MONASH University

School of Public Health and Preventive Medicine

Research Governance Committee

Annual Report 2015

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 **improve** Good Research Practice in SPHPM. This will be achieved by:
   a. evaluating and updating the research governance framework that is in place
   b. regularly reviewing the SPHPM annual self-audit form
   c. keeping up to date with relevant laws and regulations and principles of risk management standards, guidelines and/or policies for conducting research

2. To monitor, oversee and facilitate **compliance** with accepted procedures to meet ethical principles of Good Research Practice, viz., pertinent standards, guidelines and/or policies. This will be achieved by:
   a. ensuring all staff and HDR students receive an induction when they join SPHPM
   b. ensuring that all new staff and HDR students receive a copy of the Guide to Good Research Practice
   c. ensuring that all studies conduct an annual self-audit

3. To oversee and facilitate **education** regarding the pertinent standards, guidelines and/or policies. This will be achieved by:
   a. information for staff and HDR students who may have questions regarding the conduct of research
   b. education (in the form of short courses) in the conduct of clinical research
   c. disseminating relevant research practice communications

4. To make **recommendations** to the SPHPM Executive or other appropriate bodies in relation to matters under the purview of this committee.

Back row: Prof Andrew Forbes, Prof Malcolm Sim, Dr Jayamini Illesinghe, Prof Olaf Drummer, Dr Elizabeth Douglas Middle row: Ms Hana Shahkhan, A/Prof Allen Cheng Front row: A/Prof Robyn Woods, Dr Liz Bishop, Prof Robin Bell, Mrs Marina Skiba,

Membership:

a) Prof Robin Bell (Chair)
b) Dr Liz Bishop (Research Governance Officer)
c) A/Prof Allen Cheng
d) Dr Elizabeth Douglas (Doctoral Co-ordinator)
e) Prof Olaf Drummer
f) Prof Andrew Forbes
g) Dr Jayamini Illesinghe (Research Manager)
h) Prof John McNeil (Head of School)
i) Prof Malcom Sim
j) Mrs Marina Skiba (Research Governance Officer)
k) A/Prof Robyn Woods
l) Ms Hana Shahkhan

Ex-Officio Members:

Prof Susan Davis

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

Chair of the Committee:
- Position currently held by Robin Bell.
- To be appointed by the Head of School for a duration determined by the Head of School.
- Meetings are convened by the Chair of the committee.

Secretary of the Committee:
- Role to be fulfilled by the Research Governance Officer.
- Duties include:
    - preparing and distributing agendas, ensuring all necessary documents requiring discussion or comment are attached to the agenda
    - notifying committee members of meeting times, dates and locations
    - taking notes and preparing minutes of each meeting distributing minutes to all committee members

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
    - 11 full audits (11 short audits and 0 long audits) in 2015
    - 539 Self-audit requests sent out in 2015
- Percentage of studies which submitted an annual self-audit or were exempt (e.g. study closed, study not started, not a SPHPM study)
    - 75%
- Percentage of new staff and students who completed 'Onboarding' (including the RG induction) induction within two months of starting with SPHPM

- 65%
- Short courses being provided
  - Run three times in 2015 (twice on the AMREP campus and once at the Monash Medical Centre)
  - As of November 2014 this course is now free for staff as well as students.
- Related journal articles and/or presentations in 2015
  - None

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

http://www.privacy.monash.edu.au/procedure/

Collection of Personal Information

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

Whistleblowers

Conduct and Compliance Procedure – Whistleblowers

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

Checklist for Respondents to Whistleblower Complaints at Monash University

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

Checklist for Staff Receiving a Whistleblower's Disclosure

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

Checklist for Welfare Managers of Whistleblowers at Monash University

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

Checklist for Whistleblowers at Monash University

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

Conflict of Interest

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

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

Conflict of Interest – examiner

http://www.monash.edu.au/migr/examiners/conflict-of-interest/

Examples of Conflicts of Interest and Guidelines for Action

http://www.adm.monash.edu.au/workplace-policy/conduct-compliance/examples.html
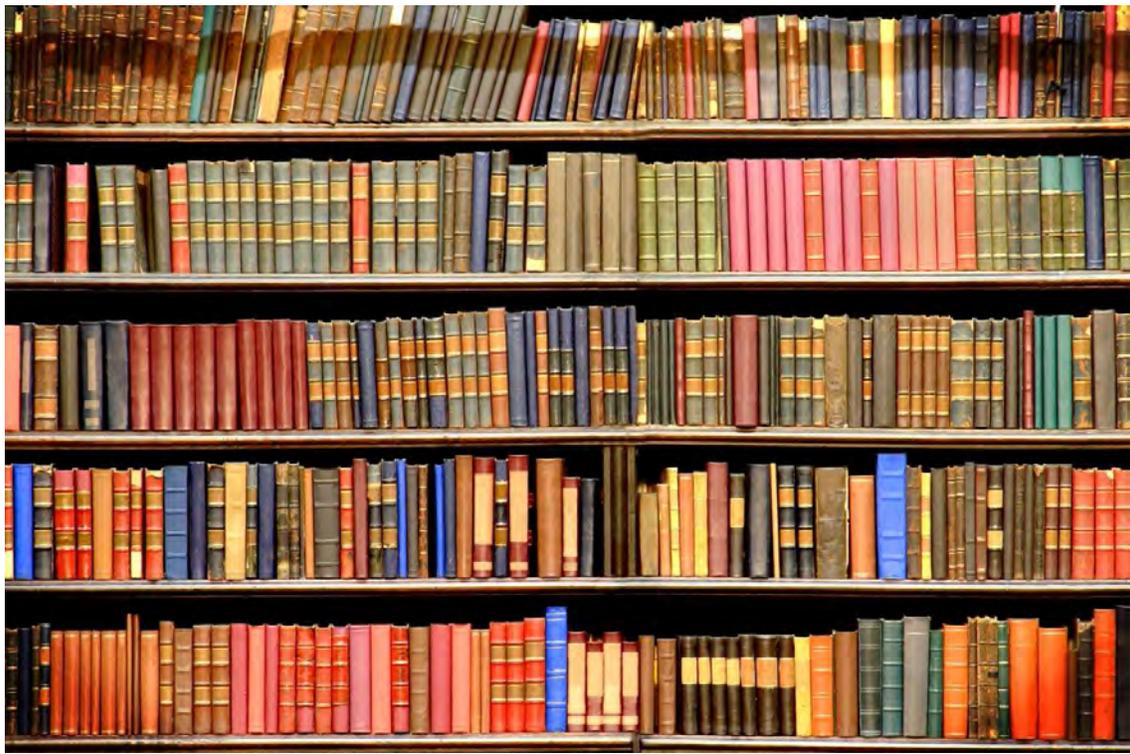
AUDITS OF RESEARCH PROJECTS

Full Audits

In 2014 the audit process was reviewed, the audit tool was updated, the grievance procedure was reviewed, modified and signed off by the universities solicitors office and three additional staff were assigned to the Research Governance unit (0.2 EFT each) to conduct audits.

Audits were divided into 'short audits' and 'long audits'. Long audits would only be conducted if the results of the short audits indicated a need for a more in-


depth look at the project.
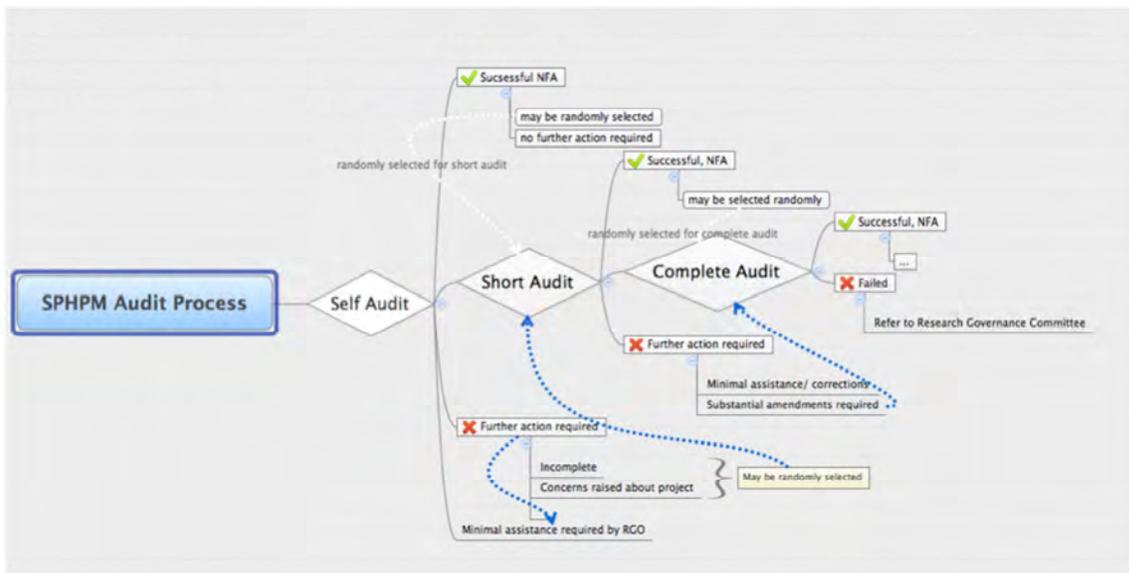
Short and long audits are conducted with the help of an audit tool. In both cases the tool covers all aspects of clinical research from ethics approval to data storage. The audit is conducted by Research Governance auditors who have been trained by the Research Governance Officer (RGO). The auditors check the project against the audit tool 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 auditors or RGO will follow up to ensure that any required changes are made.

In 2015 11 short audits were conducted and 0 long audits were deemed necessary as all short audits were considered satisfactory or requiring minimal modifications/corrections.

The SPHPM Grievance Procedure was modified and sent to the Monash University Solicitors office for review to ensure that it complied with University policy. This was to ensure that adequate protections were in place for both the auditors and the auditees.
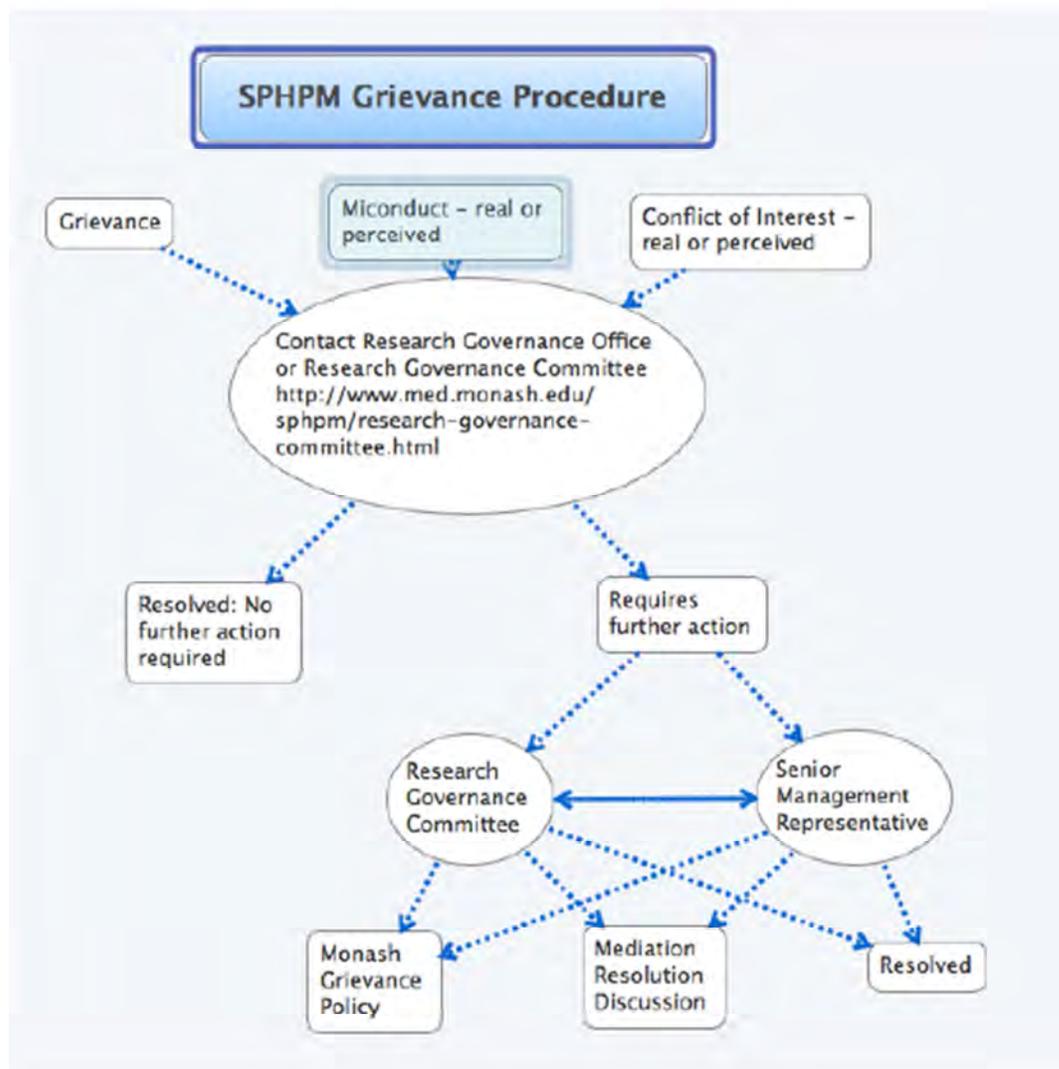
Self-Audits

The self-audit tool was introduced some years ago. This is a quick audit that is conducted by the researchers themselves. Staff were expected to complete it annually for each research project they were involved in. Without a trigger to remind staff not all staff completed this tool. As a result a self-audit was completed for fewer than 50% of projects.

The Alfred Hospital Ethics and Research Governance office included an effective self-audit reminder as part of their annual report. To optimise compliance and to ensure engagement by the principal investigators a similar approach was needed within SPHPM.

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 the self-audit must be completed by a designated due date. If the audit was not received, the Research Governance team followed

up with the study investigator. This system has increased the number of self-audits being completed considerably, with 75% received in 2015.

Issues with the online process that were identified during each audit period were addressed the following year. Changes included being able to grant access to the self-audit for researchers outside Monash and the automatic subject line in email notifications change to be study specific. Changes and updates to the system will be made as needed.

A comparison between self-audit responses and findings of the full audits conducted at the School of Public Health and Preventive Medicine
MUHREC project number: CF14/1739 - 2014000858

As the self-audit relies on self-reporting it is possible that this tool does not accurately reflect the way a project is being run. We therefore sort to compare what is self-reported by researchers with what is observed by the Research Governance Officer during a short audit.

A low risk application was submitted to Monash University Human Research Ethics Committee and approval obtained (CF14/1739 – 2014000858) to conduct a comparison between self-audits and face to face audits.

Projects for a short audit were selected at random. The only requirement for inclusion in this study was that a 2014 self-audit needed to have been completed and submitted to the Research Governance Office.   If that condition was met then the details of the randomly selected projects were provided to the RG auditor so that they could contact the investigator and the short audit could be conducted. The auditors were not provided with any information about the self-audits prior to conducting the short audits.

Once the short audits were complete and these were compared to the self-audits it quickly became apparent that the two audits were asking slightly different questions which added a level of complexity to the comparison. It was decided that 3 members of the Research Governance Committee (MS, RB and JI) would assess the self and short audits independently. The following assessment tool was drafted to guide the assessors:

Self-audit vs short audit project – CF14/17939-2014000858

Assessment of audits

Instructions:

Each plastic pocket contains the self-audit and the short audit for the same project.

Please compare the two audits for each project. The aim of our study (as stated in our protocol) is "To compare what is self-reported by research staff with what is observed by the Research Governance officer during an audit to further determine the accuracy of the self-audit process."

Please record you findings in the table below or on a separate page if you prefer. Please use the project numbers i.e. 1-8 (hand written on each audit) to identify which project you are referring to.

Assessor's name: _____

Project No.	Short audit comments	Self-audit comments	General comments
Project 1			
Project 2			
Project 3			
Project 4			
Project 5			
Project 6			
Project 7			
Project 8			

With regards to assessing each of the projects, there was considerable consistency between the three assessors. All three were in total agreement for 5 out of the 8 projects (62.5%) and 2 of the three assessors were in agreement for the remaining 3 studies (37.5%).

The assessors agreed that the self-audit and the short audit do not ask exactly the same questions.

For the short audit to build on the information collected by the self-audit we will need to modify the auditing tools.

One of the 8 projects used in this study had an issue identified on the short audit. This issue was not apparent from the self-audit however the self-audit didn't

specifically ask about this issue i.e. the researchers responses on the self-audit were accurate however the self-audit tool did not ask a question that would have highlighted to the researcher the need to rectify the error they had made.
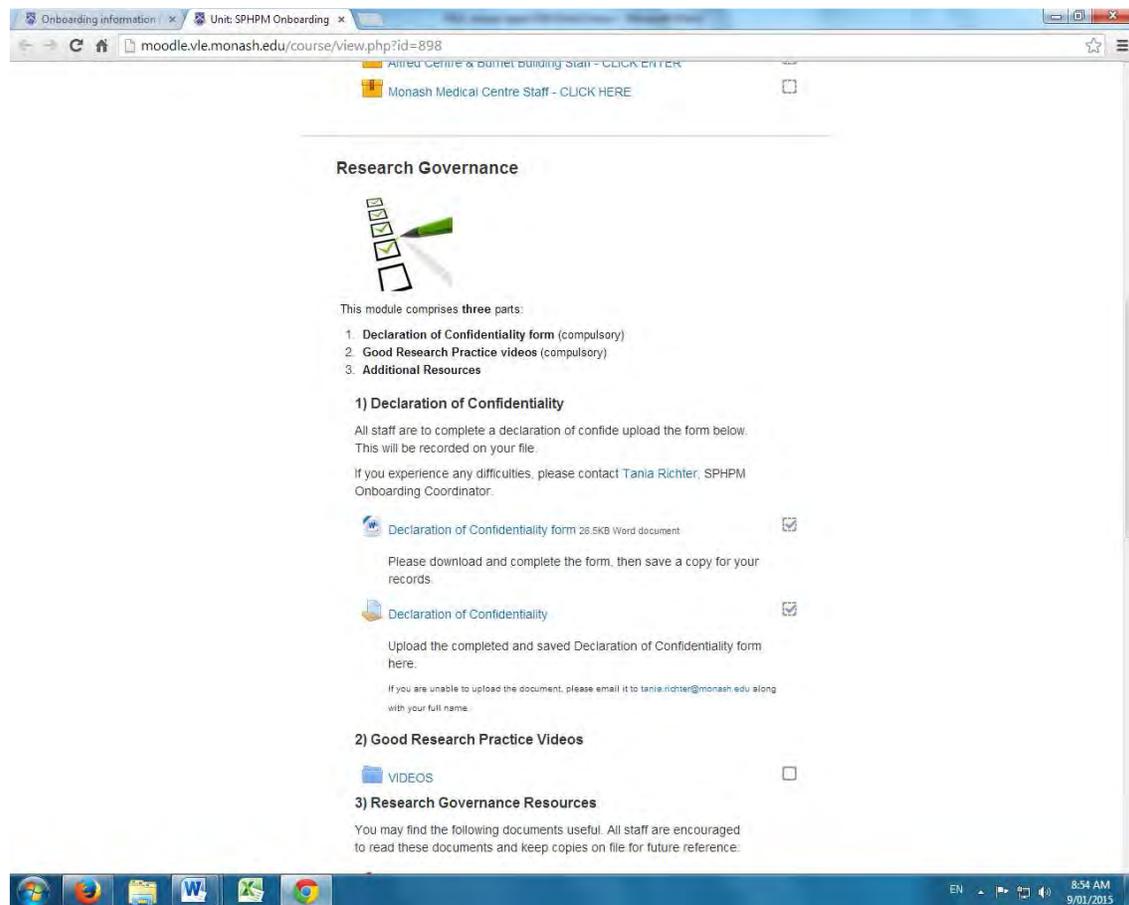
Conclusion:

We found nothing to indicate that researchers completing the self-audit were anything but totally accurate in the information they self-reported. However, our ability to compare what was self-reported with what was observed on face to face audits were hampered by the fact that the two audit tools asked different questions.

We therefore plan to update the short audit to ensure it includes (in addition to the current information) the information covered by the self-audit. We will then request an amendment to the current ethics approval and repeat the project as we feel it is important to confirm that the information that is self-reported via the self-audit tool is consistent with the finding of the short audits.

'ONBOARDING' – RESEARCH GOVERNANCE INDUCTIONS

In early 2012 face to face Research Governance Inductions were replaced by video inductions included as part of the schools compulsory "Onboarding". Onboarding is compulsory for, and accessible to, all members of the School and is found at http://www.med.monash.edu.au/intranet/sphpm/onboarding/new-staff.html.

Adjustments to the process of informing new starters (commencing staff and students) about Onboarding, assessing who has completed its compulsory aspects and following up staff and students who fail to complete it in a timely manner have been made and will continue to be made but overall this change (incorporating the training about Research Governance into Onboarding) has been a well received and successful initiative.

In 2015 65% of all new started completed the Research Governance component of the Onboarding package. A further 26% completed this component more than 2 months after commencing.

GOOD RESEARCH PRACTICE SHORT COURSE

The Good Research Practice Short Course was run three times in 2015 - twice on the AMREP campus (27th July and 11th November) and once for MCHRI (Monash Centre for Health Research and Implementation) at Monash Medical Centre (14th April). This course was open to all staff and students in SPHPM (compulsory for PhD students). Streamlined Ethical Review Process (by request, MCHRI course only)

Following the assessment of participants' feedback it was decided to condense this training into a half day course. It was further decided that all new staff should be encouraged to attend and therefore the course would be free for staff as well as students and no longer offered to the wider community. The half day course covers:

- Introduction to research ethics
- Informed consent
- ICHGCP
- Privacy/confidentiality

Additional topics are included on request. "SERP (Streamlined Ethical Review Process)" was included in the course run for MCHRI

This course is scheduled to run three times in 2016 (7th July, 2nd September and 16th November).

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.

In 2013 the Declaration of Confidentiality was converted into an online form which can be accessed as part of the Onboarding package. Anyone unable to access the form online can obtain a hard copy. To ensure these forms are signed new starters are not provided with a swipe card without confirmation that the declaration of confidentiality form has been signed.

Completed forms (electronic and hard copy) are forwarded to the Research Governance Officer who stores them for future reference.

REPORTS OF MISCONDUCT

In 2015 the Research Governance Committee has not been required to investigate any reports of research misconduct within the School nor have any instances of misconduct become apparent as part of the School's auditing process. The Research Governance Committee has met with Research Governance representatives of other organisations on the AMREP campus to discuss an issue of misconduct that occurred elsewhere on the campus with the view of learning from the incident and using the lessons to improve our auditing and education.

ONLINE TRAINING

In order to support the conduct of high quality research within SPHPM it is necessary to ensure that all staff and students have access to training in the relevant areas. In addition to the short course we set out to develop a concise online training package that could be completed at any time. This includes a short quiz to ensure the content is understood.

The quiz is located on the SPHPM Onboarding page with a link to the Research Training.

This training package was picked up by the University at large and became part of Responsible Research RST0005 which was a compulsory component of the Monash University 'New PhD' program. This ran successfully for two years and was replaced by a commercial product.

The schools online training package has since been completed and can be accessed from http://www.med.monash.edu.au/intranet/sphpm/research-training/index.html. This training will be compulsory for all new staff commencing from January 2016. Completion of the quiz will be monitored and staff who fail to successfully complete it will be followed up.

The training covers:

- Ethics
- Intellectual Property
- Privacy and Confidentiality
- Authorship
- Clinical Research
- Research Misconduct
- Collaborative Agreements
- Conflict of Interest
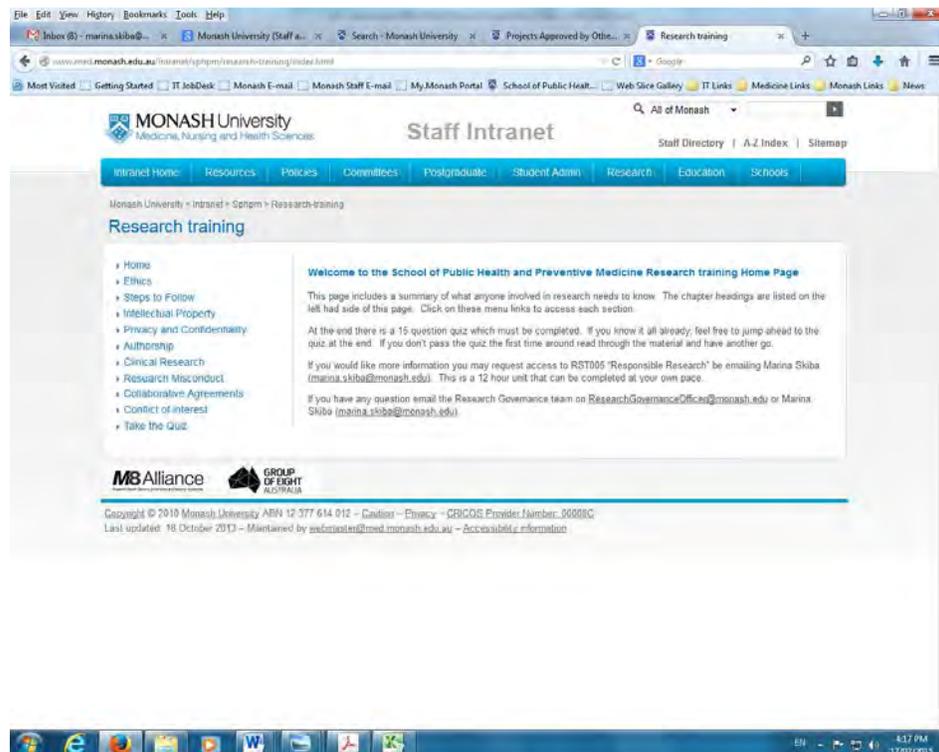
HIGHLIGHTS OF 2015

Research Governance well represented in BMS1042 Q and A panel

"Public Health and Preventive Medicine" (BMS1042) is the Schools largest undergraduate unit with approximately 480 students. The subject is co-ordinatored by Basia Diug who organised a Q and A session as a way of engaging the interest and interaction of the students. The panel consisted of Basia Diug, Robin Bell (Chair of the Research Governance Committee), Dragan Ilic, Evie Kendal and Marina Skiba (Research Governance Officer).

The topics covered included:

- Verbal and psychological autopsies
- E-professionalism and social media
- Pandemic preparedness and personal liberty

The session was well received by the students who provided positive feedback.

*Thanks to Penny Robinson for the photo*

SPHPM shared drive backup/archive

The working group was established in 2014 to update the backup and archiving of the shared drive to ensure that we continue to comply with the highest standard. This working group continued to meet to identify and implement a long term safety and security of all SPHPM electronic data and files.

LabArchives

One of the possible long term strategies being considered for SPHPM data is LabArchives. This is a commercial product that has its original in the organisation of benchtop notes and was originally designed as an electronic workbook. However, LabArchives is now a product that is just as useful for human research both large and small.

The University has decided to make the use of LabArchives compulsory for new PhD student starting in 2016. It is therefore timely that the School is considering this product for more widespread use.
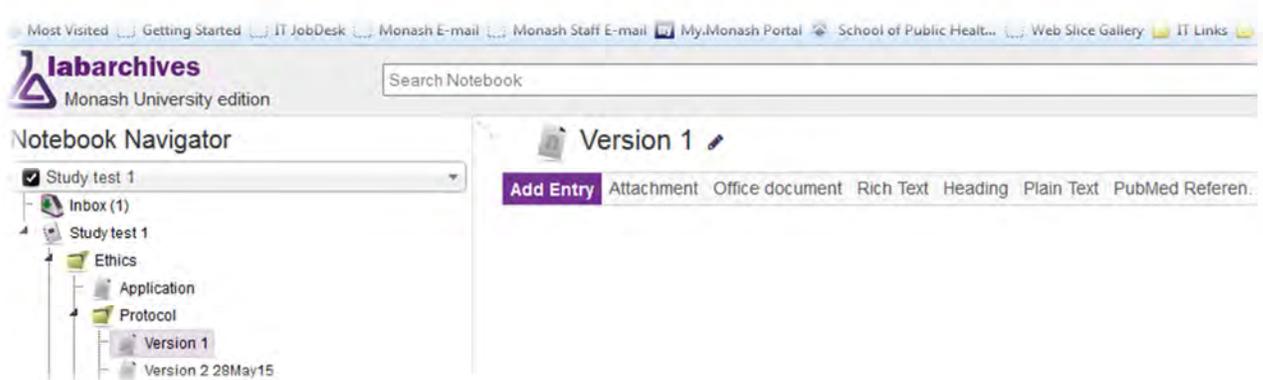

Victorian Research Governance Network (VRGN)

Marina Skiba joined the newly formed executive committee of the Victorian Research Governance Network. The VRGN was initiated by Janet Russell who chaired the executive committee in 2015. The VRGN brings together about 50 Research Governance staff from more than 25 Victorian public and private health institutions.

MUHREC

Through the Schools short audits it was noticed that some projects were being run without a formal protocol in place. It was determined that as MUHREC did not require a protocol to be included with their ethics application there was no hard trigger that ensured that projects did not progress without one.

MUHREC was contacted and Simon Barrett attended the September Research Governance Committee meeting to discuss the issue. As a result the main HREC review form (http://intranet.monash.edu.au/researchadmin/human/hrec-review.html) has been updated to include the following in section 2f "Clinical Trials":
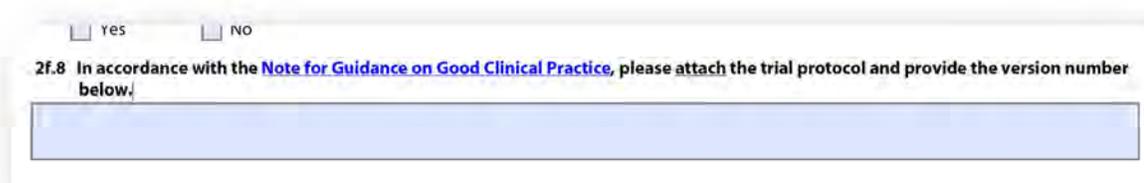
☐ Yes   ☐ No

2f.8 In accordance with the Note for Guidance on Good Clinical Practice, please attach the trial protocol and provide the version number below.

Public Access – Publication Policy

David Groenewegan from the Monash Library was invited to give a presentation to SPHPM and CCS regarding the PLOS Public access to data policy (blogs.plos.org/everyone/2014/02/24/plos-new-data-policy-public-access-data/). David came to the AMREP campus 25th March to provide an update.

It is ultimately the researcher's responsibility to ensure public access to their publication (however the library is there to help where they can). The polices vary from journal to journal and include the article being available online for a fee, the article being available in time and allowing the final proof to be made available in an open access repository.

Nuffield council on Bioethics report

The Nuffield council on Bioethics report (http://nuffieldbioethics.org/project/research-culture/) has been made available on the Onboarding page and on the Research Governance page.

PUBLICATIONS

None in 2015