Purpose

The purpose of this guidance is to outline the management and retention of data and records by Bellberry. Bellberry ensures a complete set of materials relevant to each research application is maintained to enable reconstruction of a complete history of all actions related to the review, approval and continuing review of the protocol, as per section 5.2.26 and 5.2.27 of the *National Statement on Ethical Conduct in Human Research (2007 incorporating all updates)*.

Definitions

eProtocol: Web-based system utilised for the submission of human research protocols to Bellberry Ltd.

Guidance

Bellberry administration will prepare and maintain an electronic study file in eProtocol for each individual application received and maintain a research register for all received and reviewed applications.
Bellberry utilise the electronic record management system eProtocol. Each research application stored in eProtocol includes the following:

- Name/s of the institution/s to which the research approval is provided
- Bellberry reference number
- Name/s of principal researchers
- Title of the project
- Correspondence between the review body and the researcher about the review
- Acceptance or rejection of any changes to the proposal
- Proposed date of completion of the proposal
- Formal advice of final ethical approval or non-approval with date
- Terms and conditions, if any, of approval of any proposal, including the duration of approval
- Name of any other review body whose opinion was considered as recorded on the application form, rejection or approval from other HREC's
- The approval letter includes the mechanisms to be used to monitor the conduct of the research and
- Relevance (if any) of the Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information.

Additionally, the following is retained in eProtocol:

- Copy of each research proposal and application in chronological order with a unique identification number
- Current Protocol
- Application form
- Current Investigators Brochure
- Submitted associated documents
- Information sheets and consent forms
- Letter giving the decision of the committee with versions of documents that have been approved.
- Record of amendments and their approval and acknowledgement letters where appropriate
- Any Safety Reports, progress reports, protocol violations
- Any other relevant correspondence

Studies maintained on eProtocol are kept in the system indefinitely. No archiving module is implemented.

References

National Statement on Ethical Conduct in Human Research (2007 incorporating all updates)
IT G4 Electronic Signatures