

**HDI Microdata Access  
Protocol  
– Guide for External  
Researchers**

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## **Authors and acknowledgements**

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# Contents

Authors and acknowledgements	ii
Introduction	1
Background information	2
Definitions	2
Legislation, protocols and ethics guidelines	4
HDI Microdata Access Policy	6
Overall Principle – Access to microdata for research	6
Principle 1 – Data	6
Principle 2 – Purpose	7
Principle 3 – Researchers	7
Principle 4 – Quality	8
Principle 5 – Confidentiality	8
Principle 6 – Security	8
Principle 7 – Review, modification and audit	9
General terms and conditions	10
Datasets available for microdata research	12
Retention of datasets	12
Datasets for which HDI is not custodian	12
Non-standard datasets	12
Access to microdata for external researchers	13
Applying for access to microdata	13
Making decisions about access to microdata	14
Managing access to microdata	16
Dealing with disclosure	17
Review of HDI Microdata Access Protocol	18
Roles and responsibilities	19
Templates	21
Microdata Access Application Form for External Researchers	21
Annual Research Update	25
Appendices	26
A – Statistics Act 1975	26

B – Official Statistics System (OSS) Protocols	26
C – Privacy Act 1993	26
D – Health Information Privacy Code 1994	27
E – Official Information Act 1982	29
F – Health Act 1956	29
G – Health and Disability Commissioner Act 1994	29
H – Ethics guidelines	29
<b>References</b>	<b>33</b>

## List of Tables

Table 1: Roles and responsibilities	19
-------------------------------------	----

## List of Figures

Figure 1: Process for external researchers applying for access to microdata	15
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# Introduction

Health and Disability Intelligence (HDI) of the Ministry of Health is responsible for disseminating data collected in New Zealand Health Monitor (NZHM) surveys. Data are disseminated in many ways and the range of outputs includes descriptive reports, datacubes, journal articles, summary tables, maps and datasets.

HDI aims to maximise access to NZHM survey datasets and, where it is custodian, other datasets, while ensuring responsible use to protect individual information. Allowing carefully managed access to datasets is regarded as an important way of increasing the benefit gained from the data collected.

NZHM datasets are potentially available for statistical purposes to bona fide public good researchers working within academic institutions, government agencies and the wider health sector, subject to certain conditions. If surveys are carried out jointly with Statistics New Zealand, datasets are also held by Statistics New Zealand, and access is subject to the Statistics Act 1975.

The Official Statistics System (OSS) Principles and Protocols, good statistical practice and our ethical obligations to survey participants require that information collected through NZHM surveys and from other sources, particularly personal information that could be used to identify individuals, is treated as confidential and stored securely.

HDI must balance the benefits of data access with its obligations to hold data securely and protect the confidentiality of information supplied by individuals. Failing to adequately protect individual information potentially reduces public trust and confidence in HDI, the Ministry of Health and in wider government, which in turn affects the ongoing quality of data collections.

This document outlines HDI's policy for providing access to its NZHM microdata, and describes the way the protocol is implemented for external researchers. It covers the application and approval process for accessing microdata, and the monitoring of dataset use by external researchers.

This protocol is currently under review, and will be updated as required.

# Background information

## Definitions

### Microdata

Microdata are non-aggregated or unit record data about the population unit that was sampled.

### Datasets

In this document, sets of microdata are also referred to as datasets.

### Individual information

Individual information refers to information about a person or organisation participating in a survey.

### Privacy, confidentiality and security

These terms are often used interchangeably. The following definitions are adapted from OSS Protocols.

- Privacy refers to the ability of a person to control the availability of information about themselves.
- Confidentiality refers to the protection of individuals' and organisations' information, and ensuring that the information is not made available or disclosed to unauthorised individuals or entities.
- Security refers to how an organisation stores and controls access to the data it holds.

### Disclosure

Disclosure is the inappropriate release (accidental or otherwise) of confidential information about an individual or organisation participating in a survey. Confidentiality methods are applied to datasets available for research to reduce the risk of disclosure.

### HDI researchers

HDI researchers are staff requiring access to microdata to fulfil their regular operational function or undertake approved research. HDI staff, including contractors, seconded staff and collaborative partners, may be granted status as HDI researchers at the discretion of the HDI manager.

### External researchers

External researchers include all researchers who request access to HDI microdata, other than those people who have been granted status as HDI researchers.

External researchers include the lead researcher and members of the research team.

- The lead researcher is the principal investigator and takes overall responsibility for the process of accessing microdata, and ensuring that all members of the research team meet terms and conditions for access to microdata.
- The research team includes the lead researcher and all co-investigators.

### **Datasets available for research**

Original datasets are not available for internal or external research purposes.

Main Unit Record Files (MURFs) are derived from original datasets, but have had details that are likely to lead to spontaneous recognition of an individual removed. MURFs are available only to HDI researchers.

Confidentialised Unit Record Files (CURFs) are derived from MURFs, but have been modified further to protect individual information. CURFs are available on CD-ROM to approved external researchers for use outside HDI subject to certain terms and conditions.

### **Metadata**

Metadata is information about a dataset, for example, the method of data collection, and information about the variables and codes included in the dataset.

## **Legislation, protocols and ethics guidelines**

Official statistics are defined in the Statistics Act 1975 as statistics derived by government departments from:

- statistical surveys
- administrative and registration records, and other documents from which statistics are, or could be, derived and published.

Several pieces of legislation and other guidelines are relevant to official statistics. Excerpts that are relevant to accessing individual information are discussed here; however, these cannot be relied on without reference to the full documents, which should be consulted as necessary.<sup>1</sup>

### **Statistics Act 1975**

The work of agencies that produce official statistics is guided by the Statistics Act 1975, as well as other legislation. The Statistics Act sets out obligations on Statistics New Zealand to protect the confidentiality of information provided by persons and businesses. While other agencies providing access to their datasets are not subject to this part of the Act, unless it has been collected jointly with Statistics New Zealand, it provides an example of good practice with regard to security and confidentiality of statistical information. Relevant excerpts are included in appendix A.

### **Official Statistics System Principles and Protocols**

The OSS Principles and Protocols (Statistics New Zealand 2007) embody key aspects of the Statistics Act as well as the United Nations Fundamental Principles of Official Statistics. The OSS Principles and Protocols apply to Tier 1 statistics, which do not currently include NZHM surveys. However, agencies are encouraged to use the OSS Principles and Protocols for other official statistics.

The most relevant principle is Principle 7 – Protecting respondents' information, explained in appendix B.

### **Privacy Act 1993**

The Privacy Act 1993 is designed to promote and protect individual privacy. It establishes principles with respect to collection, use and disclosure of information relating to individuals. Relevant excerpts from the privacy principles that relate to storage and access to individual information are provided in appendix C.

While there are exceptions that permit use for statistical or research purposes, it is good practice to adhere to the principles where possible. The rules in the Health Information Privacy Code 1994 modify the principles of the Privacy Act for health information.

### **Health Information Privacy Code 1994**

This code sets out specific rules for agencies in the health sector to better ensure the protection of individual privacy. The code addresses the health information collected,

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<sup>1</sup> [http://www.legislation.govt.nz/browse\\_vw.asp?content-set=pal\\_statutes](http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes)

used, held and disclosed by health agencies. It modifies the information privacy principles in the Privacy Act by rules applying to health information and health agencies. These are outlined in appendix D.

### **Official Information Act 1982**

This Act makes official information more freely available, provides for proper access by each person to official information relating to that person, and protects official information to the extent consistent with the public interest and the preservation of personal privacy. See appendix E.

### **Health Act 1956**

There are minimal requirements in the Health Act about access to information. See appendix F.

### **Health and Disability Commissioner Act 1994**

The Code of Rights is a regulation issued under this Act. It sets out 10 rights applicable to all health and disability consumers, including those involved in research. The most relevant aspect for access to information is Right 1 – Right to be treated with respect. One of its points states that ‘Every consumer has the right to have his or her privacy respected’. See appendix G for details.

### **Ethics Guidelines**

Health and disability ethics committees are established in statute, under section 11 of the New Zealand Public Health and Disability Act 2000. A statutory basis gives the committees a clear source of public authority in the exercise of their functions, as well as a clear line of accountability to parliament. A number of guidelines are available to assist their work. Excerpts from both of the following documents are included in appendix H.

### **Operational Standard**

The Operational Standard for Ethics Committees (Ministry of Health 2006) provides guidance on principles that should be considered when reviewing research proposals, and sets out consistent operational and administrative procedures common to all ethics committees.

### **Ethical Guidelines for Observational Studies**

The National Ethics Advisory Committee has developed guidelines on conducting observational studies in an ethical manner that are intended to facilitate high-quality studies, protect the interests of participants, and underpin public assurance of good study conduct (National Ethics Advisory Committee 2006).

### **Public Records Act 2005**

The Public Records Act is relevant to long-term retention and disposal of records, not to providing access to active datasets.

# HDI Microdata Access Policy

The HDI Microdata Access Policy consists of an overall principle, and seven key principles relating to data, purpose, researchers, quality, confidentiality, security and review and modification.

## Overall Principle – Access to microdata for research

HDI will make high-quality microdata available for research:

- as widely as practicable
- as soon as possible
- in as much detail as possible

while ensuring all legislative and ethical obligations governing access to, and safekeeping of, individual information are followed.

## Principle 1 – Data

- 1.1 Any microdata of suitable quality that is owned or managed by HDI is **potentially** eligible for research use.
- 1.2 Datasets will be produced in accordance with Principle 4 (Quality) and Principle 5 (Confidentiality).
- 1.3 Datasets will be made available within a reasonable time following data collection so that any research is applicable and relevant. A standard CURF (Confidentialised Unit Record File) will be produced after the release of descriptive statistics. Microdata access will not be provided to external researchers in advance of the CURF.
- 1.4 Access to non-standard datasets is subject to formal review based on the level of demand, availability of resources and confidentiality risk.
- 1.5 Where HDI does not have the authority to provide access to datasets, access is subject to the agreement of the data owner, including any additional terms, conditions and processes specified by the data owner.
- 1.6 A list of datasets available to external researchers will be kept up-to-date and published on the HDI website.
- 1.7 No ownership of datasets is conferred on researchers.
- 1.8 Where datasets are no longer considered suitable for research use they may be withdrawn from access and will be disposed of (archived or destroyed) in line with the Public Records Act 2005.

## **Principle 2 – Purpose**

- 2.1 Research must not be inconsistent with the purposes for which the data were collected.
- 2.2 Research must be for public good purposes, with clear value and benefits for New Zealand. Access to microdata is not permitted where people or organisations stand to gain commercially.
- 2.3 The value of using microdata rather than other sources of information must be shown.
- 2.4 Research must be achievable using the dataset (ie, it must be valid and possible), based on scientifically sound methodology, and satisfy any appropriate research ethics requirements.
- 2.5 Research results must be made publicly available. HDI must be informed prior to the dissemination of results, such as publications and presentations, in order to be aware, in advance, of potential public interest.
- 2.6 Researchers are expected to commit to undertaking research and disseminating results in a timely manner.

## **Principle 3 – Researchers**

- 3.1 Researchers proposing research consistent with Principle 2 (Purpose) are eligible to apply for access to microdata, subject to the following criteria:
  - they are connected to a recognised organisation
  - they have a proven history of public good research or are supervised by a person with a proven history of public good research
  - the research team includes a researcher (statistician/analyst) with recognised skills in analysing complex survey datasets
  - a student is not the lead researcher.
- 3.2 HDI staff, including contractors, seconded staff and collaborative partners may access MURFs and CURFs, at the discretion of the HDI manager. All other researchers may access CURFs, in accordance with this policy.
- 3.3 Access to microdata is a privilege not a right. In collecting the data, HDI has an obligation to individuals to protect their information. All researchers must agree to accept these obligations by adhering to terms and conditions of access. Failure to do so will result in penalties, which may include publication of details relating to any breach and a restriction on access in future.
- 3.4 The process for making decisions on access to microdata will be transparent.

## **Principle 4 – Quality**

### **Quality of datasets**

- 4.1 Datasets provided to researchers will be high quality, containing as much detail as possible, notwithstanding the need to safeguard individual information.
- 4.2 Datasets will be supported by sufficient metadata to allow appropriate research.

### **Quality of outputs**

- 4.3 Researchers must produce good quality outputs that are subject to acceptable quality assurance processes.
- 4.4 Researchers must follow any quality rules and statistical obligations stipulated in the metadata, by HDI and/or by the data owner.

## **Principle 5 – Confidentiality**

### **Dataset confidentiality**

- 5.1 The confidentiality of individual information will be maintained by modifying datasets to reduce disclosure risk in accordance with HDI disclosure control rules, as outlined:
  - MURF datasets will have all details removed that are likely to lead to spontaneous recognition of an individual.
  - CURF datasets will be further modified, using standard techniques and processes, such that the identification of individual information is unlikely without a disproportionate amount of time, effort and expertise on behalf of an intruder.

### **Output confidentiality**

- 5.2 Researchers must apply any confidentiality rules stipulated in the metadata, by HDI and/or by the data owner, before outputs are released.
- 5.3 In addition, researchers must ensure that outputs are presented in such a way that individual information is safeguarded should dataset modification and confidentiality rules be insufficient protection.

## **Principle 6 – Security**

Despite steps taken to confidentialise data, it is important to also protect the security of datasets in the event that the dataset modification is insufficient and to prevent public concerns or perceptions about how individual information is being used.

- 6.1 Researchers will maintain the security of individual information by complying with relevant terms and conditions with regard to access, use, storage and disposal of datasets.

## **Principle 7 – Review, modification and audit**

- 7.1 This policy will be updated as required and formally reviewed one year after promulgation to ensure it remains relevant and workable for both HDI and researchers.
- 7.2 Any variation or exception to this policy outside a formal review will be subject to a formal decision by the HDI manager, which will be documented and publicised.
- 7.3 HDI will periodically undertake an audit of a small number of external research projects.

# General terms and conditions

An application to access a CURF assumes that external researchers agree to comply with the following general terms and conditions.

1. The organisation responsible for the research team must enter into a Microdata Access Agreement with HDI, which sets out specific terms and conditions. The lead researcher must send a copy of the signed Microdata Access Agreement to HDI, retain the original on file and make it available for audit, as required.
2. The lead researcher and all members of the research team must sign an External Researcher Undertaking to be granted status as authorised researchers. The lead researcher must send a copy of the signed External Researcher Undertakings to HDI, retain the originals on file and make them available for audit, as required. The lead researcher must advise HDI when a new researcher joins the research project.
3. The lead researcher must also sign a Lead Researcher Undertaking, which outlines additional obligations they must comply with as lead researcher. The lead researcher must send a copy of the signed Lead Researcher Undertaking to HDI, retain the original on file and make it available for audit, as required.
4. The research team will be responsible for all research undertaken. No support will be provided by HDI staff unless they are formal collaborators on a project, apart from that necessary to ensure that sufficient information is available to allow the proposed research to be undertaken.
5. The CURF can only be used for the research project described in the Microdata Access Agreement.
6. No attempts are to be made to data-match or identify individuals in the CURF.
7. Security of datasets used off-site
  - The CURF and any outputs, which are not sufficiently confidentialised, may be accessed only by authorised researchers.
  - Limited copying of the CURF may be made where reasonably required to permit the research.
  - All researchers are to ensure the safe storage of the CURF, any part of it, and any printout. Safe storage means the data are protected from accidental or deliberate access by unauthorised people, either physically or electronically, for example, storing the CD-ROM and printouts in a locked cabinet and password protecting electronic data.
  - At the conclusion of the research, electronic copies of CURF datasets, any parts, and any insufficiently confidentialised outputs must be destroyed. The lead researcher must verify this in writing in their final update. The hard copy CD-ROM must be returned to HDI.
8. Output confidentiality
  - Researchers are responsible for output confidentiality.

- Researchers must apply any confidentiality rules stipulated in the metadata, by HDI and/or the data owner, before outputs are released.
- Researchers must actively consider whether outputs could be a disclosure risk even with the confidentiality rules applied and take further steps to protect the output if necessary.
- Outputs cannot be provided to anyone who is not an authorised researcher with the project unless they have been sufficiently confidentialised.

#### 9. Breaches in security or confidentiality

- The lead researcher is responsible for immediately advising HDI about any breach of confidentiality or security.
- Breaches that are deliberate or a result of a lack of due care may result in the termination of access and affect future access requests.

#### 10. Output quality

- Researchers are responsible for the quality of all analytical outputs.
- Researchers must follow any statistical obligations and quality rules (eg, including confidence intervals with point estimates, suppression of cells known to be of low quality) stipulated in the metadata, by HDI and/or the data owner.

#### 11. Results of research

- The lead researcher must agree to a reasonable timeframe for completing the research and publishing results.
- All results must include an acknowledgement that the Crown is the owner of the copyright of the data and the Ministry of Health is the funder of the data collection.
- All results must include a disclaimer indicating that the researchers take full responsibility for the outputs. For example, *The results presented in this paper are the work of the authors.*
- The lead researcher must send copies of results, publications and presentations to HDI at least one week **prior to dissemination**, so that HDI is informed before any public interest is generated. Failure to do so could affect current and future access to HDI microdata.
- HDI will publish links to results on its website.

12. The lead researcher must provide an **annual update** of progress, covering what was achieved in the previous year, what results were published, what is planned for the next year, and a list of the current research team.

13. At completion of the research, the lead researcher must return the CURF dataset(s), confirm in writing that all confidential material has been destroyed, and provide details of all published or forthcoming results (even where already advised). Researchers are also welcome to provide comments on their experiences with accessing the CURF.

## **Datasets available for microdata research**

An up-to-date list of CURF datasets currently available to external researchers for microdata access will be published on the HDI website. The following metadata will also be published:

- objectives of data collection
- summary of design and methods
- outline of content and copy of the questionnaire (where relevant)
- size of dataset and available formats
- any requirements for approval by other parties and any additional terms and conditions imposed on access
- disclosure control processes (where possible) and any potential limitations due to this process
- links to key documents.

### **Retention of datasets**

CURF datasets that are no longer considered suitable for research use may be withdrawn from access. For example, datasets may be no longer considered suitable because of age or because they have become a confidentiality or security risk through environmental or technological changes.

Once their original purpose is no longer relevant, datasets should be disposed of according to the Public Records Act 2005 requirements, and either destroyed or archived as appropriate. Affected researchers should be consulted when withdrawal of datasets is being considered.

### **Datasets for which HDI is not custodian**

Where HDI does not have the authority to provide access to datasets, access is subject to the agreement of the data owner, including any additional terms, conditions and processes specified by the data owner.

### **Non-standard datasets**

Access to non-standard datasets is subject to formal review based on level of demand, availability of resources and confidentiality risk.

Where a researcher requests a non-standard CURF, such as modifications to an existing CURF, it will be resubmitted to the HDI CURF creation process, including an initial assessment of the feasibility of CURF creation.

All additional costs will be recovered from the researcher, even if the decision to create the CURF is unsuccessful.

# Access to microdata for external researchers

## Applying for access to microdata

External researchers are required to apply for access to CURFs. Access to microdata is subject to the application being approved, a Microdata Access Agreement between HDI and the lead researcher's organisation being signed, all members of the research team signing an External Researcher Undertaking, and the lead researcher signing a Lead Researcher Undertaking.

It is the lead researcher's responsibility to ensure that the process described below is followed.

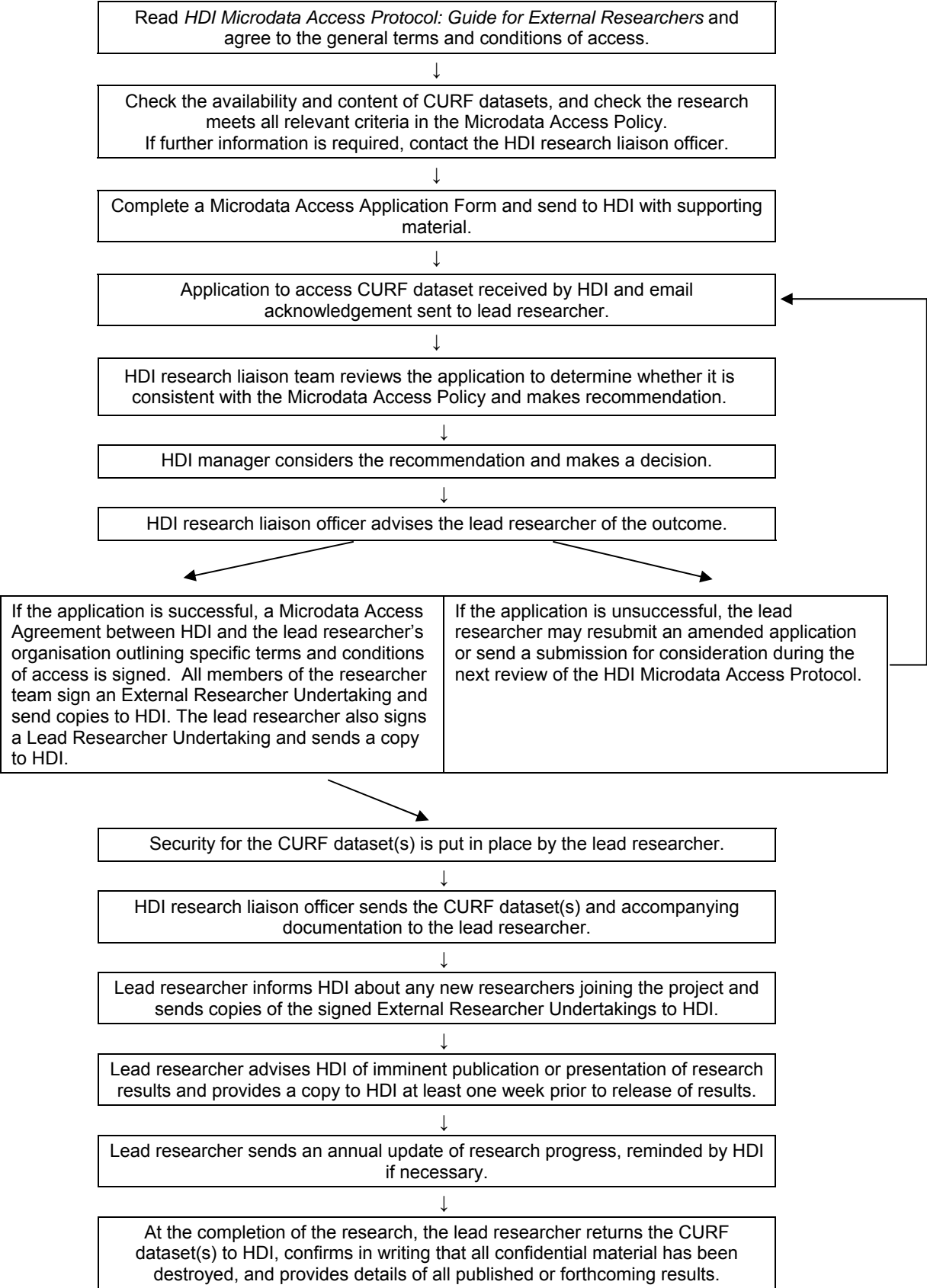
1. Read *HDI Microdata Access Protocol: Guide for External Researchers*, which is available on the HDI website. This outlines HDI's Microdata Access Policy, general terms and conditions for microdata access, and the process for requesting access to microdata. An application to access a CURF assumes researchers agree to comply with general terms and conditions for microdata access.
2. Check the availability and content of the CURF dataset(s) of interest. This involves:
  - a. consulting the list of datasets available to determine whether a dataset is available as a CURF
  - b. checking the information provided about the CURF dataset to ensure that the data are available to support the proposed research.
3. Check the fit between the proposed research and the purposes for which the data were collected to ensure that these are not inconsistent (Policy Principle 2 – Purpose).
4. Check that criteria for researcher access to the dataset are met (Policy Principle 3 – Researchers).
5. Contact the HDI research liaison officer with any queries.
6. Complete a **Microdata Access Application Form** with supporting material attached, including:
  - a. CVs for lead researcher and statistician/analyst
  - b. a declaration signed by an authorised delegate of the organisation, who is not one of the researchers, indicating support for the research and confirming that the researchers will abide by the terms and conditions of access
  - c. any other relevant background material.
7. Send the completed application form and supporting material to the HDI research liaison officer.

## **Making decisions about access to microdata**

Upon receiving the application form and supporting material from an external researcher, HDI will undertake the following steps.

1. Acknowledge receipt of the application and advise the applicant approximately how long the decision process is likely to take.
2. The HDI research liaison team (which includes the HDI research liaison officer) will consider the application and complete the Microdata Application Assessment Form with their recommendation. They will consider whether the application is consistent with the principles in the HDI Microdata Access Policy:
  - a. dataset availability
  - b. compliance with purpose and researcher criteria
  - c. likely quality (of outputs)
  - d. security or confidentiality concerns.
3. The HDI research liaison team will, if necessary, discuss any issues with a wider group of experienced staff.
4. The HDI manager will consider the recommendation and make a decision.
5. HDI will then advise the lead researcher of the outcome.
6. If the application is successful, the lead researcher's organisation must sign a Microdata Access Agreement with HDI that outlines specific terms and conditions. All members of the research team must sign an External Researcher Undertaking, and in addition, the lead researcher must sign a Lead Researcher Undertaking.
7. If the application is unsuccessful, the lead researcher may resubmit an amended application or send a submission to the HDI manager for consideration during the next review of the HDI Microdata Access Protocol.

**Figure 1: Process for external researchers applying for access to microdata**



## Managing access to microdata

1. HDI will maintain records of all requests to access to microdata, regardless of whether the application was successful or not. The records should include electronic and/or hard copies of the following forms:
  - Microdata Access Application Form
  - Microdata Application Assessment Form
  - signed Microdata Access Agreement
  - signed External Researcher Undertakings
  - signed Lead Researcher Undertaking
  - completed Annual Research Updates from the lead researcher
  - CURF creation and release forms for a non-standard CURF
  - copies of results publicly disseminated (including presentations and publications)
  - notes on any issues.
2. HDI will advise the lead researcher at least two weeks in advance when an annual update is due, and will contact the lead researcher if an update is not provided in accordance with the Microdata Access Agreement.
3. HDI will periodically undertake an audit of a small number of current research projects using CURFs. The audit will involve an on-site visit with the lead researcher, checking original signed External Researcher Undertakings, reviewing the physical and electronic security of the CURF dataset and reviewing progress of the research.

In the case of overseas research, an audit will involve a video-conference at the expense of the researchers.
4. HDI will publish on their website a register of all approved research projects, including the names of the research team, a brief summary of the research project, and links to all published results.

## Dealing with disclosure

In the event of a breach in confidentiality or security, the following steps must be taken.

1. It must be immediately reported to the HDI manager.
2. HDI staff unrelated to the incident should investigate the details and assess the impact of the incident and its seriousness.
3. HDI staff must forward recommendations about appropriate actions to the HDI manager.
4. The HDI manager is to approve proposed action to remedy the breach and impose any appropriate penalties. Penalties will be imposed in accordance with legal and ethical requirements, and with consideration of the potential impact on public trust and confidence in HDI.

The process will be transparent, except where publicising the incident could result in a further breach.

# Review of HDI Microdata Access Protocol

The HDI Microdata Access Protocol will be updated as required and formally reviewed within one year of implementation. The formal review process is outlined below.

1. Documentation of any issues that arise related to the protocol throughout the year.
2. Summary of any breaches in security or confidentiality.
3. Consultation with researchers using microdata (selected representatives) and any researchers sending a submission after having submitted an unsuccessful application for comments on:
  - any problems or issues with datasets – availability, content, timeliness, quality
  - any problems encountered using the data
  - any issues associated with obtaining access
  - compliance with security and confidentiality rules.
4. Consultation with HDI researchers with access to microdata on similar issues.
5. Summary of microdata access requests, including those that were refused.
6. Consultation with staff involved in producing datasets for comments on any problems encountered and suggestions for improvements.
7. Consultation with staff involved in access decisions about any problems encountered and suggestions for improvements.
8. Consultation with staff involved in managing access about any problems encountered and suggestions for improvements.
9. Consultation with management on the overall outcome of providing researcher access to data from the perspective of HDI and Ministry of Health, compared with the benefits obtained from the research.

The findings of the review should be used to amend the protocol as necessary. After the first review, the protocol will be reviewed every two years.

# Roles and responsibilities

The roles and responsibilities of HDI and researchers are outlined in Table 1.

**Table 1: Roles and responsibilities**

Role	Responsibilities
HDI manager	<ul style="list-style-type: none"> <li>• Approve the HDI Microdata Access Protocol.</li> <li>• Make decisions about variations to policy.</li> <li>• Agree to the creation of a new CURF.</li> <li>• Approve release of a new CURF.</li> <li>• Approve applications to access microdata.</li> <li>• Sign a Microdata Access Agreement with the lead researcher’s organisation.</li> <li>• Decide on required annual audits.</li> <li>• Request staff to investigate reported breaches.</li> <li>• Approve proposed action to deal with a breach.</li> <li>• Instigate protocol reviews.</li> <li>• Contribute to reviews of the protocol.</li> </ul>
HDI research liaison officer	<ul style="list-style-type: none"> <li>• Keep dataset lists up-to-date and available with input from data custodian.</li> <li>• Liaise with external researcher to ensure they have relevant information and documents.</li> <li>• Acknowledge applications for access from external researcher.</li> <li>• Assess applications from external researcher for access to CURFs, consulting other staff as necessary.</li> <li>• Advise external researcher of the outcome of their application.</li> <li>• Monitor access by external researchers and evaluate ongoing need for access.</li> <li>• Remind lead researcher when an annual update is due.</li> <li>• Publish research results on the HDI website.</li> <li>• Organise annual audits as directed by the HDI manager.</li> <li>• Maintain records associated with microdata access.</li> <li>• Maintain templates.</li> <li>• Seek independent advice and review about microdata access from other agencies as required.</li> <li>• Contribute to reviews of the protocol.</li> </ul>
HDI research liaison team	<ul style="list-style-type: none"> <li>• Assess applications from external researcher for access to CURFs, consulting other staff as necessary.</li> <li>• Assist the HDI research liaison officer with their roles and responsibilities.</li> </ul>
HDI staff	<ul style="list-style-type: none"> <li>• Review application assessment forms as required.</li> <li>• Advise HDI manager of any breach of security or confidentiality.</li> <li>• Investigate security or confidentiality breaches at the request of the HDI manager and make recommendations on appropriate actions.</li> <li>• Contribute to reviews of the protocol.</li> </ul>
Lead researcher	<ul style="list-style-type: none"> <li>• Be conversant with the HDI Microdata Access Protocol.</li> <li>• Check that HDI microdata is available and suitable to their proposed research.</li> <li>• Check that proposed research aligns with the HDI Microdata Access Policy.</li> <li>• Complete a microdata access application form, and provide relevant supporting information.</li> <li>• Sign an External Researcher Undertaking.</li> <li>• Sign a Lead Researcher Undertaking.</li> </ul>

	<ul style="list-style-type: none"> <li>• Ensure all researchers on their research project are aware of, and abide by, their obligations under the terms and conditions and sign an External Researcher Undertaking.</li> <li>• Remove access for any researcher no longer involved in the research project and notify HDI of any new researchers.</li> <li>• Immediately report any security or confidentiality breaches to HDI.</li> <li>• Advise HDI of the imminent release of research results, such as publications and presentations, and provide a copy to HDI at least one week prior to release.</li> <li>• Fully comply with any audit of microdata access by HDI.</li> <li>• Send annual research progress updates to HDI.</li> <li>• Return the CURF dataset(s) with the final update and confirm in writing that all confidential material has been destroyed.</li> <li>• Contribute to reviews of the protocol (if requested).</li> </ul>
Research team	<ul style="list-style-type: none"> <li>• Sign an External Researcher Undertaking.</li> <li>• Abide by the External Researcher Undertaking, specific terms and conditions in the Microdata Access Agreement and general terms and conditions of the HDI Microdata Access Protocol.</li> <li>• Contribute to reviews of the protocol (if requested).</li> </ul>
Authorised delegate of the lead researcher's organisation	<ul style="list-style-type: none"> <li>• Affirm their organisation's support for the research and that the research team will abide by terms and conditions of access.</li> <li>• Sign a Microdata Access Agreement with HDI.</li> <li>• Assist with the investigation and resolution of any issues associated with microdata access.</li> </ul>

## Templates

Copies of templates for external researchers follow. Electronic copies of these templates can be downloaded from the HDI website. Templates should be completed electronically (except for signatures). Note that once completed, templates may take up several pages.

### Microdata Access Application Form for External Researchers

This template is to be completed by the lead researcher requesting access to HDI microdata. An electronic copy of this template is available on the HDI website.

The lead researcher must undertake the necessary checks before submitting an application form.

The application form should be completed electronically (except for signatures). Note that once completed, the application is expected to take up more pages than indicated on the template.

<i>Lead researcher</i>	
Lead researcher*	
Department/section	
Organisation	
Mailing address	
Physical address for courier mail	
Telephone	
Fax	
Mobile phone	
Email	

<i>Research team</i>	
Name	
Organisation	
Role	Statistician/analyst**
Name	
Organisation	
Role	
Name	
Organisation	
Role	
Name	
Organisation	
Role	
Name	
Organisation	
Role	

\* Lead researcher cannot be a student.

\*\* Research team must include a statistician/analyst. Please also include the role and name of all associate researchers or collaborators, including students.

<b>Research project details</b>	
<b>Research project title</b>	
<b>Background</b>  (Include justification for needing microdata, and value and benefits of research to New Zealand.)	
<b>Research objectives</b>	
<b>Research methodology</b>  (Include specific details of what analyses will be carried out. This includes details on how complex multistage survey design will be taken into account in analysis.)	
<b>Research outputs</b>  (Include planned outputs, dissemination methods and timelines.)	
<b>Survey dataset(s) required</b>  (If requesting the 2006/07 New Zealand Health Survey, please indicate whether the adult or child dataset is required.)	
<b>Security of data</b>  (Identify the security of (a) the CD-ROM, (b) electronic copies of the datasets, and (c) hard copy outputs. Indicate how these will be kept secure and accessed only by authorised researchers. Note that laptops are not considered secure.)	
<b>Timeframe</b>  (Include project start and end dates, and important grant application closing dates or conference dates.)	
<b>Brief summary of research project</b>  (Approximately 100 words summarising the research objectives, methods and anticipated outputs for publishing on HDI website.)	

**Declaration**

We the undersigned confirm that the information provided in this form is accurate to the best of our knowledge.

**Lead researcher**

Name	
Signed	
Date	

**Manager or head of department**

I affirm that my organisation,  
 ....., supports this research project and requires that all researchers abide by the HDI Microdata Access Policy and the agreed terms and conditions of access.

Name	
Position	
Signed	
Date	

Please attach brief CVs for the lead researcher and the statistician/analyst, and other relevant material. In CVs, please outline:

- qualifications
- employment history
- any relevant experience and/or expertise in analysing survey datasets, particularly surveys with complex multistage designs.

## Annual Research Update

This template must be completed by the lead researcher every 12 months from the date the Microdata Access Agreement was signed. An electronic copy of this template is available on the HDI website.

To	
From	
Date	
Subject	<b>Microdata research project update</b>
Research project title	
Dataset(s) used	
Current researchers (Note any new researchers and their role; confirm that an External Researcher Undertaking has been signed and sent to HDI)	
Research progress in past year	
Results published in past year (Enclose an electronic copy of published research if not already provided to HDI)	
Research planned for next year	
Anticipated end date (If this is different to original timeframe please explain why)	
General comments	
Signature	Date:

In the final update, please return the CD-ROM with the CURF dataset(s) and confirm in writing that all other copies or parts (electronic or printouts) have been deleted or destroyed.

# Appendices

These appendices contain extracts from legislation, protocols and guidelines relevant for access to individual information.

Legislation can be viewed at the following website:  
[http://www.legislation.govt.nz/browse\\_vw.asp?content-set=pal\\_statutes](http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes)

## A – Statistics Act 1975

### 37 Security of information

- (1) Information furnished to the Statistician under this Act shall only be used for statistical purposes.
- (4) All statistical information published by the Statistician shall be arranged in such a manner as to prevent any particulars published from being identifiable by any person (other than the person by whom those particulars were supplied) as particulars relating to any particular person or undertaking, unless—
  - (a) That person or the owner of that undertaking has consented to their publication in that manner, or has already permitted their publication in that manner; or
  - (b) Their publication in that manner could not reasonably have been foreseen by the Statistician or any employee of the Department.
- (5) For the purposes of subsection (4) of this section the Statistician shall make such office rules as he considers necessary.

## B – Official Statistics System (OSS) Protocols

<http://www.statisphere.govt.nz/about-official-statistics/principles-and-protocols.htm>

### Principle 7 – Protecting respondents' information

Respondents' rights to privacy and confidentiality are respected and their information is stored securely.

Key elements

- Legislative and ethical obligations governing the collection of data, confidentiality, privacy and release of outputs are rigorously followed.
- Everyone involved in the production of official statistics is made fully aware of their obligations to protect provider confidentiality and of the legal penalties for wrongful disclosure.
- Survey data provided by respondents is only used for statistical purposes.
- Administrative data, whilst primarily collected for operational purposes, can also be used for statistical purposes as well.
- Respondents' privacy concerns are minimised.
- Respondents' confidentiality is always strictly preserved unless they have explicitly agreed to the contrary.
- Secure practices and processes are used in the production of official statistics.
- Unless specific permission provided in legislation allows otherwise, the same confidentiality standards drawn from legislation that produce data will apply to statistics derived from administrative sources collected specifically for statistical purposes.

## C – Privacy Act 1993

### Principle 5 – Storage and security of personal information

An agency that holds personal information shall ensure—

- (a) That the information is protected, by such security safeguards as it is reasonable in the circumstances to take, against—
  - (i) Loss; and
  - (ii) Access, use, modification, or disclosure, except with the authority of the agency that holds the information; and
  - (iii) Other misuse; and
- (b) That if it is necessary for the information to be given to a person in connection with the provision of a service to the agency, everything reasonably within the power of the agency is done to prevent unauthorised use or unauthorised disclosure of the information.

### **Principle 6 – Access to personal information**

- (1) Where an agency holds personal information in such a way that it can readily be retrieved, the individual concerned shall be entitled—
  - (a) To obtain from the agency confirmation of whether or not the agency holds such personal information; and
  - (b) To have access to that information.
- (2) Where, in accordance with subclause 6(1)(b) of this principle, an individual is given access to personal information, the individual shall be advised that, under principle 7, the individual may request the correction of that information.
- (3) The application of this principle is subject to the provisions of Parts 4 and 5 of this Act.

### **Principle 10 – Limits on use of personal information**

An agency that holds personal information that was obtained in connection with one purpose shall not use the information for any other purpose unless the agency believes, on reasonable grounds,—

- (a) That the source of the information is a publicly available publication; or
- (b) That the use of the information for that other purpose is authorised by the individual concerned; or
- (e) That the purpose for which the information is used is directly related to the purpose in connection with which the information was obtained; or
- (f) That the information—
  - (i) Is used in a form in which the individual concerned is not identified; or
  - (ii) Is used for statistical or research purposes and will not be published in a form that could reasonably be expected to identify the individual concerned; or .....

### **Principle 11 – Limits on disclosure of personal information**

An agency that holds personal information shall not disclose the information to a person or body or agency unless the agency believes, on reasonable grounds,—

- (a) That the disclosure of the information is one of the purposes in connection with which the information was obtained or is directly related to the purposes in connection with which the information was obtained; or
- (b) That the source of the information is a publicly available publication; or
- (c) That the disclosure is to the individual concerned; or
- (d) That the disclosure is authorised by the individual concerned; or
- (h) That the information—
  - (i) Is to be used in a form in which the individual concerned is not identified; or
  - (ii) Is to be used for statistical or research purposes and will not be published in a form that could reasonably be expected to identify the individual concerned; or .....

## **D – Health Information Privacy Code 1994**

### **Rule 5 – Storage and Security of Health Information**

- (1) A health agency that holds health information must ensure:
    - (a) that the information is protected, by such security safeguards as it is reasonable in the circumstances to take, against:
      - (i) loss;
      - (ii) access, use, modification, or disclosure, except with the authority of the agency; and
      - (iii) other misuse;
    - (b) that if it is necessary for the information to be given to a person in connection with the provision of a service to the health agency, including any storing, processing, or destruction of the information, everything reasonably within the power of the health agency is done to prevent unauthorised use or unauthorised disclosure of the information; and
    - (c) that, where a document containing health information is not to be kept, the document is disposed of in a manner that preserves the privacy of the individual.
  - (2) This rule applies to health information obtained before or after the commencement of this code.
- Note: An action is not a breach of this rule if it is authorised or required by or under law – Privacy Act 1993, section 7(4).

### **Rule 6 – Access to Personal Health Information**

- (1) Where a health agency holds health information in such a way that it can readily be retrieved, the individual concerned is entitled:
  - (a) to obtain from the agency confirmation of whether or not the agency holds such health information; and

- (b) to have access to that health information.
- (2) Where, in accordance with paragraph (1)(b), an individual is given access to health information, the individual must be advised that, under rule 7, the individual may request the correction of that information.
- (3) The application of this rule is subject to:
  - (a) Part IV of the Act (which sets out reasons for withholding information);
  - (b) Part V of the Act (which sets out procedural provisions relating to access to information); and
  - (c) clause 6 (which concerns charges).
- (4) This rule applies to health information obtained before or after the commencement of this code.

Note: This rule is subject to provisions in enactments which authorise or require personal information to be made available or Acts which prohibit, restrict, or regulate the availability of personal information – Privacy Act 1993, section 7(1) and (2). Under section 7(3) it is also subject to certain regulations which prohibit, restrict or regulate the availability of personal information.

#### **Rule 10 – Limits on Use of Health Information**

- (1) A health agency that holds health information obtained in connection with one purpose must not use the information for any other purpose unless the health agency believes on reasonable grounds:
  - (a) that the use of the information for that other purpose is authorised by:
    - (i) the individual concerned; or
    - (ii) the individual's representative where the individual is unable to give his or her authority under this rule;
  - (b) that the purpose for which the information is used is directly related to the purpose in connection with which the information was obtained;
  - (e) that the information:
    - (i) is used in a form in which the individual concerned is not identified;
    - (ii) is used for statistical purposes and will not be published in a form that could reasonably be expected to identify the individual concerned; or
    - (iii) is used for research purposes (for which approval by an ethics committee, if required, has been given) and will not be published in a form that could reasonably be expected to identify the individual concerned;
- (2) This rule does not apply to health information obtained before [1 July 1993].

Note: An action is not a breach of this rule if it is authorised or required by or under law – Privacy Act 1993, section 7(4). Subrule 10(2) was amended by Amendment No 1.

#### **Rule 11 – Limits on Disclosure of Health Information**

- (1) A health agency that holds health information must not disclose the information unless the agency believes, on reasonable grounds:
  - (a) that the disclosure is to:
    - (i) the individual concerned; or
    - (ii) the individual's representative where the individual is dead or is unable to exercise his or her rights under these rules;
  - (b) that the disclosure is authorised by:
    - (i) the individual concerned; or
    - (ii) the individual's representative where the individual is dead or is unable to give his or her authority under this rule;
  - (c) that the disclosure of the information is one of the purposes in connection with which the information was obtained;
  - (d) that the source of the information is a publicly available publication;
- (2) Compliance with paragraph (1)(b) is not necessary if the health agency believes on reasonable grounds that it is either not desirable or not practicable to obtain authorisation from the individual concerned and:
  - (a) that the disclosure of the information is directly related to one of the purposes in connection with which the information was obtained;
  - (b) that the information is disclosed by a registered health professional to a person nominated by the individual concerned or to the principal caregiver or a near relative of the individual concerned in accordance with recognised professional practice and the disclosure is not contrary to the express request of the individual or his or her representative;
  - (c) that the information:
    - (i) is to be used in a form in which the individual concerned is not identified;

- (ii) is to be used for statistical purposes and will not be published in a form that could reasonably be expected to identify the individual concerned; or
  - (iii) is to be used for research purposes (for which approval by an ethics committee, if required, has been given) and will not be published in a form which could reasonably be expected to identify the individual concerned;
- (3) Disclosure under subrule (2) is permitted only to the extent necessary for the particular purpose.
- (5) This rule applies to health information about living or deceased persons obtained before or after the commencement of this code.
- (6) Despite subrule (5), a health agency is exempted from compliance with this rule in respect of health information about an identifiable deceased person who has been dead for not less than 20 years.

Note: Except as provided in subrule 11(4) nothing in this rule derogates from any provision in an enactment which authorises or requires information to be made available, prohibits or restricts the availability of health information or regulates the manner in which health information may be obtained or made available – Privacy Act 1993, section 7. Note also that rule 11, unlike the other rules, applies not only to information about living individuals, but also about deceased persons – Privacy Act 1993, section 46(6).

## **E – Official Information Act 1982**

### **4 Purposes**

- c) To protect official information to the extent consistent with the public interest and the preservation of personal privacy.

### **5 Principle of availability**

The question whether any official information is to be made available, ..., shall be determined, except where this Act otherwise expressly requires, in accordance with the purposes of this Act and the principle that the information shall be made available unless there is good reason for withholding it.

### **9 Other reasons for withholding official information**

- (2) ..... this section applies if, and only if, the withholding of the information is necessary to—
- (a) Protect the privacy of natural persons, including that of deceased natural persons;

## **F – Health Act 1956**

### **22H Anonymous health information**

Notwithstanding any enactment, rule of law, or other obligation, any person may supply to any other person health information that does not enable the identification of the individual to whom the information relates.

## **G – Health and Disability Commissioner Act 1994**

The Code of Rights is a regulation issued under the Health and Disability Commissioner Act 1994, section 74. The Code of Rights sets out 10 rights applicable to all health and disability services consumers, including those involved in research. Investigators conducting observational research, audits and other related activities should be familiar with their responsibilities under the Code of Rights, and should consider their study in light of the rights of (proposed) participants. The Code of Rights is available at the Health and Disability Commissioner's website ([www.hdc.org.nz](http://www.hdc.org.nz)).

Note that some provisions give legal effect to ethical standards. For example, the Code of Rights, Right 4(2), states, "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards".

## **H – Ethics guidelines**

### **New Zealand Public Health and Disability Act 2000**

The Minister of Health has established health and disability ethics committees under this legislation. The Ministry of Health is involved with health and disability ethics committees in an administrative capacity. However, it has no input into the decision-making processes of the health and disability ethics committees and does not comment on individual research applications.

Guidelines assist the work of ethics committees as noted below:

### *Operational Standard for Ethics Committees*

<http://www.newhealth.govt.nz/ethicscommittees/documents/OperationalStandard2006.doc>  
(Ministry of Health 2006)

#### **2.3 Privacy and confidentiality**

48. Every person is entitled to privacy. Privacy and confidentiality are integral to the protection and promotion of human dignity and help to protect and maintain a person's mental or psychological wellbeing.
49. The need for research must be balanced against infringements of privacy and have the intention of minimising any necessary invasions of privacy. To lessen the impact such access may have, steps should be taken to ensure that individuals are protected from any potential harm that might be caused as the result of access to their personal information without prior consent. Steps to protect individuals include:
  - i. restricting access to information about identifiable individuals
  - ii. encrypting information
  - iii. recording information anonymously
  - iv. storing research in secure facilities.
50. Except as provided for under the law, information (including health information) pertaining to identifiable individuals should not be collected, disclosed or used without prior consent. Consumers and research participants should be informed of the intended or anticipated uses for health information or human tissue or a bodily substance at the time consent is sought for its collection.
51. Health professionals and researchers have an obligation to prevent the unauthorised access to health information that they have collected about identifiable individuals. The results of any research should only be published in such a manner as to protect the privacy of those individuals involved (refer to the Official Information Act 1982 and the Health Information Privacy Code 1994).
52. To help preserve the privacy of individuals, where research requires research participants and they are not already known to the investigator, it is usually desirable that the holder of the information identifying a potential participant makes the initial contact to determine whether a person would be willing to participate. This may be a primary care provider.
53. Where health information about identifiable individuals is collected, disclosed, used, stored or disposed of, it should be done in a manner that complies with the law and protects the privacy, confidentiality and cultural sensitivities of the participants. The Health Information Privacy Code 1994 provides guidance on these issues.
54. In scrutinising any proposal, an ethics committee should satisfy itself that, where the principal investigator intends to collect information directly from participants and consumers, they should be informed of the extent to which the confidentiality of the information provided can be guaranteed. Where the principal investigator intends to seek disclosure of information about identifiable individuals from a secondary source, the proposal should include a statement regarding the extent to which the principal investigator will maintain confidentiality of any gathered information. This will require the ethics committee and principal investigator to be aware of and understand relevant laws. As a general rule, the best protection of the confidentiality of personal information and records will be achieved through anonymity.
55. Collective ownership of information - a significant point of difference between Māori and western views of information, and data, is the role and rights of collectives versus individuals. The more usual western view is that aggregate, non-individual identifying statistics are able to be promulgated publicly. In contrast, many Māori would consider that collectives, such as whānau, hapū and iwi, should be treated in the same way as individuals, and that explicit approval should be sought and received from appropriate representatives in the same way that individuals give permission for their personal data to be used.
56. Researchers who intend to collect information directly from a particular Māori collective will need to negotiate the conditions under which any information is collected and used. Researchers will need to provide the details of any such agreements when submitting a research proposal for ethical review. Where researchers intend to obtain information about a particular Māori collective from alternative sources, ethics committees must consider what impact, if any, the use of the information may have on the Māori collective concerned.

## *Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities*

<http://www.neac.health.govt.nz/moh.nsf/indexcm/neac-resources-publications-ethicalguidelines>  
(National Ethics Advisory Committee 2006)

### **Identifiability of health information**

A key issue concerning health information is whether the individual concerned is “identifiable” from the information. The data used for observational studies can be identified, potentially identifiable, partially de-identified, de-identified or anonymous. These terms are defined in the box below.

**Identified data:** Data that allow a specific individual to be identified. Identifiers may include the individual’s name, date of birth or address. In particularly small sets of data even information such as a postcode may be an identifier.

**Potentially identifiable data (key-coded, re-identifiable):** Key coding is the technique of separating personally identified data from substantive data, but maintaining a potential link by assigning an arbitrary code number to each data identifier pair before splitting them. Held securely and separately, the key allows the re-associating of the substantive data with the identifiers, under specified conditions, if that is ever necessary (Lowrance, 2002). Data may be single-coded, or double-coded if extra security is required. Data can also be potentially identifiable if it is possible to infer an individual’s identity from it.

**Partially de-identified data (AIDS-type code):** Data coded with abbreviated identifiers (for example, initials, date of birth, sex) are used for reporting AIDS, HIV and some other conditions. This allows re-identification by the clinician reporting, but is anonymous to the recipient, although duplicates can be linked.

**De-identified data (not re-identifiable, anonymised, anonymous, unlinked):** The process of de-identification can be irreversible if the identifiers have been removed permanently. These data are referred to as “de-identified” data. It should be recognised that the term “de-identified” is used frequently in other documents to refer to sets of data from which only names have been removed; such data may remain “potentially identifiable”.

**Anonymous data:** Data that have been collected without personal identifiers and from which no personal identifier can be inferred.

## **8 Confidentiality of data**

### **General considerations**

- 8.1 Observational studies may involve collecting and storing personal information relating to individuals and groups, and such data, if disclosed to third parties, may cause harm or distress.
- 8.2 Investigators should make arrangements for protecting the confidentiality of such data by, for example, omitting information that might lead to the identification of individual participants, or limiting access to the data, or by other means.
- 8.3 Investigators are required to ensure the adequate physical and electronic security of data.
- 8.4 For studies involving the collection of information about illegal activities, for example, the use of illegal substances, potential participants should be made aware whether investigators can or cannot ensure confidentiality.
- 8.5 Identified or potentially identifiable personal data should not be used when the study could be done without personal identification (for example, by key coding or unlinking the data).
- 8.6 When personal identifiers remain on records used for a study, investigators should be able to justify this and ensure confidentiality will be protected.
- 8.7 In the unusual event that group confidentiality cannot be maintained or is violated, investigators should take all reasonable steps to maintain or restore a group’s good name and status.
- 8.8 In the case of an audit or related activity, the activity should be conducted by people who are under a professional or an employment obligation to maintain patient confidentiality. Such activity may be initiated from outside the organisation or by the organisation itself, and may be conducted by the organisation (internal audit or related activity) or by a party external to it (external audit or related activity).
- 8.9 Note that “privacy” is the status of information about aspects of a person’s life over which he or she claims control and may wish to exclude others from knowing. Privacy is a relative status and claims

to it must be negotiated against countering claims such as the rights of others or collective societal goods. “Confidentiality” is the respectful handling of information disclosed within relationships of trust, especially as regards further disclosure (Lowrance, 2002).

8.10 See also HIPC, Rules 5 and 11, and Privacy Act 1993, Principles 5 and 11.

### **Record linkage**

8.11 The investigator must justify to an ethics committee any observational study that involves linkage between records in which participants are identified or are potentially identifiable.

8.12 It may be justifiable to use personal information to enable record linkage without consent if:

- a) the identity of participants is not disclosed except for the purposes of the record linkage and is not retained once record linkage has been completed; and
- b) identifying information is used with sufficient security; and
- c) the research has public benefit.

8.13 For audits and related activities, the use of record linkages without specific or additional consent is ethically justifiable when these activities are part of high-quality health care delivery.

## References

Lowrance W. 2002. *Learning from Experience: Privacy and the Secondary Use of Data in Health Research*. London: The Nuffield Trust.

Ministry of Health. 2006. *Operational Standard for Ethics Committees: Updated edition*. Wellington: Ministry of Health.

National Ethics Advisory Committee. 2006. *Ethical Guidelines for Observational Studies: Observational research, audits and related activities*. Wellington: Ministry of Health.

Statistics New Zealand. 2007. *Principles and Protocols for Producers of Tier 1 Statistics*. Wellington: Statistics New Zealand.