

BARWON HEALTH HUMAN RESEARCH ETHICS COMMITTEE (BH HREC) ANNUAL SELF-AUDIT TOOL FOR RESEARCH PERSONNEL



Barwon Health Reference Number:

This document has been designed to help research personnel to reflect on their research conduct and comply with guidelines for responsible research conduct. The BH HREC advises that the project’s Principal Investigator (PI) should discuss this form with **all members** of the study team and complete this document annually, with the annual progress report. The completed self-audit tool should be forwarded to REGI and a copy retained in your study files.

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

If I left suddenly, my project could be completed or replicated because the documentation for my project is up to date, accessible, clearly ordered and comprehensible. The PI knows where to find all relevant documentation and has been provided with the passwords to the databases.	True	False	N/A
I am conducting the study in accordance with the protocol approved by the ethics committee. Any modifications have been reported to the committee and the relevant documents updated.	True	False	N/A
I have obtained signed consent forms from all participants (where applicable) and stored these securely. They are available for audit.	True	False	N/A
I have reported all serious and unexpected adverse incidents to the ethics committee.	True	False	N/A
I have provided all study participants with a copy of the Participant Information Sheet approved by the ethics committee.	True	False	N/A
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
I have received ethics committee approval for all public advertising material that seeks volunteers to participate in the study.	True	False	N/A
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 the ethics committee).	True	False	N/A
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
All principle computer files containing study data are stored on a secure network drive where they are regularly backed up.	True	False	N/A
All computer files containing study data are protected by passwords.	True	False	N/A
No personal identifying information has been transferred to portable drives including USB sticks or portable computers.	True	False	N/A
Participants know who to contact if they have a question, complaint or an emergency.	True	False	N/A
There is a regular meeting of the study team including the PI/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 REGI on (03) 4215 3372 or regi@barwonhealth.org.au

Form completed by: Date:

Principal Investigator: Date: