

## **POLICYI011 DATA STORAGE AND RETENTION POLICY**

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### **PURPOSE**

To stipulate a data management procedure for the retention of research data and records to ensure that all data is retrievable and able to be reconstructed at any time. National Statement Section 5.2.23 – 5.2.27.

- Clinical trial records and research data must comply with the relevant privacy protocols, such as the Australian Standard on Personal Privacy Protection (in health care information systems, see Australian Standard AS 4400-1995), the ICH GCP Guidelines (Annotated with TGA comments) July 2000, National Statement on Ethical Conduct in Human Research (2007, incorporating all updates), Guidelines under Section 95 of the Privacy Act 1988 (NHMRC), Australian Code for the Responsible Conduct of Research *Section 2 – Management of research data and primary materials* and if applicable the research fund granting body requirements.
- Data must be recorded and retained in durable and secure storage.
- Stored data must be referenced and the storage location recorded.
- Data that are published must be kept for a minimum of five years from the date of publication and fifteen years for clinical research following closure. (See December 1991 Guidelines for Good Clinical Research practice in Australia, published by the Therapeutic Goods Administration of the Commonwealth Department of Health and Family Services).
- Research data refer to primary data obtained through observations, measurements, interview, surveys, tests and all participant material.
- Where computer systems are accessible to networks, particular attention to the security of confidential data is required. Cloud based solutions must also be considered.
- When data are obtained from limited access databases, or via contractual arrangements, written indication of the location of the original data, or key information regarding the database from which it was collected, must be retained by the researcher.
- Security and confidentiality must be assured in a way that copes with multiple researchers and the departure of researchers from the institution.
- Also see Bellberry Confidentiality-Privacy Policy PI025.