Management of research data and records

Policy No: EP004
Issue Date: July 2010
Updated: July 2016
Review Date: August 2018

Purpose

1. The purpose of this policy is to assist eviDent members and staff to understand and fulfil their responsibilities with respect to the collection, use, storage, access and ownership of research data.

Scope

2. This policy applies to all eviDent, Australian Dental Association Victorian Branch Inc (ADAVB), Oral Health CRC and participating university[1] staff, eviDent investigators and practice staff involved in the design, collection, and storage of research data in connection with eviDent projects.

Definitions

For the purposes of this policy, the following definitions are used:

3. **Research**: The careful study and investigation of new information concerning a particular subject.[2]

4. **Research Data**: Data are facts, observations or experiences on which an argument, theory or test is based. Data may be numerical, descriptive or visual. Data may be raw or analysed, experimental or observational. Data includes: laboratory notebooks; field notebooks; primary research data (including research data in hardcopy or in computer readable form); questionnaires; audiotapes; videotapes; models; photographs; films; test responses. Research collections may include slides; artefacts; specimens; samples. [3]

5. **Chief Investigator**: eviDent members who provide 'the intellectual, administrative and ethical leadership'[4] to an eviDent research project or program.

6. **Associate Investigator:** eviDent members who are registered and practising dentists and have 'intellectual input into the research and whose participation warrants inclusion of their name on publications'[5].

7. **Research Collaborator**: eviDent members who are not eligible to be Chief or Associate Investigators, but who are closely involved with different aspects of eviDent projects.

---

[1] The University of Melbourne is the only participating university at the time of publication

[2] The University of Melbourne Policy on the Management of Research Data and Records, Approved by Academic Board, 24 February 2005, http://www.unimelb.edu.au/records/pdf/research.pdf

[3] The University of Melbourne Policy on the Management of Research Data and Records, Approved by Academic Board, 24 February 2005, http://www.unimelb.edu.au/records/pdf/research.pdf

[4] The University of Melbourne, Melbourne Research Office, Chief Investigator Responsibilities http://www.research.unimelb.edu.au/azservices/ci

[5] NHMRC Project Grants Advice and Instructions to Applicants for funding commencing in 2010

Management of research data and records

Policy No: EP004
Issue Date: July 2010
Updated: July 2016
Review Date: August 2018

Requirements

8. eviDent Chief Investigators must follow the requirements of the University of Melbourne. These requirements can be found at: http://www.unimelb.edu.au/records/research.html

Storage of and access to eviDent research data

9. eviDent takes care to ensure that both electronic and hardcopy research data are protected from misuse, loss and unauthorized access or destruction, modification or disclosure.

10. Research data are stored securely (in lockable storage or on password-protected computers and databases) at the Oral Health CRC/ Melbourne Dental School with a copy being held at the ADAVB.

11. A copy of the research data may be retained securely within the Associate (practitioner) Investigator's practice.

12. Responsibility for the management of a secure data storage area lays with the eviDent Foundation, Oral Health CRC/ University of Melbourne and the ADAVB.

13. Signed consent forms must be stored separately from the research data, but just as securely as the research data, to enhance the confidentiality.

14. Access is restricted to eviDent members named on the ethics application or staff who need the information to carry out their jobs/ research.

15. Access to research data involving human participants will be restricted to the named project team unless prior permission has been sought from the approving human ethics committee.

16. A research data register is be maintained by the Oral Health CRC/ University of Melbourne. The research data register includes a description of the research data, i.e. the name(s) of the project team, contact details for the Chief Investigator, the project title, the location of the data, the number of boxes (where applicable) and the destruction date.

17. Circumstances where this does may not apply include:
    a. Legal action
        i. Legal advisers may require access to the research data to assist and provide advice
        ii. Subpoena of research data
    b. Freedom of Information

Management of research data and records

Policy No: EP004
Issue Date: July 2010
Updated: July 2016
Review Date: August 2018

18. Research data related to publications should be made available for discussion with other researchers except where confidentiality provisions prevail. Such provisions should be specified on the research data register. Permission to access the data must also be sought from a human ethics committee.

19. Research data may be stored with the patient files for the duration of the project for ease of retrieval but must be separable from the clinical/ patient records.

20. When the research data are separated from the clinical/ patient records a file note should be made on the clinical/ patient record.

Retention period of research data

21. Research data and signed consent forms must be retained for a minimum of five (5) years after the project the publication date.

22. Circumstances that may require a longer retention period include, but are not restricted to:
    a. Retention periods stipulated by funders
    b. Legislative requirements
    c. Legal requirements, e.g. allegations of unprofessional conduct, unethical conduct
    d. Patents
    e. Archival value, e.g. controversial projects, innovative projects

Destruction of eviDent Research Data

23. The destruction of eviDent research data will be authorised by the eviDent Foundation CEO in consultation with the research data register and Chief Investigator of the appropriate research project.

24. The research data register will be updated when research data is destroyed.

25. Research data will be destroyed after a minimum of five (5) years after the project the publication date unless a longer retention period is required.

26. The destruction of research data will utilize the most secure format at the time of destruction to ensure that the information may not be re-created.

27. Signed consent forms will be destroyed five (5) years from the date the project ceases.

Management of research data and records

Policy No: EP004
Issue Date: July 2010
Updated: July 2016
Review Date: August 2018

Privacy

28. eviDent staff and members are bound by other health information legislative requirements such as the *Information Privacy Act 2000* and the *Health Records Act 2001*.

29. Chief Investigators may be bound by the employing University's Privacy Policy.

30. Information about the protection of an individual's privacy can be provided by:
    a. the Victorian Privacy Commissioner www.privacy.vic.gov.au
    b. the Federal Privacy Commissioner www.privacy.gov.au
    c. the Health Services Commissioner www.health.vic.gov.au/hsc/
    d. the University of Melbourne http://www.unimelb.edu.au/unisec/privacy/privacypolicy.html

Complaints about ownership of or access to eviDent research data

31. Queries or complaints about ownership of or access to eviDent research data the eviDent Chief Executive Officer, C/o- ADAVB, PO Box 9015, South Yarra, Vic, 3141 or fax 03 8825 4644.

Advice

32. Advice concerning this policy can be obtained from the eviDent Chief Executive Officer, tel: 03 8825 4603.

Review

33. This policy will be reviewed and updated within three (3) years of the issue date, or earlier if any changes indicate a need for review.