

Disclosure of unit record data by Local Health Districts for research or contractor services

Summary This Policy Directive provides guidance to Local Health District (LHD) staff on the procedure to be followed where identified or de-identified unit record data relating to the health of an individual or individuals is being released for the purpose of research or contractor services.

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DISCLOSURE OF UNIT RECORD DATA BY LOCAL HEALTH DISTRICTS FOR RESEARCH OR CONTRACTOR SERVICES

PURPOSE

This Policy Directive provides guidance to Local Health District (LHD) staff on the procedure to be followed where identified or de-identified unit record data relating to the health of an individual or individuals is being released for the purpose of research or contractor services.

MANDATORY REQUIREMENTS

All LHD staff must comply with this Policy Directive when releasing unit record data relating to the health of an individual or individuals in data collections held by LHDs for the purpose of research or contractor services. Unit record data may be released to parties outside the LHD, including other Local Health Districts, Pillar organisations, Universities and other organisations and individuals.

IMPLEMENTATION

This Policy Directive should be distributed to all LHD staff. Staff involved in release of unit record data must follow the procedure set out in this policy directive.

REVISION HISTORY

| Version | Approved by | Amendment notes |
|------------------------------|--|------------------------|
| January 2018 (PD2018_001) | Deputy Secretary, Population and Public Health | New Policy Directive. |

ATTACHMENT

Disclosure of Unit Record Data held by Local Health Districts for Research or Contractor Services: Procedure.

**Disclosure of unit record data by Local Health Districts
for research or contractor services**



Issue date: January 2018

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1 BACKGROUND

1.1 About this document

This Policy Directive refers to disclosure of identified or de-identified unit record data relating to the health of an individual or individuals, which are held in Local Health District (LHD) data collections, for the purpose of research or contractor services.

Health information may be disclosed under a range of legislation, including the *Health Administration Act 1982* and the *Health Records and Information Privacy Act 2002*. When disclosing to a third party for the purpose of research or contractor services, Local Health Districts must also comply with this policy.

This Policy Directive describes the process to be followed where information is being released for the purpose of research or contractor services procured by the LHD. This information may or may not include personal information. There are a range of other grounds recognised under the *Health Records and Information Privacy Act 2002* where personal health information may be lawfully disclosed, including where the person in question consents to the disclosure, or where there is a lawful obligation to disclose or the disclosure is made to prevent a serious threat to the health or welfare of an individual or individuals. Staff should refer to Section 11 of the NSW Health Privacy Manual for Health Information¹ to determine if a proposed disclosure may be authorised under these other exemptions.

1.2 Scope

This Policy Directive applies to identified or de-identified health records that are disclosed for the purposes of research or contractor services. The fundamental feature of a disclosure is that the data are released to a setting outside the direct control of the LHD. For the purpose of this policy, disclosure includes release to other Local Health Districts, universities, and all other organisations.

This Policy Directive covers identified or de-identified health data that are collected and held by the LHD. LHDs are not authorised to disclose the following health records:

- i) records collected for the purposes of the *Public Health Act 2010*, for example, data relating to notifiable conditions subject to PD2012_047 Notifiable Conditions Data Security and Confidentiality (http://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2012_047)
- ii) data collections comprising health records provided to the Ministry of Health by a third party where the Agreement between the parties specifically precludes disclosure to a third party. These include:
 - data collections provided by the Australian Bureau of Statistics, including Census data and the Cause of Death Unit Record File for NSW
 - Registry of Births, Deaths and Marriages birth and death registration records
- iii) linked datasets established under sections 97 and 98 of the NSW Public Health Act 2010 (Public Health and Disease Registers)

- iv) linked datasets that were established by use of clause 17(3)(d) of the Health Administration Regulation 2015
- v) data collections comprising health records that are managed by the Ministry of Health in accordance with the approval of a human research ethics committee

1.3 Key definitions

| | |
|---------------------------------|--|
| Data custodian | The person responsible for data storage and disposal, compliance of data with relevant legislation and policies, administration, quality assurance, and data access and release. |
| Disclosure | Release of unit record data outside of the Local Health District. This includes release to other Local Health Districts, universities, and all other organisations or individuals. |
| De-identified data | Information that is not Personal Information or Personal Health Information. |
| Human Research Ethics Committee | A committee constituted in accordance with NHMRC Ethics Committee guidelines, which protects the subjects of research and ensures that ethical standards are maintained by reviewing and advising on the ethical acceptability of research proposals. |
| Identified data | Personal Information or Personal Health Information. |
| Personal Information | Information or an opinion (including information or an opinion forming part of a database and whether or not recorded in a material form) about an individual whose identity is apparent or can reasonably be ascertained from the information or opinion. |
| Personal Health Information | <p>Personal Health Information means:</p> <ul style="list-style-type: none"> (a) Personal information that is information or an opinion about: <ul style="list-style-type: none"> (i) The physical or mental health or a disability (at any time) of an individual, or (ii) An individual's express wishes about the future provision of health services to him or her, or (iii) A health service provided, or to be provided, to an individual, or (b) Other personal information collected to provide, or in providing, a health service, or (c) Other personal information about an individual collected in connection with the donation, or intended donation, of an individual's body parts, organs or body substances, or (d) Other personal information that is genetic information about an individual arising from a health service provided to the individual in a form that is or could be predictive of the health (at any time) of the individual or of a genetic relative of the individual, or (e) Healthcare identifiers. |

| | |
|----------------------|---|
| Responsible Position | A position in an external organisation that is responsible for ensuring that unit record data supplied by the LHD are kept securely and in accordance with conditions of disclosure. |
| Unit record data | For the purpose of this policy directive 'unit record data' are electronic records of information that relate to the health of an individual, which are held by Local Health Districts. |

2 ETHICAL REVIEW PRIOR TO DISCLOSURE OF UNIT RECORD DATA THAT IS PERSONAL HEALTH INFORMATION

Applications for the release of unit record data comprising personal health information for the purposes of research should be submitted to a Human Research Ethics Committee (HREC).² Approval of an application by the HREC does not by itself constitute authority for disclosure of unit record data, but is a prerequisite for an authorisation for disclosure to occur.

There may be difficulties distinguishing research or management of health services from quality assurance activities, such as audits of data quality or adverse outcomes. Quality assurance activities should be referred to a HREC if one or more of the following triggers apply:³

- where the activity potentially infringes the privacy or professional reputation of participants, providers or organisation
- secondary use of data – using data or analysis from QA or evaluation activities for another purpose
- gathering information about the participant beyond that which is collected routinely. Information may include biospecimens or additional investigations
- testing of non-standard (innovative) protocols or equipment
- comparison of cohorts
- randomisation or the use of control groups or placebos
- targeted analysis of data involving minority/vulnerable groups whose data is to be separated out of the data collected or analysed as part of the main QA/evaluation activity.

There are specific requirements for ethical review of projects relating to Aboriginal people (see Section 5).

Data custodians may refer requests for release of unit record data to a HREC for advice as to whether the request should be formally referred to the HREC for consideration.

3 AUTHORITY FOR DISCLOSURE OF UNIT RECORD DATA

The authority to disclose unit record data is vested in the LHD Chief Executive. The Chief Executive may authorise a Tier 2 position within the LHD to exercise this delegation provided the authority is in writing and the authority is limited to information that is epidemiological data that does not identify any individual to whom the information relates.

Tier 2 officers authorised to release unit record data must not hold the position of data custodian. Separation of the authority for disclosure of data from the data custodian role is necessary to manage potential conflict of interest.

Other persons are not authorised to disclose unit record data for the purposes of research or contractor services.

Refer to the Disclosure of Information delegations in Combined Delegations Manual available from the Ministry of Health website.

4 THE LEGAL CONTEXT FOR DISCLOSURE OF UNIT RECORD DATA

There must be a legal basis for disclosure of unit record data. If there is uncertainty as to the legal basis for disclosure, the request should be referred to the Ministry's Legal and Regulatory Services Branch.

Disclosure of unit record data for the purpose of research or contractor services are governed by the following legislation:

i) **Health Records and Information Privacy Act (HRIP Act) 2002**

The HRIP Act and its Statutory Guidelines govern dealings with personal health information. For explanation of the definition of personal health information refer to the NSW Privacy Manual for Health Information at:

<http://www.health.nsw.gov.au/policies/manuals/Pages/privacy-manual-for-health-information.aspx>

The NSW Privacy Manual for Health Information also provides operations guidance to the legislative obligations imposed by the HRIP Act, and provides further detail on the regulation of personal health information.

Health Privacy Principle 11 of the Act relates to disclosure of personal health information.

<http://www.legislation.nsw.gov.au/maintop/view/inforce/act+71+2002+cd+0+N>

Statutory Guidelines exist under the HRIP Act for disclosure of health information for research. Compliance with these guidelines is required under the HRIP Act. The guidelines may be found at:

<http://www.ipc.nsw.gov.au/hrip-act>

Under the HRIP Act and its Statutory Guidelines, applications for the disclosure of unit record data comprising personal health information for the purposes of research should be submitted to an institutional HREC.

ii) [Health Administration Act 1982](#)

Section 22 of the *Health Administration Act 1982* relates to the disclosure of information that was obtained in connection with the administration or execution of this Act or any other Act conferring or imposing responsibilities or functions on the Minister, the Ministry of Health or the Director-General. Disclosure can only be made under certain circumstances, such as after obtaining consent from the person from whom the information was obtained, or in any other prescribed circumstances.

iii) [Health Administration Regulation 2015](#)

Clause 17 of the *Health Administration Regulation 2015* allows the Chief Health Officer to release epidemiological data and the Director-General of the NSW Ministry of Health to release other information. If the disclosure relates to information that may identify an individual and is for the purpose of medical research, the Director General must be satisfied that the research is being conducted in accordance with any guidelines of the National Health and Medical Research Council that the Director-General considers relevant. In practice, this means that approval of an HREC is required before disclosure can be authorised.

5 DISCLOSURE OF ABORIGINAL HEALTH INFORMATION

Due to the relatively small number of Aboriginal people in NSW specific guidelines for the release of Aboriginal health information are required to protect Aboriginal people from the risk of identification as individuals or communities. Disclosure of Aboriginal health information must comply with the NSW Aboriginal Health Information Guidelines.⁴

Proponents should submit projects to the NSW Aboriginal Health and Medical Research Council (AH&MRC) Ethics Committee if one or more of the following apply:

- the experience of Aboriginal people is an explicit focus of all or part of the research
- data collection is explicitly directed at Aboriginal peoples
- Aboriginal peoples, as a group, are to be examined in the results
- the information has an impact on one or more Aboriginal communities
- Aboriginal health funds are a source of funding

Information on making applications to the AH&MRC Ethics Committee may be found at the AH&MRC website at: <http://www.ahmrc.org.au/ethics.html>.

Further advice regarding release of Aboriginal Health Information can be obtained from the Centre for Aboriginal Health, NSW Ministry of Health.

6 DATA SECURITY

Data that are disclosed must be transferred using encryption technologies approved by the LHD. Accellion Secure File Transfer product is available for LHDs (<http://hseh.intranet.health.nsw.gov.au/it-support/sft>).

Communication standards such as email, FTP, telnet, Mobile SMS,

instant messaging and web traffic (HTTP) are not considered secure and should be avoided in accordance with NSW Health Policy Directive PD2013_033 *Electronic Information Security Policy - NSW Health*

(http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2013_033.pdf)

Data that are disclosed must be stored by the recipient in a secure fashion at all times. Acceptable secure storage includes storage on physically secure file servers that are configured in such a way that password protection is universally enforced, or in files that are encrypted by “strong” encryption software such as PGP, provided that the passwords used for encryption are also kept secure. The encryption offered by PkZip and other file compression utilities or by word processors, spreadsheets and other software that is not specifically designed to offer high-level encryption are inadequate and can be easily broken. Storage on portable media, laptops and desktop computer hard-drives is not acceptable.

7 PROCEDURE FOR PROCESSING REQUESTS FOR DISCLOSURE OF UNIT RECORD DATA

All applications for release of unit record data, including disclosures made under a contractual arrangement, whether the unit record data comprise personal health information or otherwise, should follow the procedure described below. The procedure is summarised in the flow chart shown at Appendix 1. Template documents for disclosure of data are shown in Appendix 2.

7.1 On receiving a request for disclosure of unit record data, the data custodian should consider the following:

- i) Whether aggregate data would be sufficient to meet the needs of the person making the request
- ii) Whether the request should be refused

Requests may be refused, but there should be reasonable grounds for this. Examples of reasonable grounds might include:

- There is no legal basis for the disclosure
- There is insufficient security for the data to be stored
- The organisation/person requesting the data does not have sufficient experience to reasonably be able to analyse the data and interpret the results.

- iii) Whether the request should be referred to a Human Research Ethics Committee

If the request is for personal health information, the request should be referred to the HREC.

If the request is for Aboriginal health information, consideration should be given as to whether the project should be submitted to the AH&MRC Ethics Committee, as described in Section 5. Information on the AH&MRC Ethics

Committee and the process for submitting applications may be found at:

www.ahmrc.org.au/ethics.html.

iv) Policy implications

Disclosure of unit record data will usually result in a publication or report at some time, which may or may not have policy implications for the LHD or the Ministry of Health. If the data release is likely to result in information being published that will have policy implications for the LHD or the Ministry of Health, or the data are of a particularly sensitive nature in terms of the policy context, the data custodian should discuss the data request with the relevant LHD Tier 2 officer and, if necessary, with the policy area in the Ministry of Health. The result of such a discussion might be that additional conditions are placed on the release of the information.

7.2 After consideration of the above, if ethics committee approval/advice has been obtained where appropriate, and a decision is made to support disclosure of the information, a brief should be prepared for approval of the data release.

7.2.1 Determine the person who will be accountable for the data at the external site (the "Responsible Position"). The data will be authorised to be released to the person in the Responsible Position. The Responsible Position must be a senior position in the external organisation with the authority to ensure the data are kept securely and in accordance with conditions of disclosure. The Responsible Position is not a position held by a data analyst, project officer, data manager or student.

7.2.2 Prepare a brief containing the following:

i) A cover sheet routing the brief to:

- the LHD data custodian
- the relevant policy area (where appropriate)
- the person delegated to approve the data release (see Section 3)

ii) An Approval for Disclosure of Information

The Approval templates shown at Appendix 2 contain a Schedule that specifies a set of conditions, which are a minimum. Any conditions imposed by a HREC should also be included. Additional conditions arising from consideration of policy implications may be included (see Section 7.1). If additional conditions are to be imposed, the terms should be negotiated with the organisation requesting the data prior to the Approval being submitted.

The Approval templates also contain a Schedule that specifies the data to be released. The Schedule should refer to the name of the data collection, the period of time to which the data relate, and the range of fields to be released. Where a project or scope of work is ongoing the end date for the data may be a future date.

If the unit record data to be released do not comprise personal health information, the data custodian should ensure that the data are released in such a way that minimises the chance of individuals being recognised or in some other way identified. Some options for doing this are:

- Minimising the range of fields to be released
- Avoid the disclosure of dates. For example, disclose age rather than date of birth, or length of hospital stay rather than date of admission and date of separation.
- Grouping categories. For example, age could be grouped into 5-year age groups or geographic areas grouped into larger areas.

Care should be taken when considering the disclosure of information concerning relatively small communities, where the chance of individuals being recognised may be greater than in large communities.

iii) A confidentiality undertaking

The confidentiality undertaking refers to the conditions described in the Approval for Disclosure. A copy of Section 22 of the *Health Administration Act* should be attached to the confidentiality undertaking. This can be found at: [Health Administration Act 1982](#)

iv) A covering letter to the person in the Responsible Position.

v) After the brief is approved and the Approval for Disclosure is signed, the letter and confidentiality undertaking may be sent to the Responsible Person.

vi) When the confidentiality undertaking has been signed and returned, the unit record data may be securely transferred (see Section 6) to a person within the external organisation who is nominated by the Responsible Person, such as the data analyst or data manager.

8 ADDITIONAL REQUIREMENTS FOR CONTRACTORS

Sections 6.4 and A.3.1 of the NSW Health Privacy Manual for Health Information¹ provide information on the types of provisions that should be included in a contract where data are transferred to an external contractor for work.

Where unit record data are disclosed for the purpose of contracted services, each contractor who has access to LHD unit record data must:

- sign the NSW Health Code of Conduct, which can be found at PD2015_049 http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2015_049.pdf
- sign a confidentiality agreement. A template confidentiality agreement is shown at Appendix 3.

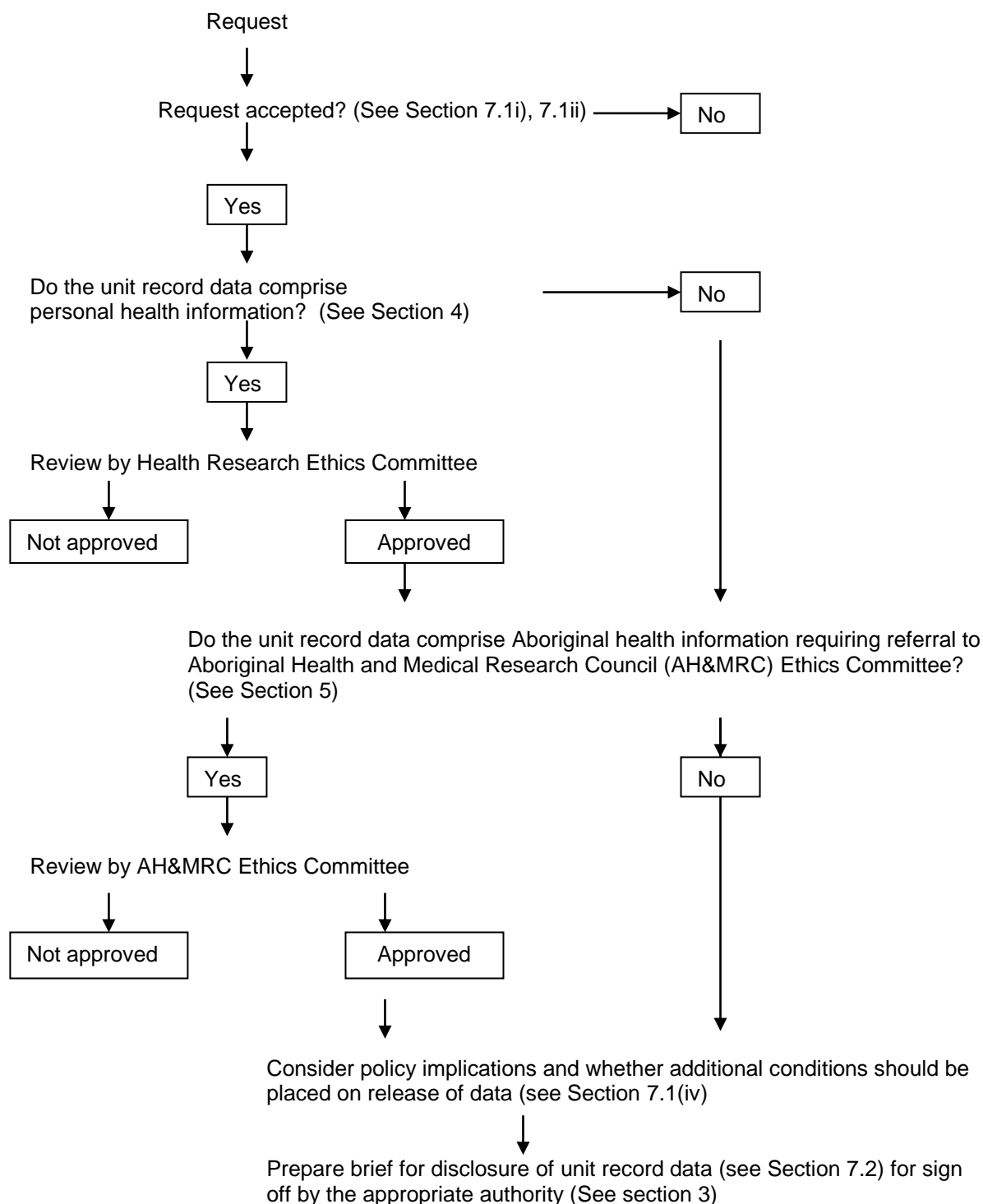
9 BREACH OF CONDITIONS

LHDs must establish procedures to manage potential breaches of conditions of disclosure of unit record data. An example is shown at Appendix 4.

10 REFERENCES

1. Privacy Manual for Health Information. Sydney: NSW Ministry of Health, 2015. Available at: <http://www.health.nsw.gov.au/policies/manuals/Documents/privacy-manual-for-health-information.pdf>
2. NSW Ministry of Health Policy Directive PD2010_055 *Ethical & Scientific Review of Human Research in NSW Public Health Organisations*. Available at: http://www1.health.nsw.gov.au/PDS/pages/doc.aspx?dn=PD2010_055
3. National Health and Medical Research Council. Ethical considerations in quality assurance and evaluation activities. Canberra: Commonwealth of Australia, March, 2014. Available at: www.nhmrc.gov.au/guidelines-publications/e111
4. New South Wales Department of Health. *NSW Aboriginal Health Information Guidelines*. Sydney, 1998. Available at: <http://www.ahmrc.org.au/media/resources/ethics/ethics-background-resources/281-nsw-health-information-guidelines/file.html>

APPENDIX 1: FLOW DIAGRAM FOR PROCEDURE FOR RELEASE OF HEALTH UNIT RECORD DATA FOR THE PURPOSES OF RESEARCH OR CONTRACTOR SERVICES



APPENDIX 2: TEMPLATE FOR DISCLOSURE OF UNIT RECORD DATA

HEALTH ADMINISTRATION REGULATION 2015

APPROVAL UNDER CLAUSE 17(2) - DISCLOSURE OF INFORMATION

I, **[NAME OF AUTHORISED PERSON]**, **[POSITION]** of **[SPECIFY]** Local Health District, pursuant to clause 17(2) of the *Health Administration Regulation 2010*, hereby approve the release of information described in Schedule 1 below, to **[NAME]**, **[POSITION]**, subject to the following conditions:

1. The conditions of data release outlined in Schedule 2.

[ADDITIONAL CONDITIONS MAY BE INCLUDED AS REQUIRED]

Signed this day of [YEAR]

.....

[NAME OF AUTHORISED PERSON]
[POSITION]

SCHEDULE 1

[IDENTIFIED/DE-IDENTIFIED] unit record data as follows:

1. A dataset of the [NAME OF DATA COLLECTION] comprising records relating to [CRITERIA FOR INCLUSION OF RECORDS] held by the [NAME OF BRANCH] of [SPECIFY] Local Health District for the period [DATE to DATE], including the following fields:
 - [LIST VARIABLES]

SCHEDULE 2

CONDITIONS OF DATA RELEASE

A breach of any of these conditions may result in further data access being restricted or current access being revoked:

1. The data are to be used only for [NAME OF PROJECT]
2. [WHERE APPROVAL IS SUBJECT TO THE APPROVAL OF A HUMAN RESEARCH ETHICS COMMITTEE] the project is carried out in accordance with the approved ethics application and all subsequent amendments
3. The data are to be kept in a secure physical and electronic environment that is accessible only by persons directly involved in the above project
4. A confidentiality undertaking will be completed prior to the information being released
5. The [NAME OF LHD] is to be acknowledged in any publication or report that arises from the use of the data
6. The data will not be matched with information on individuals from another source [WHERE APPROVAL IS SUBJECT TO THE APPROVAL OF A HUMAN RESEARCH ETHICS COMMITTEE] other than the datasets specified in the approved ethics application
7. A copy of any publication or report is to be provided to the [NAME OF LHD] at least two weeks prior to public release, emailed to [LHD EMAIL ADDRESS]
8. The data are to be destroyed after [NUMBER] years
9. No information will be released with which it may be possible to identify an individual person
10. Individuals identified in the data are not to be personally identified in any publication or report
11. The use of information on Aboriginal and Torres Strait Islander status is subject to the approval of the Aboriginal Health and Medical Research Council Ethics Committee if one or more of the following apply:
 - Aboriginality is a key determinant
 - Data collection is explicitly directed at Aboriginal peoples
 - Aboriginal peoples, as a group, are to be examined in the results
 - The information may have an impact on one or more Aboriginal communities
 - Aboriginal health funds are a source of funding.
12. This authority continues until and unless it has been revoked in writing

CONFIDENTIALITY UNDERTAKING

I, **[NAME]**, **[POSITION]**, understand that, in receiving unit record data of the **[NAME OF DATA COLLECTION]** Data Collection, I will have access to confidential data, which includes personal and health information in respect of individual persons.

I undertake strictly to preserve the confidentiality of these data, and understand that the disclosure of information may constitute an offence under section 22 of the *Health Administration Act 1982* (attached). I understand that I must comply with the conditions described in the Approval Under Clause 17(2) - Disclosure of Information.

I agree to ensure that any staff of **[NAME OF ORGANISATION]** working on the above project are aware of the provisions of this Undertaking and the need to comply with them. I further agree that any report that is derived from the data will present information in an aggregate form only and that no personal information, or personal health information, will be included in any report.

Signed:

in the presence of

(name):

(signature):

(position):

Date:

[NAME]
[POSITION]
[ADDRESS]

Dear [NAME]

I refer to your request for unit record data relating to [NAME OF DATA COLLECTION].

Under clause 17(2) of the *Health Administration Regulation 2015*, these data may be released with my approval. I am pleased to advise that access to the data has been granted for the purpose of [NAME OF PROJECT].

The release of this data is subject to the conditions set out in the attached instrument of approval and I ask that you read these conditions carefully. Also attached is confidentiality undertaking which will need to be completed and returned before the data are released.

Should you have any queries about the data release, please contact [NAME OF CONTACT] on [TELEPHONE NUMBER].

Yours sincerely

[NAME OF AUTHORISED PERSON]
[POSITION]

[DATE]

APPENDIX 3: TEMPLATE CONFIDENTIALITY AGREEMENT FOR CONTRACTED STAFF

CONFIDENTIALITY UNDERTAKING

I, **[NAME]**, **[POSITION]**, understand that, in having access to unit record data of the **[NAME OF DATA COLLECTION]** Data Collection, I will have access to confidential data, which includes personal and health information in respect of individual persons.

I undertake strictly to preserve the confidentiality of these data, and understand that the disclosure of information may constitute an offence under section 22 of the *Health Administration Act 1982* (attached). I understand that I must comply with the conditions described in the Approval Under Clause 17(2) - Disclosure of Information.

I further undertake to inform **[MY SUPERVISOR/ TITLE OF RELEVANT OFFICER]** immediately if I become aware of any breach of privacy or security relating to the information that I, or other staff, access in the course of my duties.

Signed:

in the presence of

(name):

(signature):

(position):

Date:

APPENDIX 4: PROCEDURE FOR RESPONSE TO A BREACH OF CONDITIONS BY A RESEARCHER OR CONTRACTOR FOLLOWING DISCLOSURE OF UNIT RECORD DATA

Introduction

A wide range of circumstances might potentially represent a breach of conditions of use of unit record data. Breaches may range from minor infringements such as failure to make proper acknowledgements in a publication, or failure to report changes in named staff working on the project, to serious breaches such as data being sold for commercial or personal gain, or data being unlawfully linked with personal information from another source in order to re-identify an individual.

Procedure

On becoming aware of any actual or possible breach of conditions the LHD Data Custodian will:

1. make inquiries to ensure that the full facts of the situation are available for consideration; and
2. provide the information to the relevant LHD Tier 2 officer.

The LHD Tier 2 Office will consider each situation on its merits, taking into account any previous breaches of conditions, and make a determination on one or more of the following actions:

1. No action (e.g. because the conclusion is that no breach took place).
2. A request for rectification of the circumstances causing the breach within a specified timeframe.
3. Counselling in the form of a warning.
4. A sanction, which may include:
 - revision of the project approval so as to require stricter conditions;
 - revoking project approval (with the requirement that all data files are returned or destroyed immediately);
 - barring the researcher(s) responsible for the breach from future access to data held by the LHD for a period of time or indefinitely;
 - revision of any other project approvals where the investigator is a named party, so as to require stricter conditions, or revoking approval;
 - reporting the researcher(s) responsible for the breach to employer(s) with a complaint of misconduct;
 - reporting the researcher(s) responsible for the breach to the funding agency that has supported the project with a complaint of misconduct; or

- where applicable, reporting the researcher(s) responsible for the breach to the appropriate statutory registration board (such as a medical, dental, nurses or psychologists board) with a complaint of misconduct; or
- reporting the researcher(s) responsible for the breach to the Ministry of Health Legal Branch with a recommendation to take legal action.

In the case of a breach of conditions imposed by a HREC, information on any actions considered or taken will be forwarded to the HREC.

The LHD Chief Executive will be advised where a breach of conditions has occurred involving possible or actual breach of individual privacy.