



Medicine, Nursing and Health Sciences

School of Public Health and Preventive Medicine

Risk Management Plan



Creating Knowledge for Improved Health

Introduction

Experience elsewhere has demonstrated that a serious misadventure in our research activities could have repercussions. This could result in disrepute of our entire research program and possibly compromise research activities elsewhere in our University.

Although such episodes have generally resulted from aberrant behaviour by individuals, responsibility for establishing a culture that reduces the likelihood of such an event rests with management of a research department or institution.

Within the School of Public Health and Preventative Medicine (SPHPM) we have certain vulnerabilities to research misadventure that puts us at risk. These include:

- Research projects with responsibility dispersed amongst several senior investigators.
- No single individual or committee with oversight responsibility for standards across our research program.
- Heavy reliance on relatively junior staff and PhD students to collect and analyse research results.
- High level of investigator initiated research that is not monitored by external bodies such as pharmaceutical companies.
- Data collected off-site by research assistants working without direct supervision.

Because of these concerns the School has established a Risk Management Plan with the following components:

- Development of a “Research Governance Induction Session” which ensures that all new staff and students are aware of the expectations and support available within the school with regards to research activities.
- Development of “Good Research Practice Guidelines” that are distributed to all staff and students which sets a standard for research activities conducted within the school.
- Implementation of an online training package for all new staff and students. The training gives an overview of ethics and good research practice and should take about 2 hours to complete.
- Development of an annual “Good Research Practice Course” which must be attended by all PhD students and all new staff employed at level C or below. Although not compulsory this course is recommended for all other employees of SPHPM.
- Developed a short online training package in Good Research Practice which is compulsory for all new staff and students.
- Establishment of a “Research Governance Committee” and appointment of a part-time “Research Governance Officer” to assist in achieving/maintaining a high standard of research within the school by ensuring research projects comply the Good Research Guidelines.
- Establishment of a “Research Risk Management Plan” that attempts to foresee our major areas of risk and ensure that barriers are in place to reduce the likelihood of occurrence.
- None of these initiatives will guarantee a reduction in the likelihood of serious events occurring. However, this document will emphasise to senior staff their responsibility and our basic expectations of all others involved in our research program.



Purpose of the Research Risk Management Plan

The purpose of the Research Risk Management Plan is to attempt to identify the most significant risks that we face in the conduct of research within the Monash School of Public Health and Preventive Medicine. The program also outlines approaches taken by department management and staff to reduce the likelihood of these risks eventuating. The document will be constantly updated as new risks are identified and new strategies are devised to counter them.

Risks

1 Fraud in Collection of Data

Description of risk

Data collected and used in the analysis of a research project must be accurate. Data may be inaccurate as a result of carelessness. It may also be inaccurate as a result of intentional falsification, manipulation or alteration. This is research fraud. Examples include:

- A research assistant responsible for interviewing patients in their homes invents data rather than taking the time to make the visits.
- A research student 'adjusts' a subject's characteristics to make it appear that they meet the eligibility criteria for entry to a study
- A senior researcher fraudulently adjusts data to fit his/her preconceived idea as to what the results should show.

Likelihood of occurrence

Data fraud is more likely to occur in the following "risk settings":

- Research personnel are collecting data in remote locations with inadequate supervision
- Research personnel responsible for data collection are new to research and have not been adequately trained or briefed
- Situations where there is a low likelihood that data collection will be checked or audited
- Situations where senior staff are overcommitted and do not have adequate time to discharge their supervisory responsibilities

Likely consequences

- Results of the study may not be reportable and published. If the study has already been published the article will need to be withdrawn leading to the individuals involved losing their opportunity for a successful research career.
- If the study has influenced clinical practice patients may be treated with ineffective interventions or not receive effective therapy. This may potentially affect the health of very large numbers of individuals.
- Falsified data may lead to a breach of contract with an external research sponsor and liability for damages. The study may have to be repeated at a heavy cost to the department.
- The relevant ethics committees must be notified and additional penalties and restrictions may result.

Barriers to the occurrence of this risk within SPHPM

SPHPM must establish a strong research culture that emphasises accuracy and integrity in data collection and all subsequent research procedures.

- Ensure that all new staff and research students are adequately trained in good research practice and research integrity. (All SPHPM staff must complete the "research governance induction" which is part of the onboarding process undertaken by all new staff).
- Require all research projects with 'remote' data collection to have adequate data-quality control procedures that would be likely to detect falsified data.
- Require all chief investigators to hold regular study meetings which should include a review of data-quality measures and audit results.
- Ensure that Standard Operating Procedures (SOPs) are in place for most key data collection procedures including quality control procedures

2 Carelessness or errors in the collection or analysis of data

Description of risk

The conclusion drawn from a published research project can alter clinical practice or public health policy. It is therefore important that every project is conducted and analysed with utmost care.

- A serious error in the analysis of research data may lead to retraction of a published article which is likely to have considerable cost implications to the university as well as substantial legal liability, not to mention putting patients at risk of not receiving the best possible treatment.

Likelihood of occurrence

- Analysis of large data-sets requires considerable expertise with modern data-management packages. This expertise is obtained only from extensive experience gained under expert supervision. Modern statistical packages allow advanced analysis to be undertaken by junior researchers but at a high risk of inappropriate application.
- Serious errors are more likely when the analysis of data is delegated to unsupervised junior researchers or research students. Mistakes are easy to make, and are more often difficult to detect because the intuitive feeling for data is less than with small paper-based data-sets.

Likely consequences

- If the study has been published it may require formal withdrawal at substantial cost to the reputation of the research team. Other consequences may be similar to these listed above under 'Fraud'.

Barriers to occurrence with SPHPM

- All research data should be analysed under the direction of (or in collaboration with) a biostatistician. All research projects should involve a member of the biostatistics unit and an appropriate allocation of research funds for statistical analysis should be included in all research grants.
- No significant original result should be published without the senior researcher being able to certify that a statistician has undertaken the analysis (or checked the analysis). The only exception is when a small project involving a statistician has reported (to the principal investigator) sufficient confidence in the statistical expertise to the researcher to make direct supervision unnecessary.



3

Loss of data due to inadequate filing or backup or as a result of malicious destruction

Description of risk

- Clinical and public health research commonly involves the use of large computer databases which are regularly being updated as new data is added and older data is checked and edited.
- A highly organised and systematic process is needed to ensure that changes are being made to the appropriate (ie the latest) copy of the databases.
- Portable data storage devices such as laptops, ipads and memory sticks increase the risk of security breaches due to theft or loss. If the data is not adequately backed up this can result in the loss of some or all of the database. In addition, if the portable device does not have adequate security e.g. password protection, participant and/or sponsor confidentiality may be breached resulting in adverse publicity.
- To avoid data loss the most current copy of the database should be stored and backed up according to University policy. For guidance see http://monash.edu/library/researchdata/file_links/storage_options_web_vers15_10_2013.pdf
- Irreversible data loss may destroy an entire research project and (in the case of sponsored studies) may lead to legal liability.

Likelihood of occurrence

Loss of particularly sensitive data is a high probability occurrence unless every member of the department with access to such data observes a series of specific precautions.

The risk of losing track of which is the latest version of the database is greatest:

- when databases are established and maintained by inexperienced researchers, without close support of an experienced database manager.
- when a low-cost database has been established by researchers themselves rather than experienced programmers. The risk is also higher than when data is constantly being added, especially if more than one person is involved with the data entry.
- a high risk exists in the data entry/checking/editing of stage where it is easy to lose track of the most current version of the database.
- when a researcher fails to develop a regular schedule of back-ups of every one of their active databases.
- The risk of loss or theft of laptops, ipads or USB sticks is greatest when researchers fail to take basic precautions (e.g. leaving it in a car). However, occasional loss or theft is a common and almost predictable occurrence and must be addressed by security barriers on the device
- The malicious alteration or destruction of a database is typically the result of actions of a hacker or a disaffected employee.

Likely consequences

- The likely consequences may range from irreversible loss of essential data to a highly expensive and time consuming process in reconstructing a database.

Barriers to occurrence within SPHPM

Because of the high likelihood of this problem arising it is necessary to have highly detailed procedures in place to lessen the risk. These include:

- Development of detailed SOP's which are incorporated into the Good Research Practice Guidelines and regularly updated. Compliance with guidelines must be regularly audited by the Research Governance Officer.
- Databases managed outside CIDMU must have patient identifiers, stored separately from the remainder of the databases. The identification key must be encrypted and password protected. The two database components must be linked only by a common ID code.
- The School has an ABSOLUTE BAN on the holding of any patient identifying data (encrypted, unencrypted or code-protected) onto laptops, ipads and USB sticks. The only exception is when data is being transferred directly to the Data Centre (under which circumstances it must be encrypted and code-protected).
- During the establishment phase of new projects staff from the relevant units must meet with a representative of CIDMU for advice and verification of appropriate storage and back-up procedures and review the construction of the database.
- Data access privileges must be removed immediately by the unit from any staff member who is no longer responsible for a specific project.
- A yearly review will be undertaken (led by CIDMU) on data-management policies and testing of the data-recovery plan.

4

Serious Breach of Protocol or Ethics Committee Conditions

Description of risk

- All research involving humans must be endorsed by an appropriate ethics committee. Ethics approvals are specific to the particular protocol (including Participant Information and Consent Forms [PICFs]). Entry of patients to a study whose personal characteristics do not meet those of the approved entry criteria is a breach of the condition of ethics approval. It may also lead to a breach of contract with a study sponsor. If an individual who was ineligible for entry to a study experiences an adverse event they may have grounds for legal action that would not be covered by the institution's insurers.
- Once approved, the study protocol must be followed closely throughout the study. Any changes must be presented to the ethics committee as an amendment and approval obtained before implementation. Failure to obtain approval for a change to the protocol may constitute a breach of ICH GCP and the National Statement.
- Ethics committees pay particular attention to circumstances of consent. They require all study participants to be provided with an approved Participant Information and Consent Form to sign to signify their preparedness to participate in the project. These forms must be carefully filed and must be made available for scrutiny by auditors. Should an individual claim that they had not been adequately informed of the risks and benefits of participation this documentation (in addition to a description of the consent process documented in the medical record) provides an important line of defence for investigators. Entry of patients to a study without consent is an egregious error which could lead to severe sanctions and highly adverse publicity.
- Serious adverse events affecting any study participant, and considered reasonably likely to have resulted from study participation, must be notified urgently to study sponsors and the appropriate ethics committee. Failure to do this may lead to sanctions by either of these agencies.

Likelihood of occurrence

Due to the nature of the research that is undertaken within this school it is highly possible that this will occur unless specific precautions are put in place to prevent it.

The areas of greatest risk are studies involving significant risk to participants such as drug trials and invasive studies.

The risk is higher in investigator initiated research where there is no independent monitoring by a study sponsor.

The risk is also likely to be higher in units with research programs where senior staff are too busy to provide adequate supervision of their research programs.

Failure to meet ethics committee requirements is usually a result of a lack of knowledge of an ethics committee's role in the regulation and monitoring of an institution's research program.

Thus it is more likely amongst those who have not undertaken formal research governance training.

Likely consequences

- Failure to follow the appropriate process i.e. to adhere to the approved protocol, to obtain consent for each participant before they begin the study, to only include participants who qualify for the study and to ensure that all adverse events are appropriately reported; may result in the research being stopped by the ethics committee. The investigators may lose the protection of insurers. They may also lose the confidence of their ethics committee and the senior management of their institution. They may not be allowed to undertake further research.
- Adverse events that are not reported to an ethics committee may also result in a study being suspended.

Barriers to occurrence within SPHPM

SPHPM requires a strong culture that emphasises care and accuracy in the conduct of each clinical trial. This will involve:

- New staff and research students being required to complete the Research Governance Induction which is part of the SPHPM Onboarding process. Those without strong research background should be required to attend courses in research methodology and complete the Research Governance Online training (RTS0005 Research Integrity).
- All new staff must be briefed by a senior researcher about the need to adhere to the approved study protocol, report adverse events and follow carefully the approved processes for consenting participants.
- Compliance with these requirements will be monitored as part of the routine study audits.

5

Serious Breach of Confidentiality

Description of risk

- Clinical and public health research commonly collects information of considerable sensitivity which is divulged only because of guarantees of confidentiality provided by the researchers. In other instances ethics committees may approve the use of health-related data without the consent of individuals when the public benefit is considered to substantially outweigh concerns regarding privacy.
- Ethics committees approve the collection of personal health-related data for research purposes if they are assured that the data (both paper records and electronic files) will be maintained under strict conditions that protect the confidentiality of the participants.
- Breaches of privacy legislation may result in criminal penalties.
- Modern, portable data storage devices such as laptop computers and memory sticks which are used to transport data also increase the risk that identified, confidential data may be revealed through loss or theft of the laptop or memory stick.
- A specific instance of risk is where:
 - a. a research staff member handles data from an individual known to the researcher and is tempted to mention this outside the department;
 - b. a staff member, leaves a memory stick in a public computer or has their laptop stolen

Likelihood of occurrence

- Due to the volume and nature of data handled by the school this is considered to be a high risk.
- Breaches of privacy are most likely in cases where there has been little attempt to create a culture of confidentiality and to reinforce it.
- Privacy breaches are also more likely where new researchers who have not been adequately educated about the rationale for confidential data handling are given responsibilities in this area.
- Under privacy law it is required to notify each individual whose privacy may have been breached. This may be a very major task.

Likely consequences

- A serious breach of confidentiality could result in serious adverse publicity that could significantly lessen the likelihood of future participants providing confidential information.
- It would probably reduce the likelihood of gaining ethics approval for future projects requiring collection of personal data.
- It might lead to legal action from the individuals whose privacy has been breached.

Barriers to occurrence.

The procedures required for privacy protection include:

- restriction of access to personal data to a small number of individuals with a clear cut need for access.
- training of researchers at all levels on issues related to data confidentiality.
- provision of secure storage of confidential data which includes restricted access to areas where such data is stored, separation of identifying data from the other data elements, secure password access to data in computers and development of a specific protocol for destruction of identifying data when no further need exists to retain this information.
- To ensure that all staff and students understand the need for confidentiality they are:
 - a. required to sign declarations of confidentiality.
 - b. required to undergo good research practice training if they are involved in research (the schools good research practice course is compulsory for all students and staff).
 - c. required to complete the Research Governance Induction as part of the SPPM Onboarding.
- Requirement for privacy to be emphasised to new staff by unit head and research governance officer.
- Staff and students are discouraged from transporting identified, confidential information on devices such as laptops, ipads and memory sticks. If researchers are required to transport data on such devices they must ensure this is done in accordance with the university guidelines (http://monash.edu/library/researchdata/file_links/storage_options_web_vers15_10_2013.pdf) and are advised to meet with IT and Data Management staff to ensure the data is encrypted.
- Senior management must create a culture of confidentiality and respect for all patient-related data

6

Failure to Identify and Follow-up an Abnormal Pathology Result

Description of risk

- Many SPHPM studies involve the measurement of variables (such as blood pressure) and the undertaking of various pathology tests (such as full blood examinations or liver function tests). When large numbers of individuals are tested there is a strong possibility of finding abnormalities of clinical significance that may not be known to the individual or his/her medical practitioner. In some instances recognition of the abnormality may allow effective treatment to be introduced.
- If an abnormal result is not noted and flagged to the patient and/or the medical practitioner the patient may not receive the necessary treatment.

Likelihood of occurrence

- There is a high likelihood of occurrence of 'missed results' in clinical research unless the issue is anticipated and a highly organised approach is developed to assess and handle abnormal results.
- The principal risk is where screening tests are being done on large numbers of individuals either as part of eligibility screening for a clinical trial or as part of an epidemiological study.

Likely consequences

- Failure to include an efficient procedure to pass on important clinical information may mean that a potentially curable illness is not detected. This could lead to legal action for negligence.

Barriers to occurrence within SPHPM

- All studies involving physiological measurement or laboratory testing must include specific procedures to review all abnormal results. These procedures must be documented in the protocol and/or procedure manual and adherence monitored during the study.
- Assessment of processes for reviewing abnormal results should be audited regularly by the research governance officer.

7

Failure of Emergency Procedures Leading to Death or Injury

Description of risk

- Some clinical research projects, particularly those conducted on patients with conditions such as asthma or hypertension, may require special attention to monitoring and the availability of emergency care. For example clinical trials of new drugs may require withdrawal of usual therapy with clinical monitoring to ensure the detection of deterioration. The risk of medical complications resulting from such actions may be sufficiently high to mandate the availability of urgent medical assessment and/or emergency care.
- If such emergency care is not immediately available and, as a result a study participant developed serious complications both the investigator and the school may face legal action.

Likelihood of occurrence

- This risk is most likely to be encountered in drug trials and in physiological studies, particularly those involving the administering of medication or those involving elderly subjects. The risk is greater when studies are supervised by inexperienced staff and when senior clinical investigators are unavailable or uncontactable.
- It is important that research staff make participants aware of the way to get emergency assistance if required. In the case of a medical emergency you are required to call an ambulance on 000.

Likely consequences

- Injury to participant, legal action against researcher, adverse publicity.

Barriers to occurrence

- Appropriately trained staff available to review research participants.
- Emerging responses must be reviewed and tested. This includes the use of the defibrillation unit.

8

Loss of Biorepository Specimens

Description of Risk:

- A number of research projects within the SPHPM collect clinical data coupled with biological specimens (blood, urine, saliva, tissue) for long term storage and analysis throughout or at the completion of the project.
- Adequate and appropriate storage of the biospecimens is of the utmost importance to maintain the sample integrity and maximise the quality of the biospecimens for ongoing and future analysis.
- Loss of biospecimens due to a breakdown of storage facility equipment or staff mismanagement is a major risk to these projects. Having multiple storage sites may also pose a risk as it involves management of different physical locations and alarm systems.

Likelihood of occurrence:

- Storage systems are sourced from reputable suppliers with a good track record. The use of reliable storage systems along with adequate staff training and emergency back up plans makes the loss of biospecimens a medium to low risk.

Likely Consequences:

- Loss of partial or entire collections of biospecimens would be devastating for the research project for which it was collected. Biospecimens are collected at certain time points in a study or disease state and in most projects cannot be replaced.
- The loss of biospecimens from a small collection may result in a reduction in sample size that is too small for statistical analysis.

Barriers to occurrence within SPHPM:

- All research staff involved in the handling of biospecimens are trained in storage of samples at different conditions (room temperature, -80 freezers, Vapour Phase Nitrogen).
- Alarm systems are set up on all freezers so that in the event of an alarm due to temperature fluctuation, four key staff are contacted by SMS to ensure the alarm is attended to. Alarm systems are tested every 6 months to ensure they are working.
- Staff responsible for responding to the freezer alarms have access to SOPs at home and at the biospecimen storage location detailing the plan of action. All other staff handling biospecimens have access to the SOPs and have received training on how to respond.
- Duplicates of biospecimens are stored as backup in separate physical locations to avoid the loss of an entire set of biospecimens from one individual participant.
- All storage equipment is serviced regularly and back-up batteries are installed where appropriate.

9

Attack on a Research Nurse or Research Assistant

Description of risk

- Several epidemiological studies involve visits to participants' homes to conduct interviews or to collect samples. Often these visits are conducted by research nurses or research assistants after hours. Under these circumstances there is a risk to the safety of the research staff.

Likelihood of occurrence

- There is a moderate risk of harm to staff if they conduct home visits, particularly after hours, without consideration for safety or back-up procedures

Likely consequences

- Injury to staff member with senior SPHPM management accountable for lack of appropriate preventive action.

Barriers to occurrence

- Research staff will contact participants by phone in advance of visit to assess acceptability of visit.
- If there are any concerns visits will be undertaken with a companion and during daylight hours.
- The school will ensure that all research staff undertaking such visits have mobile phones or personal alerts. They will call a designated individual before and after the visit.
- Adherence to this protocol will be checked by the Research Governance Officer.

References

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2. European Medicines Agency,
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Further information

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