

PROCEDURE

Research Management - Ethical and Scientific Review of Human Research

PR2017/113
Version No. 1.0

PURPOSE

The Metro South Hospital and Health Service (Metro South Health) is committed to the highest standards and practices in the ethical and scientific review of human research. This Procedure identifies a consistent and enforceable process for ethical and scientific review of human research being conducted in or in collaboration with Metro South Health

OUTCOME

Adherence to this Procedure will ensure all research conducted within Metro South Health or in collaboration with external entities, is of the highest ethical and scientific standard and is compliant with relevant legislation, standards and guidelines.

This Procedure applies to:

- All Metro South Health employees who conduct human research within or in association with Metro South Health facilities, or through access to Metro South Health participants; and
- All personnel (including researchers, students and visitors) involved in all aspects of human research in or in association with Metro South Health.

Failure to comply with this Procedure may amount to research misconduct on the part of the responsible individual. This Procedure must be read in conjunction with other Metro South Health Research Management Procedures.

KEY PRINCIPLES

The following key principles guide Metro South Health in establishing appropriate ethical and scientific review of human research processes:

- Metro South Health is committed to the highest standard of integrity in research practices across all research activities.
- Researchers must protect human participants in research in accordance with the National Statement on Ethical Conduct in Human Research (2007) ("National Statement") and follow the Metro South Health process for Human Research Ethics Committee (HREC) approval.
- Research involving human participants, their data or biospecimen/s must undergo ethical and scientific review, approval and monitoring by a HREC or other National Health and Medical Research Council (NHMRC) ethical review body.
- Researchers must comply with ethical principles of integrity, respect for persons, justice and beneficence.

- Any interventional research on patients must be conducted in accordance with the 'Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) 2000 - Annotated with TGA Comments'.
- It is recommended that ethical review be undertaken in parallel with Metro South Health research governance reviewing using the [Australia Online Forms for Research](#) internet site.
- Written approval from appropriate ethics committees, safety and other regulatory bodies must be obtained (when required).
- It is acknowledged that research with Aboriginal and Torres Strait Islander peoples spans many methodologies and disciplines. There are wide variations in the ways in which Aboriginal and Torres Strait Islander individuals, communities or groups are involved in, or affected by, research. This Procedure must be read in conjunction with Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research and the Guidelines for Ethical Research in Australian Indigenous Studies.

LEGISLATION OR OTHER AUTHORITY

Legislation

- *Defence Trade Controls Act 2012 (Cth)*
- *Gene Technology (Queensland) Act 2016 (Qld)*
- *Gene Technology Act 2000 (Cth)*
- *Hospital and Health Boards Act 2011 (Qld)*
- *Information Privacy Act 2009 (Qld)*
- *Privacy Act 1988 (Cth)*
- *Public Health Act 2005 (Qld)*
- *Therapeutic Goods Act 1989 (Cth)*

Regulations and Standards

- Gene Technology Regulations 2001 (Cth)
- Information Privacy Regulation 2009 (Qld)
- Therapeutic Good (Medical Devices) Regulations 2002 (Cth)
- Therapeutic Goods Regulations 1990 (Cth)

Statements, Papers and Guidelines

- National Health and Medical Research Council (NHMRC):
 - [Australian Code for the Responsible Conduct of Research 2007](#)
 - [National Statement on Ethical Conduct in Human Research \(2007\) - Updated May 2015](#)
 - [Research Governance Handbook: Guidance for the national approach to single ethical review 2011](#)
 - [Standardised Participant Information and Consent Forms](#)
 - [Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods](#)
 - [Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research 2003](#)
- Queensland Health: [Health Service Directive: Research Ethics and Governance HSD-035:2016](#)
- Queensland Government: [Queensland Biotechnology Code of Ethics: Update of the Code of Ethical Practice for Biotechnology in Queensland \(2006\)](#)
- Therapeutic Goods Administration: [Note for Guidance on Good Clinical Practice \(CPMP/ICH/135/95\) 2000 - Annotated with TGA Comments](#)

Metro South Health Policies, Procedures, Manuals, Frameworks etc.

- [Finance Management Practice Manual \(FMPM\)](#)
- [Integrated Risk Management Framework](#)
- [Management of Conflict of Interest – All Staff Procedure \(PR2016-66\)](#)
- [Management of Conflict of Interest Policy \(PL 2014/0038\)](#)
- [Research Biorepositories Policy \(PL2017/53\)](#)
- [Risk Assessment Guide \(V12 6-11-2013\)](#)
- [Risk Management Policy \(PL2013-06\)](#)

RESPONSIBILITIES

Executive Management Team

Ensure collaborative, harmonised, clear and detailed publicly available Policies and Procedures are in place for the ethical and scientific review of all Metro South Health research.

Metro South Health Human Research Ethics Committee (HREC)

Provide oversight of the ethical and scientific review of Metro South Health human research by keeping abreast of international, national and state-wide legislation, regulations and guidelines. Promote Metro South Health strategic requirements and ethical and responsible decision-making which respects the rights of Metro South Health participants.

Centres for Health Research

Update Metro South Health ethical and scientific review documents in accordance with Metro South Health HREC requirements. Provision of secretariat/administrative support to maintain and uphold principles outlined in the Metro South Health Research Management Policy and related Procedures.

Researchers

Adhere to all relevant Policies, Procedures, Research Protocols and Standing Operating Procedures (SOPs) when conducting research.

All Metro South Health Employees

Are required to be aware of and comply with this Procedure when conducting research.

SUPPORTING DOCUMENTS

Attachments

Attachment 1 - [Application](#)

Attachment 2 - [Metro South Health Research Protocol Template](#)

Attachment 3 - [Metro South Health Human Research Ethics Committee Terms of Reference](#)

Forms

[MSF40 Metro South Application Form for Exemption of HREC Review](#)

[MSF31 Metro South HREC and Governance Standard Risk Submission Checklist Form](#)

[HREC/RGO Annual Progress Report/Final Report](#)

[MSF49 Amendment Form](#)

DEFINITIONS

See the [Metro South Health Research Management Glossary](#)

PROCEDURE - ETHICAL AND SCIENTIFIC REVIEW OF HUMAN RESEARCH

PRIOR TO THE HREC REVIEW PROCESS

Step 1: Establish the Research Question

Establishing a research question requires rigorous review of literature to ensure there is an unmet need within healthcare delivery. Human Research, as defined by the National Statement, provides guidelines on ethical considerations that must be addressed when preparing research materials for review and approval by a HREC. When establishing the research question it is important to identify if any specific human and animal ethical and scientific review requirements are necessary. Please see [Specific Human and Animal Ethical and Scientific Review Requirements Procedure \(PR2017/114\)](#) for more information.

Step 2: Develop the Research Protocol

Preparation of a Research Protocol is mandatory. Researchers may utilise the Metro South Health Research Protocol Template ([Attachment 2](#)) however it is important to note that not all fields are required. Researchers are encouraged to consult with a research mentor in determining the most appropriate template to use when preparing a Research Protocol. Researchers must also develop an appropriate Participant Information and Consent Form (PICF) and other associated supporting documents relevant to the research project. The Metro South Health HREC Office/r recommends the use of the NHMRC endorsed standardised [PICFs](#). Researchers may also refer to the [Biospecimen Ethical and Scientific Review of Human Research Procedure \(PR2017/113\)](#) for more information. Please see [Section 5.0 Supporting Documentation Requirements](#) (below) for more information regarding required supporting documentation.

Step 3: Commencing the HREC Review Process

It is strongly recommended to commence completion of the HREC review process at the same time as the Site Specific Assessment (SSA) application. Please see [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#) for more information.

Step 4: Single Site and Multi-centre Research

As the Metro South Health HREC is a NHMRC Certified Committee, it is able to provide single ethical review for multi-centre research projects that participate in the National Mutual Acceptance (NMA) model.

Single Site - If the research project constitutes single site research please proceed to Step 5: Metro South Health HREC Office/r.

Multi-centre Research - If the research project constitutes multi-centre research researchers must complete the Booking Form on the [Central Coordinating Service](#) (CCS) internet site and email to QHCCS@health.qld.gov.au for allocation to a certified HREC. If the multi-centre research project is allocated to Metro South Health by the CCS please proceed to Step 5: Metro South Health HREC Office/r.

Step 5: Metro South Health HREC Office/r

Researchers must contact the Metro South Health HREC Office/r via telephone (07) 3443 8049 or email EthicsResearch.PAH@health.qld.gov.au to discuss the proposed research project and identify whether the research project is suitable for an alternative review other than a Full HREC Review.

The Metro South Health HREC Office/r may choose to grant exemption from Full HREC Review or categorise the research project as a low or negligible risk and offer an alternative review process.

Upon receipt of advice from the Metro South Health HREC Office/r please proceed with **either** Exemption from Full HREC Review, Low and Negligible Risk Research Review or Full HREC Review processes outlined below.

EXEMPTION FROM FULL HREC REVIEW

Step 1: Application Requirements

If advised by the Metro South Health HREC Office/r:

1. Complete [MSF40 Metro South Application Form for Exemption of HREC Review](#) (this form must be signed by both the researcher and the head of department. In the case where the researcher is the head of department, the form must be signed by their line manager); and
2. Collate supporting documentation as required. Please see [Section 5.0 Supporting Documentation Requirements](#) for more information on submission requirements.

Submit one (1) original copy of the completed form and all supporting documentation to the following address:

Metro South Health HREC
Centres for Health Research
Level 7, Translational Research Institute
37 Kent Street
Woolloongabba QLD 4102

Step 2: Exemption from Full HREC Review Determination

The review of Exemption from Full HREC Review in Metro South Health takes approximately one (1) week. The request will be reviewed by the HREC Chair/Deputy Chair and a determination will be made. Upon receipt the determination the Metro South Health HREC Office/r will advise in formal correspondence if the research project:

- is able to proceed with records being maintained by the Metro South Health HREC Office/r; or
- requires further action/information to be provided.

Step 3: Commence Research/Publish

The research project may only proceed upon receipt of advice/confirmation in writing from the Metro South Health HREC Office/r.

LOW AND NEGLIGIBLE RISK RESEARCH REVIEW

Step 1: Research Fee Review

If applicable, assess research fees for the Metro South HREC. Please see Research Fees Procedure (PR2017/123) for more information. Researchers must ensure appropriate invoicing details are included in the initial submission.

Step 2: Submission Requirements

If advised by the Metro South Health HREC Office/r:

1. Complete the online Low and Negligible Risk Form available on the [Australia Online Forms for Research](#) internet site.

If Single Site – research projects conducted within Metro South Health facilities:

- Also complete the online Site Specific Assessment (SSA) form available on the [Australia Online Forms for Research](#) internet site (to be considered complete, the following must be included on the Site Specific Assessment (SSA): Business Manager/Finance Officer and/or Cost Centre Manager sign-off, research cost centre details, head of department sign-off (if any investigator is the head of department, please ensure that appropriate line manager signs as head of department). Please see [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#) for more information.

If Multi-centre Research

- Ensure application has been booked into the Metro South Health HREC through the [Central Coordinating Service](#) (CCS). The CCS will assign a HREC reference number for the application. Please ensure that the HREC reference number is included on the above mentioned Low and Negligible Risk Form available on the [Australia Online Forms for Research](#) internet site. Submission of the Site Specific Assessment (SSA) application for Metro South Health sites is not mandatory, however it is highly encouraged.
2. Submit the completed Low and Negligible Risk Form available on the [Australia Online Forms for Research](#) internet site online with the following:
 - a. Completed Site Specific Assessment (SSA) (if required); and
 - b. Supporting documentation uploaded against the online form.
 3. Obtain submission code and print completed Low and Negligible Risk Form.

Submit the following documents in hard copy to the Metro South Health HREC Office/r:

Metro South Health HREC
Centres for Health Research
Level 7, Translational Research Institute
37 Kent Street
Woolloongabba QLD 4102

Ref.	Document Type	Hard Copy Req.
a.	MSF31 Metro South HREC and Governance Standard Risk Submission Checklist Form <ul style="list-style-type: none"> completed (seek authorisation through the relevant channels of review) clearly articulate on the Form if the study is single site or multi-centre clearly identify costs - see Research Fees Procedure (PR2017/123) 	1 original copy
b.	Low and Negligible Risk Form - available on the Australia Online Forms for Research internet site <ul style="list-style-type: none"> note submission code printed and scanned from online site 	1 copy
c.	Supporting Documentation <ul style="list-style-type: none"> See Section 5.0 Supporting Documentation Requirements below for more information on submission requirements 	1 copy

Please note, the original (hardcopy) applications must be submitted as the Metro South Health HREC Office/r cannot process emailed or faxed copies.

Step 3: Low and Negligible Risk Research Determination

The review of low and negligible risk research projects in Metro South Health takes approximately two (2) weeks. Upon receipt the determination the Metro South Health HREC Office/r will advise if the research project is:

- Low and Negligible Risk thus exempt from Full HREC Review: proceed to the Site Specific Assessment (SSA) process; see [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#); or
- More than low and negligible risk research: proceed with Full HREC Review process (see below).

Step 4: Ensure Research Governance Authorisation Prior to Commencement of Research

The research project may only proceed upon receipt of authorisation from the Metro South Health Chief Executive Officer or delegate. See [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#) for more information.

FULL HREC REVIEW

Step 1: Research Fee Review

Assess research fees for the Metro South HREC. Please see Research Fees Procedure (PR2017/123) for more information. Researchers must ensure appropriate invoicing details are included in the initial submission.

Step 2: Review Closing Dates

Researchers are required to submit their research applications for full HREC review to the Metro South Health HREC Office/r by the appropriate closing date. Meeting and closing dates are listed on the [Centres for Health Research](#) internet page.

Step 3: Submit Application for Full HREC Review

If advised by the Metro South Health HREC Office/r:

1. Complete the online Human Research Ethics Application (HREA) available on the [Australia Online Forms for Research](#) internet site (Note: this is to obtain a submission code only);
2. Submit the completed Human Research Ethics Application (HREA) online with the following:
 - a. Completed Site Specific Assessment (SSA) online (if required); and
 - b. Supporting documentation uploaded against the online form.
3. Obtain submission code and print completed Human Research Ethics Application (HREA).

Submit the following documents in hard copy to the Metro South Health HREC Office/r:

Metro South Health HREC
Centres for Health Research
Level 7, Translational Research Institute
37 Kent Street
Woolloongabba QLD 4102

Please note, the original (hardcopy) applications must be submitted as the Metro South Health HREC Office/r cannot process emailed or faxed copies. Please see [HREC Meeting Dates Checklist](#) for further information.

Ref.	Document Type	Hard Copy Req.
a.	MSF31 Metro South HREC and Governance Standard Risk Submission Checklist Form <ul style="list-style-type: none"> • completed (seek authorisation through the relevant channels of review) • clearly articulate on the Form if the research project is single site or multi-centre • clearly identify costs - see Research Fees Procedure (PR2017/123) 	1 original copy 5copies
b.	Human Research Ethics Application (HREA) available on the Australia Online Forms for Research internet site <ul style="list-style-type: none"> • printed and scanned from online site - note submission code 	1 original copy 5 copies
c.	Research Protocol and PICF <ul style="list-style-type: none"> • see Biospecimen Ethics and Participant Information and Consent Form Procedure (PR2017/115) 	1 original copy 5 copies
d.	Clinical Trial Exemption Form (CTX) or Clinical Trial Notification Form (CTN) from the Therapeutic Goods Administration <ul style="list-style-type: none"> • signed by Principal Investigator 	1 original copy
e.	Indemnity Arrangements <ul style="list-style-type: none"> • for industry sponsored research projects, Medicines Australia form of indemnity may be required if the HREC is not located at a participating site 	1 original copies
f.	Curriculum Vitae (CV) <ul style="list-style-type: none"> • researchers who have not submitted a CV within the past two (2) years 	1 original copy 5 copies
g.	Supporting Documentation <ul style="list-style-type: none"> • see Section 5.0 Supporting Documentation Requirements for more information on submission requirements 	1 original copy 5 copies
h.	For research using radiological procedures that are performed specifically for research: <ul style="list-style-type: none"> • independent assessment report or verification by a medical physicist (or radiation safety officer) or the total effective dose and relevant organ doses for those radiological procedures that are performed specifically for the Research Protocol. 	1 original 5 copies

Step 4: Full HREC Review Determination

The evaluation of Full HREC Review in Metro South Health takes approximately four (4) weeks. Upon receipt the determination the Metro South Health HREC Office/r will advise if the research project is:

- able to proceed;
- requires further information to be provided; or
- unable to proceed.

Step 5: Commence Research/Publish

The research project may only proceed upon receipt of authorisation from the Metro South Health Chief Executive Officer or delegate. Please see [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#) for more information.

METRO SOUTH HEALTH HREC REVIEW PROCESS

Step 1: HREC Review Administration

The Metro South Health HREC Office/r registers the application on an appropriate register for HREC applications (in line with specifications as set in the Health Service Directive - Research Ethics and Governance QH-HSD-035:2016).

A package of received HREC applications (including listing of allocated reviewers) is compiled by the Metro South Health HREC Office/r, within the Centres for Health Research, and distributed to HREC members prior to the next scheduled Metro South Health HREC meeting.

Metro South Health HREC members are required to review allocated HREC applications prior to the scheduled meeting.

Step 2: Conflicts of Interest in the Metro South Health HREC Review Process

If any person believes they may have a Conflict of Interest in relation to Metro South Health HREC Review Process, the conflict must be declared and detailed prior to the commencement of the Metro South Health HREC meeting.

Step 3: Metro South Health HREC Meeting

The Metro South Health HREC is convened and all HREC applications are discussed and reviewed.

Step 4: Metro South Health HREC Determination

Following the scheduled Metro South Health HREC meeting, Committee feedback on the submission is provided and in some circumstances a request for further information is sought. The Metro South Health HREC Office/r facilitates review of the reply to the “further information letter” to the researcher.

Once all required information has been obtained, the submission is considered by the Metro South Health HREC Chair. Please note the Metro South Health HREC Chair may again request further information or recommend approval of the application.

Step 5: Approval

Researchers will be formally notified of Metro South Health HREC clearance; by letter from the Metro South Health HREC Chair. This letter will be sent in a pdf form via email to the Principal Investigator and nominated contact person as well as the Metro South Health Research Governance Office/r.

The time to reach HREC approval will not take more than the sixty (60) day (stop-clock days) benchmark as set by the NHMRC. Registration of the Metro South Health HREC approval of the research is documented within AU-RED and the Metro South Health Research Ethics and Governance SharePoint site.

Researchers are responsible for ensuring research activities **do not** commence prior to receiving Site Specific Assessment (SSA) authorisation. Refer to [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#) for further information.

ONGOING MANAGEMENT OF HREC CLEARANCE

Step 1: HREC/RGO Annual Progress Report/Final Report

Researchers are responsible for ensuring that the [HREC/RGO Annual Progress Report/Final Report](#) is submitted prior to the Metro South Health HREC clearance anniversary (or sooner as required), to comply with Metro South Health HREC clearance requirements. Please see [Research Governance \(Monitoring\) Procedure \(PR2017/117\)](#) for more information.

Step 2: Amendments to Research Protocols

Any changes to the research project, in respect of aims, design and anticipated outcomes, which have previously been approved by the Metro South Health HREC, must be formally submitted as an amendment, for review and approval by the Metro South Health HREC via the [MSF49 Amendment Form](#). If multiple documents are submitted for an amendment, then these should be submitted in one (1) hard copy to the Metro South Health HREC Office/r.

Metro South Health HREC
Centres for Health Research
Level 7, Translational Research Institute
37 Kent Street
Woolloongabba QLD 4102

Please note, the original (hardcopy) applications must be submitted as the Metro South Health HREC Office/r cannot process emailed or faxed copies.

Upon receipt, the Metro South Health HREC Office/r will validate the submission and prepare documentation for Metro South Health HREC Chair/Deputy Chair review. Amendments are reviewed out of session by the Metro South Health HREC Chair/Deputy Chair, and when necessary, the Metro South Health HREC Office/r. Upon HREC approval, a formal letter in pdf format is sent to the Principal Investigator and nominated contact person as per initial submission.

In addition, a copy of the amendment approval letter is sent to the Metro South Health Research Governance Office/r in order to assess any implications of the amendment on ongoing site acceptability. If there is, further assessment and research governance approval of the amendment will occur as per [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#).

Step 3: Serious Adverse Event (SAE)/Suspected Unexpected Serious Adverse Reaction (SUSAR) Report

Researchers must report serious adverse events (SAE) and suspected unexpected serious adverse reactions (SUSAR) to the Metro South Health HREC Office/r and/or the Metro South Health Research Governance Office/r. This applies to all research including investigator initiated research projects, university and student research. In the event of a serious adverse event, the Principal Investigator must:

- report the event to the sponsor immediately (within twenty-four (24) hours); and
- complete and sign an [MSF19: Metro South HREC Serious Adverse Event \(SAE\)/Suspected Unexpected Serious Adverse Reaction \(SUSAR\) Report](#) within forty-eight (48) hours of notification.

Completed documentation must be submitted to the Metro South Health HREC Office/r and Metro South Health Research Governance Office/r via PAH-Research@health.qld.gov.au and/or EthicsResearch.PAH@health.qld.gov.au.

If a multi-centre research project, serious adverse events (SAE) and suspected unexpected serious adverse reactions (SUSAR) must be submitted in accordance with the below guidance notices:

- Multi-centre Research Projects only – [Lead Site Guidance](#);
- Multi-centre Research Projects only – [Accepting Site Guidance](#) (when Metro South Health HREC is the reviewing HREC);
- Multi-centre Research Projects only – [Accepting Site Guidance](#) (when Metro South Health HREC is **not** the reviewing HREC); or
- Commercially Sponsored or Collaborative Research Group Trials must follow the NHMRC Position Statement: Monitoring and Reporting of Safety for Clinical Trials (November 2016).

Step 4: Other Post Clearance Submissions

Upon receipt, the Metro South Health HREC Office/r will validate the submission and prepare documentation for Metro South Health HREC Chair review. Post clearance submissions are reviewed out of session by the Metro South Health HREC Chair and when necessary, the Metro South Health HREC Office/r. Appropriate correspondence confirming review is sent to the Principal Investigator and nominated contact person.

PROCEDURE DETAILS

Procedure Number

PR2017/113

Procedure Name

Metro South Health Research Management - Ethical and Scientific Review of Human Research Procedure

Policy Reference

PL2017/55

Metro South Health Research Management Policy

Supersedes

Nil

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Approving Officer

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Approving Date

30 June 2017

Effective From

30 June 2017

Date of Last Review

30 June 2017

Date of Next Review

30 June 2020

1.0 Types of Ethical and Scientific Review

All human research that takes place in the Department of Health and Hospital and Health Services (HHSs) must be reviewed and approved in accordance with the National Statement.

This requirement must be met in order for the Department of Health and the HHSs to grant authorisation for the commencement of human research projects, in accordance with Health Service Directive: Research Ethics and Governance HSD-035:2016.

HHSs may establish their own HREC use the review outcome of an HREC established by another institution. In either circumstance, the HREC that undertakes the review must be constituted and operate in accordance with the National Statement. HHSs with an established HREC must provide at least two (2) pathways for ethical and scientific review Full HREC Review and Expedited HREC Review for low and negligible risk research.

A summary of routes to obtaining ethical and scientific approval from the Metro South Health HREC, and how they relate to obtaining authorisation for the commencement of a research project in Metro South Health is provided in [Section 3.0 Metro South Health HREC Review](#).

2.0 Single Ethical and Scientific Review of Multi-centre Research

Metro South Health supports the Queensland system of single ethical and scientific review, in line with the National Statement requirement to minimise duplication of ethical review. Notwithstanding the special requirements stipulated in [Specific Human and Animal Ethical and Scientific Review Requirements Procedure \(PR2017/114\)](#), under this system a human research project will be ethically and scientifically reviewed once only, irrespective of the number of HHSs and/or sites involved in the research project.

Each HHS must accept ethical and scientific review undertaken by its local HREC or a lead HREC as sufficient review for the purposes of the research project being conducted at site(s) under its control. This applies to both full and expedited HREC review.

- A local HREC is an HREC established by a health service site to provide ethical and scientific review of human research to be conducted at sites under its control. The Department of Health and HHSs may support more than one local HREC.
- A lead HREC is a local HREC certified by the NHMRC to conduct ethical and scientific review of human research in the categories of:
 - clinical trials/interventional clinical research; and/or
 - general research.

Where the human research project involves the conduct of research at sites under the jurisdiction of more than one (1) local HREC, the research project must be reviewed by a lead HREC.

Multi-centre research must be submitted to the Department of Health Central Coordinating Service (CCS) who will allocate the research project to a designated certified HREC.

A designated certified HREC will conduct the Full HREC Review of a multi-centre research protocol. The site specific aspects of the research project will be conducted outside the business of the HREC, by the researcher, in accordance with the research governance processes at that site.

In Australia, a benchmark of sixty (60) calendar days has been set for the completion of the ethical and scientific review process by the NHMRC. The review time does not include the time taken for the Principal Investigator to attend to the requested amendments or provide additional information to the reviewing HREC. If, due to the complexity of the research project, the ethical and scientific review may be compromised by the sixty (60) day completion time, the HREC may extend the time taken to complete the review process.

2.1 Multi-centre Research

All multi-centre Research Protocols will have an Australian based Coordinating Principal Investigator who will coordinate:

- HREC review of the research project and/or any amendments;
- Progress reporting requirements as specified by the approving HREC;
- Reporting of any serious adverse events; and
- Communication with the site Principal Investigators, funders and sponsors.

2.2 Central Coordinating Service

Allocation of a multi-centre research project to a Queensland Health reviewing HREC will be through the Department of Health [Central Coordinating Service](#) (CCS) located with the Health Innovation, Investment and Research Office within the Director General Office.

The coordinating Principal Investigator or delegate will be required to contact the CCS via phone and answer a series of short questions of which will determine which HREC the research project will be allocated to. Where possible, the application will be submitted to a HREC associated with one (1) or more of the sites at which the research is to be conducted.

3.0 HREC Review

3.1 Types of Research that may be Exempted from Full HREC Review

Some research projects, such as internal quality assurance or quality type activities, may be eligible for exemption from Full HREC Review. Research projects which qualify for an exemption of Full HREC Review are of a low or negligible risk level (inconvenience only) and involve the use of existing collections of data or records that contain only non-identifiable data (National Statement S5.1.22).

Under the National Statement, institutions may establish non-HREC levels of ethical review to expedite the Full HREC Review process. Institutions have the discretion to exempt from Full HREC Review a research project that:

- is low or negligible risk research; and
- involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

The National Statement describes research as “low risk” where the only foreseeable risk is one of discomfort.

Discomfort may include minor side-effects of medication, discomforts related to measuring blood pressure or anxiety induced by an interview. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.

Research with “negligible risk” is described in the National Statement as where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience to the participants. Inconvenience is the least form of harm that is possible for human participants in research. The most common examples of inconvenience in human research are filling in a form, participating in a survey or giving up time to participate in a research activity. Where the risk, even if unlikely, is more than inconvenience, the research is not low or negligible risk.

Researchers are reminded that academic journals often require evidence that a research project has been reviewed by a HREC or that it has been exempt from review by a HREC. For information regarding the Metro South Health process for classifying a research project please see [Section 4.1 Research Project Classification](#) below.

3.2 Types of Research Requiring Full HREC Review i.e. More than Low or Negligible Risk Research

A ‘standard risk’ application is, by virtue of its form and content, an activity which constitutes something more than discomfort or inconvenience for research project participants. The National Statement defines ‘discomfort’ as a low level risk activity such as a participant having their blood pressure measured or attending a research project interview (Chapter 2.1). A standard full Human Research Ethics Application (HREA) may need to be submitted when the risk involved is greater than this.

In accordance with the National Statement, the following types of human research must be ethically and scientifically reviewed and approved by a HREC before they take place in HHS.

Type of Research	Ethical Review Requirements
Research that involves more than low or negligible risk to participants.	The level of ethical review required should be commensurate with the level of risk involved. If a research project or activity involves more than ‘discomfort’ (emotional, physical, spiritual and psychological), then it is a standard application and warrants a full Human Research Ethics Application (HREA).
Research that is personally intrusive or confronting or involves potentially embarrassing questions.	The research project looks at and/or involves subject matters (e.g. in a survey, questionnaire or interview) that participants may be uncomfortable discussing or find distressing (e.g. anxiety, depression or sexuality).
Employees are participants.	Research project involving staff participation generally requires a standard, full Human Research Ethics Application (HREA). This is to best ensure that the right of the participants in the workplace are protected, and that any participation or refusal to participate does not have a negative impact on the participants’ workplace relations, both now and in the future.

Any of the following participants groups are specifically targeted.	<ul style="list-style-type: none"> • Women who are pregnant and the human foetus; • Children and young people; • People in dependent or unequal relationships; • People highly dependent on medical care who are unable to consent for themselves’; • People with a cognitive impairment, an intellectual disability or a mental illness; • People who may be involved in illegal activities or residents of custodial institutions; • Aboriginal and Torres Strait Islander Peoples; and/or • People who are unable to give informed consent because of difficulties understanding information sheets (e.g. non English speakers).
The research project involves genetic research or stem cells.	The application requires Full HREC Review. A full Human Research Ethics Application (HREA) to the HREC is required (National Statement Chapter 3.5).
An intervention.	The research project involves an intervention to routine care (e.g. clinical trial of a device or drug, an educational intervention or an alternate treatment option) (National Statement Section 2.1.6).
Time commitment.	Participants are required to commit more than twenty (20) minutes of their time (either in one or multiple sessions).

3.4 Applications for Full HREC Review

All applications for Full HREC Review by the institutional HREC, whether in its capacity as local or lead HREC, must be made by the Coordinating Principal Investigator using the online Human Research Ethics Application (HREA) available on the [Australia Online Forms for Research](#) internet site. The [Australia Online Forms for Research](#) internet site provides guidance on completing the Human Research Ethics Application (HREA) and supporting documentation required for making an application.

The completed Human Research Ethics Application (HREA) and supporting documentation must be submitted both electronically and in hard copy to the HREC Office/r of the HREC that will review the application.

HREC Office/rs must use an online research application tracking and management system known as the Australian Research Ethics Database (AU-RED) for the management of all applications for Full HREC Review for research projects involving the Department of Health and/or HHS sites. This does not prevent the parallel use of other research management systems employed by other institutions.

4.0 Metro South Health HREC

In Metro South Health, there are two (2) components of approval for all research projects, both of these must be addressed in full before a research project can be given approval to commence:

1. HREC (HREC) Approval; and
2. Research Governance (Site Specific Assessment (SSA) and Monitoring).

To reduce unnecessary delay, Metro South Health recommends both HREC and Site Specific Assessment (SSA) applications are submitted simultaneously. Please see [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#) for more information on the Site Specific Assessment (SSA) authorisation process.

Metro South Health operates a HREC which gives ethical approval to clinical research projects. The Metro South Health HREC reviews the ethical and scientific validity of proposed research within the Metro South Hospital and Health Service, as well as research project conducted in Queensland, New South Wales, Victoria and South Australia. The Metro South Health HREC aims to:

- protect the mental and physical welfare, rights, dignity and safety of research participants;
- facilitate and promote high caliber ethical research through efficient and effective review processes; and
- ensure that all clinical and ethical research is conducted responsibly.

The Metro South Health HREC is registered with the [National Health and Medical Research Council \(NHMRC\)](#) (registration number EC00167). It is constituted and functions in accordance with the National Statement. Please review Attachment 3 - [Metro South Health HREC Terms of Reference](#) for further information.

4.1 Research Project Classification

In Metro South Health, research projects which appear to contain low and negligible risk levels (inconvenience only), involving the use of existing collection of data or records that contain only non-identifiable data, currently requires ethical oversight to determine if there are any ethical implications. The Coordinating Principal Investigator must consult the Metro South Health HREC Office/r to determine if the research project can be classified as low or negligible risk research, before completing the online Low and Negligible Risk Form available on the [Australia Online Forms for Research](#) internet site. The Metro South Health HREC Office/r has the discretion to request that the research project is submitted for Full HREC Review using Human Research Ethics Application (HREA) if they consider the risk to participants to be greater than low risk.

Applications for expedited review of research with low and negligible risk to participants by the Metro South Health HREC must be made by the Coordinating Principal Investigator using the [MSF31 Metro South HREC and Governance Standard Risk Submission Checklist Form](#). The following table provides guidance in determining whether a low or negligible risk application is appropriate for a research project.

Are any of the following relevant to the research project?	Yes
The research project involves a risk to participants, even if unlikely, that is more than discomfort. Risks can include physical, psychological, social, economic or legal harms or devaluation of personal worth (National Statement Chapter 2.1).	The research project would not fit the definition of low or negligible risk research (National Statement S 2.1.6). A full Human Research Ethics Application (HREA) to the Metro South Health HREC is required.

<p>Employees are participants.</p>	<p>Research projects involving employee participation are generally considered more than low or negligible risk and a full Human Research Ethics Application (HREA) is required. This is to best ensure that the right of the participants in the workplace are protected, and that any participation or refusal to participate does not have a negative impact on the participants' workplace relations, both now and in the future. Please contact the Metro South Health HREC Office/r for advice.</p>
<p>Any of the following participant groups are specifically targeted:</p> <ul style="list-style-type: none"> • Women who are pregnant and the human foetus • Children and young people; • People in dependent or unequal relationships; • People highly dependent on medical care who are unable to consent for themselves; • People with a cognitive impairment, an intellectual disability or a mental illness; • People who may be involved in illegal activities or residents of custodial institutions; • Aboriginal and Torres Strait Islander Peoples; and/or • People who are unable to give informed consent because of difficulties in understanding information sheets (e.g. non English speakers). 	<p>It is unlikely that the research project will be able to be reviewed as low or negligible risk. Please contact the Metro South Health HREC Office/r for advice.</p>
<p>The research project involves genetic research.</p>	<p>The application cannot be reviewed as low or negligible risk. A full Human Research Ethics Application (HREA) to the Metro South Health HREC is required (National Statement Chapter 3.5).</p>
<p>The research project involves an intervention to routine care (e.g. clinical trial of a device or drug, an educational intervention or an alternate treatment option).</p>	<p>It is unlikely that the research project will fit the definition of low or negligible risk research (National Statement Section 2.1.6). Please contact the Metro South Health HREC Office/r for advice.</p>
<p>Participants are required to commit more than twenty (20) minutes of their time (either in one or multiple sessions).</p>	<p>Please contact the Metro South Health HREC Office/r to discuss the details of the research project and whether it may be considered low or negligible risk research.</p>

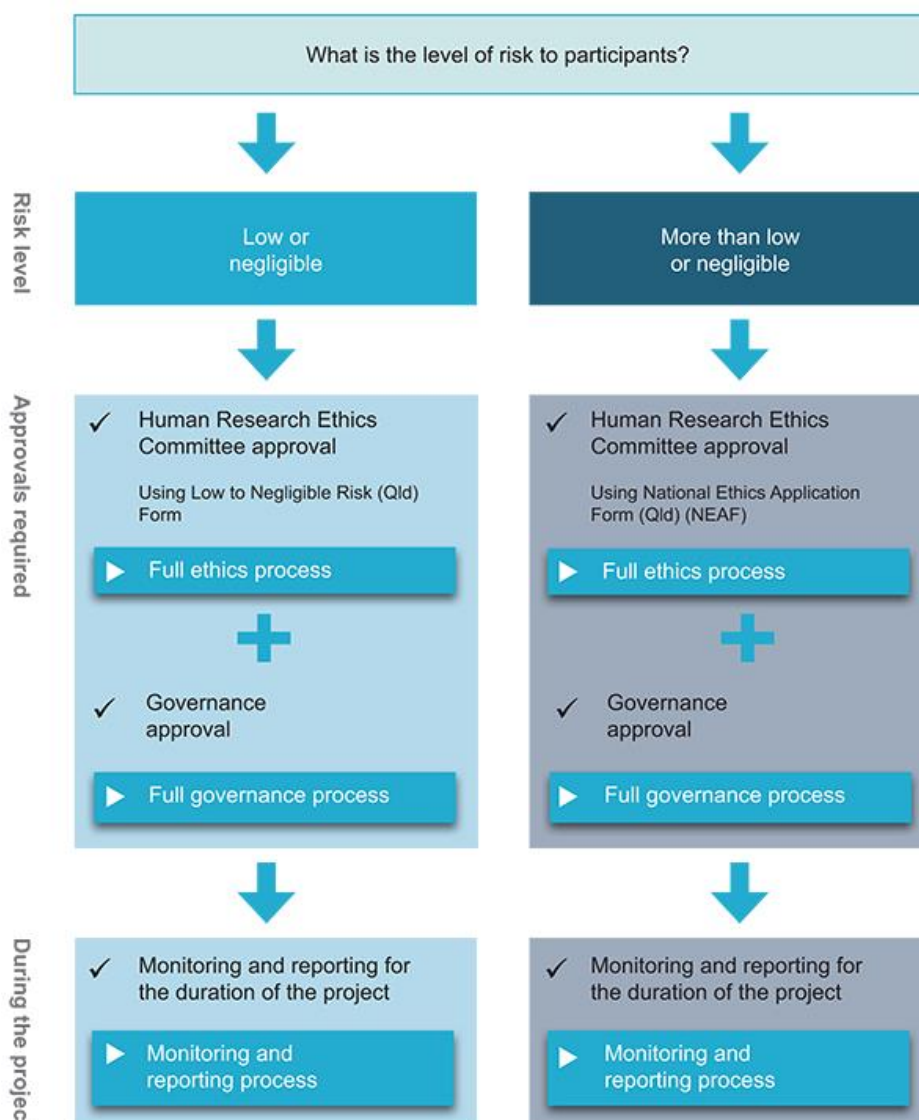
The research project looks at and/or involves subject matters (e.g. in a survey, questionnaire or interview) that participants may be uncomfortable discussing or find distressing (e.g. anxiety, depression or sexuality).

The research project may not fit the definition of low or negligible risk research (National Statement Section 2.1.6). Please contact the [Metro South Health HREC Office/r](#) for advice.

All human research as defined by the National Statement as being higher than low or negligible risk, conducted in or accessing patients, data, facilities and/or staff in Metro South Health must, at a minimum, be reviewed and approved by a HREC.

Requests for additional information or amendments made by the Metro South Health HREC to a researcher will be provided in a timely manner to ensure prompt review and resolution. Delays in providing information to the Metro South Health HREC may result in a Research Protocol being withdrawn from Metro South Health HREC review.

The Metro South Health HREC has the discretion to request a Full HREC Review using the Human Research Ethics Application (HREA) following assessment of the application for expedited review if it considers the risk to participants to be greater than low or negligible risk. Please see the below diagram which pertains to the decision-making process in Metro South Health.



All Research Protocols submitted to the Metro South Health HREC must be presented on either the Human Research Ethics Application (HREA) or Low and Negligible Risk Form (LNR) available on the [Australia Online Forms for Research](#) internet site.

4.2 Research Fees

Please see Research Fees Procedure (PR2017/123) for more information.

4.3 Membership

As per Section 5.1.30 of the National Statement, the membership of the Metro South Health HREC includes:

- a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement;
- at least two (2) lay people, one man and one woman, who have no affiliation with Metro South Health and do not currently engage in medical, scientific, legal or academic work;
- at least one (1) person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;
- at least one (1) person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
- at least one (1) lawyer, where possible one who is not engaged to advise Metro South Health; and
- at least two (2) people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two (2) members may be selected, according to need, from an established pool of inducted members with relevant expertise.

Please see the [Metro South Health HREC](#) internet page for more information regarding meeting dates and categories of membership.

4.4 Conflicts of Interest in Metro South Health HREC Review

Identification and management of perceived, potential and actual Conflicts of Interest will be in accordance with the Metro South Health [Management of Conflict of Interest Policy \(PL2014/0038\)](#) and [Management of Conflict of Interest - All Staff Procedure \(PR2016-66\)](#).

If a member of the Metro South Health HREC believes they may have a Conflict of Interest in relation to any application, that conflict must be declared and detailed prior to any consideration of applications.

Conflicts of Interest in this context may include a material connection to an application or researcher, which could bias the assessment of that application.

In the event of a Conflict of Interest a Metro South Health HREC member may be required to absent themselves from consideration of the relevant application.

4.5 Reporting Adverse Events to the Metro South Health HREC

Metro South Health HREC is responsible for review of Serious Adverse Events (SAE)/Suspected Unexpected Serious Adverse Events (SUSAR) reports arising from all sites involved. The details in regard to SAE/SUSAR reporting are set out in the NHMRC [Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods \(November 2016\)](#). Please see [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#) for more information.

4.6 Amendments to Research Protocols

Amendments to research projects may affect the ongoing ethical acceptability of the research project or the suitability of the research site must be submitted to the Metro South Health HREC for review.

Research project amendments that only affect the site acceptability of the research must be submitted to the Metro South Health Research Governance Office/r. Please see [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#) for more information.

Research project amendments that may affect both the ongoing ethical acceptability AND the site acceptability of the research must be submitted to the Metro South Health HREC Office/r for review by the Metro South Health HREC and, once HREC approval has been granted, are submitted to the Metro South Health Research Governance Office/r for final authorisation. Please see [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#) for more information.

Research project amendments that do not affect the ongoing ethical acceptability OR the site acceptability of the research (e.g. typographical errors) must be submitted in hard copy to the Metro South Health HREC Office/r.

For research projects that are externally HREC approved, researchers must submit the HREC approval of the amendment along with any updated site specific changes to the Metro South Health HREC Office/r.

Please see Research Fees Procedure (PR2017/123) for more information regarding amendment fees.

5.0 Supporting Documentation Requirements

5.1 Research Protocol

The development of a Research Protocol is an important step in the research process for the following reasons:

- it states the research question to be addressed;
- it encourages adequate consideration and planning of research project detail before commencement;
- it allows co-investigators or peers a living and dynamic document for contribution and early review prior to its completion;
- it acts as a record and reminder for the researchers (co-investigator or co-worker) of the initial research project aims and stated procedures (this record also enables monitoring of research project progress); and
- it provides the basis for funding of Human Research Ethics Applications (HREA).

The Metro South Health HREC Office/r offers a monthly [Drop In Session](#) to provide initial overview of submissions with the provision of advice to ensure the submission package is complete and all administrative requirements are complete based on research project requirements. A Metro South Health Research Protocol Template has also been developed to assist researchers (Attachment 2).

When revisions occur during the course of the research, researchers must submit a revised Research Protocol as an amendment.

5.2 Participant Information and Consent Forms

Researchers must develop an appropriate Participant Information and Consent Form (PICF) relevant to the research project. The Metro South Health HREC Office/r recommends the use of the NHMRC endorsed standardised PICFs. Researchers may also refer to [Biospecimen Ethics and Participant Information and Consent Form Procedure \(PR2017/115\)](#) for more information.

5.3 Other Supporting Documents

Other supporting documents which may be required to be submitted with a Metro South Health HREC application include:

- Therapeutic Goods Administration [Clinical Trial Exemption Form \(CTX\)](#) or [Clinical Trial Notification Form \(CTN\)](#).
- Indemnity arrangements (for industry sponsored studies, Medicines Australia [form of indemnity](#) may be required if the HREC is not located at a participating site).
- Curriculum vitae (CV) of researchers who have not submitted a CV within the past two (2) years.
- Any advertising or marketing material that is to be given to participants.
- Data collection tool(s), e.g. case report form.
- Questionnaires or other instruments.
- Letter of invitation/letter to GP, etc.
- Participant diaries.
- Participant wallet card.
- Other correspondence, e.g. Food and Drug Administration (FDA) reviews, correspondence from other HRECs, expert independent reviews, peer reviews, etc.