Data Collections – Disclosure of Unit Record Data for Research or Management of Health Services

Summary This Policy Directive refers to the disclosure of unit record data relating to the health of an individual or individuals, which are contained in data collections held by the NSW Ministry of Health, including those data collections that are managed by an external agency of behalf of the Ministry. It is mandatory that all NSW Ministry of Health staff comply with this Policy Directive.

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Applies to Ministry of Health

Distributed to Ministry of Health

Audience Staff of the Ministry of Health involved in the release of unit record data

Secretary, NSW Health

POLICY STATEMENT

DISCLOSURE OF UNIT RECORD DATA HELD BY THE NSW MINISTRY FOR HEALTH FOR RESEARCH OR MANAGEMENT OF HEALTH SERVICES

PURPOSE

This Policy Directive provides guidance to all NSW Ministry of Health staff on the procedure to be followed where unit record data is being released for the purpose of research or management of health services.

MANDATORY REQUIREMENTS

All NSW Ministry of Health staff must comply with this Policy Directive when releasing unit record data relating to the health of an individual or individuals that are held in data collections held by the NSW Ministry of Health, including those data collections that are managed by an external agency on behalf of the Ministry. The unit record data may be released to parties outside the NSW Ministry of Health, including Local Health Districts, Pillar organisation, Universities and all other organisations and individuals.

IMPLEMENTATION

This Policy Directive should be distributed to all NSW Ministry of Health 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
September 2015 (PD2015_037)	Deputy Director-General Population and Public Health	Updated guidance for quality assurance activities, approval for disclosure templates and conditions of data release to include conditions related to the use of Aboriginal data and use of the Cause of Death Unit Record File. Replaces PD2012_051
September 2012 (PD2012_051)	Deputy Director-General Population and Public Health	Updated templates and confidentiality agreement to reflect changes to the Public Health Act. Replaces PD2012_010
January 2012 (PD2012_010)	Deputy Director-General Population and Public Health and Chief Health Officer	Updated templates; additional advice on approval Section 8 and conditions of approval; updated confidentiality agreement. Replaces PD2006_077
October 2006 (PD2006_077)	Director-General	New Policy Directive

ATTACHMENT

Disclosure of Unit Record Data held in NSW Ministry of Health for Research or Management of Health Services: Procedure.

Disclosure of Unit Record Data held in NSW Ministry of Health for Research or Management of Health Services

NSW GOVERNMENT Health

PROCEDURES

Issue date: September-2015

PD2015_037

CONTENTS

1 BACKGROUND

1.1 About this document

This Policy Directive rescinds and replaces Policy Directive PD2012_051 *Disclosure of unit record data for research or management on health services*.

This Policy Directive refers to disclosure of unit record data relating to the health of an individual or individuals, which are held in data collections held by the NSW Ministry of Health, including those data collections that are managed by an external agency on behalf of the Ministry.

Health information may be disclosed for research or management of health services under a range of legislation, including the *Health Administration Act 1982*, the *Public Health Act 2010* and the *Health Records and Information Privacy Act 1982*.When disclosing to a third party under any of these Acts, in addition this policy must be complied with.

This Policy Directive describes the process to be followed where information is being released for the purpose of research or management of health services. This information may or may not include personal information. There are also however 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 health or welfare. Staff should also refer to Section 11 of the NSW Health Privacy Manual for Health Information (Version 3) IB2015_015 (http://www.health.nsw.gov.au/policies/manuals/Pages/privacy-manual-for-health-information.aspx) to identify if a proposed disclosure may be authorised under these other exemptions.

1.2 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 the Ministry of Health. This includes release to Local Health Districts, universities, and all other organisations or individuals
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.
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	Personal health information means: (a) Personal information that is information or an opinion about: (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.
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 NSW state data collections and held by the NSW Ministry of Health, including those data collections that are managed by an external agency on behalf of the Ministry.

2 DISCLOSURE ON A 'BACK TO NOTIFIER' BASIS

An organisation that has provided unit record data to the NSW Ministry of Health may request a copy of that information to be returned to them. This is called 'back to notifier' disclosure.

Unit record data may be returned to the original notifying agency without further approval, providing that the information returned does not contain additional personal information from another source. Enhancements to the unit record data such as grouping postcodes into health service areas or diseases into disease groupings are acceptable.

It is important to note that public health organisations own data that relate to patient attendances at public health services that they manage, and do not own data relating to people who live in the local area but who attended public health services managed by other organisations.

Other than a disclosure on a 'back to notifier' basis or disclosures made under a contractual arrangement, all applications for release of unit record data, whether the unit record data comprise personal information or otherwise, should follow the procedure described in section 8.

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

Other than a disclosure on a 'back to notifier' basis, applications for the release of unit record data comprising personal health information for the purposes of management of health services or research should be submitted to the NSW Population and Health Services Research Ethics Committee (PHSREC).[1] Approval of an application by the

PHSREC 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 Human Research Ethics Committee (HREC) if one or more of the following triggers apply:[2]

- 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
- Randomization 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.

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.

4 AUTHORITY FOR DISCLOSURE OF UNIT RECORD DATA

The authority to disclose unit record data is vested in:

i) The Director General or his / her delegate under the *Health Administration Act 1982*

ii) The Chief Health Officer (in the case of information that is epidemiological data that does not identify any individual to whom the information relates) under the *Health Administration Act 1982* and

iii) The Chief Health Officer for epidemiological data under the *Public Health Act 2010*.

The delegations under the *Health Administration Act 1982* can be found in the Section 10 of the Combined Delegations Manual on the Ministry's web site at:
http://www.health.nsw.gov.au/policies/manuals/Pages/combined-delegations.aspx

The delegations under the *Public Health Act 2010* can be found in the Section 8 of the Public Health Delegations Manual on the Ministry's web site at:
http://www.health.nsw.gov.au/policies/manuals/Pages/combined-delegations.aspx

Disclosure under the *Health Records and Information Privacy Act 2002* must be approved by the Secretary.

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

5 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 management of health 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.

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 the management of health services and 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

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

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 management of health services or research should be submitted to an institutional HREC.

ii) Public Health Act 2010

Section 130 of the *Public Health Act 2010* relates to the disclosure of information obtained in connection with the administration of the Act. It states that the disclosure can only be made under certain circumstances, such as with the consent of the person to whom the information relates, or in other prescribed circumstances.

Section 130(d) of the *Public Health Act 2010* allows the release of epidemiological data where there is approval from the Chief Health Officer or a person authorised by the Chief Health Officer. The person or persons and the kind of epidemiological data must be specified.

iii) 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.

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.

Clause 17(3)(d) permits the Secretary to approve disclosure of information that may identify an individual to the Centre for Health Record Linkage (CHeReL), or any other similar organisation approved by the Secretary, for the purposes of obtaining a unique identifier to be used for the funding, management, planning or evaluation of health services. Such an approval does not cover disclosure of a linked dataset of health information or personal health information by the linkage organisation and separate approval for creation and disclosure of the linked dataset are required.

6 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.[3]

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: www.ahmrc.org.au.

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

7 DATA SECURITY

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. Data should be strongly encrypted and password protected before being transferred electronically using Accellion Secure File Transfer.
http://internal.health.nsw.gov.au/ecsd/ssc/howdoi/Accellion-Secure-File-Transfer.pdf

8 PROCEDURE FOR PROCESSING REQUESTS FOR DISCLOSURE OF UNIT RECORD DATA

Other than a disclosure on a 'back to notifier' basis or disclosures made under a contractual arrangement, all applications for release of unit record data, 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.

Templates for disclosure of data collected under the *Health Administration Act* and the *Public Health Act* are shown in Appendix 2 and Appendix 3 respectively.

8.1 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 PHSREC.

If the request is for linked records, even if the records to be provided do not contain personal information, the request should be referred to the PHSREC.

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 6. Information on the AH&MRC Ethics Committee and the process for submitting applications may be found at: www.ahmrc.org.au.

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 NSW Ministry of Health. If the data release is likely to result in information being published that will have policy implications for the Ministry, 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 policy area in the Ministry. The result of such a discussion might be that additional conditions are placed on the release of the information.

8.2 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 containing the following:

i) A cover sheet routing the brief to:

- The data custodian, or all relevant data custodians where data linkage is involved
- Relevant policy area (where appropriate)
- Director, Legal Branch (if legal advice is sought)
- The person legally authorised to approve the data release

ii) An Approval for Disclosure of Information

The decision as to whether the disclosure should be approved under the *Health Administration Act* or *the Public Health Act* is made as follows:

- In general, approval for disclosure of information is made under the same legislation as the data are authorised to be collected. For example, if data are collected under the *Public Health Act*, then the template for approval of disclosure under the *Public Health Act* (Appendix 3) should be used.
- However, if the unit record data to be released comprise personal health information the template for approval of disclosure under the *Health Administration Act* (Appendix 2) should be used.
- Where data have been collected by some other authority than the provisions of the *Public Health Act* or the *Health Administration Act,* then the template for approval of disclosure under the *Health Administration Act* should be used (provided that the data was collected under an Act conferring responsibilities of functions on the Minister, the Director-General, the Ministry or the Health Administration Corporation).

Note that the Approval templates contain a Schedule that specified a set of conditions, which are a minimum. Any conditions imposed by an ethics committee should also be included. Additional conditions arising from consideration of policy implications may be included (see 8.1). If additional conditions are to be imposed, the terms should be negotiated with the organisation requesting the data prior to the Approval being submitted for approval.

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 duration of time to which the data relate, and the range of fields to be released.

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 the section of the relevant Act should be attached to the confidentiality undertaking. These can be found at:

Health Administration Act 1982 - Section 22

Public Health Act 2010 – Section 130

iv) A letter to the data recipient by the person authorised to approve disclosure.

After the submission is approved and the Approval for Disclosure is signed, the letter and confidentiality undertaking may be sent to the applicant. When the confidentiality undertaking has been signed and returned, the unit record data may be released.

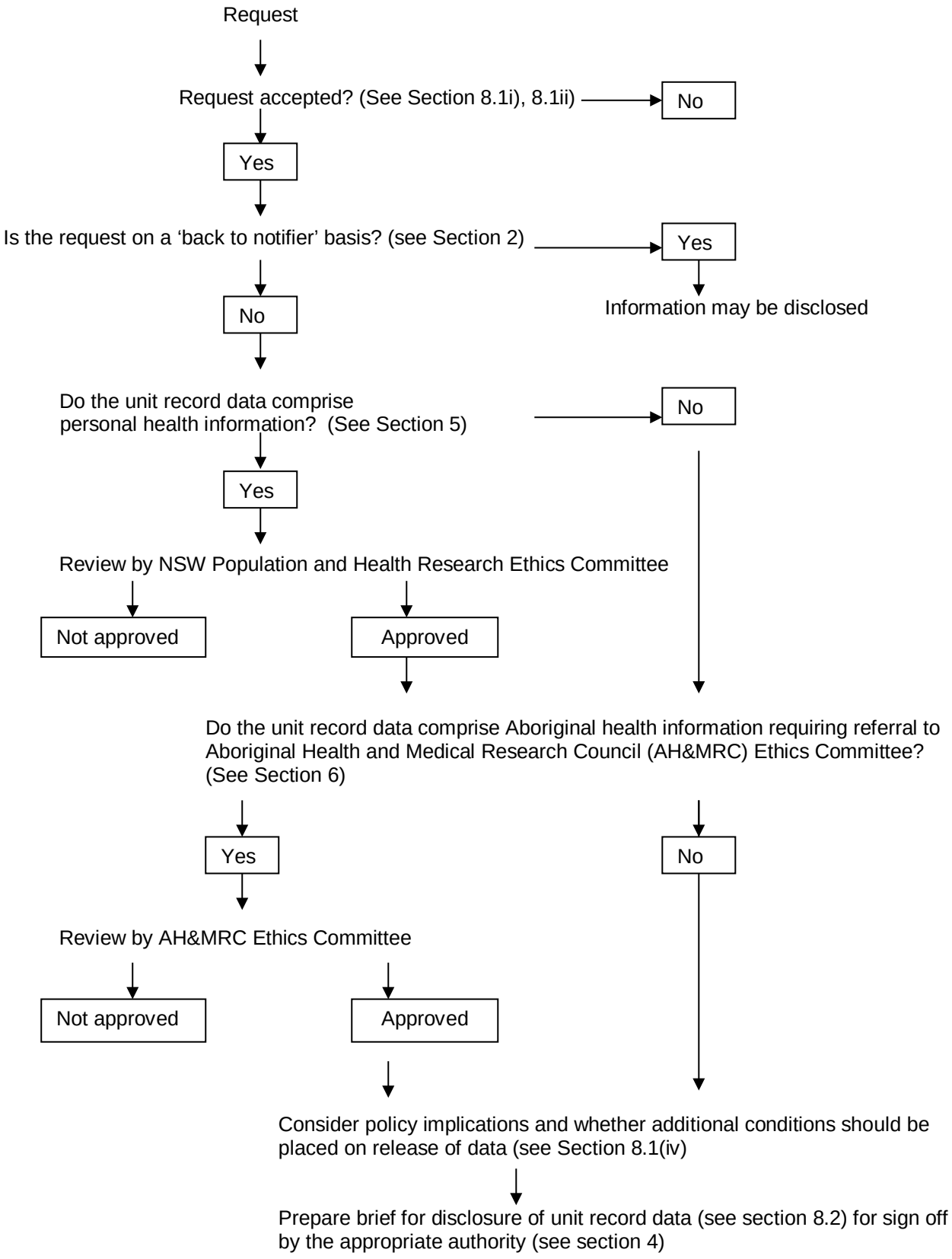
9 REFERENCES

1. NSW Ministry of Health Policy Directive PD2010_055 *Ethical & Scientific Review of Human Research in NSW Public Health Organisations.* Available at: www.health.nsw.gov.au/policies/pd/2010/PD2010_055.html

2. 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

3. New South Wales Department of Health. *NSW Aboriginal Health Information Guidelines.* Sydney, 1998. Available at: www.ahmrc.org.au/ethics2.php

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



11 APPENDIX 2: TEMPLATE FOR RELEASE OF UNIT RECORD DATA UNDER THE *HEALTH ADMINISTRATION ACT 1982*

HEALTH ADMINISTRATION REGULATION 2015

APPROVAL UNDER CLAUSE 17(2) - DISCLOSURE OF INFORMATION

I, **[NAME OF AUTHORISED PERSON]**, [POSITION] of the NSW Ministry of Health, 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

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 the New South Wales Ministry of Health for the period [DATE to DATE], including the following fields:

    - [LIST VARIABLES]

SCHEDULE 2

CONDITIONS OF DATA RELEASE

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 NSW Ministry of Health 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 Schedule/s
7. A copy of any publication or report is to be provided to the NSW Ministry of Health at least two weeks prior to public release, emailed to cermail@doh.health.nsw.gov.au
8. [WHERE APPROVAL IS SUBJECT TO THE APPROVAL OF A HUMAN RESEARCH ETHICS COMMITTEE] 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. [WHERE DATA ARE BEING PROVIDED IN THE FUTURE AS THEY BECOME AVAILABLE] this authority continues until and unless it has been revoked in writing

Additional conditions for use of linked data

12. [WHERE RECORD LINKAGE WAS CARRIED OUT BY THE CENTRE FOR HEALTH RECORD LINKAGE] the Centre for Health Record Linkage (where applicable) is to be acknowledged in any publication, report or presentation that arises from the use of the data

Additional conditions for use of information about Aboriginal people

13. The use of the 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.

Additional conditions for use of Cause of Death Unit Record File (COD URF)

14. A copy of any publication or report is to be provided to the to the Australian Coordinating Registry (ACR) for the COD URF at least two weeks prior to public release, emailed to BDM.CODURF@justice.qld.gov.au
15. Any publication, report or data output will include:
    - The following source: "Source: Cause of Death Unit Record File held by the NSW Ministry of Health Secure Analytics for Population Health Research and Intelligence" and
    - The following acknowledgement: "The Cause of Death Unit Record File (COD URF) is provided by the Australian Coordinating Registry COD URF on behalf of the NSW Registry of Births, Deaths and Marriages, NSW Coroner and the National Coronial Information System."
16. Securely destroy the data and notify the ACR within the timeframe specified in the ethics application or earlier as to the destruction (unless approval for extension or indefinite retention has been provided by the ACR/data custodians). Notification should be to the ACR, emailed to BDM.CODURF@justice.qld.gov.au, and to the NSW Ministry of Health, emailed to cermail@doh.health.nsw.gov.au
17. Acknowledge that these conditions continue to apply after projects end and/or approvals expire and will comply with any audit processes required to check the compliance of these and any additional conditions of approval
18. Acknowledge that a breach of any of these conditions may result in further data access being restricted or current access being revoked.

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*, such epidemiological 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]

12 APPENDIX 3: TEMPLATE FOR RELEASE OF UNIT RECORD DATA UNDER THE PUBLIC HEALTH ACT 2010

PUBLIC HEALTH ACT 2010

APPROVAL UNDER SECTION 130(d) - DISCLOSURE OF INFORMATION

I, **[NAME OF AUTHORISED PERSON]**, [POSITION] of the NSW Ministry of Health, pursuant to section 130(d) of the *Public Health Act 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

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 the NSW Ministry of Health for the period [DATE to DATE], including the following fields:

    - [LIST VARIABLES]

SCHEDULE 2

CONDITIONS OF DATA RELEASE

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 NSW Ministry of Health 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 Schedule/s
7. A copy of any publication or report is to be provided to the NSW Ministry of Health at least two weeks prior to public release, emailed to cermail@doh.health.nsw.gov.au;
8. [WHERE APPROVAL IS SUBJECT TO THE APPROVAL OF A HUMAN RESEARCH ETHICS COMMITTEE] 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. [WHERE DATA ARE BEING PROVIDED IN THE FUTURE AS THEY BECOME AVAILABLE] this authority continues until and unless it has been revoked in writing

Additional conditions for use of linked data

12. [WHERE RECORD LINKAGE WAS CARRIED OUT BY THE CENTRE FOR HEALTH RECORD LINKAGE] the Centre for Health Record Linkage (where applicable) is to be acknowledged in any publication, report or presentation that arises from the use of the data

Additional conditions for use of information about Aboriginal people

13. The use of the 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.

Additional conditions for use of Cause of Death Unit Record File (COD URF)

14. A copy of any publication or report is to be provided to the to the Australian Coordinating Registry (ACR) for the COD URF at least two weeks prior to public release, emailed to BDM.CODURF@justice.qld.gov.au
15. Any publication, report or data output will include:
    - The following source: “Source: Cause of Death Unit Record File held by the NSW Ministry of Health Secure Analytics for Population Health Research and Intelligence” and
    - The following acknowledgement: “The Cause of Death Unit Record File (COD URF) is provided by the Australian Coordinating Registry COD URF on behalf of the NSW Registry of Births, Deaths and Marriages, NSW Coroner and the National Coronial Information System.”
16. Securely destroy the data and notify the ACR within the timeframe specified in the ethics application or earlier as to the destruction (unless approval for extension or indefinite retention has been provided by the ACR/data custodians). Notification should be to the ACR, emailed to BDM.CODURF@justice.qld.gov.au, and to the NSW Ministry of Health, emailed to cermail@doh.health.nsw.gov.au
17. Acknowledge that these conditions continue to apply after projects end and/or approvals expire and will comply with any audit processes required to check the compliance of these and any additional conditions of approval
18. Acknowledge that a breach of any of these conditions may result in further data access being restricted or current access being revoked.

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 130 of the *Public Health Act 2010* (attached). I understand that I must comply with the conditions described in the Approval Under Section 130(d) - 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 section 130(d) of the *Public Health Act 2010*, such epidemiological 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 a 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]