**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.
**Membership:**

a) Prof Sophia Zoungas  
b) Prof Robin Bell  
c) A/Prof Allen Cheng  
d) Dr Elizabeth Douglas (Doctoral Co-ordinator)  
e) Prof Olaf Drummer  
f) Prof Richard Bassed  
g) Prof Andrew Forbes  
h) Dr Jayamini Illesinghe (Research Manager)  
i) Prof John McNeil (Head of School)  
j) Prof Malcom Sim  
k) Mrs Marina Skiba (Research Governance Officer)  
l) A/Prof Robyn Woods  
m) Prof Danny Liew  
n) Dr Nupur Nag  
o) Dr Susannah Ahern

**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:**

- Prof Sophia Zoungas chaired the committee throughout 2017.
- 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 Senior Management Committee via the Research Governance Officer and/or the Chair of the Research Governance Committee.

Key Performance Indicators:
- Number of projects audited in a calendar year
  - 22 full audits initiated
    - 22 completed (12 short audits and 0 long audits) in 2017
    - 0 ongoing
  - 513 Self-audit requests sent out in 2017
- Percentage of studies which submitted an annual self-audit or were exempt (e.g. study closed, study not started, not a SPHPM study)
  - 88%
- Percentage of new staff and students who completed ‘Onboarding’ (including the RG induction) induction within two months of starting with SPHPM
  - 81%
- Short courses being provided
  - Run twice in 2017
- Related journal articles and/or presentations in 2011
  - 1 poster presentation
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


Collection of Personal Information


Whistleblowers

Whistleblowers Procedure


Checklist for Whistleblowers


Data Management

Digital data storage options at Monash


Conflict of Interest

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


Conflict of Interest – examiner

https://www.monash.edu/graduate-research/faqs-and-resources/content/chapter-twelve/i

Examples of Conflicts of Interest and Guidelines for Action

AUDITS OF RESEARCH PROJECTS

Full Audits

SPHPM audits are 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.

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**SPHPM Audit Summary**

<table>
<thead>
<tr>
<th>Self-Audit</th>
<th>For all current research projects (annual requirement)</th>
<th>Conducted by researchers or project representatives themselves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short Audit</td>
<td>For randomly selected projects only (researchers will be notified via email)</td>
<td>Conducted by SPHPM Research Governance Auditors</td>
</tr>
<tr>
<td>Long Audit</td>
<td>For a subset of projects that require further attention after short auditing</td>
<td>Conducted by SPHPM Research Governance Auditors</td>
</tr>
</tbody>
</table>

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 2017 22 short audits were completed and 0 long audits were deemed necessary as all short audits were considered satisfactory or requiring minimal modifications/corrections.

When the SPHPM Grievance Procedure was modified it was 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.
SPHPM Grievance Procedure

Grievance

- Misdemeanor - real or perceived
- Conflict of Interest - real or perceived

Contact Research Governance Office or Research Governance Committee:
http://www.med.monash.edu/spphpm/research-governance-committee.html

Resolved: No further action required

Requires further action

Research Governance Committee

Senior Management Representative

Monash Grievance Policy

Mediation Resolution Discussion

Resolved
Self-Audits

The self-audit tool was introduced some years ago. A co-ordinator/investigator for each project was identified and an email is sent annually 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 has resulted in 88% of projects completing the self-audit in 2017.

In 2017 the SPHPM self-audit tool was available on the MUHREC platform ERM. This allows any Monash University staff member and student access to the tool and anyone outside SPHPM is welcome to complete and submit a self-audit.

As in previous years, SPHPM researchers are sent an email requesting that they complete a self-audit for each study. The email includes instructions on where and how to access the tool as well as how to complete and submit the form. Submitted forms are accessed by the RG team and the audits are reviewed online.
‘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 https://www.intranet.monash/medicine/sphpm/onboarding

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. Overall this change to the process (incorporating the Research Governance Induction into Onboarding) has been a well received and successful initiative.

In 2017 75% of all new starters completed the Research Governance component of the Onboarding package within 1 month. A further 10% completed this component within 2 months of commencing. By the end of the year only 8% of new starters had not completed this induction.
ETHICS AND GOOD RESEARCH PRACTICE SHORT COURSE

The Good Research Practice Short Course was run twice in 2017 (24th March, 11th September). This course was open to all staff and students in SPHPM (compulsory for PhD students). An additional session was included as part of the 2 week DFAT Sri Lankan program and was run on 31st October.

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 in 2015.

Not all HDR students can attend the short course (e.g. students located offshore) so one of the training days has been recorded and a podcast made which students can watch. A 12 question, multiple choice quiz has also been developed. This was deemed necessary as confirmation that the student had viewed the entire podcast.

This course is currently scheduled to run twice in 2018 (14th March and 20th September).

Monash Partners are considering offering this course as part of the training offered to paid employees of Monash Partner institutions.

We are looking at developing an online version of this course which should benefit not only SPHPM students who are unable to attend but also Monash Partners.
GOVERNANCE LECTURES

The Research Governance team provides support to a number of undergraduate and post graduate subjects by delivering lectures and/or providing course material in topics such as Ethics, Governance and Research Misconduct. Support provided in 2017 includes:

**BME3032**: Introduction to the Health System – *Quality in Health and Medical Research*

**MPH5236**: Clinical Trials – *Confidentiality in Research and Risk Management; Misconduct workshop*

**MPH5283**: Ethics, good research practice and practical research methods - *Good research practice (GCP, practical applications, risk management, indemnity and insurance, sponsors and quality control)*

**Honours students (local and international)** – *Research Governance Induction; Ethics and Governance lecture*

**Summer Vacation students** – *Research Governance Induction*
TRANSCELERATE ACCREDITED ICH GCP TRAINING

Monash Partners is supporting its member institutions by offering free TransCelerate accredited training to all paid employees on Monash Partner institutions. This program was initiated in 2016 and will continue until the end of 2018.

Monash Partners is an academic health science centre formed from a collaboration between the following institutions:

- Monash University
- Alfred hospital
- Cabrini hospital
- Epworth Health Care
- Monash Health
- Hudson Institute
- Baker IDI
- Burnet Institution
- Peninsula Health
- Eastern Health

Their goal is to increase collaboration between member institutions which will result in improved health care for the community.

TransCelerate BioPharma Inc. (http://www.transcelebratebiopharmainc.com/) is a conglomeration of pharmaceutical companies who have joined forces in order to streamline aspects of the research and development process. As part of this initiative they have developed a process of accredited GCP training.
They have a set a minimum criteria for ICH GCP training and will provide accreditation to courses that meet this minimum. Prior to this initiative pharmaceutical companies provided GCP training for research staff each time they commenced a clinical trial. Researchers who undergo TransCelerate accredited training are considered certified so that sponsors save time by not having to deliver GCP training at the commencement of a clinical trial.

Pharmaceutical companies have indicated that they will favour sites whose staff have TransCelerate accredited ICH GCP training. Hospitals are keen for their research staff to undergo this training to ensure the hospitals continue to attract cutting edge research that will allow their patients access to the newest therapies.

Monash Partners has purchased a TransCelerate accredited ICH GCP training package from Sophie Mepham and currently has 5 accredited trainers to deliver the training.

Alfred campus trainers:

- Marina Skiba
- Louise Shiel
- Lynne Murray

Monash Medical Centre trainers:

- Cheryl-Ann Hawkins
- Kurian Thomas

The training package purchased offers the following training:

- GCP course – a complete course that covers ICH GCP (delivery time – 6½ hours)
- GCP Refresher course – a two hour course designed for researchers who have previous GCP training and only need an update
- Short sessions – An array of 1 hour sessions designed for support staff whose primary role is not research e.g. Pharmacy, Pathology, nursing and Radiology (these sessions do not constitute accredited training)

To receive a certificate of accredited training for the GCP course and the Refresher course participants must attend the whole session and complete (and pass) a quiz at the end.

Monash Partners is currently looking to source an online version of the main GCP and it is hoped that this will be available in 2018. This will relieve the demand on the course generated by the interest of the researcher and the requirement of an increasing number of ethics committee who are mandating this training for all researchers.
In 2017 the following courses were run:

**GCP** – 17 sessions were run (between the Alfred campus, MMCC, Cabrini and Epworth)

**Refresher course** – 5 sessions were run across the two main sites

As a result of the ICH GCP addendum that came into effect globally in November 2016 (but has not yet been endorsed by the TGA) the GCP course and the Refresher course has been updated. The May 2017 version of the courses are currently being delivered by the Monash Partner trainers.

Monash Partners is also exploring to possibility of purchasing an online version of the TransCelerate accredited course as well as a course suitable for researchers involved in low risk projects.
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 from Reception at 553 St Kilda Road or level 6 of the Alfred Centre. 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 2017 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. However, the RGC and/or RGO have been asked for advice on a number of issues including how best to manage issues that may have developed into misconduct if inappropriately handled.
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 (which is compulsory for all HDR students) 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 has become 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 https://www.intranet.monash/medicine/sphpm/onboarding This training is 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 2017**

**Research Governance well represented in BMS1042 Q and A panel**

“Public Health and Preventive Medicine” (BMS1042) is the School's largest undergraduate unit with approximately 680 students. The subject is co-ordinated by Basia Diug who organises a Q and A session as a way of engaging the interest and interaction of the students. Due to the size of the class in 2017, the panel was run twice. The first panel consisted of Evie Kendal, Marina Skiba (Research Governance Officer) and Julian Koplin. The second panel consisted of Evie Kendal, Marina Skiba (Research Governance Officer) and Neal Smith. Both sessions were chaired by Basia.

The topics covered included:

- The case of Charlie Gard – Who should decide what is in the best interest of a child (parents, doctors or the court)?
- Pandemic preparedness
- Resource allocation dilemma

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. In 2016 SPHPM established a SPHPM Data Management Steering Committee and this task is being shared with them.

**Australian Research Management Society (ARMS) – Wellington, New Zealand 2017**
Marina Skiba presented a poster entitled “Risk Management – the plan, the process the implementation” at this year’s ARMS conference held in Wellington New Zealand.

The poster pointed out that Risk Management forms an integral part of the SPHPM Research Governance strategy for the prevention of misconduct, loss of data, breaches of confidentiality etc. in light of the large, sensitive data sets held here and the remote/off site collect of a much of that data. Having a Risk Management plan in place is a very important starting point but it doesn’t stop there. The plan must be workable, it must be disseminated to researchers and students and it needs to be “used”. The poster told how our strategy for implementing the Risk Management plan has changed over time to achieve this.

**Risk Management – the plan, the process, the implementation**
Marina Skiba, Jayamini Illesinghe, John McNeil
School of Public Health and Preventive Medicine, Monash University, Melbourne, Australia

It described that the risk management strategy implemented by the school includes: advertising the existence of the school’s Risk Management plan, educating staff about its content, obtaining feedback from many research groups within the school around the risks they face, drafting a risk matrix to be completed by each study on an annual basis as well as implementing the risk matrix.
Australian Fellowship Award (Department of Foreign Affairs and Trade) – Sri Lanaka

In late 2016 SPHPM School Manager, Dr Jayamini Illesinghe, was approached by representatives from the Ministry of Health in Sri Lanka who asked for SPHPM’s assistance in writing a Code of Conduct and Research Governance Strategy for Sri Lanka. With an Australian Fellowship Award from the Department of Foreign Affairs and Trade (DFAT) and support from the World Health Organisation in Sri Lanka we were able to host 15 senior Sri Lankan Researchers for 2 weeks from 30th October, 2017.

The diverse program provided training in ethics, research governance and research methodology, presentations from SPHPM staff, the NHMRC, the Consultative Council and various institutional ethics committees, presentations from the Sri Lankan delegates and intensive writing workshops delivered by Tomas Zahora of the Monash Library.

The Sri Lankan delegation consisted of representatives from their Ministry of Health (including the Director of Research), the National Health Research Council (including the Chairperson) and the Sri Lankan branch of the World Health Organisation (WHO).

This initial phase of the program was well received by all. Jay Illesinghe and Marian Skiba plan to travel to Sri Lanka in the New Year for the second phase of the program. This will involve review of the draft Code of Conduct and Research Governance Strategy.

Vacation student

N’arweet Carolyn Briggs delivering the Welcome to Country

Summer
From 20th November to 15th December, 2017 Research Governance hosted Summer Vacation student Emily Prior. Emily was supervised by Jay Illesinghe and Marina Skiba and conducted a rapid systematic review of literature on audits designed to prevent and identify fraud. It is hoped that Emily’s findings will be published.
GOALS FOR 2018

Risk Management

We plan to include a risk matrix as part of the annual self-audit. This will ensure that each study considers their risk position on an annual basis.

Australian Fellowship Award (Department of Foreign Affairs and Trade) – Sri Lanka

Jayamini Illesinghe and Marina Skiba plan to visit Sri Lanka in early 2018 to follow up on the progress of their Code of conduct and Governance strategy documents.
PUBLICATIONS/PRESENTATIONS

2017:

Poster Presentation:


Previous Publication/Presentations:

Publications:


Abstracts:


Poster Presentations:


Oral Presentations: