Our Mission
As Mater Research, together with our partners, we conduct, enable and translate exceptional clinically relevant health research.

Our Vision
Achieving better health for all through exceptional research.

Our Values
Mercy
Dignity
Care
Commitment
Quality

Affirmation
This governance document is consistent with the Mater Values and supports the Mater Research Mission and Vision by establishing and mandating appropriate controls to support the delivery of health care services.
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1 Document Controls

1.1 Document Revision History

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<tr>
<td>1.0</td>
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1.2 Document Review and Approval

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<td>Michael McGuckin</td>
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<td>Corporate Policy Governance Committee</td>
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1.3 References

**Internal Documents**

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<td>PR-PAL-002010</td>
<td>Management of Exposure to Blood and Body Fluids Procedure</td>
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2 Introduction

2.1 Purpose
This policy describes the responsibilities of Mater Health Services (MHS) and Mater Research (MR) researchers, and others using MHS resources, when conducting research involving the use of human biospecimens safely.

2.2 Scope and context
This policy outlines the requirements for ethical and governance approval of research studies involving the use of human biospecimens, including the requirement for donor consent for the use of the human biospecimens and when and how human biospecimens may be used. This policy applies to all MR and MHS employees (permanent, temporary and casual) and students, non-MHS research collaborators, MR honorary appointees, sponsors and agents (including Visiting Medical Officers, visiting health professionals, contractors, consultants and volunteers) who propose to undertake research involving patients, staff and resources of MHS and MR.

This policy governs:

- Collection, storage, use and disposal of human biospecimens in research (including tissue collected for Biobanks);
- Use of human biospecimens that have previously been collected and stored for research or other purposes and which a researcher may wish to access for new research; and
- Use of biospecimens in low risk projects (e.g. the collection and use of blood samples for establishment of ‘normal levels’, instrument calibration),
and provides guidance for researchers:

- using human genetics in research; and
- using stem cells in research.

2.3 Definitions

<table>
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<tr>
<td>Human Biospecimens</td>
<td>Any biological material obtained from a person including tissue, blood, urine, sputum and any derivative from these including cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person (<em>National Statement</em> Section 3.2).</td>
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<td>Tissue Bank</td>
<td>A repository of biospecimens that is kept for a period of time and may foreseeably be used for research purposes. It does not include collections of biospecimens that are stored for defined periods prior to being shipped to a laboratory for testing. A key component of any tissue bank is the associated pathological, clinical or epidemiological data.</td>
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<td>Research</td>
<td>Activities other than diagnostic, biochemical, or pathological examinations performed as a component of patient care, audit type activities and calibration of equipment. Research can include overall evaluation of new diagnostic, prognostic or biological techniques in a series of studies even if these are quality assurance activities.</td>
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2.4 Legislative compliance

This policy mandates compliance with laws, regulations, guidelines and codes of practice governing

a) the conduct of research in Australia
b) privacy, including the Privacy Act (1988) (including the Australian Privacy Principles), Hospital & Health Boards Act (2011) and Public Health Act (2005); and

Common law obligations also arise from the relationships between institutions, researchers and participants, while contractual arrangements may impose further obligations.

2.5 Industry Standards

- National Health and Medical Research Council Biobanks Information Paper (2012)
3 Principles

The following set of principles describes the objectives and outcomes of the policy:

3.1 Principle 1: Safety

Mater Health Services is committed to building a safe workplace, free from harm. The work health and safety hazards associated with the collection, storage, use and disposal of human biospecimens in research must be identified, assessed and mitigated in compliance with relevant Mater Health Services procedures (see PY-PAL-000001 Commitment to Work Health and Safety Policy).

3.2 Principle 2: Use of human biospecimens in research

The fundamental ethical principle of respect for the human biospecimens donor must be observed in research involving human biospecimens. This includes:

- consideration of the cultural or religious sensitivities of the donor when soliciting or accepting human biospecimens samples;
- the provision of full information about the purpose of the research;
- consent by the donor to the taking of human biospecimens;
- consent by the donor for the use of the human biospecimens for research, unless the HREC approves use of the human biospecimens without consent, with restricted consent or using an opt-out approach (see paragraphs 2.3.5 – 2.3.11 and 3.4.12 of the National Statement for criteria used for waiving consent and an opt-out approach);
- professional removal of the human biospecimens;
- the provision of secure storage of the human biospecimens;
- the provision of appropriate and secure systems to maintain confidentiality and privacy in the recording, storage and release of data; and
- accountability in the care and usage of human biospecimens.

There must be consideration of the cultural or religious sensitivities of the donor when soliciting, accepting, using or disposing of human biospecimens samples.

3.3 Principle 3: Use of embryonic or fetal tissue in research

Research at Mater Health Services (MHS) and/or Mater Research (MR) involving an embryo or fetus, or embryonic or fetal tissue, will adhere to Sections 6.13, 6.14 and 6.18 of the “Code of Ethical Standards for Catholic Health and Aged Care Services in Australia” (2001) which states that:

- it is permissible (with informed consent) for research to be undertaken on in vivo embryos and fetuses when there is moral certainty of causing no harm to the life or the integrity of the embryo or fetus;
- research is never to be undertaken on an embryo or fetus, or on tissue from an embryo or fetus, that has been procured through deliberate abortion;
- it is not permissible to produce embryos for research purposes or use embryos discarded from IVF programmes for research purposes; and
- genetic research must not involve any techniques that may lead to the asexual creation or reproduction of human embryos or other eventualities that are contrary to respect for human life or human dignity.
4 Policy Requirements

The following are the specific requirements of this policy.

4.1 Source of human biospecimens

The HREC approval of the use of human biospecimens may relate to, but is not limited to:

- Human biospecimens discarded after surgery;
- Human biospecimens stored specifically for clinical purposes;
- Human biospecimens removed at autopsy;
- Human biospecimens collected for ‘one-off’ research projects;
- Human biospecimens collected and stored in human biospecimens banks;
- Human biospecimens transferred to and from MHS within Australia; and
- Imported and exported human biospecimens.

4.1.1 Human biospecimens from autopsies

Research involving access to coronial material must be referred to the Queensland Health Forensic and Scientific Services Human Ethics Committee (FSS-HEC) for ethical and legal approvals. This also applies to clinical research studies where there is a component involving coronial material. In this context, examples of coronial material include tissues from coronial autopsies, slides and blocks, blood samples, autopsy reports and other documents and data relating to coronial autopsies.

The use of material from coronial autopsies for research requires the approval of the State Coroner. If the research involves access to coronial documents approval as a ‘genuine researcher’ under s53 of the Coroners Act 2003 is also required. These approvals are subject to reviews by an ethics committee whose membership includes representatives of the State Coroner.

4.1.2 Human biospecimens transfer

Acquisition of human biospecimens from an external source for research at MHS or MR, or supply of human biospecimens to an external source, requires review by an HREC through a formal application. Where human biospecimens to be used in an MHS or MR research project are to be obtained from an external human biobank and are to be transferred to the control of the MHS, the transfer of human biospecimens shall be subject to a Material Transfer Agreement (MTA). The MTA must document the formal transfer of authority from the external institution to MHS or MR with respect to the management of the human biospecimens. Transfer of human biospecimens between an MHS or MR biobank and an external human tissue repository is also subject to an MTA.

4.1.3 Imported human biospecimens

The importation of human biospecimens from another country for use in research at MHS or MR is governed by the National Statement Sections 3.4.13-3.4.14 and 3.4.16. It must be ensured that imported human biospecimens have been obtained in line with relevant Australian legislation. If this is not possible, or the biospecimens have not been obtained in line with relevant legislation, they must not be used.

4.1.4 Cadaveric human biospecimens

Use of cadaveric human biospecimens for research at MHS or MR is governed by the National Statement Section 3.4.5. Researchers must respect any wish expressed by a person about the use of their biospecimens post-mortem and if no such wish is discovered, consent should be obtained from the person(s) authorised by relevant legislation.
4.2 Use of human biospecimens in research

4.2.1 Clinical research involving the use of human biospecimens

The use of human biospecimens in research at MHS and MR must be compliant with the legislation, regulations and guidelines of the Therapeutic Goods Administration.

*National Statement* Section 3.4.11 describes the use of human biospecimens that have been collected for clinical purposes and have been retained by an accredited clinical pathology service.

4.2.2 Ethical consideration specific to women who are pregnant and the human fetus

In addition to the ethical considerations pertaining to all research participants, specific issues arise in the design, conduct and ethical review of research involving women who are pregnant, the human fetus and human fetal biospecimens after the separation of the fetus from the woman:

- The term fetus applies to the developing human being from fertilisation to delivery, and whether alive or dead at delivery.
- Fetal includes membranes, placenta, umbilical cord, amniotic fluid, and other tissue that contain the genome of a fetus prior to separation of the fetus from the woman.
- All researchers conducting research which requires the use of human biospecimens from within the above categories must refer to Chapter 4.1 the *National Statement* and *the Code*. If researchers have any doubts as to compatibility of their proposed research with the NHMRC guidelines and/or the Catholic ethos then consultation with the Chairperson of the HREC and/or the MHS Executive Director Mission Leadership is strongly recommended.

4.3 Information and consent

The use of written, signed donor consent for the use of human biospecimens in research is necessary in most cases for compliance with ethical requirements. The requirement for donor consent may be waived or an opt-out approach may be approved by a HREC in appropriate circumstances (see *National Statement* Sections 2.3.5 – 2.3.11 and 3.4.12 for circumstances where waiver of consent or the opt-out approach may be justified). The following sections of the *National Statement* provide further detail relating to information and consent:

- Chapter 2.2: requirements for participant consent.
- Section 3.4.3: information that should be supplied to participants prior to potential participant consent.
- Section 3.4.10: HREC-approved plan that researchers should prepare that describes the disclosure or non-disclosure of information where proposed research involving the use of human biospecimens may reveal information that may be important for the health of the donor(s), their blood relatives or their community.
- Chapter 3.5: addresses issues related to genetic research, and the implications of such research. The possibility of such research occurring in the future should be addressed in the information provision process, and the fact that the implications may require future contact with the donor and/or relatives.

Consent to use human biospecimens in research may be:

- ‘specific’: limited to the specific project under consideration
- ‘extended’: given for the use of biospecimens in future research projects that are:
  - an extension of, or closely related to, the original project; or
  - in the same general area of research
• ‘unspecified’: given for the use of biospecimens in any future research (National Statement Section 2.2.14).

A full copy of the written informed consent for the research project must be stored in the participant’s hospital medical records with an entry that includes: the name of the study, who conducted the consent process and what biospecimens the participant has consented to being taken (see PY-RSH-300300 Ownership, Storage and Retention of Human Research Materials and Data Policy). A further entry should be made when the biospecimens are taken.

If researchers planning new research want to access biospecimens that have previously been collected and stored for research, they will need to check whether the consent for the original research covers the new research. If not they will need to submit a request for ethical review and approval to access and use the biospecimens in their ethics application for the new research.

If researchers planning research want to access biospecimens that have previously been collected and stored for clinical purposes, researchers need to submit a request for ethical review and approval to access and use the biospecimens in their ethics application for the research. This process may either involve going back to the patients and obtaining consent to use their stored biospecimens for the purposes of research or requesting the review body to grant a waiver of consent, as per National Statement Section 3.4.12, to use the biospecimens for research purposes.

4.4 Privacy of biospecimens and related data

PY-RSH-300300 Ownership, Storage and Retention of Human Research Materials and Data Policy should be followed in relation to research data. With advances in genetic knowledge and data linkage, and the proliferation of tissue banks of identified material, human tissue samples should always be regarded as re-identifiable (National Statement Section 3.2).

4.5 Confidentiality

Researchers given access to confidential information must maintain that confidentiality and must comply with all legislation and policy relating to information privacy.

Human biospecimens for research and the relating confidential research data must be kept in secure storage.

Confidential information must only be used in ways agreed with those who provided it or as otherwise authorised by law. Particular care must be exercised when confidential data are made available for discussion (the Code 2.7).

4.6 Collection of human biospecimens

Human biospecimens must be collected in accordance with the participant information sheet, including the stated amount, frequency and type of collection that has been approved by the HREC. The participant information sheet must contain full disclosure relating to how the biospecimens will be collected, who will collect the biospecimens, who will have access to the biospecimens, how long the biospecimens will be stored, method of disposal of biospecimens and any risks involved in the collection of the biospecimens.

Human biospecimens (including blood and its derivatives) collected specifically for use in research must be treated as potentially infectious. Standard precautions must be adhered to during sample collection, transport and subsequent analysis. Risk management strategies must be put in place to ensure there is minimal risk to all personnel working with the sample.

Mandatory risk management strategies include:
A risk assessment of the analysis required including identifying risk mitigation strategies must be performed prior to the initiation of the research; and

Appropriate training of staff prior to commencing the research project using any human biospecimens and on an annual basis thereafter. The research supervisor is responsible for ensuring that training is completed.

In addition, other strategies as specified in the HREC approved protocol or site specific assessment must be adhered to.

4.7 Ownership

Mater Health Services or MR remains the custodian of all human biospecimens, collected at, or processed through the Mater site.

Biospecimens may be loaned to investigators for research purposes but must be returned to MHS or MRI at the completion of the research or upon the request of MHS or MR. Such biospecimens may only be used for the purpose for which HREC approval has been granted. The biospecimens (and accompanying data) must not be released to another group without the approval of the HREC and a material transfer agreement being in place for the transfer of samples.

4.8 Disposal of human biospecimens samples

Human biospecimens should be disposed of according to the time frame stated in the participant information sheet.

Biospecimens must be disposed of in a manner that does not risk the confidentiality of the participant/patient and according to standard laboratory practices.

Procedures should be in place to assist with the proper disposal of the specimens when they are no longer being used.

Documentation relating to the disposal of human biospecimens must be kept.

4.9 Human genetics in research

Genes and genetic information are being studied increasingly in clinical, epidemiological and social research, as well as basic research (National Statement Chapter 3.5). Genetic research includes but is not limited to the study of:

- Single or multiple genes, gene-to-gene interaction or gene-environment interaction
- Acquired somatic variation
- Inherited gene sequences, and their variants or their products
- Gene expression, including the influence on those genes of environmental factors, pharmaceuticals and other therapeutic products
- The genes of individuals, families or populations
- Epigenetics
- Use of informatics and genetic information
- Clinical phenotypes.

All research involving human genetics must be reviewed by either the MHS HREC or, if applicable, an NHMRC HREC certified to review and approve multi-centre research studies, except where that research uses collections of non-identifiable data and involves negligible risk, and may therefore be exempted from ethical review (this will need to be discussed with an appropriate HREC to have this category confirmed).
However, human tissue biospecimens should always be regarded as, in principle, re-identifiable which therefore require full ethical review.

For genetic research using stored data also see PY-RSH-300300 Ownership, Storage and Retention of Human Research Materials and Data Policy.

4.10 Stem cells

Only stem cell research that does not involve an embryo or fetus or tissue from an embryo or fetus that has been procured through deliberate abortion can be undertaken at the MHS or MR. It is not permissible to produce embryos for research purposes or use embryos discarded from IVF programmes for research purposes.