/or information from individual patient medical records.
- Deal with all MercyCare information collected, used or disclosed for the purposes of the abovementioned study in strict accordance with the conditions specified in the approved protocol for the project.

Name:.....

Signature:.....

Date: .....

**Appendix B: Checklist for Researchers Making New Submissions**

**CHECKLIST AND DECLARATION TO BE FILLED IN AND ATTACHED AS COVER PAGE TO NATIONAL ETHICS APPLICATION FORM (NEAF) ONLY.**  
 (form available on [www.mercycare.com.au/ethics](http://www.mercycare.com.au/ethics))

**Please tick boxes as appropriate or mark N/A**

**Have you read the relevant sections of the MercyCare Policies and Procedures Manual?**  
 YES    NO

**Please submit one (1) electronic copy and one hard copy of completed and signed National Ethics Application Form, including the following, where applicable:**

National Ethics Application Form (NEAF) ( <a href="http://www.mercycare.com.au/ethics">www.mercycare.com.au/ethics</a> )	<input type="checkbox"/>
Lay Summary of Study	<input type="checkbox"/>
Patient / Participant Information and Consent Form (PICF). Page 23 P&P Manual	<input type="checkbox"/>
Evidence of approval / rejection by other HRECs, Scientific Review Committees or other relevant Authorities(ie final/conditional/withheld etc)	<input type="checkbox"/>
Where applicable, copy of questionnaire(s), survey questions, interview topics to be covered,, Brochures, advertisements, letters of invitation and any other material to be used in recruitment of participants in to the study.	<input type="checkbox"/>
Statement from Medical / Paramedical Practitioner accepting responsibility for specific procedures	<input type="checkbox"/>
Clinical Trial Agreement (CTA) and Clinical Trial Registration details; Indemnity form(s): Certificate of Insurance.(at: <a href="http://www.mercycare.com.au/ethics">www.mercycare.com.au/ethics</a> )	<input type="checkbox"/>
Research Protocol	<input type="checkbox"/>
Current Resume and publications list of Researcher/s	<input type="checkbox"/>
Budget outline for research project	<input type="checkbox"/>
Where applicable, any form requiring signature by the SJGHCEC and /or MercyCare’s Chief Executive Officer	<input type="checkbox"/>
Signed copy of the Researcher Confidentiality and Conflict of Interest Declaration and each researcher undertaking research at a MercyCare site or accessing Medical Records for research purposes. (Refer Page 35)	<input type="checkbox"/>
Copy of Descriptor System for tracking participants (implantable Device Trials only)	<input type="checkbox"/>
Constitution of Independent Data Safety Monitoring Committee (CTA only)	<input type="checkbox"/>

## **Appendix C: 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](http://www.nhmrc.health.gov.au/publicat/pdf/e35.pdf)

### **National Health and Medical Research Council (NHMRC) Statement on Ethical Conduct in Research Involving Humans (2007) 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](http://www.nhmrc.health.gov.au/publicat/pdf/e35.pdf)

### **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](http://www.cha.org.au/publications/index.html)

### **Guidelines Approved under Section 95A of the Privacy Act 1988 (NHMRC, 2001)**

Provides a framework to ensure privacy protection of health information that is collected, used or disclosed in the conduct of research and the compilation or analysis of statistics, relevant to public health or public safety, and in the conduct of health service management activities.

[www.nhmrc.gov.au/publications.synopses/e43syn.htm](http://www.nhmrc.gov.au/publications.synopses/e43syn.htm)

### **Australian Code for the Responsible Conduct of Research (NHMRC, 2007)**

provides guidelines on development of responsible research practice and how to handle breaches of the Code and research misconduct. It is written specifically for universities and other public sector research institutions.

[www.nhmrc.gov.au/publications/synopses/r39syn.htm](http://www.nhmrc.gov.au/publications/synopses/r39syn.htm)

### **The Australian Clinical Trials Registry (ACTR)**

This is a national, online register of clinical trials being undertaken in Australia. The ACTR includes trials from the full spectrum of therapeutic areas of pharmaceuticals, surgical procedures, preventative measures, lifestyle, devices, treatment and rehabilitation strategies and complementary therapies. It has nationwide coverage of all clinical trials involving Australian researchers or Australian participants.

[www.actr.org.au](http://www.actr.org.au)

### **The Australian Clinical Trial Handbook**

A simple, practical guide to the conduct of clinical trials to International standards of Good Clinical Practice (GCP) in the Australian Context (TGA,2006)

[www.tga.gov.au/cthandbook.htm](http://www.tga.gov.au/cthandbook.htm)

### **NHMRC Policy on Complaints (NHMRC, 2008)**

[www.nhmrc.gov.au](http://www.nhmrc.gov.au)

**Medicines Australia**

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. Also contains useful links to many other relevant sites

[www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au)

## Contact information

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## SJGHC Ethics Committee Meeting Schedule for 2011-2012

### Submission Dates

29 August 2011

31 October 2011

22 December 2011

27 February 2012

30 April 2012

2 July 2012

3 September 2012

29 October 2012

### Meeting Dates

12 October 2011

7 December 2011

8 February 2012

11 April 2012

13 June 2012

8 August 2012

10 October 2012

12 December 2012