

Human Research Ethics Audit & Monitoring Information

In line with Chapter 5.5 of the [National Statement on Ethical Conduct in Human Research](#), the ACU HREC will monitor research through a combination of annual/final reports and audits. The HREC will conduct periodic audits of various research projects to establish whether the research is being conducted in line with the approved ethics protocol.

Research projects may be selected for a variety of reasons:

- identification as high risk;
- adverse event/incident or receipt of a complaint;
- discrepancies in Annual Progress Report compared with the approved protocol;
- large number of modifications; and
- random audits.

Researchers are required to keep a record of all approved documentation including consent forms, questionnaires, permissions, modifications etc.

Normally researchers will be given at least two (2) weeks' notice of an audit.

Researchers/responsible administrators are encouraged to audit their own research to ensure that it adheres to the approved protocol.

Audit Procedures

Representatives of the HREC will meet with the researcher(s) to review documentation and data storage and to ask the following questions:

1. Tell us how your research is progressing?
2. How has the recruitment and consent process gone?
3. Have there been any changes of staff?
 - a. Have new staff been provided with appropriate instruction, training, access to files and fully informed about the project/protocol?
 - b. Have departing staff handed over their data properly?
4. Have there been any unexpected incidents/events?
5. Have there been any changes to the way the project is carried out since the original ethics approval?
6. Do you have any comments on the ethical review process?

AUDIT CHECKLIST

Lead Researcher:	
Ethics Reference Number:	HREC 201
Title:	
Protocol End Date:	/ /

<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A.	Information letter as per HREC records. (Correct id listed).
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A.	Consent form as per HREC records.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A.	Any other written information (eg questionnaires, advertisements etc) as per HREC records.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A.	Check all current investigators are listed on the protocol.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A.	Check that any outstanding items/conditions have been met e.g.: WWCCs, permissions, questionnaires etc.
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A.	Confirm research data (including consent form) are stored appropriately and in the format described in the ethics protocol (e.g. de-identified) .

Satisfactory

Not Satisfactory

Comments:

Name: _____

Name: _____

Signature: _____ Date: _____

Signature: _____ Date: _____