School of Public Health and Preventive Medicine

Research Governance Committee

Annual Report 2018

monash.edu/medicine/sphpm/research/governance
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 methodologically, sound and ethically rigorous research.

Objectives:
1. To maintain a suitable level of 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:

Prof Sophia Zoungas (Chair)
Prof Robin Bell (Women’s Health Research)
A/Prof Allen Cheng (Chair of Research Committee)
Dr Rosanne Freak-Poli (HDR Coordinator)
Prof Richard Bassed (Dept of Forensic Medicine)
Prof Andrew Forbes (Research Methodology)
Dr Jayamini Illesinghe (Research Manager)
Prof John McNeil (Head of School)
Prof Malcom Sim (Occupational & Environmental Health Sciences)
Mrs Marina Skiba (Research Governance Officer)
A/Prof Robyn Woods (ASPREE)
Prof Danny Liew (Clinical Epidemiology)
Ms Joanne Dean (Health Services)
Dr Susannah Ahern (Data Safety Committee)
A/Prof Barbora de Courten (MICHRI)
HDR representative (observer)

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 Auditor.
• Duties include:
  o preparing and distributing agendas, ensuring all necessary documents requiring discussion or comment are attached to the agenda
  o notifying committee members of meeting times, dates and locations
  o taking notes and preparing minutes of each meeting
  o 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 and/or the Chair of the Research Governance Committee.

Key Performance Indicators:
- Number of projects audited in a calendar year
  - 3 full audits initiated
    - 2 completed (2 short audits and 0 long audits) in 2018
    - 1 ongoing
  - 654 Self-audit requests sent out in 2018
- Percentage of studies which submitted either an annual self-audit or a risk assessment or were exempt (e.g. study closed, study not started, not a SPHPM study)
  - 76%
- Percentage of studies which submitted both a self-audit and a risk assessment
  - 59%
- Percentage of new staff and students who completed ‘Onboarding’ (including the RG induction) induction within two months of starting with SPHPM
  - 63%
- Short courses being provided
  - Run once in 2018
- Related journal articles and/or presentations in 2018
  - 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


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


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.

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 2018 2 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/sphp/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 and Risk Assessment

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 strategy resulted in 88% of projects completing the self-audit in 2017. In 2018 researcher were asked to complete a risk assessment tool as well as a self-audit for each project. The number of projects that completed either the self-audit or the risk assessment (or told us that the study was closed) dropped to 76% and only 59% of projects completed both the self-audit and the risk assessment. It is possible that the addition of the risk assessment tool as a separate form could have created confusion (researchers believing they had fulfilled their after completing one form) or frustration at having to complete two separate forms. It is planned that the risk assessment tool will be incorporated into the current self-audit tool for 2019.

In 2017 the SPHPM self-audit tool became 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.
The risk assessment tool was developed in Qualtrics. This program enabled the generation of a risk registry from the completed risk assessments. Researchers were asked to complete a risk rating calculation grid for each of the school’s 9 risks as well as a 10th risk on OHS. For any risk with rating of ‘high’ or ‘extreme’ researchers were asked to provide a risk mitigation strategy.

SPHPM researchers are sent an email requesting that they complete a self-audit and risk assessment for each study. The email includes instructions on where and how to access both tools as well as how to complete and submit the forms.

Submitted self-audit forms and risk assessment tools are accessed by the RG team. Researchers are contacted if their self-audit indicates a potential problem. They are provided with support and guidance to rectify any issues. Researchers are also contacted if there is a high or extreme risk in their project and the risk mitigation strategy did not seem sufficient to manage the risk. Again, researchers are offered support and guidance to rectify the issue.

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**Likelihood criteria**
- Minor - Although this is a possibility it is very unlikely to occur except in extreme circumstances
- Moderate - The event may occur at some time
- Major - Very likely that this event will occur.

**Impact criteria**
- Minor - Unlikely to have an impact, little or no disruption, little or no damage to reputation, minimal financial loss
- Moderate - Some financial impact, negative media coverage, illness/injury
‘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 2018 41% of all new starters completed the Research Governance component of the Onboarding package within 1 month. A further 22% completed this component within 2 months of commencing. By the end of the year only 7% of new starters had not completed this induction.
ETHICS AND GOOD RESEARCH PRACTICE SHORT COURSE

The Good Research Practice Short Course was run once in 2018 (14\textsuperscript{th} March). The 20\textsuperscript{th} September was cancelled due to staff issues (additional staff are being recruited to offer this course to avoid this in the future). This course was open to all staff and students in SPHPM (compulsory for PhD students). The course was also run as part of the 2 day collaborative workshop that took place in Sri Lanka on 1\textsuperscript{st} and 2\textsuperscript{nd} February as part of the DFAT Sri Lankan program.

The half day course covers:

- Introduction to research ethics
- Informed consent
- ICH GCP
- 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 off shore) 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.

In order to make this course more accessible for staff and students unable to attend the face-to-face course an online version is being developed in conjunction with the Teaching Research Support Unit (TRSU). To date, two of the four modules have been drafted and will soon be finalised with the remaining 2 course modules to follow shortly.

Monash Partners are considering providing this course as part of the training offered to paid employees of Monash Partner institutions and are particularly interested in the online version of the course that is under development.

This course is currently scheduled to run twice in 2018 (7\textsuperscript{th} March and 10\textsuperscript{th} September).
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 2018 includes:

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

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

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

**BMS1042**: *Public Health Ethics*

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

**BMS3990**: *Research Governance Induction*

**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.transceleratebiopharmainc.com/) is a conglomerate 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 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 2019. 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.
Each year the main GCP course is run 8 times at each of the two main locations (Alfred campus and Monash Medical Centre), the Refresher course is run 3 times and once each at Cabrini, Epworth and Peninsula hospital.

As a result of the ICH GCP addendum that came into effect globally in November 2016 (which was endorsed by the TGA in February 2018) 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 offering an online version of the TransCelerate accredited course as well as a course suitable for researchers involved in low risk projects.
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 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**
Research Training options for SPHPM staff and students

**Staff**

- TransCelerate Accredited ICH GCP training (Face-to-face)
  - Must be a paid employee of a Monash Partners organisation.
  - Dates and Registration are available at: https://www.monash.edu/medicine/sphpm/teaching/shortcourses

- TransCelerate Accredited ICH GCP training (Online)
  - Neither of these courses are endorsed by Monash Partners at this time but they do provide a TransCelerate Accredited certificate.
  - Note: neither of these courses cover Australia specific requirements such as CTN.
  - National Institute of Health - https://gcp.nidatraining.org/help

**Students**

- TransCelerate Accredited ICH GCP training (Online)
  - Neither of these courses are endorsed by Monash Partners at this time but they do provide a TransCelerate Accredited certificate.
  - Note: neither of these courses cover Australia specific requirements such as CTN.
  - National Institute of Health - https://gcp.nidatraining.org/help

- Ethics and Good Research Practice short course
  - This is an internal course which is compulsory for all Doctoral students.
  - Note: this course is NOT an accredited course.
  - Dates and registration available from: https://www.monash.edu/medicine/sphpm/teaching/shortcourses

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Note – from January 2018 some Ethics Committees (including Alfred Health) require TransCelerate Accredited ICH GCP training for all researchers submitting clinical trials and/or interventional studies for ethics approval.
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 from Reception. 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 2018 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.
HIGHLIGHTS OF 2018

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

Phase 1(Australia – 39th October to 10th November, 2017)

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.
Phase 2 (Sri Lanka – 1st and 2nd February, 2018)

Jay Illesinghe and Marian Skiba travelled to Sri Lanka in February for the second phase of the program where they participated in a 2 day workshop.

The first day was opened by Hon Dr Rajitha Senaratne, Minister of Health, Sri Lanka. Jay and Marina delivered training in ethics and good research practice and participated in the review of the Code of Conduct. This day was targeted at members of ethics committees across Sri Lanka. 75 attendees had been invited but many more turned up to hear what Monash University had to say. The feedback received around the training was very positive.

The second day focussed on the draft Research Governance strategy. Jay and Marina were invited panel members along with a number of prominent Sri Lankan researchers. The panel lead a discussion on the draft Research Governance document.
Launch of the Code of Conduct

The final document “Code of Conduct for Health Research in Sri Lanka” was officially launched by the Minister of Health as part of World Health day in April 2018. It is hoped that the Research Governance strategy will be finalised by the end of 2018.

While in Sri Lanka Jay and Marina did find time to see some of the sites, indulge in the local food and enjoy the experience.
**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. After exploring various options it has been decided that SPHPM researcher data is to be transitioned to a new X: drive. The X: drive will function in the same way as the S: drive but will have more robust archiving of the drives backups:

- Daily backup will be archived for 31 days
- Monthly backups will be archived for 12 months
- Quarterly backups will be archived for 7 years
- Yearly backups will be archived for 15 years

A small number of research units tested the X: drive during 2018. It is anticipated that research projects will begin moving across to the X: drive in early 2019.

**SPHPM File naming policy**

To encourage all staff and students to name and store their electronic files in a way that will enable them to always be identified and located, the SPHPM file naming policy was printed, laminated and placed on every desk within the school. A full copy of the policy can be found in Appendix H of the Guide to Good Research Practice.
GOALS FOR 2018

X: drive

It is planned that all research projects within SPHPM will be transitioned to the X: drive by the end of 2019.

Guide to Good Research Practice

The Guide to Good Research Practice will be updated during 2019 and the 8th edition will be available by the end of the year.
PUBLICATIONS, PRESENTATIONS AND AWARDS

2018:

Awards:

1. Dean’s Awards for Excellence – “Excellence in Research Impact (Economic and Social Impact)”

Previous Publications, Presentations and Awards:

Publications:


Abstracts:


Poster Presentations:


Oral Presentations: