POLICYI025 CONFIDENTIALITY/PRIVACY

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Purpose

To uphold the rights of participants of research in relation to their privacy and provide safeguards for the disclosure of clinical, non clinical and personal information.

Policy

1. Bellberry HRECs expect all researchers and sponsors of research to conform to relevant legislation, standards and guidelines in relation to Privacy and Confidentiality of research participants' information.

2. Privacy rights and confidentiality in relation to personal and/or sensitive information will be upheld regardless of whether the information is stored and communicated through manual or electronic systems or is communicated verbally.

3. Disclosure of personal and health information will only occur where allowed under law and with required consent.

4. Consent to future use of data and tissues in research must comply with relevant guidelines of the National Statement i.e. 2.2.14 and 3.4.5 – 3.4.7.

5. It must be clear to participants of research whether any of the information used by the research team will be in an identifiable, re-identifiable (coded) or non-identifiable form.

6. Information should be provided generally on plans by the researchers for the storage and disposal of data where the data will be kept, who will have access to it, how long it will be stored and what will happen to that data at the end of the storage period.

7. If additional use of the information is contemplated, this should be explained and specific consent sought from the participants for that additional use and the information will only be disclosed with their permission except as required by law.

8. Participants must be informed, where relevant, regarding the review of health records by researchers and by representatives of regulatory authorities and the sponsor for the purposes of verifying the procedures and the data collected during the research.

9. If there may be commercial development of the research results this should be stated. In any publication, information must be provided in such a way that participants cannot be identified. A description of how information privacy will be maintained should be provided.

10. A detailed description of how confidentiality will be ensured and how privacy will be protected is required for research concerning focus groups.

11. Bellberry HREC's require (in most cases) a participants' treating Doctor/s to be notified of their participation in the research and their consent for the exchange of clinically relevant information noted by the trial doctor in the conduct of the trial. A statement to this effect must be included in the Participant Information Sheet and Consent Form (PICF). See Sample PICF.

12. Sections 95, 95A and 95AA of the Privacy Act
In certain circumstances, the Privacy Act permits the handling of health information for health and medical research purposes where researchers are unable to seek the individuals consent. The Privacy Commissioner has approved three sets of legally binding guidelines, issued by the National Health and Medical Research Council:

- Guidelines under Section 95 of the Privacy Act 1988 (November 2014) – sets out procedures that researchers and HRECs must follow when personal information is disclosed from a Commonwealth agency for medical research purposes.

- Guidelines approved under Section 95A of the Privacy Act 1988 (March 2014) – provides a framework for HREC's to assess proposals to handle health information for health and medical research (without individuals' consent). They ensure that the public interest in the research activities substantially outweighs the public interest in the protection of privacy.

- Use and disclosure of genetic information to a patient's genetic relatives under Section 95AA of the Privacy Act 1988 (March 2014) – specifies the requirements that must be met by health practitioners in the private sector if they choose to use or disclose genetic information without patient consent.

These above guidelines set out detailed information to be provided by the researcher to the HREC with their application for review.

Bellberry HRECs will be guided by the considerations for HRECs set out in these guidelines.

Standard Bellberry Clause

The study will gather certain personal information about you. This information will be held by (insert Sponsor) and its authorised representatives and will be (identifiable) (re-identifiable) or (non-identifiable). (A description of how data will be identifiable is required eg by participant initials and/or study number). (If applicable, if additional use of the information is contemplated, this should be explained and specific consent sought from the participants for that additional use).

Your data will be stored (location) for a period of (time) and will be accessed by (cite all who will access the data). At the end of this storage period your data will be (describe what will happen to the data).

Your treating doctor/s will be notified of your participation in this study and the exchange of clinically relevant information noted by the trial doctor in the conduct of the trial, will occur.

Unless required by law, only your doctor, the study team, the Sponsor and its authorised representatives, the Therapeutic Goods Administration (TGA), health authorities from other countries where the study drug may be considered for approval (or already approved) and the Bellberry Human Research Ethics Committee will have access to data which identifies you by name or from which your identity is otherwise apparent or can be reasonably ascertained.

(If the study involves both an international and an Australian sponsor, insert the names of both in this section.)

All personal information will be used only for the purpose of administering your participation in this study and in accordance with the laws governing the protection and privacy of personal information under Australian privacy legislation.

Participants should note that, some data derived from your participation in this study will be sent overseas; the regulatory regimes governing data access and use in other countries may not be the same as those that are in place in Australia. If you have any questions about this direct them to the Principal Investigator.

By signing the attached consent form, you authorise the release of/or access to this confidential information to the relevant study personnel and regulatory authorities as noted above.

In most cases, you have the right to access personal information collected from you in connection with the study and request corrections of any such personal information that is incorrect.

Acknowledgements – VMIA Victoria Guidelines for Clinical Trials 2006
Privacy Commissioner Website