



Medicine, Nursing and Health Sciences

School of Public Health and Preventive Medicine

Research Governance Committee
Annual Report 2012





Contents

Purpose:.....	2
Objectives:	2
Membership:	2
Meeting Frequency:	2
Quorum:	2
Reporting relationships:	2
Key Performance Indicators:.....	2
Monash University Policies	4
Audits of research projects	6
Full Audits.....	6
Self Audit.....	7
'Onboarding' – Research Governance Inductions	8
Good Research Practice Short course.....	9
Declaration of Confidentiality.....	10
Reports of Misconduct	11
Publications.....	12

Purpose:

The Purpose of the Research Governance Committee (RGC) is to support researchers and research students at the School of Public Health and Preventive Medicine (SPHPM) in the conduct of high quality research.

Objectives:

1. To ensure that accepted **procedures** are in place to meet ethical principles of good research practice.
2. To **improve** Good Research Practice in SPHPM.
3. To oversee and facilitate **education** regarding the pertinent standards, guidelines and/or policies.
4. To monitor oversee and facilitate **compliance** with the pertinent standards, guidelines and/or policies.
5. To make **recommendations** to the SPHPM Executive or other appropriate bodies in relation to matters under the purview of this committee.

Membership:

Ex-Officio Members:

- a) Head of School (Prof John McNeil)
- b) Chair of SPHPM Research Committee (Prof Susan Davis)
- c) SPHPM Research Manager (Dr Jayamini Illesinghe)
- d) Research Governance Officers (Dr Liz Bishop; Acting: Mrs Marina Skiba)
- e) Doctoral Coordinator (Dr Elizabeth Douglas)
- f) Australasian Cochrane Centre (Dr Joanne McKenzie)
- g) Centre for Obesity Research and Education (Dr Leah Brennan)
- h) Department of Forensic Medicine (Prof Olaf Drummer/Prof Joan Ozanne-Smith)
- i) The Jean Hailes Research Unit (Prof Jane Fisher)
- j) Women's Health (A/Prof Robin Bell)
- k) PhD student representative (Danielle Horyniak)
- l) ASPREE (Dr. Esther Apos)

Additional Members invited on to the committee due to their knowledge and experience:

- a) A/Prof Allen Cheng
- b) Prof Andrew Forbes
- c) A/Prof Damien Jolley

The Committee may consider membership of or make provision to co-opt someone who brings expertise in research or governance issues.

Meeting Frequency:

Monthly

Quorum:

A minimum of 4 members must be present to form a quorum.

Reporting relationships:

The Research Governance Committee will report to the Head of School and the SPHPM Executive Committee via the Research Governance Officer.

Key Performance Indicators:

- Number of projects audited in a calendar year
 - 0 full audits
 - 250 Self-audits
- Percentage of studies which submit an annual self audit
 - 87%
- Percentage of new staff and students who have received induction within 2 months of starting with SPHPM
 - 39%
- Short courses being provided
 - Run twice in 2012
- Related journal articles accepted for publication
 - 1 poster presentation



Back row: Prof Olaf Drummer, Dr Elizabeth Douglas, Prof Jane Fisher, A/Prof Allen Cheng, A/Prof Robin Bell, Prof John McNeil

Front row: Dr Jayamini Illesinghe, Dr Liz Bishop, Mrs Marina Skiba, Dr Esther Apos

In absentia: Prof Susan Davis, Dr Joanne McKenzie, Dr Leah Brennan, Danielle Horyniak, Prof Andrew Forbes, A/Prof Damien Jolley

Monash University Policies

There are a number of university policies which provide guidance, support and information for both staff and students. The following are policies that all staff and students should be aware of:

Privacy and Confidentiality

Conduct and Compliance Procedure - Privacy

www.privacy.monash.edu/procedure/

Collection of Personal Information

www.privacy.monash.edu/guidelines/collection-personal-information.html

Whistleblowers

Conduct and Compliance Procedure – Whistleblowers

www.adm.monash.edu/workplace-policy/conduct-compliance/whistleblowers.html

Checklist for Respondents to Whistleblower Complaints at Monash University

www.adm.monash.edu/workplace-policy/conduct-compliance/checklist-for-respondents.pdf

Checklist for Staff Receiving a Whistleblower's Disclosure

www.adm.monash.edu/workplace-policy/conduct-compliance/checklist-staff-receiving.pdf

Checklist for Welfare Managers of Whistleblowers at Monash University

www.adm.monash.edu/workplace-policy/conduct-compliance/checklist-for-welfare-managers.pdf

Checklist for Whistleblowers at Monash University

www.adm.monash.edu/workplace-policy/conduct-compliance/checklist-for-whistleblowers.pdf

Conflict of Interest

Conduct and Compliance Procedure - Conflict of Interest (including Conflict of Interest in Research)

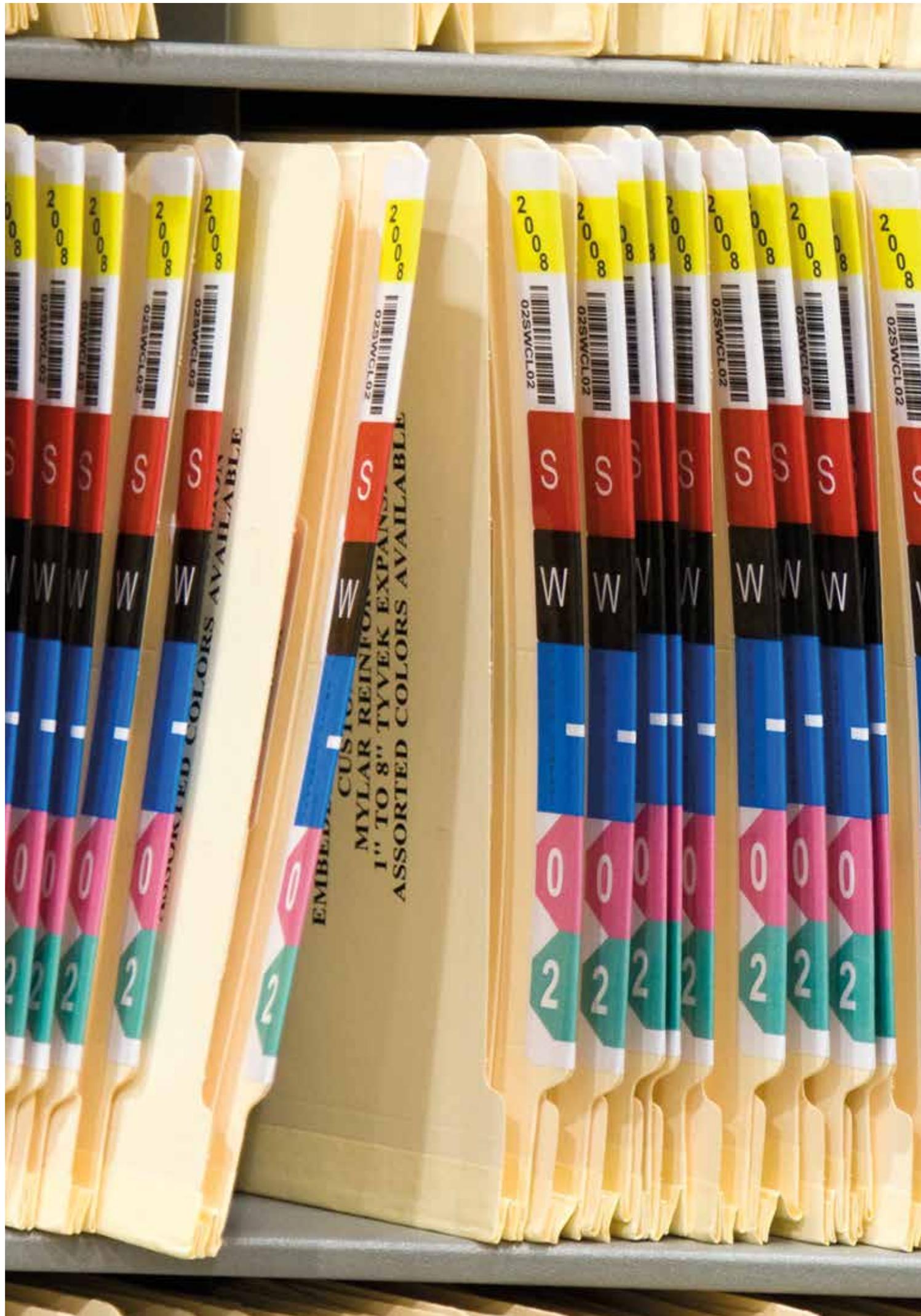
www.adm.monash.edu/workplace-policy/conduct-compliance/conflict-interest.html

Conflict of Interest – examiner

www.monash.edu/migr/examiners/conflict-of-interest/

Examples of Conflicts of Interest and Guidelines for Action

www.adm.monash.edu/workplace-policy/conduct-compliance/examples.html



EMBEDDED CUSTOMER
MYLAR REINFORCED
1" TO 8" TYVEK EXPANSION
ASSORTED COLORS AVAILABLE

Audits of research projects

Full Audits

SPHPM has a full audit tool. This tool covers all aspects of clinical research from the protocol, to ethics approval and data storage. It is based on the SPHPM Guide to Good Research Practice. The audit is conducted by the Research Governance Officer (RGO), who first contacts the investigator(s) of the project and makes a time to meet with a representative of the project. The RGO then checks the project against the audit tool (this may require a number of visits to complete). The RGO then provides a copy of the completed audit to the study team. The completed audit acts as an audit report. The study team is requested to make any changes necessary to ensure that the project complies with the SPHPM Guide to Good Research Practice. The RGO will follow up to ensure that any required changes are made.

Due to limited staffing hours no full audits were conducted in 2012.



Self Audit

The self-audit tool was introduced in the Department of Epidemiology and Preventive medicine some years ago. This is a short audit that is conducted by the researchers themselves. Staff were reminded that they were expected to complete it annually for each research project in which they were involved. Not all staff completed this tool but the Research Governance Committee was not able to follow up. As a result a self-audit was completed for less than 50% projects.

In 2012, the process for managing the self-audits was changed. An online version of the audit tool was developed to make it easier to complete, approve and submit. A co-ordinator/investigator for each project was identified and an email was sent explaining that it was required that the self-audit be completed by a designated due date. If the audit was not received, the Research Governance team followed up. As a result, self-audits were received for 87% of active projects this year. The self-audits revealed that an issue relating to data storage needed to be addressed. It was apparent that not all projects were stored on a shared drive (necessary for restricted access and regular, automated backups). Data storage is now being assessed, new instructions are being drafted and all staff are being re-educated.

Some issues with the online process were also identified and are being addressed for 2013.

Staff were asked to complete a short survey regarding their view of the self-audit.

The results of the online self-audit were presented by Dr Jayamini Illesinghe at Society of Research Administrators International Annual Meeting.

Figure 1: Flow-chart outline of the Self-audit process:



‘Onboarding’ – Research Governance Inductions

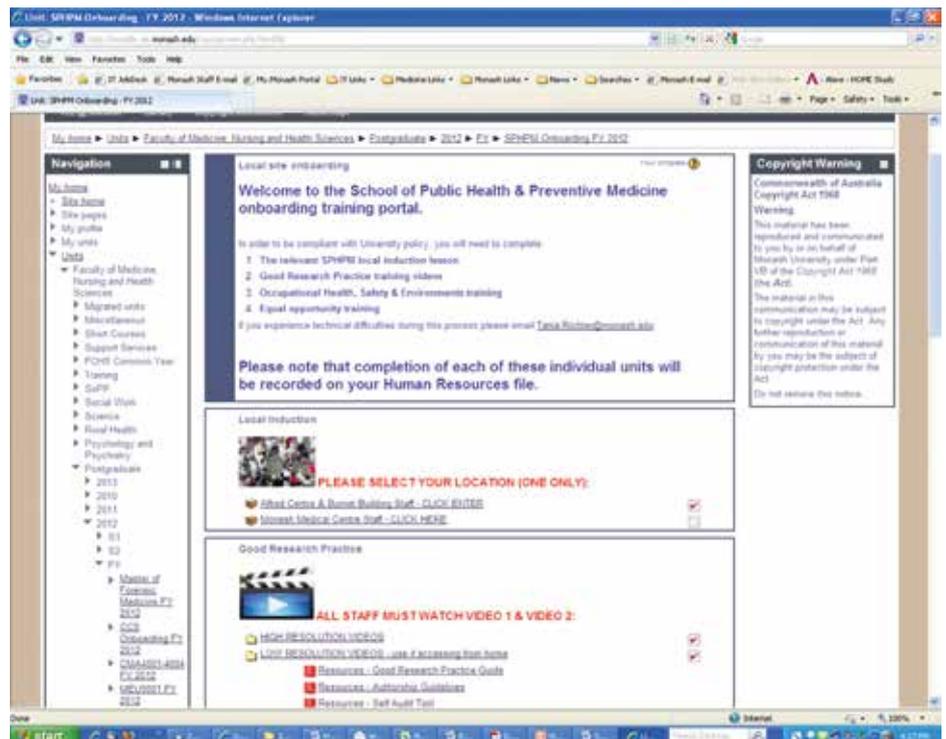
For many years the Research Governance Officer has met each new staff member and student in person to provide them with a Research Governance Induction. The inductions covered the following:

- The Research Governance Committee and its membership
- The Guide to Good Research Practice - all new staff and students were provided with a hard copy of this document
- Identification of other relevant research documents e.g., The National Statement and International Conference on harmonisation Good Clinical Practice (ICH GCP)
- Authorship guidelines
- Document guide – a template for a site file to help organise research documentation
- Hard copy of the self-audit tool – to ensure everyone understands the areas to be audited
- Grievance procedures

As the number of new starters increased, individual inductions became too cumbersome and it was decided to run monthly group inductions. These induction sessions included both the topics above and additional topics, e.g., information on confidentiality and ROPES (Researchers’ Online Project Enquiry System).

In 2012 the Research Governance Inductions were filmed and posted online as part of the School’s ‘Onboarding’, which replaces the monthly induction sessions. Onboarding is compulsory for, and accessible to, all members of the School and is found at www.med.monash.edu/intranet/sphpm/onboarding/new-staff.html.

We are still making adjustments to the process of informing new starters about Onboarding, assessing who has completed its compulsory aspects and following up staff and students who fail to complete it in a timely manner.



Good Research Practice Short course



The Good Research Practice Short Course was run twice (25th May and 14th November) in 2012. This course is open to all staff and students in SPHPM (compulsory for PhD students) and to anyone in the wider community. The course covers:

- Historical Perspectives on Research Ethics
- Research with Vulnerable Populations
- Privacy and Confidentiality in Research
- Informed Consent
- Submitting an HREC Application
- Data Management
- Practical Aspects of Clinical Trial Management
- ICH GCP

It is anticipated that this course will run twice in 2013.

Declaration of Confidentiality



SPHPM takes confidentiality very seriously. In order to ensure that all staff and students are aware of their obligations with regards to confidentiality all new starters are asked to sign a Declaration of Confidentiality when they join the School. This is highlighted as part of the Research Governance Induction included in the Onboarding. To ensure that this form is signed it is provided as part of the new starter's pack and required to be completed before an access swipe card is issued. The reception desk on level 6 of the Alfred Centre provides authorisation for the access cards and the drop off point for the signed declaration. Reception is happy to provide a blank declaration of confidentiality form to anyone who requires access but does not have their signed form (then waits while the declaration is signed).

Reception then scans the signed confidentiality form and forwards it to HR where it is filed in the staff members file.

Reports of Misconduct



In 2012 the Research Governance Committee was not aware of any episodes of research misconduct, either from reports or through auditing.

Publications

Online Self-audits to Improve Governance of Health Research, Conference Presentation (2012, **SRA International Annual Meeting**, Orlando, Florida, October 2012).

Online Self-audits to Improve Governance of Health Research

Jayamini Illesinghe, PhD, BBioMedSci (Hons), DipEd, Marina Skiba BEdSci.,

John McNeil, MBBS, MSc, PhD, FRACP, FAFPHM,

School of Public Health and Preventive Medicine, Monash University, Level 6, Alfred Centre, Melbourne 3004

Email: Jayamini.illesinghe@monash.edu

Clinical research has been an area of increasing activity for hospitals, universities and research institutions in Australia.¹ To manage the increasing risks for both patients and institutions strategies to better monitor research governance are now receiving greater attention.

The National Health and Medical research Council (NHMRC) requires individual institutions to take responsibility and to monitor their research activities. School of Public Health and Preventive Medicine (SPHPM) at Monash University use a variety of strategies to monitor their research, which include annual progress reports and detailed audits.²

The detailed audit, although effective is extremely time consuming, especially with a School of 1000 staff and high degree students. To improve the institutional oversight of research, SPHPM adopted a tiered approach to audits. This included the introduction of a self-audit that can be compiled within a day. These were completed by the researchers by themselves without the intervention of governance staff.

When the self-audit was first introduced the biggest difficulty was getting researchers to complete it (48% completion rate).¹ The local ethics committee (who had adopted our form) would prompt researchers to complete it as part of their annual report but the SPHPM had no such trigger to prompt researchers to complete it. In 2012 an online version of the self-audit was developed and simultaneously sent to a representative of each project within SPHPM. Researchers were given approximately 6 weeks to complete the self-audit and their views of the online system were evaluated with a survey.

Method



Results

No. projects that completed and returned the self-audit	250
No. of completed projects	37
No. Projects that hadn't started yet	5
No. Projects that were housed on other institutions	5
No projects that a completed self-audit was not received	21
No Projects where the CIA couldn't be contacted	16
Total number of audits sent	336

The audit was sent out to 336 projects. Of these 37 were completed, 5 had not yet started and 5 were housed at other institutions. We expected to receive an audit from the remaining 289 but only received 250 (87%). Of the audits received, 69 (28%) had compliance issues. The three most common issues were:

The documentation for my project are filed in a SPHPM 'Study Document File' on the V: drive	32 (48%)
This database is regularly backed-up onto a Monash University network drive	15 (22%)
Another key person involved in the study (preferably my supervisor) has a copy of the password for my database	13 (19%)

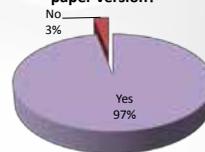
The Evaluation Survey and findings

The evaluation was conducted and analysed anonymously using an online survey tool (SurveyMonkey, Palo Alto, Calif, USA). The same survey was used to evaluate the previous audit with the exception of the last question around the online form.

The evaluation survey was sent to the investigators and project managers associated with the 250 projects that completed the audit. This included a cohort of 150 researchers as many of these were responsible for multiple projects. We received 60 completed surveys (40%) and the findings are summarised below:

Evaluation questionnaire results: participants answering 'yes', by question	
Were any questions on the self-audit difficult to understand?	4 (7%)
Are the questions raised in the self-audit relevant to promoting good research practice?	57 (98%)
Did it make you think of any ethical / good research practice considerations you hadn't previously?	20 (34%)
Have you, or do you plan to, make changes to your research practices as a result of completing the self-audit?	18 (31%)
Do you think it has, or will improve the ethical quality of your research?	21 (36%)
Do you think the self-audit requires follow-up from research ethics staff to be useful?	22 (38%)
Did you discuss the questions with the Principal Investigator or other members of your research team?	33 (56%)
How would you rate your knowledge of ethical compliance issues? Good or excellent	52 (88%)

Was the online form easier to complete/authorise and submit than a paper version?



Discussion

Research governance in SPHPM has a "Prevention is better than cure" principle.³ Auditing research is one way to discover irregularities and prevent damage. It is envisaged that the most important role of the self-audit will be helping to create a culture that is conducive to responsible conduct of research.

When carried out previously the self-audit had a poor compliance rate (48%). However, this year we had 87% of the projects complete an audit. The high compliance could be due to the following changes made in our approach: 1. In 2012 we focused on projects with ethics approval and identified a representative (usually the study co-ordinator) whom we asked to complete the self-audit. Previously we have simply reminded all staff that they should complete the self audit for all projects they are responsible for (without naming the projects)

2. We contacted all projects simultaneously and provided them with a due date. We also followed up with everyone who did not submit and audit.

3. Developing the online form made it easier to complete the audit and submit it.

The first two issues identified by the self-audit were closely related and highlighted a problem within SPHPM that we had been unaware of. All projects were asked to store their data on the shared drive (which has restricted access and regular back ups). However a recent space shortage had meant that many groups were not doing this even after the space issue has been rectified. Data storage is being assessed, new instructions are being drafted and the staff will be re-educated. A similar process was followed to ensure that a backup person could always access the database for each project.

Improvements in the process for next year

The online version, although easily accessible to the Monash Staff, staff based off site and adjunct staff found it difficult to access. This is an issues that needs looking into and fixing for the next round. Furthermore dual authorisation from the project manager and the chief investigator was difficult. Most chief investigators assigned this task to their personal assistants that defeated the purpose of the exercise.

References

1. Crammond BR, Parker AV, Brooks M, Skiba M, McNeil JJ. Self-Audit as part of a research governance framework for health research. *Med J Aust* 2011; 194:310-312.
2. Victorian Managed Insurance Authority. Research governance toolkit. Melbourne: VMIA, 2010. <http://www.vmia.vic.gov.au/~media/Content/Documents/Risk-Management/Clinical-Risk-and-Trials/Clinical-Trials/Guidebooks-Tools-and-Templates/research-governance-toolkit.aspx> (accessed Feb 2011)
3. Babi FE, Sharwood LN. Research governance: current knowledge among clinical researchers. *Med J Aust* 2008; 188:649-652.

Further information

www.med.monash.edu/sphpm/research-governance-committee.html
email: ResearchGovernanceOfficer@monash.edu