



University Of Adelaide
School of Medical Sciences, Discipline of Pharmacology

Title: Record Management Policy

1. Purpose

The purpose of these guidelines is to describe the records management policy within the University of Adelaide Discipline of Pharmacology.

2. Scope

These guidelines are applicable to all staff that are involved in the access, storage and disposal of records pertaining to academic, research, commercial or administrative activities.

3. Definitions

3.1 Collecting information

Collection of information for records is when you gather or acquire or obtain information from any source and by any means.

For example, questionnaires, surveys, interviews, database information, data sets, institutional records collecting data, tissue and blood samples, as well as protocol SDW's and CRF's.

Examples of collection include, but are not limited to

- Using a consent form
- Interview-taped or notes
- Identifiable questionnaire/survey (including coded when linked to a name)

3.2 Using Information

Use of information is when an organisation or individual handles the information in any way. Use of information includes any form of quantitative or qualitative analysis and any inclusion of the information in any form of publication. Note that contacting a person based on contact details is considered to be use of that information.

Examples of use include but are not limited to:

- Reading files/records.
- Contacting participants using contact details.
- Analysing the information.
- Publishing including a thesis, journal article, report or summary.

- Handling of information in any way.

3.3 Personal Information

Personal information generally means information or an opinion (including information or an opinion forming part of a database), whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

Examples of personal information:

- Names
- Addresses
- Email addresses
- Name on a consent form
- Personal opinions in an interview or focus group

3.4 Health Information

Health information is information or an opinion about:

- The physical, mental or psychological health or a disability (at any time) of an individual; or
- An individual's expressed wishes about future provision of health, disability or aged care services to him or her; or
- A health, disability or aged care service provided, or to be provided, to an individual.
- Personal information about an individual collected in connection with the donation, or intended donation, by the individual of his or her body parts, organs or body substances; or
- Personal information that is genetic information about an individual in a form, which is or could be predictive of the health (at any time) of the individual or any of his or her descendants.

Examples of health information include but are not limited to

- Samples of saliva or body fluids.
- Diagnostic therapeutic tests.
- Information about medical conditions that a person has had.
- Information about a medical treatment that a person is receiving/has received.

3.5 Sensitive Information

Sensitive information means information or an opinion about an individual's:

- Racial or ethnic origin; or
- Political opinions; or
- Membership of a political association; or
- Religious beliefs or affiliations; or
- Philosophical beliefs; or
- Membership of a professional or trade association; or

- Membership of a trade union or
- Sexual preferences or practices; or
- Criminal record

4. Length of Storage Of Such Information

All information that is obtained by the department through academic records, academic research, commercial research and administrative activities arising from such ventures *should be kept intact and accessible for 15 years.*

The length of storage of such information complies with NHMRC guidelines for the Ethical Conduct of Research Involving Humans (June 1999) South Australian Hospital and Tertiary Guidelines as well as commercial industry requirements for clinical trials.

4.1 Storage and Security of Such Information

A record keeper who has possession or control of a record that contains personal information shall ensure:

- a) That the record is protected, by such security safeguards, as it is reasonable in the circumstances to take, against loss. Against unauthorized access, use, modification or disclosure, and against other misuse; and
- b) That if it is necessary for the record to be given to a person in connection with the provision of a service to the record-keeper, everything reasonably within the power of the record-keeper is done to prevent unauthorized use or disclosure of information contained in the record.

5. Access to Records

Where a collector collects personal information for inclusion in a record or in a generally available publication; and the information is solicited by the collector from the individual concerned; the collector shall take steps (if any) as are, in the circumstances, reasonable to ensure that, before the information is collected or, if that is not practicable after the information is collected, the individual concerned is generally aware of:

- The purpose for which the information is being collected
- If the collection of the information is authorised or required by or under law-the fact that the collection of the information is so authorised or required ; and
- Any person to whom, or any body or agency to which, it is the collector's usual practice to disclose personal information of the kind so collected, and (if known by the collector) any person to whom, or any body or agency to which, it is the usual practice of that first-mentioned person, body or agency to pass on that information.

5.1 Supervisor Rights to Access Records

Academic supervisors may request to view records pertaining to students research projects at any time. This policy ensures that monitoring of projects adhere to GCP guidelines and follow standards set out by the Declaration of Helsinki. This right of record access by the supervisor is indefinite and may undertaken once the student has graduated or left the faculty.

The head of the department may access records at his or her discretion at any time regardless of project involvement. This applies to joint project if the student is enrolled within the department.

6. Biological Storage

Where materials of biological origin are being used in a clinical trial, records should be preserved for such periods as will enable participants to be traced in the event the evidence of late or long term effect emerge. If samples are preserved after 15 years it is at the discretion of the principal investigator or sponsor company to dispose of such samples.

6.1 Identification of Biological Materials

The following statement distinguishes between the responsibilities of researchers within the department in respect to identifying personal data pertaining to biological samples that may be stored within the department.

The three types of personal data are as follows.

Identified

Data that allow the identification of a specific individual are referred to as “identified data”. Examples of 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 identified (coded, re-identified)

Data may have identifiers removed and replaced by a code. In such cases it is possible to use the code to re-identify the person to whom the data relate so that the process of “de-identification” is reversible. In these cases the data are referred to as “potentially identifiable”.

De-identified, (not re-identifiable, anonymous).

The process of de-identification can be irreversible if the identifiers have been removed permanently or if the data have never been identified. These data are referred to as “de-identified”. It should be recognised that the term “de-identified” is used frequently, in documents other than this Statement, to refer to sets of data from which only names have been removed. Such data may remain “potentially identifiable”

It is the responsibility of the researcher to choose which types of identification are required for their projects.

It is the policy of this department to aim for clinical research involving humans to follow potentially identified practice. Ensuring that the safety of the research subject is kept intact. This policy is adhered to with all biological material used for research purposes.

7. Disposal of Records

All records that have become obsolete are to be disposed of in a manner, which ensures that the information that is contained in such records is not reproducible once the records have been destroyed. All records should have all subject identifying factors removed to ensure subject and patient confidentiality. The University of Adelaide provides confidential bins for the disposal of such records. Before any record is destroyed pertaining to clinic research permission has to be obtained by either or, the department clinical trials manager, academic supervisors involved within the records that are to be destroyed or the department head.