

PROCEDURE

Research Management - Research Data Integrity and Information

PR2017/125
Version No. 1.0

PURPOSE

This procedure identifies a consistent and enforceable process for the use of confidential health information and research data integrity for research being conducted in or in collaboration with the Metro South Hospital and Health Service (Metro South Health). It aims to inform staff and researchers of the correct course of action when requesting clinical health records (electronic, paper based or hybrid) for research and clinical audit purposes to ensure that patient confidentiality is protected, consistent with evidenced based practice. Patient confidentiality must be protected in the conduct of all research and clinical audits. This document is underpinned by relevant legislation, policy and standards as identified below.

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 within, 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 the management of research data integrity and information:

- Data underpinning research conducted in Metro South Health (including electronic data) must be recorded in a durable and appropriately referenced form i.e. researchers must maintain a catalogue of all research data in an accessible form.
- Research material and data related to publications must be available for discussion with other researchers (unless confidentiality provisions apply).

- Research data and materials remain the property of Metro South Health, unless subject to a third party agreement.
- Research data is recognised as a valuable product of the research process and are useful to researchers throughout the research cycle.
- All research data, including primary materials, are considered to be Metro South Health records and must be stored, disposed of or transferred in accordance with relevant Policies and Procedures.
- Metro South is committed to the protection of personal information which may be contained in research data and primary materials. When collecting, storing, using or disclosing personal information, researchers must abide by the mandatory requirements of the *Hospital and Health Boards Act 2001 (Qld)*, *Information Privacy Act 2009 (Qld)* and Metro South Health Policies and Procedures pertaining to information privacy e.g. Princess Alexandra Hospital employees must review relevant Princess Alexandra Hospital Procedures [Patient Information Access, Applications and Requests for Access \(60053/v4/07/2016\)](#) and [Confidentiality of Patient, Staff and Organisational Information \(60008/v7/07/2016\)](#).
- Research Data should generally be made available, via open access, for use by other researchers unless specific and valid reason exists for not doing so.

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

- Department of Health: [Retention and Disposal of Clinical Records Standard QH-IMP-280-1:2014](#)
- EQUIP National Standards (ACSQHC):
 - [Standard 14, Criteria 1 – Health records management systems support the collection of information and meet the consumer / patient and organisation’s needs](#)
 - [Standard 14, Criteria 3 – Data and information are collected, stored and used for strategic, operational and service improvement purposes](#)
- 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 - Establishment of a Research Biorepository Procedure \(PR2017/100\)](#)
- [Research Biorepositories Policy \(PL2017/53\)](#)
- [Risk Assessment Guide \(V12 6-11-2013\)](#)
- [Risk Management Policy \(PL2013-06\)](#)

RESPONSIBILITIES

Metro South Health Executive

Review and support/not support data or health record requests through endorsement/non-endorsement of Site Specific Assessment (SSA) application forms.

Department/Divisional Delegates

Be aware of access to data and/or health records in their departments/divisions. Maintain local work practices to ensure all researchers are authorised before research health records or data is provided.

Centres for Health Research

The Centres for Health Research is responsible for maintaining a register of the establishment and ownership of databases containing confidential information within Metro South Health. Access to these databases must be restricted to researchers with approved involvement in a research project.

Metro South Health Research Governance Office/r

The Metro South Health Research Governance Office/r provides a recommendation of research authorisation – including access to data and/or health records undertaken in compliance with the [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#).

Data Custodian

Acts as the main point of contact for enquiries regarding confidentiality, privacy and the release of information for their portfolio e.g. Information Access Unit within the Princess Alexandra Hospital is the unit responsible for releasing patient information in accordance with legislative provisions (around 20,000 requests per year) for the Princess Alexandra Hospital and Metro South Health.

Health Information Management Services (HIMS)

The Health Information Management Service (HIMS) is the 'Data Custodian' for Metro South Health and:

- Provides support and advice to both the public and staff on how to access medical records held by Metro South Health.
- Manages the requests for information received from patients and third parties in accordance with the relevant legislation (including *Hospital and Health Boards Act 2011 (Qld)*, *Right to Information Act 2009 (Qld)*, *Information Privacy Act 2009 (Qld)* and Queensland Health Policies).
- Manages the requests for medical records for Patients, Agents representing patients, Insurance companies, WorkCover, Health Professionals, the Coroner, Queensland Police Service, Courts and other third parties.
- Manages all privacy complaints under the position of the Privacy and Confidentiality Contact Officer (PCCO).
- Provides training to staff in relation to the release of information, privacy and confidentiality guidelines.

Line Managers

Line Managers are to be aware of research activities being conducted in their teams. Maintain local work practices to ensure all researchers are authorised before health records or data is provided.

Metro South Health Employees

Metro South Health employees must ensure research activities are not conducted without appropriate approval and that participation in research activities only occur where research has been authorised.

Researchers

Researchers are responsible for ensuring appropriate security for any confidential material including that held in computing systems. Where computing systems are accessible through networks, particular attention to security of confidential data is required.

Researchers have a responsibility to keep full, accurate and legible records of research methods, research data and primary materials (including laboratory notebooks and electronic data) in a durable, organised and accessible manner. Adequate records of the source of research material, experimental data and authorship must be maintained in a secure place after publication and must be recoverable should questions arise.

SUPPORTING DOCUMENTS

Attachment 1 - [Application](#)

DEFINITIONS

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

PROCEDURE - RESEARCH DATA INTEGRITY AND INFORMATION

STEP 1: Ethical Approval

Researchers must receive ethical approval of their research project in accordance with [Ethical and Scientific Review of Human Research Procedure \(PR2017/113\)](#) and discuss their data requirements with the relevant Data Custodian e.g. Health Information Management Services (HIMS). Applicants may be charged a fee for retrieval of health information for the purposes of research and should ensure research project budget workups include these fees. Please see Research Funding, Budgets and Infrastructure Support Procedure (PR2017/121) for more information.

Please note this excludes clinical trials as all HRECs providing approval must be Queensland Government Hospital and Health Service HRECs, the National Mutual Acceptance scheme is in place for recognition of ethics approval for some clinical trials. An ethics approval granted by an academic institution HREC is not recognised by Metro South Health.

STEP 2: Consent

A certified Human Research Ethics Committee (HREC) may grant a waiver of consent for the use of personal information in the conduct of research. If a waiver of consent is approved and the researchers are designated persons as defined by the *Hospital and Health Boards Act 2011 (Qld)* – S150a, the researcher is able to access the confidential information without consent for the purposes of health service planning, delivery and evaluation (i.e. research). If the designated person is to transfer confidential information to a third party, they third party must obtain Public Health Act approval from the Office of the Director General via the PHA Application Form. If the designated person removes identifiers from the dataset, they are able to transfer the data to a third party via the terms and conditions as set out in the overarching agreement as per research governance authorisation.

Research projects that seek to have unspecified use of personal information (including information from biospecimens) must detail the purpose and relationship of the information to the existing research project in terms of the future use in the consenting process in the review protocol.

Consent must be sought to access this additional information from data or biospecimens unless the need for consent has been waived by the HREC. Please see [Ethical and Scientific Review of Human Research Procedure \(PR2017/113\)](#) for more information.

STEP 3: Site Specific Assessment (SSA) Authorisation

Researchers must receive written research governance authorisation from the Metro South Health Research Governance Office/r prior to commencement of research or request for health records. Please see [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#) for more information.

STEP 4: Electronic Medical Record (EMR)

Receive approval to access data from the Electronic Medical Record (EMR) if required from the Director, Health Information Management System (HIMS), Metro South Health (if required).

STEP 5: Application

The applicant must prepare an application for access to confidential information with an MS Excel spreadsheet list of health records required in consultation with the Data Custodian.

NOTE: In the case of Clinical Trials approval is only required at the commencement of the trial. This approval will cover access to individual health records required for patient appointments and health records required for data abstraction.

STEP 6: PHA Approvals

All information about the application approved by the Director General, Department of Health, Chief Executive Officer, Metro South Health and/or delegate is kept on a Research Registry by the Office of Health and Medical Research in accordance with Division 3 s288 *Public Health Act 2005 (Qld)*.

STEP 7: Retrieval Fee (may or may not be applied)

As stated above, applicants may be charged a retrieval fee which will be invoiced from the relevant finance department in Metro South Health. Please view Part 9 of the Queensland Health [Fees and Charges Register](#) more information.

Where external researchers (non-Metro South Health staff) have research projects which involve access to health records the application should include the budget allocation, including invoice details, which provide the details of the contribution to the Metro South Health costs associated with accessing health records.

This information will be found in the budget section of the Site Specific Assessment (SSA) application (budget to be included as a per project budget for single invoicing rather than a per site cost). Please see Research Funding, Budgets and Infrastructure Support Procedure (PR2017/121) for more information.

When a request for access to health records for research or clinical audit is received and the 'funded research' box has been checked, the quotation for the cost of the retrieval of the health records which has been prepared by the Data Custodian and accepted by the requestor will then allow for an Invoice to be raised and the retrieval of the health records will proceed.

STEP 8: Reporting

Researchers must utilise the [HREC/RGO Annual Progress Report/Final Report](#) to report on relevant research projects. The researcher must provide an annual and final report on the outcomes of the research to the Chief Executive Officer, Metro South Health and/or delegate.

PROCEDURE DETAILS

Procedure Number

PR2017/125

Procedure Name

Research Management - Research Data Integrity and Information Procedure

Policy Reference

PL2017/55

Metro South Health Research Management Policy

Supersedes

Nil

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Attachment 1 - Application

1.0 Access and Use of Confidential Information for the Purpose of Research

Health care professionals are generally permitted to access patient information for research purposes provided they have been given approval to conduct clinical audit and research projects from the appropriate Metro South Health authority/delegate and have Human Research Ethics Committee (HREC) approval (if required). Access is dependent upon the nature of the information requested, the volume of information requested and the function to be performed by the researcher as the requestor of the information.

The relevant Data Custodian may pass on charges for administrative services associated with the retrieval and provision of health records. Charges associated with data analysis and data provision are provided on request by the Data Custodian.

As a general rule, Medical Record Departments at Metro South Health Hospitals, Multi-Purpose Health Services and Primary Health Care Centres do not have staff resources to locate records and do not have separate storage areas for health records required for research or clinical audit to be reviewed (without prior agreement and arrangement).

Only health records that are available at the requested site can be retrieved. A site-specific list will be supplied to a researcher indicating the current HBCIS location codes of unavailable health records.

It is the responsibility of the requestor to follow-up these health records by either recording a "Request" on HBCIS or by contacting the department holding the health record and arranging a suitable time for access. Alternatively, subsequent lists may be submitted.

A limit of twenty (20) health records, as paper version, may be retrieved and supplied at one time. The requestor must make arrangements for the collection of health information. It is the responsibility of the requestor to review health record paper based information as provided and request further records (20 health records at a time) if required.

Health records (as a paper version) are not available to be taken off-site and may only be reviewed at their site of storage. Electronic Medical Record (EMR) data may be supplied where ethics approval has indicated there is sufficient security access for their storage provided by the research protocol. Health record loans between facilities will not occur without specific authorisation included within the research governance Site Specific Assessment (SSA) authorisation.

1.1 Consent

Access to health information for the purposes of research is governed by legislation and is dependent on whether the patient has given specific consent for their records to be accessed. Where patient consent is not obtained, researchers may access identifiable (or re-identifiable) patient information for the purpose of research 9s150a *Hospital and Health Boards Act 2011 (Qld)*.

The most common circumstances where a waiver of consent may be approved by a HREC are:

- Consent is unable to be obtained - patient contact to obtain consent may be difficult or inappropriate;

- Patient consent has expired; or
- Patient consent does not cover the collection of information from medical records or does not cover the full range of data that will be collected.

Researchers must refer to should refer to [Ethical and Scientific Review of Human Research Procedure \(PR2017/113\)](#) and use of confidential health information/data under either the *Public Health Act 2005 (Qld)* or *Hospital and Health Boards Act 2011 (Qld)*.

1.2 Access to Confidential Health Information Retained by Queensland Health

Applications for the release of confidential information retained by Queensland Health for the purposes of research, to a third party under Section 280 of the *Public Health Act 2005 (Qld)* must include:

- Copy of approval letter from a HREC
- Evidence of authorisation from the relevant Queensland Health data custodians

Researchers must review to the Department of Health: [Health and Medical Research Unit - Access to Confidential Health Information](#) internet site when requesting access.

Important documentation/information

- [PHA Information & Application Form](#)
- [Data Custodian Contacts](#)
- [Annual Progress Report template](#)
- [Final Report template](#)

Researchers must submit applications electronically to PHA@health.qld.gov.au.

1.3 Access to Confidential Health Information Retained by Metro South Health

When researchers require access and use of confidential information held by Metro South Health for the purposes of research, the provisions of the *Public Health Act 2005 (Qld)* Chapter 6, Part 4, Division 2, s281 must be considered.

Databanks include any collection of personal information that may be used for the purposes of research. Use of databanks must follow the principles and guidelines for databanks as described in the National Statement on the Ethical Conduct of Human Research 2007 (“National Statement”).

Confidential Information for the purposes of research under the provisions of the *Public Health Act 2005 (Qld)* refers to information that is identifiable or potentially identifiable and is obtained without participant consent. Researchers must review the Health Information Management Services (HIMS) intranet site with requested access to Metro South Health information.

1.4 Storage and Retention of Confidential Information

All patient information relating to a research project must comply with the Department of Health [Retention and Disposal of Clinical Records Standard QH-IMP-280-1:2014](#), and the National Statement and the [Australian Code for the Responsible Conduct of Research 2007](#) (“the Code”).

Research material and data, and registers of that material and data, must be kept in a format, and for a period, that conforms to the requirements of the *Information Privacy Act 2009 (Qld)* and *Privacy Act 1988 (Cth)*, funding agency or publisher guidelines or in accordance with discipline norms, whichever is the longer period.

Wherever possible, original data (and, where relevant, materials or samples) should be retained in the department/division and/or research unit in which they were generated. If required, individual researchers can hold copies of the data for their own use. Retention solely by the individual researcher is not permitted, as it may not protect the researcher or Metro South Health in the event that the veracity of the data is questioned.

If the original data are retained by the researcher, the department/divisional delegate must be formally advised of its location and have the ability to access the data.

Researchers should also give consideration as to whether biospecimens or samples should be retained in research biorepositories such as the [Cancer Collaborative Biobank](#). Please see Metro South Health [Research Biorepositories - Establishment of a Research Biorepository Procedure \(PR2017/100\)](#) for more information.

Where research material is not kept within Metro South Health, a written record of the location of data must be retained by the researcher and department/division.

At the end of a research project which has been hosted by Metro South Health, research data and materials remain the property of Metro South Health, unless subject to a third party agreement. Please see Research Contracts and Study Execution Procedure (PR2017/122) for more information.

Where a researcher moves from Metro South Health, original data must remain at Metro South Health, otherwise written agreement must be reached with the new organisation covering ownership and storage of research data. When research is carried out at multiple organisations, agreement must be reached in writing and these must clearly specify the principles of storage and retention of research data within each organisation.

When the data is obtained from limited access databases (or an external database), or via a contractual arrangement, written indication of the location of the original data, or key information regarding the database from which it was collected, must be retained by the researcher or division/department.

1.5 Import and Export of Research Material

Researchers must ensure that they meet the relevant Customs, Australian Quarantine Inspection Service (AQIS), or other requirements for the import and export of research material (i.e. biospecimens). Please see Metro South Health [Research Biorepositories - Material Transfer Agreements, Packaging & Shipping Procedure \(PR2017/107\)](#) for more information.

1.6 Data Accessibility

Data related to publications must be available for discussion with other researchers. Where confidentiality provisions apply (for example, where the researchers or the institution have given undertakings to third parties, such as the subjects of the research), it is desirable for data to be kept in a way such that reference to them by third parties can occur without breaching such confidentiality.

1.7 Disposal of Research Data and Material

When the specified period of retention has finished, researchers have a responsibility to dispose of research data in a secure and safe manner, and in accordance with the Department of Health [Retention and Disposal of Clinical Records Standard QH-IMP-280-1:2014](#).

1.8 Access to Biospecimens

Researchers requiring access to biospecimens held by Metro South Health must make application through processes outlined within the [Metro South Health Research Biorepository Governance Framework](#).

1.9 Clinical Audit

Health records are frequently required for clinical audit and include:

- Clinical review
- Variable Life Adjustment Displays (VLADs)
- Quality and Safety reporting
- Morbidity and Mortality meetings
- Metro South Health data registries, (e.g. peri-natal registry)
- Other clinical governance and clinical Quality improvement purposes

As a general rule, there is no restriction to access of health records for these purposes provided the requesting officer is a member of staff at Metro South Health or a Department of Health employee, and has a legitimate reason to request the health record(s) (*Hospital and Health Boards Act 2011 (Qld)*).

Any other requests will be reviewed on a case by case basis. Externally published clinical audits are regarded as research. Please refer to [Research Governance \(Site Specific Assessment\) Procedure \(PR2017/116\)](#) for information on how to obtain research governance authorisation.

Students who are on placement within Metro South Health may also access health records following provision of a letter of approval from the area of enquiry department/divisional delegate, for the purposes of completing assignments which are part of their education; or for assisting Metro South Health staff in clinical audit activities as part of their placement. Students who access records as part of placement are bound by agreements (e.g. ClinEdQ) between the Metro South Health and the education provider.

All other requests for access to health records (electronic, paper based or hybrid) are reviewed on a case by case basis. Receipt of requests for records for research and clinical audit purposes are processed as a 'Non-Urgent Request'.

2.0 Electronic Medical Records (EMR)

2.1 Login

Login to the EMR is through the desktop icon or the enterprise application page on QHEPS. Access is gained using Novell credentials. The users' electronic signature (Novell login/password) is under no circumstances to be divulged to other persons. Novell passwords expire every ninety (90) days.

Staff request access to the EMR through the Self Service Centre, via QHEPS. All requests require approval from the nominated line manager and/or delegate prior to access being granted. Details required for this process include Novell login, payroll number, role description and AHPRA registration number (if applicable).

It is the responsibility of the line managers to ensure all new staff are able to fulfil the duties of their role by organising timely access and training to the EMR Digital Hospital Program.

2.2 Maintenance of access to the EMR

To ensure clinical information security managers are to remove access to the EMR and all clinical systems when a staff member leaves Metro South Health. Removal of access to the EMR and all clinical systems is to be requested through the Self Service Centre, via QHEPS.

2.3 Student access

All health students are able to be allocated a role within the EMR and access can be requested and authorised as per above. The only prerequisite is a Novell login, which can also be requested via the Self Service Centre. If a student is currently employed by Metro South Health, they should request a separate Novell Login to use whilst performing in a student capacity.

2.4 Agency Staff Access

Agency staff will need to gain access to the EMR when on a Metro South Health campus. Agency staff must follow the steps for access outlined in EMR General Business Rules. Metro South Health employees must not to log into EMR for agency staff using their own Novell login i.e. to allow them to view notes under their access.

2.5 Accessing Data Outside of an Employee's Facility/Service

2.5.1 Metro South Health Employee Access

Staff within the Metro South Health, who would like to access data outside of the service/facility, can apply for access to the EMR with approval from the Director of their clinical stream. An email detailing the approval from the Director is to be sent to Health Information Management Systems (HIMS). The staff member must then apply for access through the Self Service Centre, via QHEPS, nominating the Director, HIMS as the approver.

2.5.2 External User Access

All EMR access requests generated for external users such as Monitors or Auditors of the patient EMR record are to be approved by the Director, Health Information Management Systems (HIMS) and/or delegate in accordance with each Hospital's Procedures. For example, a Princess Alexandra Hospital employee must review the following procedures [Patient Information Access, Applications and Requests for Access \(60053/v4/07/2016\)](#) and [Confidentiality of Patient, Staff and Organisational Information \(60008/v7/07/2016\)](#).

In instances where external user access is required for research purposes, initial review and recommendation for the user's EMR access requirements is to be undertaken by the nominated Clinical Trial Co-ordinator/Responsible approver who will then apply for the access through the Self Service Centre, via QHEPS, nominating the Director, HIMS as the approver.

External users that have been approved for access must also complete and sign the 'Consumer & Community Representative- Confidentiality and Privacy Deed' (Attachment A). The signed deed is retained by the Clinical Trial Co-ordinator/Responsible approver.

It is recommended that:

- 'View Only' role be requested for all monitors and/or auditors.

Both Clinical Research Auditor and R2 Clinical Research Auditor roles provide single-site access and are read/view only.

External researcher access to authorised patient information is managed through the creation of a patient list within PowerChart. It is the responsibility of the nominated Clinical Trial Co-ordinator and/or Responsible approver to create a patient list and proxy this list to the external researcher. The external researcher's access to patient information is restricted to the proxy patient list only. Please see [PowerTrials - Electronic Medical Record Research Support Module Procedure \(PR2017/118\)](#) for more information.

If multi-site access is required this can be requested by logging a job through the Self Service Centre, via QHEPS. It is the responsibility of the approver to terminate access when no longer required.

If single site, partial record access is appropriate then a request is to be forwarded to HIMS for an EMR report extract of the appropriate information required. Access by patients or other areas not covered above, to digitised patient information is managed by the Health Information Management Service (HIMS) of the relevant Metro South Health service/facility.

2.6 Management of Inappropriate Access

HIMS has the ability to interrogate EMR access data to investigate and report on potential breaches. EMR access audits are conducted regularly by the HIMS, and may include (but are not limited to):

- Staff accessing patient records with the same name, family members of employees.
- Staff accessing patient records who are the subject of an event covered by recent media.
- Staff accessing records of high profile public figures.
- All access undertaken by an individual employee across a defined period.

2.7 Conflicts of Interest

Employees must make alternative arrangements if accessing EMR records of relatives, fellow staff or team members is required to perform their duties. Alternative arrangements include notifying the relevant supervisor and identifying another staff member who can undertake the task.

2.8 Management of a Breach

If a potential breach is identified the relevant line manager and/or delegate may meet with the Metro South Health employee to determine if a breach has occurred. Where a breach has occurred the relevant line manager and/or delegate may take appropriate action to reach a resolution. Where a resolution has not been reached the breach is escalated to the Director, HIMS or relevant facility/service Privacy Officer.

2.9 Specific requests for investigation

Specific requests to investigate a breach by staff or management are to be directed to the Director, HIMS or relevant Privacy Officer.

3.0 Integrity

3.1 Research Conduct

In Metro South Health, the Research Integrity Adviser is able to advise a staff member who is unsure about a research conduct issue and may be considering whether to make an allegation or a complaint about research. Please see Research Complaints and Misconduct Procedure (PR2017/124) for more information.

3.2 Authorship and Dissemination of Research Findings

Authorship must be formally certified or acknowledged before publications are submitted. Author eligibility and author order should be agreed upon as early as reasonably possible following the commencement of a research project. Please see Research Complaints and Misconduct Procedure (PR2017/124) for more information.

All Metro South Health authors are required to cite their institutional affiliation as 'The Metro South Hospital and Health Service'. Metro South Health will not, otherwise, be credited in any external analysis of publication data, which may lead to Metro South Health not receiving appropriate academic and financial recognition from the work of its staff, students and affiliates.

3.3 Failure to Handle Research Material and Data as Breaches of the Code

Metro South Health supports the [Australian Code for the Responsible Conduct of Research 2007](#) ("the Code"). Failure to handle research material and data as breaches of the code will be managed in accordance with Research Complaints and Misconduct Procedure (PR2017/124).

3.4 Creation of Datasets in Metro South Health

Researchers in Metro South Health who create datasets throughout research projects must acknowledge that this data remains the property of Metro South Health. Please refer to the Research Contracts and Study Execution Procedure (PR2017/122) for more information.