Guidance

The following clauses or their equivalent are required to be included in the Participant Information and Consent Form, where relevant.

Clauses

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 e.g., 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 from your participation in this study will be sent overseas or shared with persons outside Australia. The regulatory regimes governing data access and use in other countries may not be the same as those that are in place in Australia. In the case of data that identifies you, or from which your identity may be ascertained, a person or organisation subject to Australian privacy laws that has collected your information must take reasonable steps to ensure that an overseas recipient handles the information in accordance with any relevant Australian privacy principle (unless an exemption applies). 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.

References

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