Secondary Use of Data — Guidance for Researchers

Overview

Researchers have both a legal and ethical obligation to address issues of privacy when proposing to use existing data in their research. This guidance is intended to assist researchers in preparing a submission to the HREC that meets the requirements of the privacy legislation and the National Statement on Ethical Conduct in Human Research 2025 (National Statement).

** Please note: If your existing data is to be sourced from social media or online platforms, please refer to the separate Research Using Social Media Data guidance instead.*

Legal Framework

Researchers must familiarise themselves with the key principles of the following legislation before proposing to use existing datasets in their research:

Privacy Act 1988 (Commonwealth)

Health Records and Information Privacy Act 2002 (NSW) (HRIP Act)

Privacy and Personal Information Protection Act 1998 (NSW) (PPIP Act)

These laws apply to information about an identified individual or an individual who is reasonably identifiable from that information.

Researchers should be aware that removing names or other direct identifiers does not automatically mean that data has been de-identified to an adequate standard. What constitutes "reasonably identifiable" information will vary depending on the context of the data. For example, in a dataset drawn from patients with a rare medical condition, details such as age, location and year of diagnosis may be enough to identify specific individuals even in the absence of names or other direct identifiers, simply because so few people share that particular profile.

The Office of the Australian Information Commissioner and the NSW Information and Privacy Commission both provide resources on this issue, such as this fact sheet on de-identifying personal information. Chapter 3.1 of the National Statement also contains useful information on the secondary use of data.

Information About the Dataset

When preparing your ethics submission, you will need to provide detailed information about the dataset you intend to use. This includes the following.

- Identify the custodian of the data. You will need to confirm whether the data custodian has agreed to provide the data to the research team for the purpose of

this project. If agreement has already been obtained, provide evidence of this. If agreement has not yet been obtained, explain how and when it will be sought.

- Specify all data fields that will be received by the research team. Be comprehensive, for example, name, age, gender, height, weight, ethnicity, health condition, surgery date, and so on.
- State how many participant, patient, or client records will be included in the dataset. An approximation is acceptable if the precise number is not yet known.
- Indicate whether the dataset will include any qualitative data, such as notes from patient or client files or records and if so, describe the nature of that content.

Ethics Considerations

Your submission must address the ethical context in which the data was originally collected. Specifically, you will need to explain when, where, and for what purpose the data was first collected. If it was originally collected for research purposes, identify the ethics approval under which that collection occurred.

You must also describe what participants were told about how their data would be used at the original point of collection. Where available, copies of original participant information sheets or consent forms should be attached to your submission to the HREC.

Legal Considerations

When proposing to use existing data that is reasonably identifiable, researchers are required to work through the following three options in order. Each option should be considered before moving to the next.

1. Restructure the research methodology to use only de-identified data
   Both NSW and Commonwealth privacy laws require that personal information only be collected and used where doing so is **reasonably necessary** for the given purpose. In a research context, this means that if the research aims can be achieved using de-identified data, that approach must be taken. Researchers should first consider whether the research questions can be adequately addressed without receiving identifiable information.

2. Obtain consent
   If de-identified data is insufficient to meet the research aims, researchers should seek consent from participants to use their data in this project. In some cases, participants may have already provided explicit consent for their data to be used in future research, and if so, provide details of this consent. Where such consent has not previously been obtained, researchers should seek it prospectively if doing so is practicable.

3. Apply for a waiver of consent
   If obtaining consent is not practicable, researchers may apply to the HREC for a waiver of consent. This allows a researcher to use an individual's personal information in a research project without obtaining their consent, subject to the HREC being satisfied that specific criteria are met. See the section below for the criteria that must be addressed in a waiver of consent application.

Applying for a Waiver of Consent

If the dataset is directly or reasonably identifiable and participant consent has not been obtained, you must apply to the HREC for a waiver of consent. Your application must satisfy the HREC of the National Statement criteria at section 2.3.10, that is:

- Explain why the proposed use of secondary data carries no more than low risk to participants.
- Provide a clear explanation of how the proposed research is in the public interest. The public interest in conducting the research must substantially outweigh the public interest in respecting individual privacy. Describe the benefits of the research and explain why these justify any risks of harm associated with not seeking consent.
- Explain why it is impracticable to obtain consent from participants. Relevant factors may include the volume, age, or accessibility of the records involved.
- Address whether there is any known or likely reason to believe that participants would have objected to their data being used in this way had they been asked.
- Describe how sufficient protection of participant privacy will be achieved. For example, explain how the research team will ensure that any published information cannot be used to reasonably identify individuals.
- Explain the measures that will be taken to adequately protect the confidentiality of the data throughout the research process.
- Where the results of the research may have significance for the welfare of participants, confirm whether there is a plan — where practicable — for making information arising from the research available to them.
- Confirm that the possibility of commercial exploitation of derivatives of the data will not deprive participants of any financial benefits to which they would otherwise be entitled.
- Confirm that the waiver of consent is not prohibited under any applicable state, federal, or international law.

Applying for a Waiver of Consent for Health Information

If the existing data you propose to use is health information, you must also satisfy the HREC that the requirements under the relevant privacy legislation have been met (in addition to the National Statement criteria). To assist you in addressing these requirements, ensure that the information in Appendix A is incorporated into your protocol.

Appendix A

Requesting a Waiver of Consent for Health Information

The *Health Records and Information Privacy Act 2002* (NSW) regulates the collection, use, and disclosure of personal health information and requires Human Research Ethics Committees (HREC's) to be satisfied that specific statutory requirements are met. The criteria under which a waiver of consent may be granted are set out in **section 2.3.10 of the National Statement of Ethical Conduct in Human Research (2025)** Please ensure that the information provided in this form is incorporated into the study protocol.

1. Do you plan to collect, use or disclosure personal health information about individuals without their consent which is identifiable, or potentially identifiable? Note: if you initially access identifiable information, even if it is later de-identified, you should answer 'yes'.

- ☐ Yes – go to Question 2
- ☐ No – you do not need to read any further

2. Indicate which sources you intend to collect information from (you can select more than one option):

- ☐ Third parties, such as non-government organisations, including private practice (GP or specialist rooms), private hospital, research institutions and universities. This is reviewed in accordance with Section 95A of the Clth Privacy Act 1988.
- ☐ State departments or agencies, including public hospital records. In NSW this is reviewed in accordance with the Statutory Guidelines for Research under the HRIP Act. **Important: for public hospital data, the reviewing HREC must be affiliated with a public health organisation.**
- ☐ Commonwealth departments or agencies e.g. National Death Index (NDI) held by the AIHW. This is reviewed in accordance with Section 95 of the Clth Privacy Act 1988.
- ☐ Other – please specify

3. Specify the type of information and the number of records to be accessed:

Number of records accessed	**Source of data E.g. Electronic Medical Records, private practice**	**Data collected (List all variables)**

4. Indicate the reason(s) why de-identified information cannot be used (you can select more than one option):

- ☐ The project involves the linkage of data
- ☐ Scientific deficiencies would result if de-identified information were used. Please specify
- ☐ Other – please specify

5. Why is it impracticable to obtain the consent of the individual to collect use or disclose their health information (you can select more than one option):

- ☐ The size of the population involved in the research
- ☐ The proportion of individuals who are likely to have moved or died since the information was originally collected
- ☐ The risk of introducing potential bias into the research, thereby affecting the generalisability and validity of the results
- ☐ The risk of creating additional threats to privacy by having to link information to locate and contact individuals to seek their consent
- ☐ The risk of inflicting psychological, social or other harm by contacting individuals with particular conditions in certain circumstances
- ☐ The difficulty of contacting individuals directly when there is no existing or continual relationship between the organisation and the individuals
- ☐ The difficulty of contacting individuals indirectly through public means, such as advertisement and notices
- ☐ Other – please specify

6. Please explain why the collection, use or disclosure of this information is in the public interest, and why the public interest in the project substantially outweighs the public interest in the protection of privacy.