

# Site Audit Report for Research

This form requests information regarding an ethically approved research project being conducted at an organisation.

## Research Project Details

HREC Reference Number	<input type="text"/>	CPI for Research Project	<input type="text"/>
Local Reference Number	<input type="text"/>	HREC Approval Date	<input type="text"/>
Project Title	<input type="text"/>		
Mode of HREC Approval	<input type="checkbox"/> Single state only <input type="checkbox"/> National Mutual Acceptance		

## Site Audit Details

Site Name (Organisation)	<input type="text"/>	State/Territory	<input type="text"/>
Principal Investigator	<input type="text"/>	Date of this Report	<input type="text"/>
Person Requesting Audit	<input type="text"/>	Reporting Period	<input type="text"/>
Position of Person Requesting Audit		<input type="text"/>	

## Participant Recruitment

Does the project involve recruitment of participants?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Total number of participants recruited at the site during the reporting period	<input type="text"/>	
Has recruitment been completed at the site?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Has participant involvement been completed at the site?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Have any participants at the site withdrawn from the research project?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Provide reason(s) for participant withdrawal		
<input type="text"/>		
Has recruitment at the site been on target?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If recruitment is not on target, provide an explanation		
<input type="text"/>		
Comment on recruitment		
<input type="text"/>		

## Participant Information and Consent Form (PICF)

Have all participants been given a copy of the PICF?

☐ Yes

☐ No

If No, provide an explanation

Where are the original signed copies of the PICF stored?

## Database/Databank

Has a database/databank been established for this research project?

☐ Yes

☐ No

☐ N/A

Database/databank Name

Provide relevant details of database/databank

## Tissue Bank

Has a tissue bank been established for this research project?

☐ Yes

☐ No

☐ N/A

Name of Tissue Bank

Has an existing tissue bank been accessed for this research project?

☐ Yes

☐ No

☐ N/A

Name of Tissue Bank

Provide relevant details of tissue bank(s)

## Self-Audit for Investigators

	Yes	No	N/A
If I left, my project could be completed or replicated because the documentation from my projects is up to date, accessible, clearly ordered and comprehensible. The Principal Investigator knows where to find all relevant documentation and has been provided with the passwords to the databases.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am conducting the project in accordance with the protocol approved by the reviewing HREC. Any amendments have been reported to the reviewing HREC and the relevant documents updated.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I have provided all participants with a copy of the PICF approved by the reviewing HREC.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I have obtained signed consent forms from all participants (where applicable) and stored these securely. These are available to audit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I have reported all AEs and SAEs, including SUSARs and USADEs, to the reviewing HREC.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I have provided a translator and/or a translated copy of the PICF in his/her own language to all non-English speaking participants.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I have received HREC approval for all public advertising material that seeks volunteers to participate in the project. This includes any media e.g. printed material or media interviews.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Approaches to potential participants have been made only by individuals with full knowledge of the project protocol and of the risks and inconveniences associated with participation (and approved by the reviewing HREC).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
All computer files containing project data are stored on a secure network drive where they are regularly backed up.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
All computer files containing project data are protected by passwords.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Any personal identifying information that has been transferred to portable devices, including USB sticks or portable computers, is protected by security measures on those devices to ensure no unauthorised access.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
There is a regular meeting of the project team including the Principal Investigators to discuss the progress of the project and a record of these meetings is maintained.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Provide explanation for any 'No' responses to the above statements

## Declaration

I confirm that this project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved).

I confirm that the project is being conducted in compliance with the NHMRC *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) or as amended.

I confirm that I have not received any information in any form from anyone involved in the research project to suggest this report does not accurately reflect the progress of the project at the above site(s).

Principal Investigator	
Signature	
Date	
Organisation	
Email	
Telephone	

Project Coordinator	
Signature	
Date	
Organisation	
Email	
Telephone	

## HREC Acknowledgement *(Office Use Only)*

Name	
Signature	
Comment	

Position	
Date	