

**The Austin Health Human Research Ethics Committee
Self Audit for Researchers**

Project No:
Project title:

Are all of the following *true* for your research project?

1. If I left suddenly, my project could be completed or replicated because the documentation for my projects is up to date, accessible, clearly ordered and comprehensible. The Principal Researcher knows where to find all relevant documentation and has been provided with the passwords to the databases.	True	False	N/A
2. I am conducting the study in accordance with the protocol approved by the Austin Health Ethics Committee. Any modifications have been reported to the committee and the relevant documents updated.	True	False	N/A
3. I have obtained signed consent forms from all participants (where applicable) and stored these securely. They are available for audit.	True	False	N/A
4. I have reported all serious and unexpected adverse incidents to the Austin Health Ethics Office.	True	False	N/A
5. I have provided all study participants with a copy of the Participant Information sheet approved by the Austin Health Ethics Committee.	True	False	N/A
6. I have provided a translator and/or a translated copy of the Participant Information sheet in his/her own language to all non-English speaking participants.	True	False	N/A
7. I have received ethics committee approval for all public advertising material that seeks volunteers to participate in the study.	True	False	N/A
8. Approaches to potential participants have been made only by the individuals with full knowledge of the study protocol and of the risks and inconveniences associated with participation (& approved by a human research ethics committee).	True	False	N/A
9. All paper-based questionnaires have the identifying information removed immediately after processing and are then identifiable only by a code. The 'code-key' is stored separately under lock and key at all times.	True	False	N/A
10. All principal computer files containing study data are stored on a secure network drive where they are regularly backed up.	True	False	N/A
11. All computer files containing study data are protected by passwords.	True	False	N/A
12. Any personal identifying information has been transferred to portable drives including USB sticks or portable computers that have security measures in place to ensure no unauthorized access.	True	False	N/A
13. Participants know whom to contact if they have a question, complaint or an emergency.	True	False	N/A
14. There is a regular meeting of the study team including the Principal Researcher/s to discuss the progress of the study and a record of these meetings is maintained.	True	False	N/A

If there are problems you can't fix, seek advice from Ms Eva Booth, or the REU, on 9496 4099

Principal Researcher:.....

Date:.....

This document has been designed to help researchers to reflect on their research conduct and to comply with guidelines for responsible research conduct. The Committee suggests that study coordinators complete this document annually, discuss and obtain 'sign-off' from the Principal Researcher, and then file the signed document with other study documents.

Tool Developed by The Alfred Research and Ethics Unit and the Department of Epidemiology and Preventive Medicine, Monash University.