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MERCY UNIQUE REQUIREMENTS.

(For All Research Applications to Mercy Health HREC).

Dear Research Applicant,

Thank you for your interest in submitting an application to Mercy Health Human Research Ethics Committee (Mercy Health HREC).

For review by Mercy Health HREC your application needs to be completed on either the National Ethics Application Form (NEAF) with the Victorian Site Specific (SSA)Form or the HREA (Human Research Ethics Application) with Victorian (SSA) Site Specific form.

Links to these forms are provided on the Mercy Health HREC Submissions web page. mercyhealth.com.au/about-us/research/human-research-ethics-committee-hrec/

For review of low risk research or an audit, it may be possible that this research can be reviewed by the Expedited Review Working Party (between meetings) and not by the FULL Mercy Health HREC. Please contact the Administrative Officer, Mercy Health HREC if you believe your research can be reviewed by this method.

The relevant forms for this process can be found on the Mercy Health, HREC Submissions webpage also.

The Mercy Health HREC requires that all applications conform with the National Health & Medical Research Council's National Statement on Ethical Conduct in Research Involving Humans (2007 – updated May 2010) (**The National Statement**), Catholic Health Australia Guidelines and any other applicable Guidelines.

It is expected that any guidelines related to the completion of these forms will have been read by the Principal Investigator prior to the submission of the new research to Mercy Health HREC.

The completion of an application does not absolve the researcher from the responsibility of ethical considerations. Those considerations are listed in Appendix 1(situated at the end of this document).

Privacy Legislation

Researchers must ensure that their application conforms to the Health Privacy Principles of the Health Records Act 2001 (Vic), in particular, with respect to the

collection, use and disclosure of health information. This Act came into effect on 1 March 2002. The Health Services Commissioner has issued statutory guidelines for the processes that must be followed in accordance with the Health Privacy Principles 1.1(e) paragraph (iii) and 2.2(g) paragraph (iii). The guidelines can be obtained from the Health Services Commissioner at

https://www2.health.vic.gov.au/mental-health/rights-and-advocacy/privacy/rights-and-privacy-principles

Since Mercy Health HREC became a paperless Committee with the introduction of I Pads in 2012/2013, for review by the researcher to the full HREC at it's bi-monthly meetings, is just one electronic copy and one paper copy (with original signatures) which is to be forwarded to:

The Administrative Officer, Mercy Health Human Research Ethics Committee,

c/o; Mercy Hospital for Women, Floor 6, Administration, 163 Studley Road, HEIDELBERG, VIC. 3084

These documents are required on the **submission date** no later than 3pm of that day.
No projects will be accepted after this time.

The submissions dates are listed separately on the Mercy Health website - see Current Submission & Meeting Dates.

Mercy Health HREC meets approximately 8weeks following the submission date to discuss all new research and amendments/updates to approved research.

This submission process does not usually apply to low-risk/audits requiring ethical review.
Please contact the HREC Administrative Officer if you believe your research is low-risk or an audit to discuss this.

GENERAL INFORMATION FOR RESEARCH UNDERTAKEN BY FULL HREC REVIEW

1.1 Prior to any commencement of the research, all research must have the approval from Mercy Health HREC. Investigators will be advised by email and letter approximately 3 weeks after the Mercy Health HREC meeting.

1.2 Approval is valid for one year unless agreed otherwise..

Please note: Continuation of ethics approval is contingent on submission of an annual report. Should you require an extension of ethics approval, the HREC office must be contacted before the ethics approval runs out and your request must be accompanied with a current progress report

Failure to comply with this requirement may result in suspension of this research.

1.3 **Research projects must not commence until:**

- Final approval of ethical clearance has been received in writing;

- Conditions imposed on the project, as specified by a letter from Mercy Health HREC, have been completed and notified to the Administrative Officer of the Mercy Health HREC, including governance issues

- If after review by the FULL HREC amendments are requested, the research applicant has four (4) months to undertake these. If there has been no communication from the researcher within that time, a reminder will be forwarded by the Administrative Officer, and an extension of 2 months will be given. If after six (6) months no communication or progress has been made regarding any requested amendments, Mercy Health Human Research Ethics Committee will ask to have the project **resubmitted** for ethical review.

1.4 Mercy Health HREC does not recognise other institution's HREC approval. However, evidence of approval by any other institutional human research ethics committee is important and will be considered as 'peer review' and should be included with any application to Mercy Health HREC.

1.5 All projects are reviewed by a Facilitator prior to the Mercy Health HREC meeting day. The Facilitator may or may not be a member of Mercy Health HREC. It is believed this process produces a quicker path towards approval from the Mercy Health HREC. It is recognised that any projects which require further information/ amendments results in a delay to the approval process.

1.6 Upon receipt of the research application the Mercy Health HREC Administrative Officer will notify the applicant of the facilitator responsible for his/her project and contact details will be provided. The Administrative Officer will also forward a copy of the application to the facilitator for perusal. The applicant must initiate contact with the nominated facilitator, in order to receive advice in relation to the suitability of the application for submission to the Mercy Health Human Research Ethics Committee. This process may involve amendments being made to the initial application. Following advice by the facilitator that the proposal is satisfactory, an amended paper copy (original signatures not required if already supplied in initial application) and an updated electronic copy must be forwarded to the Administrative Officer, Human Research Ethics Committee prior to the upcoming Mercy Health HREC meeting.

1.7 Researchers may be required to attend the Mercy Health HREC in person before approval can be given. If required, the researcher will be notified of the time and date of attendance of the Mercy Health HREC meeting.

1.8 A medical, nursing or executive representative of the Mercy Health facility at which the project is proposed to be undertaken, may be invited to attend the meeting;

1.9 The Mercy Health HREC would usually expect a nominated employee of the relevant Mercy Health facility to be a co-investigator in the project. Where co-investigator status is not appropriate, a nominated employee will act as a local liaison person in order to:
- facilitate progress of the project within the institution

- ensure the interest of patients, staff and institution are maintained
- act as a local contact should unforeseen problems arise

1.10 If access to medical records is required by the research, that access must be obtained through the Hospital Manager of the relevant Mercy Health facility. A "Consent to Access Medical Records Form" will be raised at the same time as the approval letter by the Mercy Health HREC Administrative Officer. Please note, the researcher may be liable for the cost of accessing medical records.

1.11 Mercy Health HREC Administrative Officer will forward to you a Progress Report Form when your research is approved. At 12 month intervals until the completion of the research, the HREC Administrative Officer will expect a Progress Report to be completed and returned for review by Mercy Health HREC. Should there be a significant delay in receiving the annual Progress Report Form Mercy Health HREC has the right to withdraw its approval on the research.

1.12 Mercy Health HREC approval may be withdrawn if a research project is not commenced within six (6) months of final written approval, unless the Mercy Health HREC Administrator has been previously advised as to the delay. Should the Principal Investigator not do this, he/she may be required to **resubmit their application for continued ethical approval.**

1.13 Approval must be obtained for changes to an existing protocol before the changes are implemented. An "Amendment Request Form" and copy of amended documentation (with tracked changes) must be submitted to the Mercy Health HREC for consideration.

(See HREC Submissions page on Mercy Health website for link to this form).

1.14 Depending on the target group, researchers might like to consider subjects from a non-English speaking background. This should be considered in the recruitment plan along with budget for translating the consent form and information sheet into languages other than English.

1.15 Please also note, in accordance with the National Health and Medical Research Council National Statement guidelines, the Mercy Health HREC is required to conduct periodic audits of research projects. From time to time, the Mercy Health HREC may seek to view copies of signed participant consent forms and may also seek to contact research participants directly to ask them about their research experience. This will be done to ensure that approved research projects are being undertaken according to the Guidelines set out in the NHMRC National Statement. Any contact with research participants will only be undertaken with the consent of the participant.

SECTION 2: ADDITIONAL REQUIREMENTS FOR CLINICAL DRUG TRIALS – CTN/CTX / COMMERCIALLY SPONSORED STUDIES

2.01 **Institutional Overheads Charge**

Mercy Public Hospitals (includes Mercy Hospital for Women, Werribee Mercy, Mercy Mental Health, Mercy Palliative Care Sunshine, O'Connell Family Centre, Mercy Health Services Albury & Mercy Care

Centre, Young) have an institutional overheads charge of a $5000 + $500 GST upfront fee (non-refundable) to cover administrative support of **commercially sponsored** drug and device trials.

If possible, ***to allow the sponsor sufficient time to raise a cheque so that it may be submitted with the initial application***, the Principal Investigator must advise the Administrative Officer, Human Research Ethics Committee the following information ***prior to the deadline*** so that a complying tax invoice can be generated as required by law:

- clinical protocol number
- sponsor's company name
- contact name
- address & phone number

The cheque should be made out to Mercy Hospitals Victoria Ltd Services and forwarded to the Mercy Health HREC Administrative Officer, c/o Mercy Hospital for Women.

Researchers should ensure that this fee is included in the budget/contract with a sponsoring company.

Mercy Hospitals Victoria Ltd ABN is 74762 230 429.

Mercy Health & Aged Care Facilities are private facilities. If a Clinical Trial is undertaken at one of these institutions, the cheque should be made out to:

Mercy Health & Aged Care Inc (MHACI), Level 2, 12 Shelley Street, Richmond, VIC 3121

Mercy Health & Aged Care ABN is 77191 901 062

N.B. GST is not payable if the sponsor is an overseas company and does not have an Australian subsidiary and there is no Australian-based contract research organisation supporting the sponsor for the study. As a rule, the same applies if the sponsor is an overseas company and the agreement is between the sponsor and the Principal Investigator and data are sent directly to the sponsor even if support is being provided by an Australian-based contract research organisation.

If the research involves a drug or device which is not commercially funded, then there are potentially lesser fees for ethical review. Please contact the HREC Administrator directly to discuss this.

2.02 Approval for Clinical Drug and Device Trials

All clinical drug and device trials require the approval of the Mercy Health HREC.

Clinical drug and device trials conducted in Australia are subject to Government regulations administered by the Therapeutic Goods Authority (TGA). In 1991 the Government introduced regulations which provide for a two track system for submitting drug trials for approval. The two methods which can be used for submission are:

- The Clinical Trial Exemption Scheme (CTX)

- The Clinical Trial Notification Scheme (CTN)

The principal difference between the two schemes lies in who has responsibility for assessing the scientific efficacy and safety of the drug which is the subject of the trial.

Under the Clinical Trial Exemption Scheme (CTX), the TGA carries out an assessment of the investigational agent and if it receives their endorsement, the drug trial protocol can then be submitted to the Institutional Ethics Committee of the hospital in which the trial is to be conducted.

Under the Clinical Trial Notification Scheme, (CTN) the trial protocol is submitted directly to the Institutional Ethics Committee of the hospital which then becomes responsible for assessing the efficacy and safety of the investigational agent.

2.02a. **CTN Scheme**

Mercy Health HREC will normally consider an application for a trial under the CTN Scheme only if it is in Phase 3 or 4 of the study and has been evaluated previously by the TGA or an acceptable comparable overseas authority e.g. Food and Drug Administration (USA), Medical Control Authority (UK) and Swedish Medicines Agency (Sweden).

Where a drug has been evaluated and approved by the TGA the Mercy Health HREC may consider an application under the CTN Scheme for a new use, a higher dose, a new route in the same patient group, a new patient group or a new duration of the treatment, provided adequate information is available about the efficacy, safety and justification of the proposal.

Where a drug in its proposed use has not been approved by the TGA, the Mercy Health HREC may consider an application under the CTN Scheme if:

a) It is in Phase 3 or 4 of the study and/or has been approved by an acceptable overseas authority;

b) The drug has been approved by the TGA and the new use proposed has been approved by an acceptable overseas agency and full documentation of that approval is provided.

Please contact the HREC Administrator for further advice/discussion if your potential drug/device trial does not fall into any of these categories.

DOCUMENTATION REQUIRED

- Initially, 1 paper copy (with original / electronic signatures) and 1 electronic copy of the application of National Ethics Application Form (NEAF) with Victorian Site Specific (SSA) Form or HREA (Human Research Ethics Application) with SSA form. Also included should be the Participant Information Sheet and Consent Form. Once liaised

with Facilitator any amended copies of these documents need to be resubmitted (electronically) prior to the Mercy Health HREC meeting.

- Similarity 1 (paper and electronic) copy of the Sponsor's Protocol
- Also, 1 copy each (paper and electronic) of the Sponsor's Investigators Brochure.
- 1 copy each (paper and electronic) of Indemnity Statement
- 1 copy each (paper and electronic) of Clinical Trial Agreement
- 1 copy each (paper and electronic) of the budget with all costs including Institutional Overheads Charges and
- 1 copy each (paper and electronic) of proof of sponsor's valid insurance for the trial (including any limits of cover and dates of expiration of policy).

Note: The proof of insurance/insurance cover note must specify a MINIMUM of $10M AUD (or equivalent) for public liability and a MINIMUM of $10M AUD (or equivalent) for product liability.

Indemnity for clinical trials can use the Medicines Australia Form of Indemnity for Clinical Trials.

2.02b. **CTX Scheme**

A proposed trial which the investigator or the Committee considers unsuitable for the CTN scheme should be submitted to the Therapeutic Goods Administration. The Mercy Health HREC will consider all other aspects of the proposed trial once the TGA has evaluated the safety and toxicity of the drug/s.

The Mercy Health HREC should be kept fully informed of any application under the CTX scheme.

ADDITIONAL WORDING FOR CTN / CTX / SPONSORED TRIALS

CONSENT FORM / PARTICIPANT INFORMATION SHEET

When preparing the Participant Information Sheet and Consent Form (using Department of Health, Victoria, documentation), the information in the following items must be included. The Compensation Provisions must be verbatim.

- **Compensation Provisions – Clinical Drug and Device trials**

The sponsor of this study, **[Sponsor's name]**, has agreed to provide compensation to you for an injury suffered as a result of your participation in the trial in accordance with the Medicines Australia (formerly Australian Pharmaceutical Manufacturer's Association) "Guidelines for Compensation for Injury resulting from participation in a Company Sponsored Trial".

(A copy of this document should be available to participants of the research by the research staff if requested).

Also add - 'In the unlikely event that you suffer an injury as a result of participating in this trial, hospital care and treatment will be provided to you free of charge.'

- **Advice On Avoiding Pregnancy (if relevant)**

Please note that all health and aged care providers under the auspices of Mercy Health are Catholic facilities. It is acceptable within Catholic teaching to counsel a woman and/or her partner to avoid becoming pregnant when either the woman or partner is undergoing treatment that might affect a foetus. Where a drug trial may cause harm to the foetus, potentially fertile women should be warned of the risks and to avoid conception. Before entering the study, women will be required to have a pregnancy test. Sexually active women who are potentially fertile will be excluded from such trials unless they are using a medically reliable method of preventing conception. The Hospital however, does not accept any statements in the application (e.g. participant information sheet, scientific description) to the effect that participants must practise methods of contraception.

It is recommended that, if relevant, the following paragraphs are used in the Participant Information & Consent Form:

The effects of (Name of investigational product) on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant or breast feeding. If you are female and child -bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project. If you are male you should not father a child or donate sperm for at least (number) months after the last dose of study medication.

Both male and female participants must avoid pregnancy during the course of the research and for a period of (number) months after completion of the research project. You should discuss effective methods of avoiding pregnancy with your doctor.

(For Female Participants). If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. <u>You must not continue in the research, if you become pregnant.</u>

(For Male Participants). You should advise your doctor if you father a child while participating in the research project. Your doctor will advise on medical attention for your partner should this be necessary.

- **Profits**

In addition, in trials where a profit is expected to be made by the researcher, the participant information sheet should include a

statement to the effect that 'The profit from this study will be used to fund other research' to follow the statement 'This trial is sponsored by ...'.

SECTION 3: OTHER REQUIREMENTS

3.1 **Hospitalisation**

If hospitalisation is required specifically for the purposes of the project; please state the duration.

3.2 **Protocol for dealing with research participants who may become distressed or at risk to themselves as a result of involvement in a research study:**

Research applicants conducting investigations dealing with psychological or other matters, which may cause participants to become distressed or at risk to themselves as a result of their involvement in such an investigation, are to be aware of the following requirements of the Mercy Health HREC:

- The level of distress that may be caused to participants by virtue of their involvement in the research project is to be assessed by the researcher;
- The Human Research Ethics Committee is to examine on a case by case basis, the provision made by researchers, of appropriate support services, in relation to the potential level of distress;
- The Human Research Ethics Committee is to examine on a case by case basis, the appropriate skills of the researchers in relation to the potential level of participant distress.

3.3. **Copyright**

- Research applicants are required to assure the Human Research Ethics Committee that steps have been taken to manage copyright, and
- It is the responsibility of the investigator to ensure that there is no infringement of copyright.

3.4 **Prior written support must be obtained from:**

- Any relevant internal Department Head, *plus* below;

- Mercy Hospital for Women & Werribee Mercy – Any relevant Clinical Division of the following:

    - Women's & Children's Services
    - Surgical & Specialist Services
    - Medical, Sub Acute and Palliative Care Services
    - Ambulatory, Allied Health and Community Services
    - Mental Health Services

  Plus the signature of support from the Chief Executive Health Services

  The Administrative Officer, Human Research Ethics Committee can advise on the contact details of the relevant Clinical Director(s) and Chief Executive Health Services.

* Certain research applications will require the support of the Mercy Hospital for Women Senior Medical Staff and this will be ascertained on a case by case basis, by the Human Research Ethics Committee.

- Other Mercy Health facilities – the Hospital Manager

Note: The Hospital Manager may not support the project on the basis that patients are already involved in a number of similar or conflicting studies.

- If the research involves private patients of medical staff (other than the researchers) it is the responsibility of the applicant to obtain the agreement of relevant medical staff before the application is submitted to the Mercy Health HREC;

3.5 Where appropriate, the Mercy Health HREC may require the Researcher to provide a statement that the proposed study does not conflict with any other study which the participant may be involved in;

3.6 **Participant Information Sheet and Consent Form**

The Mercy Health HREC requires specific information to be included in the Participant Information Sheet/Consent Form.

This includes the statement (below) within the Information Sheet.

If I have an ethical concern, I can contact the Administrative Officer, Human Research Ethics Committee [tel. 8458 4808] for referral of this concern to the Human Research Ethics Committee.

Privacy, Confidentiality and Disclosure of Information

The following statement (in italics below) must be included under the Section of the **Participant Information Sheet** which details "Privacy, Confidentiality and Disclosure of Information", to inform potential participants of the Mercy Health-HREC monitoring obligations under the NHMRC (2007) National Statement:

In accordance with the National Medical Health and Research Council guidelines, the Human Research Ethics Committee is required to conduct audits of research projects from time to time. It may therefore be possible that the Human Research Ethics Committee which has approved this research, will seek to view a copy of your signed consent form, or to contact you, to ensure that the research is being conducted according to the ethical standards required by these guidelines

The following statement (in italics below) must be included on the **Consent Form**, to enable potential participants to consent to their information being accessed for the purposes of monitoring, by the Human Research Ethics Committee:

I consent to the Mercy Health Human Research Ethics Committee which approved this study to access my information, or to contact me to ask about my research experience, in order to ensure that the project is being run in accordance with government standards

- Where the Chief Investigator is also responsible for the care of the patient, the consent form must be witnessed by a third party.

- For research at Mercy Hospital for Women and Werribee Mercy Hospital, the appropriate logo must be used on the Participant Information Sheet/Consent Form, and the organisation's ABN must appear at the bottom of each page that has the logo displayed. The Mercy Hospitals Victoria Ltd ABN is 747 622 30429.

The Mercy Health logo can be obtained from the Administrative Officer, Human Research Ethics Committee.

3.7. **Review of Medical Records**
Patient Consent

Patients may not be contacted for the purposes of research, unless they have indicated on their Admission Privacy Statement, that they consent to be approached for research purposes. If the patient indicates within their health record that they do not wish to be contacted for research, then a researcher must conform to this request.

Patient/participant records cannot be viewed without participant consent except where it is impracticable to obtain consent, and prior approval has been granted by the Human Research Ethics Committee. You will need to complete the Privacy Form, COLLECTION/USE/DISCLOSURE OF INFORMATION mercyhealth.com.au/legal-policy-information/access-to-information/

Within your Participant Information Sheet/Consent Form there must be included:

- A specific request to the patients, seeking their consent to access their medical record/ patient information;
- A statement that only information relevant to the study will be accessed;
- That the researcher will undertake to preserve the confidentiality of all information concerning any individual taking part in the project;
- That the researcher will not make any direct copy of the participant's medical records, and shall identify transcribed data by code only, which may be the Hospital Unit Record number.

Permission of the Hospital Manager

- The policy of the Human Research Ethics Committee with respect to outside monitors/research applicants (external to the Mercy organisation) is as follows:

- A condition of final approval is to receive from the Administrative Officer, an “Approval to Examine Records” form. This will be signed by the Administrative Officer. Please note, the PI may be charged for accessing this information.

- The original of the Form will be sent to the researcher with the approval letter. A copy will be kept in the office of the Administrative Officer, Human Research Ethics Committee, and the Medical Record Department will be notified.

- The designated monitor for any registered project is to be a person with appropriate tertiary, biomedical or scientific qualifications and with appropriate appreciation of the ethical issues involved with respect to confidentiality.

- If the Principal Researcher is not a member of staff of Mercy Health facility, the selected monitor must be approved by the Clinical Division associated with the project.

- If the researcher is not an employee of Mercy Health, then an honorary appointment is needed to be organised. The documents which need to be supplied for this process will be advised to the Principal Researcher by the Mercy Health HREC Administrator.

- Direct copies of the patient’s notes may not be taken. Transcribed data must be identified by code only, which may be the unit record number. Names and/or addresses may not be recorded.

- In the case of participants who are not registered patients of Mercy Hospitals Victoria Ltd and/or Mercy Health & Aged Care facilities- e.g. volunteers, or patients from elsewhere - the complete record should be kept solely in the care of the investigator as required by the NHMRC guidelines, and any transcription of the record by the monitor is to follow the same rules as for registered patients of Mercy Health.

4. FINAL CHECK LIST For RESEARCH to be reviewed by FULL HREC

Time frame	Details	Included
1. Initial Submission to Administrative Officer Human Research Ethics Committee	One (1) paper copy of the completed form (HREA or NEAF) (with original/ Electronic signatures) plus SSA form and one (1) electronic copy of same to be forwarded to the HREC Administrative Officer, by 3 pm on the closing date for the submission to the HREC bi-monthly meeting.	
	Curriculum Vitae of Principal Investigator i and Mercy Health researcher who are submitting a research proposal to Mercy Health HREC.	
	Copies of any ethics approval from other institutions.	
	Statement of support from (1) relevant Department Head which must be supplied at the time of your submission. Plus (2) Support of the relevant Clinical Division and Executive Director, Mercy Health Services. (**Note**: It is an important condition of approval, that your application gains the support of the relevant Clinical Division (for Mercy Hospital for Women and Werribee Mercy) and the Executive Director of Mercy Health Services. The Administrative Officer, Human Research Ethics Committee will facilitate the process for these signatures (detailed by (2)) by submitting a copy of your application to these relevant personnel once your initial copy has been received. The Clinical Division (MHW and Werribee Mercy) and the Chief Executive are required to advise the Administrative Officer, in writing, of their support. This written support may be received at any time during the application process (occasionally after the Human Research Ethics Committee meeting). However, it is a condition of approval, and must be received by the Administrative Officer prior to final approval being granted by the Administrative Officer. Within other facilities of the Mercy Health organisation, a signature of support from the relevant Department Head must be obtained prior to the research being reviewed. Any additional signatures of support will be obtained by the Administrative Officer of Mercy Health HREC during the process of review. **(If there is no proof of support for your research in a particular facility, then ethical approval can not be granted.)**	
	For ethical approval there must be either one of the named investigators works for Mercy Health OR the	

	Chief Investigator has identified and named an appropriate contact person within the Mercy facility where the research is to be undertaken.	
2. **Between initial and final submissions**	Research applicant are to make contact with the relevant facilitator shortly after the initial submission. The name and contact details of the facilitator will be advised to the researcher by the HREC Administrative Officer. The facilitator will advise the researcher of any changes that are required before the final submission. The researchers are to make amendments as requested prior to the HREC meeting if possible. These updated documents can be submitted electronically.	
3. **Final submission**	After amendments have been satisfactorily completed, forward one (1) amended electronic application (original signatures not required if already supplied) but any missing or additional signatures must be supplied to the HREC Administrative Officer.	
4. **Accessing Medical Records (if applicable to your research)**	The Administrative Officer will send to you, with your letter of approval (following the HREC meeting), an "Approval to Examine Records" form. You are to complete and sign this document and use it to access medical records. A copy will be kept with your study file by the Administrative Officer HREC and a copy will be sent down to Health Information Services. Please note: Health Information Services may not allow you to access the information without this form. A charge for this service may be levied at the Principal Researcher. Patient/participant records cannot be viewed without participant consent except where it is impracticable to obtain consent, and prior approved has been granted by the Human Research Ethics Committee. It may be necessary to obtain a 'waiver of consent' for this from the Mercy Health HREC. If you require this please discuss with the HREC Administrator. Only potential participants who have indicated "yes" on the Admission Privacy Statement may be approached for the purposes of research.	

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Appendix 1

ETHICAL CONSIDERATIONS

All investigators must be aware that:

1. The research must conform to generally accepted scientific principles and to the moral principles expressed in the Philosophy of Health Services under the care of Sisters of Mercy of Australia and the requirements of the National Statement on the Ethical Conduct in Human Research plus the Australian Code for the Responsible Conduct of Research.

2. The possible advantages to be gained from the work must justify any discomfort or risks involved.

3. Whenever appropriate, the work should be based on prior laboratory and/or animal experimentation.

4. (a) The work should be conducted only by suitably qualified persons with appropriate professional competence having available facilities for the proper conduct of the work and for dealing with emergencies.

   (b) Where students or non-qualified persons are to be involved in the conduct of the project, a supervisor must be identified who will be responsible for overseeing the conduct of the project.

   (c) All projects must have a contact person who is a hospital staff member and in most circumstances a co-investigator. External applicants must nominate the contact person prior to commencement of the project.

5. New therapeutic or experimental procedures which are at the stage of early evaluation and which may have long term effects should not be undertaken unless appropriate provision has been made for long-term care, observation, assessment and evaluation.

6. If during the course of the study it becomes apparent that continuation may be harmful, the investigator must discontinue or modify the research.

7. Participants have a right to know how their name was obtained for consideration.

8. The investigator must inform participants in writing that they [participants] must give their consent to participate but may withdraw at any time and that a refusal to participate will not in any way have an

adverse impact on treatment. The investigator should not employ any active or passive coercion. 9. Participants should not be asked to commit acts that diminish self-respect, or might cause them to experience shame, embarrassment or regret.

10. Participants should not be exposed to unreasonable physical or mental stress and be notified of all risks. All aspects of safety and comfort should be considered.

11. The investigator must notify the Administrative Officer, Human Research Ethics Committee of adverse events and reactions resulting from the project:

12. Serious Adverse Events on site that are related to/possibly related to study agent are to be reported immediately and at the latest, within 24 hours.

13. All other Serious Adverse Events (on site and at other sites) should be reported as soon as possible, or at the latest within 72 hours.

14. Notification must be accompanied by a signed statement from the investigator indicating what relevance he or she believe -Mercy Health HREC should attach to the adverse event as far as future conduct of the study within the institution is concerned.

15. Notification should also be given to the committee as soon as possible of any new information from other published or unpublished studies which may have an impact on the continued ethical acceptability of the trial or which may indicate the need for amendments to the trial protocol.

16. Investigators should respect the privacy of participants.

17. Investigators should ensure that in a study which involves the recruitment of a control group, those allocated to the control group will receive the same high quality care to that received by those in groups receiving other interventions.

18. Investigators must treat all participants with respect.

19. Where necessary appropriate referral should be made to suitably qualified persons to ensure all participants receive adequate care for issues that may arise during the study.

20. Confidentiality of research records must be maintained at all times and method of storage and duration of storage is to be identified.

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