Data archiving, retention and disposal guidelines

Archiving of data

- All records relating to the research project should be stored together.
- A list of the contents of each archive box should be placed on the outside of the boxes (which should be numbered for easy identification). This list should be duplicated and stored separately where it is easily accessible if needed (e.g. Computer hard drive).
- Arrangements for long term storage of research records are the responsibility of the project team. It is not the responsibility of the Metro North Office of Research or the Institutional Ethics or Governance Offices.
- For sponsored clinical trials, where data is to be stored for 15 years, the site investigator should liaise
 with the trial sponsor to discuss arrangements for the off-site storage of research records.
- Research data and primary materials must be kept in safe and secure storage during the project and for the appropriate time after completion.

Data retention

The period for which data should be retained at completion of the project should be determined by the specific type of research. *The Australian Code for the Responsible Conduct of Research*, Section 2.1.1, gives the following guidance:

- For short-term research projects that are for assessment purposes only (such as research projects completed by students), retaining data for 12 months after completion of the project may be sufficient.
- In general, the minimum recommended period for retention of research data is 5 years from the date of publication.
- For most clinical trials, data should be retained for a minimum of 15 years, and longer if necessary.
- For areas such as Gene Therapy, research data must be retained permanently.
- If the research work has community or heritage value, research data should be kept permanently at this stage, preferably within a national collection.
- Research data from subjects under 18 years of age, should be retained for 15 years from the date they turn 18.

Section 2.5 of *The Australian Code for the Responsible Conduct of Research* suggests that the following considerations be noted when retaining data:

- Researchers should retain research data and primary materials (i.e source documents) for sufficient time
 to allow reference to them by other researchers and interested parties. For published research data, this
 may be for as long as interest and discussion persist following publication.
- Research data should be made available for use by other researchers unless this is prevented by ethical, privacy or confidentiality matters.
- Research data should be retained for at least the minimum period specified in the institutional policy.

If the results from research are challenged, all relevant data and materials must be retained until the matter is resolved. Research records that may be relevant to allegations of research misconduct must not be destroyed.

Data destruction

According to *The Australian Code for the Responsible Conduct of Research*, Section 2, paragraph 2 of the introduction states: "While it may not be practical to keep all the primary material (such as ore, biological material, questionnaires or recordings), durable records derived from them (such as assays, test results, transcripts and laboratory and field notes) must be retained and be accessible.

Research data must be disposed of in a confidential manner. Shredding is optional, and paper shredders are located throughout the hospital.

Where possible, de-identify all study materials and place in blue bins which are located within lockable areas of the hospital.

For further information, please use the contact details below:

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