


Guidelines for the Auditing of Research

- Who** Principal investigators and study co-ordinators who are conducting research at Southern Health which has been approved by a relevant Human Research Ethics Committee at Southern Health.
- Expected Outcomes** That all research being conducted at Southern Health complies to approved research in accordance with
- the *National Statement on Ethical Conduct in Human Research (2007)*¹,
 - the *Australian Code for the Responsible Conduct of Research*²,
 - *Standard Operating Procedures to achieve Good Clinical Practice in Australian Clinical Research*³, and
 - All Applicable regulatory requirements.
- Precautions** All researchers at Southern Health must strive to conduct research in the manner indicated in the 'Human Research Policy' document no. SHP-R00 Version 1.1, Nov 2007
-  Researchers are directed to audit their own project procedures for compliance annually using the Research Governance Self Auditing tool⁴ and it is recommended that this occur simultaneously when completing the annual report form (Form 13).
- Projects may be selected for auditing by the Research Directorate for a variety of reasons:
- Human Research Ethics Committee review – following approval of a new protocol; as part of the approval process; or due to the classification of risk.
 - Random selection.
 - A complaint.
 - Annual report and/or Research Governance Auditing Tool return verification.
- Step 1** The Principal Investigator or Study Co-ordinator is to complete a self-auditing tool annually when they complete their annual report. A copy of the self audit tool will accompany the annual report request.
- Step 2** The Principal Investigator is notified of the selection for audit and the Research Governance Officer arranges an audit time with the Principal Investigator or Study Co-ordinator. The Research Governance Officer will ensure the Principal Investigator or Study Co-ordinator has a copy of the Southern Health Auditing Tool⁵ so they can prepare in advance.
- Step 3** The Research Governance Officer will undertake the audit process and document observations and findings using the Southern Health Auditing Tool.

- Step 4** The Research Governance Officer communicates via an audit report with the Principal Investigator and the Study Co-ordinator on the summary of the main findings and the list of items that require action in order to comply with all applicable regulatory requirements. The Research Governance Officer works together with the Principal Investigator and the Study Co-ordinator to ensure that any compliance breaches are rectified.
- Step 5** The Principal Investigator and the Study Co-ordinator address issues highlighted as requiring attention and communication is open between the Principal Investigator/Study Co-ordinator and the Research Governance Officer/Research Directorate regarding any clarification.
- Step 6** The Research Governance Officer reports on the audit to the Human Research Ethics Committee and the Research Advisory Council via the Research Governance Report.
- Step 7** The Principal Investigator and Study Co-ordinator notifies the Research Governance Officer of the resolution of any Research Governance issues and the Research Governance Officer reports to the Human Research Ethics Committee and Research Advisory Council of the resolution. The Human Research Ethics Committee and Research Advisory Council make a decision regarding compliance with the Research Directorate and the Principal Investigator is notified of that decision in writing.
- Step 8** If it is decided that there is non-compliance, prompt action may be taken to secure compliance. If there is persistent non-compliance then the Human Research Ethics Committee may decide to terminate the study⁶.

Appendices Appendix 1: Research Governance and Audit Process

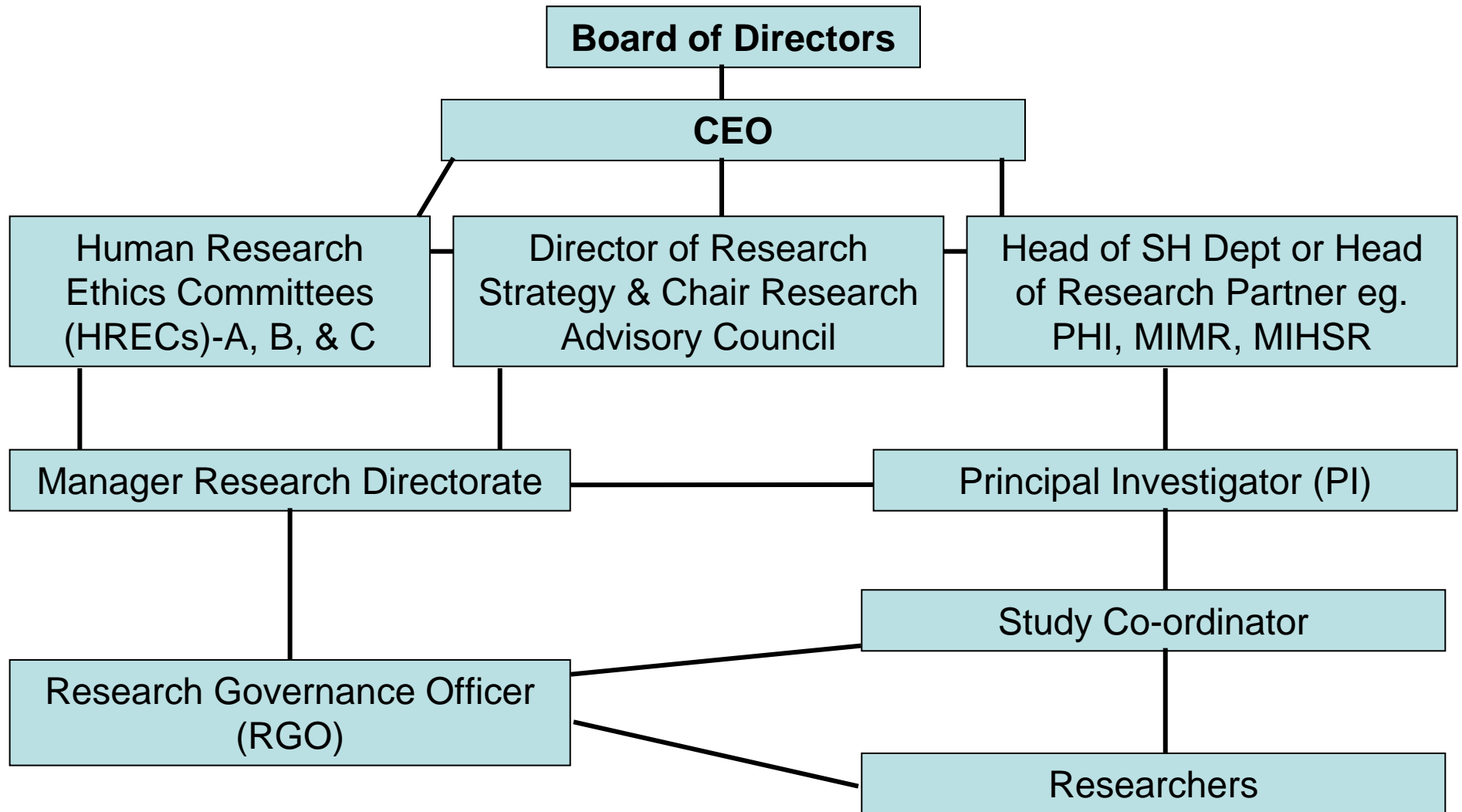


1. National Health and Medical Research Council, Australian Research Council and Australian Vice-Chancellors' Committee (2007). *National Statement on Ethical Conduct in Human Research*, Commonwealth of Australia, Canberra.
2. National Health and Medical Research Council, Australian Research Council and Australian Vice-Chancellors' Committee (2007). *Australian code for the responsible conduct of research*, Commonwealth of Australia, Canberra.
3. Victorian Managed Insurance Authority (2007). *Standard Operating Procedures to achieve Good Clinical Practice in Australian Clinical Research*, Victoria.
4. Southern Health Research Governance Self-auditing Tool (2008). www.southernhealth.org.au/research
5. Southern Health Research Governance Auditing Tool–Short Audit (2008). www.southernhealth.org.au/research
6. Therapeutic Goods Administration (2000). *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)*, paragraphs 5.20.1 & 5.20.2, Department of Health and Ageing, Australian Government, Canberra.

SH Policy	Human Research Policy	ACHS	Research Standard B.2.5
Reviewer	Director Research Services	Last review date	July 2008
Authoriser	Research Advisory Council	Next review date	July 2010

This hard copy might not be the latest version of this document. Please see the Southern Health Policy and Protocol Intranet site for current policies, protocols and guidelines.

Research Governance at Southern Health



SH Research Governance: Audit Process

Selection criteria:
HREC Review –
.Submission
.Approval
.Classification (Risk)
Random selection
Complaint
Annual report

Project selected for research governance (RG) audit

RGO arranges audit time with Study Co-ordinator

Audit process undertaken

RGO communicates with PI & Study Co-ord. re compliance

RGO reports on project in
RG Report to HREC & RAC

Project team address issues
highlighted as requiring attention

Issues of concern clarified (if necessary)

HREC makes decision
regarding compliance

PI notified of HREC decision
Copy provided to Manager Research Ethics &
Compliance at Monash University (if approp)

