MONASH University

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PUBLIC HEALTH
AND PREVENTIVE
MEDICINE

A GUIDE TO GOOD RESEARCH PRACTICE

8TH EDITION, JULY 2020

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A GUIDE TO GOOD RESEARCH PRACTICE

The history of clinical research is a long and colourful one. Past events have resulted in the introduction of legislation, guidelines and codes that have shaped the way research is conducted today.

The **Guide to Good Research Practice** brings together the latest national and international guidance for ethical and responsible research conduct and contextualises it to research within the School of Public Health and Preventive Medicine to provide staff and students with a comprehensive reference.

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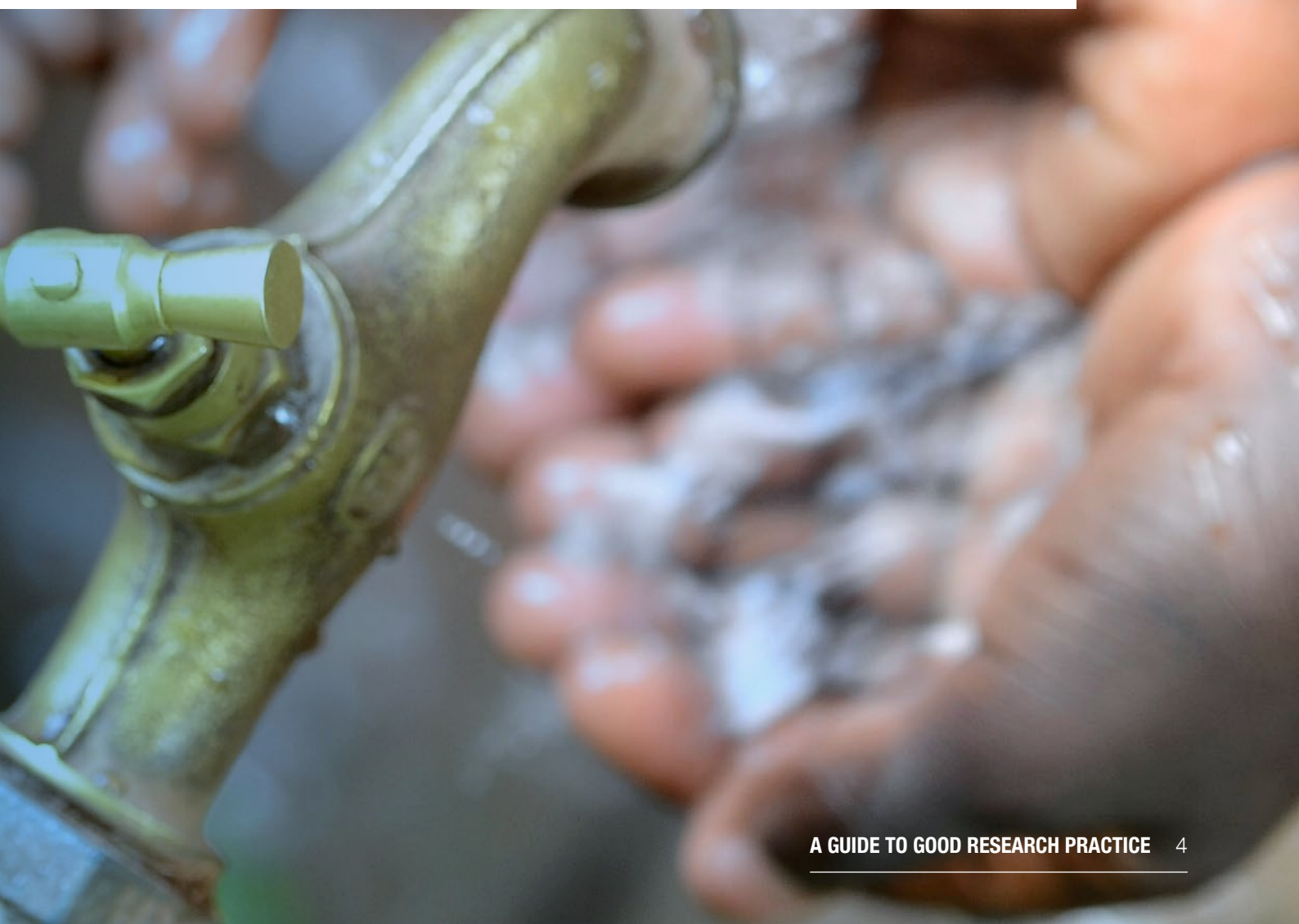
ABBREVIATIONS

CTN	Clinical Trial Notification
CTX	Clinical Trial Exemption
EMR	Electronic Medical Record
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
HREC	Human Research Ethics Committee
NHMRC	National Health and Medical Research Council
ICH	International Conference on Harmonisation
IP	Intellectual Property
MUHREC	Monash University Human Research Ethics Committee
PI	Principal Investigator
PICF	Participant Information and Consent Form
RGC	Research Governance Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SPHPM	School of Public Health and Preventive Medicine



1. INTRODUCTION

Clinical and public health research must be conducted in accordance with a large number of laws, regulations and conventions. These are designed to protect the participants, the researchers and the institutions where research is conducted.

Well-conducted research flourishes best in a culture that emphasises respect for research subjects and a focus on accuracy and honesty.

At Monash University's School of Public Health and Preventive Medicine (SPHPM) we are fortunate to have a number of our staff involved in ethics and research governance. Over several years we have developed activities designed to ensure that our research is conducted at the highest standard and that our working culture emphasises all of the attributes needed to support this goal.

In addition to producing this guide, we have focused on careful induction of new staff and ongoing education and quality assurance activities, all directed by our Research Governance Officer and a very active Research Governance Committee.

I would like to acknowledge the many people who have participated in the development of this guide and in the development of the research governance framework of the School. In particular I would like to thank Marina Skiba, Danny Liew, Andrew Forbes, Maria La China, Jay Illesinghe and the chairs, past and present, of the Research Governance Committee.

Professor Sophia Zoungas

2. PROMOTING HIGH QUALITY RESEARCH

2.1 PURPOSE

The purpose of this document is to ensure that medical research conducted within our School meets the highest scientific and ethical standards.

- This guide outlines a set of standards that must be adhered to by all those involved in research in any capacity.
- If you identify any significant departure from these guidelines, you must bring it to the attention of your supervisor and/or the Research Governance Officer or Research Manager.
- Diligent supervision and monitoring of research projects by appropriately trained and experienced individuals within the School is an essential requirement.
- Particular care must be taken to ensure full compliance with consent and privacy requirements. The highest level of confidentiality must be maintained at all times when handling research data.
- Research misconduct in any form is unacceptable. This behaviour has implications, not only for the individual researcher, but also for the School and the University.
- The position of Research Governance Officer was established in the School to oversee the School's research conduct and to assist investigators in all aspects of good research practice. The Research Governance Officer has been authorised to conduct audits of all the School's research projects.
- The guidelines outlined in this booklet are available for quick reference. It is highly recommended that investigators enrol in programs and courses on ethics, good research practice and/or International Conference on Harmonisation, Good Clinical Practice (ICH GCP).

2.2 GOOD RESEARCH PRACTICE: FUNDAMENTALS

The following principles have been adapted from international 'Guidelines for good clinical practice in clinical trials'[1] (see Appendix M).

- Clinical studies should be conducted in accordance with the ethical principles outlined in the Declaration of Helsinki, The National Statement on Ethical Conduct in Human Research[2] and the ICH GCP Guidelines[3] (see Appendix M).
- A study should only be initiated and continued if the perceived benefits for the individual participant or society justify the risks and inconvenience.
- The rights, safety and wellbeing of participants are the most important consideration and should outweigh other considerations.
- Clinical studies should be scientifically sound and clearly described in the study protocol.
- Studies should be conducted in compliance with a protocol that has been authorised by an appropriate Human Research Ethics Committee (HREC).
- Individuals conducting the study should have an appropriate level of education, training and experience to perform their tasks.
- Freely given informed consent should be obtained from every participant prior to study participation, unless HREC approval has been given for a waiver of consent or an opt-out consent process (for more information on opt-out consent processes see section 4.3).
- All study data should be recorded, handled and stored in a way that allows their accurate reporting, interpretation and verification.
- The confidentiality of participant records should be protected, respecting the privacy and confidentiality rules of the applicable regulatory authority.
- Systems that ensure the quality of every aspect of the study should be implemented.

2.3 RISK MANAGEMENT

Although research misconduct is generally the result of aberrant behaviour by individuals, the senior staff of the School have a responsibility to establish a culture and environment that reduces the likelihood of such an event.

Within SPHPM, certain vulnerabilities to research misadventure have been identified. These include:

- a large number of research projects with responsibility dispersed among many senior investigators;
- a heavy reliance on relatively junior staff and PhD students to supervise research assistants and to analyse research results;
- a high level of investigator-initiated research that is not monitored by external bodies such as pharmaceutical companies; and
- data collected off-site by research staff working away from direct supervision.

In addition, the changing privacy and data protection landscape presents new and changing requirements.

Researchers should be aware that Monash University needs to be informed of research involving pregnant women, children under the age of five years or participants outside Australia. A check list is available from the Research Governance webpage or from Monash Insurance Services (**InsuranceServices@monash.edu**). This is to ensure that the University is able to assess whether it has the appropriate insurance cover.

Furthermore, if the research is being conducted in Europe or is collecting information from Europe, General Data Protection Regulation (GDPR) may apply. If you have questions about GDPR, please contact the Office of the General Council, Data Protection and Privacy (**dataprotectionofficer@monash.edu**).

Accordingly, the School has established a Risk Management Plan that attempts to foresee major areas of risk and to identify and implement mitigation strategies.

The School's Risk Management Plan is Appendix D of this document.

2.4 RESEARCH ETHICS: FUNDAMENTALS

It is important that researchers understand the approach taken by HRECs to various types of projects. This is described in Appendix A.

A brief description of the responsibility of researchers in dealing with HRECs is provided below.

a. HREC Approval

HRECs have been established in all institutions that receive funds for medical research from the National Health and Medical Research Council (NHMRC). Their purpose is to look after the rights and safety of research participants. It is a requirement that researchers seek HREC approval for any project that involves contact with individuals or use of their data.

All research undertaken must comply with the authorising HREC's requirements. In particular:

- Projects must not begin until HREC approval and governance authorisation has been obtained in writing.
- The authorised study protocol must be followed in all cases.
- HREC approval must be sought for protocol amendments, even if they are minor.
- Projects must not run longer than the approved completion date, unless an extension has been approved in writing.

Consent/Explanatory Statements

HRECs require all study participants (or their legal representative) to be provided with information about the study and be provided an opportunity to ask questions before deciding whether or not to participate in a study. HRECs also require participants to be provided with an approved Participant Information and Consent Form (PICF) / Explanatory Statement and Consent form and to sign their name to signify their preparedness to participate in the project (except in cases where the HREC has approved the use of an opt-out process or waived the requirement of consent, see section 4.3). These forms must be carefully filed and made available for scrutiny as required; e.g. by auditors operating on behalf of the HREC or the study sponsors.

Safety Reporting

Safety reporting (identifying and communicating unexpected, untoward events that occur in participants during an interventional study) is important to ensure the safety of the research participants and the patients who will ultimately receive the intervention.

All adverse events should be recorded regardless of causation.

A Serious Adverse Event (SAE) is any untoward medical occurrence that at any dose:

- **results in death,**
- **is life-threatening,**
- **requires inpatient hospitalisation or prolongation of existing hospitalisation,**
- **results in persistent or significant disability/ incapacity, or**
- **is a congenital anomaly/birth defect**

Any SAEs that occur during the study must be notified in accordance to the HREC, sponsor (if applicable) and regulatory body requirements. Check HREC requirements. Many are satisfied to receive summary reports on an annual basis and may or may not expect to receive individual reports for SAEs occurring in participants for which they are responsible. Check the study protocol for sponsor SAE reporting requirements. Some sponsors will list events that do not need to be reported to the sponsor. The protocol should provide the time frame for reporting regardless of whether the study is sponsored.

Exemption from HREC Review

Some projects may be deemed very low in risk (e.g. some quality control projects) and thus exempt from formal review and approval by an HREC. In such cases, SPHPM requires that researchers contact an HREC and receive written confirmation that formal review and approval is not required for their study. Please note, many journals require confirmation of formal exemption from ethical review before results can be published.

The work of HRECs is guided by:

- The National Statement on Ethical Conduct in Human Research[2] **nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018;** and
- ICH GCP Guidelines, an international ethical and scientific quality standard[3] **tga.gov.au/publication/note-guidance-good-clinical-practice**

Research institutions also have their own specific requirements that need to be observed. For example:

Monash University:
Monash University has a central HREC, the Monash University Human Research HREC (MUHREC)[4].
The MUHREC web address is: **intranet.monash/researchadmin/start/ethics.**

All Monash University staff and students must obtain approval from MUHREC even if they are conducting their research at another institution (e.g. a public hospital) and have received ethics approval from that institution. Monash has a memorandum of understanding with a number of institutions to make this process as easy as possible (for details see the website under ‘multicentre research’).

The only exception to this is for Monash staff with dual appointments who are conducting research without Monash involvement, and their Monash affiliation is not being included in the by-line of any resulting publications.

The Alfred Hospital:
Application forms and guidance on applying can be downloaded from **alfredhealth.org.au/research/ethics-research-governance.**

Monash Health:
Application forms and guidance on applying can be downloaded from: **monashhealth.org/research/.**

b. Special Restrictions

HREC approval may be provided with specific caveats or special conditions of approval. When multiple HRECs are involved, it will be necessary to liaise with each of the relevant committees to ensure that the final agreed protocol meets the requirements of each.

c. Documentation

An approval letter containing caveats should be copied to all study staff. All study staff must be made aware of site-specific requirements.

d. Duration of Approvals

HREC approvals may be time-limited (e.g. for a two- or three-year period) or may be ongoing but approval is usually contingent on satisfactory progress reports submitted annually. If progress reports are not received, the HREC may revoke approval for the study.

e. Clinical Trial Registration

Ensuring that all clinical trials are listed on a publicly accessible registry is an initiative of the World Health Organisation (WHO)[14], This has been implemented to ensure transparency in the clinical trial process. "For the purposes of registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."[14]. The International Committee of Medical Journal Authors (ICMJE) now requires that a clinical trial is registered prior to enrolment of the first participant for most journals to consider the results of the project for publication.

The registry chosen must meet the ICMJE criteria. Some registries that comply are:

ClinicalTrials.gov (US based registry): **clinicaltrials.gov**

Australian Clinical Trials Registry (developed by the NHMRC) **actr.org.au**

f. Plagiarism

Quoting someone else's work, or even quoting your own, without properly referencing it is considered plagiarism. The university's policy on Academic integrity, plagiarism and collusion can be found at i**ntranet.monash/medicine/business-practices/academic-integrity-procedure**. The student equivalent is **monash.edu/__data/assets/pdf_file/0004/801841/Student-Academic-Integrity-Policy.pdf**.

Learn how to reference properly and avoid plagiarism. The following link provides information developed by the University Library: **lib.monash.edu.au/tutorials/citing/**.

2.5 HREC REVIEW OF PROJECTS

The primary goal of an HREC is to protect the rights and welfare of human subjects. This goes beyond simply protecting them from egregious behaviour or undue risk. In general, it looks to ensure that research subjects are treated in accordance with three basic principles referred to in the 1978 Belmont Report (US)[18] . These are:

1. Respect – for the individual, i.e. individuals should have total control and authority over everything that happens to them;
2. Beneficence– refers to the obligation of carers and researchers to maximise benefits and minimise harm; and
3. Justice – a more general concept that includes the undesirability of certain disadvantaged groups taking all the risks of research while other groups benefit.

In practice these principles are put into operation as follows:

Scientific Validity:
HRECs now take the view that it is unethical to approve scientifically flawed research because individuals should not be expected to undergo the risks, inconvenience and expense of research that is unlikely to provide a scientifically valuable result. As a result, studies with substantial design errors or a major susceptibility to bias are unlikely to be approved until these deficiencies are remedied. HRECs are increasingly scrutinising sample-size calculations since underpowered studies are unlikely to provide scientifically useful results.

Experience has also made most HRECs aware of the adage that 'the devil is in the detail'. This is the reason for insisting on the provision of detailed protocols with every application.

Scientific Value:
It is also unethical to expect sacrifices from volunteers that are out of keeping with the value of the potential findings.

Credentials:
The HREC requires that a current curriculum vitae of each investigator be held on file. The research credentials and previous experience of investigators are matched against the nature of the study and a judgement made about whether the individuals involved are appropriately trained to be undertaking the proposed research. A research team may be asked to add a more experienced investigator, or someone experienced in a particular specialty of medicine. NHMRC guidelines require that a clinical pharmacologist be involved in very early phase investigational drug studies.

Increasingly, there is an expectation that all investigators and staff involved in research have appropriate research practice certification. Investigators are encouraged to ensure that all their staff are adequately trained. SPHPM offers a short course in Ethics and Good Research Practice that covers the key information that research staff need to know. Researchers involved in clinical trials and interventional studies must also have TransCelerate accredited GCP training. Face-to-face courses are offered by Monash Partners **(monashpartners.org.au/2020/01/13/training-good-clinical-practice-intro-and-refresher-training-dates-and-times-for-2020/)** and free online courses are offered by Genesis Research Services **(genesisresearchservices.com/education/).**

Risks (Including Treatment Forgone):

A fundamental requirement for an HREC is to ensure that the foreseeable risks of the study have been identified and presented in an explicit fashion to the participants in the PICF/Explanatory Statement (see below). The most significant risks to health arise during early phase interventional studies, when relatively little may be known about the intervention's safety profile.

In general, HRECs are guided by the following principles:

1. Studies involving healthy volunteers, children and those where there is no likely benefit, should not pose risks that are much greater than those of everyday life.
2. Studies involving patients treated with new or experimental techniques should not have known risks substantially greater than the best alternative treatment, (unless there is a substantial possibility of significant benefit and the individual understands and freely accepts the risks involved).

It is unlikely that any HREC would approve a research project with a high level of physical risk (regardless of an individual's willingness to accept those risks, and regardless of the community benefit involved) unless there was a correspondingly high likelihood of benefit for the participant.

One particularly common form of risk is that arising from withdrawal of regular treatment (e.g. from anti-hypertensive or anti-asthmatic medication). Under such circumstances, HRECs will require strict limits on the severity of illness involved and the duration of the period without therapy. Careful and frequent clinical monitoring and instructions to participants about procedures in case of emergency are also mandated.

Safety Monitoring:

In many research studies, the risks are not fully established at the time the research commences.

If substantial numbers of participants are involved in such studies, HRECs usually require a safety committee or safety monitor to be appointed. This committee or individual will regularly review unblinded study data and alert the investigators and HRECs about safety concerns.

Other safety monitoring during the course of clinical research projects may also be required. For example, blood tests may need to be regularly undertaken. In such circumstances, it is imperative that arrangements are in place for the study co-ordinator to immediately receive and review results and bring abnormalities to the attention of the investigators and the individual's usual treating doctors.

Inconvenience:

Studies may involve considerable numbers of trips to hospital and/or time away from work, which must be explicitly described in the PICF.

Informed Consent:

Participants in clinical research must be fully informed about the nature of any research project that they participate in and be free to choose whether or not to take part. The researcher conducting the consent interview and obtaining informed consent should have an understanding of the consent process, have an understanding of the project and be listed on the ethics application form as undertaking this role.

Basic ethical principles dictate that:

1. Participants have an unambiguous right to decline participation or to withdraw their consent at any time without an obligation to provide a reason.
2. There is a full disclosure of any known risks that might influence their decision about whether or not to participate.
3. Participants involved are provided with the most explicit and accurate account of personal inconvenience and expenses likely to be encountered.

In some circumstances, the HREC may approve a waiver of consent or the use of an opt out process (see section 4.3).

The PICF/Explanatory Statement is the key document in the consent process (see section 4.4). Its purpose is to provide prospective participants with a simple and easily understood account of the rationale for the research and a detailed description of all foreseeable risks and benefits. HRECs are required to review these documents and to endorse their contents as providing a fair and balanced account of risks and benefits. In fact, much of an HREC's time is spent adjusting the language of PICFs/Explanatory Statements so that it can be understood by an average person. A checklist of contents is shown in section 4.4.

Early Cessation:

A study that continues well beyond the time required to demonstrate convincing evidence of benefit (or harm) may deny patients access to a superior therapy (or expose participants to unnecessary risk). Procedures are therefore commonly implemented to stop a study early in the event that a significant benefit (or risk) becomes evident before the study's scheduled end.

Protocol Deviations/Violations:

Deviations from the approved protocol need to be reported to the HREC using the Protocol Deviation/ Violation Report.

SPECIAL ISSUES

Clinical Trial Notification/Clinical Trial Exemption (CTN/CTX) studies:

In the early 1990s, the Commonwealth Government introduced new procedures designed to speed up the approval process for clinical trials of therapies and new indications for existing therapies. In brief, companies can choose to introduce new agents to clinical research under a CTN scheme or a CTX scheme. If the CTX route is chosen, the company submits available data on their drug to the Therapeutics Goods Administration (TGA), which then undertakes an evaluation of its safety and suitability for use in clinical trials.

Companies wishing to avoid the inherent delays in this process can alternatively introduce their drug through the CTN scheme, under which the relevant HRECs assume responsibility for evaluating the drug and the study design with simple notification to the TGA of the intention to undertake the studies.

In practice, unless the HREC has the experience to evaluate preclinical data, most will only approve CTN drugs if they have been evaluated through a CTX process or CTX-type process in one of the three countries with similar drug evaluation standards to Australia (the US, UK and Sweden).

Consent in Special Circumstances

In some studies, special additional procedures are required for informed consent. These may include studies on:

- human genetics;
- vulnerable patients (e.g. mentally handicapped);
- minors; and
- participants unable to provide consent (e.g. unconscious, demented, long term intellectually impaired).

In these circumstances, advice must be obtained from the relevant HREC(s) during development of the consent documentation. It is imperative that researchers who may be recruiting from these special groups receive advice on the legal framework in the jurisdictions they intend to conduct the study. In most situations, privacy legislation will also require consideration.

Research Involving People Who are Unable to Provide Consent for Themselves

For situations in which an individual is not in a position to provide informed consent, an HREC is authorised to approve applications for important research to proceed on the basis of consent from an authorised person, normally the next of kin (the next of kin hierarchy is defined in law).

In rare instances, an HREC is authorised to approve applications for highly important research to proceed without consent of either a participant or their next of kin.

HRECs will not approve any such research unless it clearly will not disadvantage the research participant and it cannot be undertaken with consenting participants.

It is imperative that researchers receive advice on the legal framework in the jurisdictions they intend to conduct their study. In most situations, an understanding of the privacy legislation in that jurisdiction will also be necessary. The need for a legal opinion should be considered. A legal opinion may also be a mandatory requirement of an HREC prior to issuing an approval – Monash University Office of General Council (OGC) is an important step for this advice.

Detailed discussions should be held in advance with the HREC Secretariat if either approach is contemplated.

Children:

If children are involved, there must be no risks greater than those of everyday living and permission should be obtained from both the participant (if appropriate) and their parents.

Genetic Research:

Collection of blood or other biological samples for genetic testing is a rapidly developing area of research with the potential to improve the diagnosis and treatment of many common diseases. It is becoming increasingly common for approving HRECs to require an ethically defensible plan for the return of the genetic information at the completion of the research (regardless of whether there is no return or full return of the genetic material). It also raises a number of particular ethical issues that have led the NHMRC to develop a specific policy on this type of research. The policy incorporates the following principles:

1. Gene banks should be established within an academic research environment under the control of experienced and highly reputable researchers.

2. The researchers involved must be aware of the potential ethical issues associated with access to data and samples from the bank and have adequate resources and strategies in place to deal appropriately with them.

3. Committees typically, in the first instance, approve the establishment of the gene bank and the specific project linked to the application. Future research involving different markers will require further separate applications before approval will be given.

4. Individuals providing samples for a gene bank should be aware of potential uses of genetic information. Although genetic discrimination in health insurance and employment are currently prohibited, life insurers can legally discriminate on the basis of genetic test results. As at 1 July 2019, life insurance companies have agreed by way of a voluntary moratorium not to ask for genetic test results for cover under $500,000, however for life insurance policies over this amount, insurers can still ask for and use genetic test results in underwriting. The moratorium will be reviewed in 2022. Researchers should be mindful that this landscape is changing and evolving and ensure they are providing current advice to research participants

5. Individuals should also be aware of the possibility that information held by the gene bank may be discoverable by a court of law.

6. The researcher in charge of the gene bank should also have a protocol to determine what information should be provided unsolicited to individuals as a result of findings generated by the research. Generally, the HREC should be informed of such actions.

Innovative Therapy:

Increasingly, the introduction of new and innovative therapy is being handled in a fashion similar to a research project. Applications involve a justification and literature review, a protocol and a PICF. Commonly, new procedures are referred to an HREC and an innovations committee.

Research in Private Rooms:

HRECs are often asked to review projects conducted in private settings. There has been some reluctance to do this because some committees feel insufficiently familiar with the governance of research in such settings to be able to provide endorsement. Sometimes there may also be unease about the financial arrangements involved. With the progressive decline in hospital outpatients it is likely that more and more research will move to such settings. Contact the HREC for details regarding special requirements; e.g. access to the site for monitoring purposes and evidence of insurance that covers the research activities.

Audit:

The NHMRC requires that, as a minimum, HRECs monitor research conducted in their institutions by requiring a structured annual report. Some HRECs supplement this by an audit program that covers such matters as consent forms, data storage, randomisation processes, bias control and source data verification.

Vignette:
A researcher was conducting a trial comparing two standard treatments for heart failure. He decided to commence with a pilot study without obtaining HREC approval or consent from the participants (like all other studies, pilot studies require ethics approval as the risks to the participants and the need for consent are the same). The HREC required the researcher to attend a meeting, at which he was reprimanded. It was made clear that it was unacceptable to conduct an unapproved pilot study.

Vignette:
A researcher decided that since his research only involved the collection of some additional blood (during routine sampling), it was reasonable to enrol participants without obtaining their consent. A member of the hospital staff notified their concern to the HREC and an audit was conducted. The researcher was reprimanded (participants always have the right to choose regardless of how simple the study is) and the HREC required that the study could continue only if that researcher was not involved.

Breaching HREC Requirements

Examples of serious breaches include:

- entry to a study of participants whose personal characteristics do not meet those of the approved entry criteria (this may also breach the contract with the study sponsor);
- failure to inform a participant of the risks of participation in a research project;
- alterations to a protocol without HREC approval; and
- failure to respect the privacy of an individual's personal information.

In some cases, a breach of HREC requirements also constitutes a data breach (i.e. personal information being lost, accessed or disclosed without authorisation). All data breaches are to be reported to the Monash University Data Protection Officer at the **Office of the General Counsel** on +61 3 9902 0117 or **adm-ogc@monash.edu**, who will determine if this constitutes a Notifiable data breach (see Section 5.2 for further information).

2.6 NATIONAL MUTUAL ACCEPTANCE (NMA)

The introduction of mutual acceptance of ethics approval was designed to streamline the approval process and enable a multi-site protocol to undergo one ethical review rather than being reviewed by each institution where the study is taking place. The latter is still acceptable and may be preferable in some circumstances. Under NMA, the study protocol and master PICF is approved by a single HREC. Each institution participating in the study then provides its own governance authorisation. Details can be found at **health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/national-mutual-acceptance**.

Ethics Versus Governance

As mentioned, the ethics approval process focuses on participants' health, wellbeing and rights. The governance authorisation focused on contracts, indemnity and insurance, as well as ensuring the institution has the resources to run the study and that the costs are appropriately covered.

3. INSTITUTIONAL REQUIREMENTS

3.1 CONFLICTS OF INTEREST

SPHPM requires that all investigators pay careful attention to compliance with institutional policies regarding conflict of interest. Every significant conflict of interest must be declared both to the HREC (at the start of the study) and the journal (when the results are being published). Sponsors and institutions may require an annual report of conflict of interest from all investigators.

HRECs generally require a detailed account of the budget of a study and an explicit description of any personal benefits that an investigator will receive as a result of undertaking the research project. There is often a requirement for such matters to be mentioned in the PICF/Explanatory statement.

In addition to conflict of interest, the HREC will scrutinise the financial statement to determine whether the funding is sufficient to allow the study to proceed.

Most journals also require a detailed statement of conflicts of interest to accompany published manuscripts. Undeclared conflicts that are subsequently identified may require statements of contrition that are highly detrimental to a researcher, his/her colleagues and their institution.

The Monash University conflict of interest policy is provided at: **monash.edu/__data/assets/pdf_file/0009/792297/Conflict-of-interest.pdf**

3.2 PARTICIPANT REIMBURSEMENT

Compensation of study participants for incidental expenses is appropriate, as are small payments to compensate for inconvenience etc. Unlike the US, Australian HRECs have generally been unwilling to allow more substantial payments in case they provide an inducement to participation against better judgement.

3.3 INTELLECTUAL PROPERTY

As an education and research facility, SPHPM is involved in the generation of data by both staff and students. Students and staff are encouraged to identify new innovations or inventions that may arise from their work. Monash University has a policy to enable students and researchers to share in any commercial rewards that arise from such developments.

However, the rights and responsibilities differ between staff and students when it comes to intellectual property (IP).

Staff:
The University owns the IP rights in research data generated by a staff member's work in their employment with Monash University. Staff are encouraged to engage in collaborative research but must ensure that an appropriate collaborative agreement is in place before the collaboration commences. Staff are advised to contact the University Solicitors Office for assistance in drafting the agreement. Staff are also reminded that the agreement should be between institutions not individuals i.e. Monash University, not the staff member, should be a party to the agreement.

Students:
Within Monash University students own the IP within their research unless:

1. The University has made a specific contribution of funding, resources, facilities or apparatus to the research to create intellectual property AND the candidate has made or contributed to a patent worthy discovery or invention.
2. The IP created by the candidate will use background intellectual property owned by the University.
3. The University has entered into an agreement under which the IP created by the candidate is to be owned or partly owned by a person/party other than the candidate.

Due to the nature of the research conducted within SPHPM, it is extremely unusual for one of the above criteria not to be met. For that reason, the default position with SPHPM is that student IP belongs to the University. Students are required to complete one of the three possible Deed of Assignments forms available. Students are required to make a case to the contrary if they feel they are an exception. Students are encouraged to engage in collaborative research but must ensure that an appropriate collaborative agreement is in place before the collaboration commences. Students are advised to contact the University Solicitors Office for assistance in drafting the agreement. Students are also reminded that the agreement should be between institutions not individuals; i.e. Monash University, not the student, should be a party to the agreement.

Useful Links:

Research Data, Ownership and Rights:
monash.edu/library/researchdata/guidelines/ownership

PhD Candidate Intellectual Property and Confidentiality Declaration:
monash.edu/__data/assets/pdf_file/0006/170925/IP-declaration-as-at-Version-4-2017.pdf

Copyright at Monash University:
monash.edu/copyright

3.4 RESEARCH AGREEMENTS BETWEEN INSTITUTIONS

Clinical and public health research increasingly involves a multi-institution collaboration, in which different aspects of a project are undertaken by different organisations. To avoid disputes, it is essential that multi-institution agreements be accompanied by a document that specifies exactly what each institution (and employee of the institution) will be responsible for and what funds will flow as a result of these activities.

Agreements should also specify the composition of any committees involved in supervising the research activity and the approach to be taken in relation to authorship and financial reporting.

4. PIVOTAL RESEARCH DOCUMENTATION

The following are a number of important documents for the conduct of research. These documents are essential for all clinical trials.

4.1 THE PROTOCOL

The study protocol is a document that describes the rationale, objective(s), design, methods and organisation of a study.

The protocol provides the basis for HREC approval and up-to-date copies should be made available to every member of the study team. NO research activities, even relatively minor ones such as a pilot study, should be undertaken except in accordance with a protocol that has been approved by an HREC. A study plan may be substituted for a protocol in very low risks projects.

For projects in which the main emphasis is on mathematical derivations, numerical simulations or the development of models, a protocol/study plan that focuses on what is being done, where the files are stored and how the files are organise is required, even if other components of a standard protocol are not. This protocol/study plan must be approved by the supervisor/head of unit especially if ethics approval is not deemed necessary.

See Appendix B for details on what the protocol should contain.

Protocol Changes:
Once a project has been approved by an HREC, any change (e.g. changing the questionnaire to collect new information), should be immediately notified in writing to the HREC(s) where approval has been obtained. All protocol changes should be clearly identified on an updated version of the protocol and procedure manual. Changes to a protocol may also necessitate changes to the PICF.

4.2 PROCEDURE MANUAL

All large studies require a detailed procedure manual that incorporates and expands upon the study protocol. The purpose of the procedure manual is to provide a detailed account of all study procedures. It is the day-to-day reference document for all staff involved in any large research project. It should provide enough information to allow a new staff member to take any role in the study at any time. Copies of the procedure manual must be provided to all research staff involved in a study (including updates or amendments agreed to at study meetings).

See Appendix C for details on what the Procedure Manual should contain.

4.3 CONSENT DOCUMENTATION

Informed consent must be sought from all participants involved in medical research. The consent process typically involves a detailed discussion with each participant that includes the reason that the study is being undertaken, together with an explicit description of any risks or inconveniences involved. The person involved in discussions with the participant must be 'manifestly capable' of describing the risks and benefits of the study. This means that the person involved in the consent discussions must be either an investigator or a research officer who has become fully acquainted with all aspects of the study. The consent process must never be delegated to junior members of a study team unless the project is of relatively low-risk.

Sometimes an HREC may vary the normal requirements for consent. For example, in some settings a committee may approve an opt-out consent process. The opt-out approach involves dissemination of the study information to the participants with their involvement presumed unless they act to decline to participate[2]. If neither explicit consent nor an opt-out approach is appropriate, the requirement for consent may sometimes be justifiably waived by an HREC. Research participants will not know that they (or their tissue or data, etc.) are involved in research. Such circumstances are only approved in situations where the HREC determines that consent is impractical, undesirable (e.g. by the likelihood of distressing participants) or would impair the scientific validity of the study.

4.4 THE PARTICIPANT INFORMATION AND CONSENT FORM (PICF)/ EXPLANATORY STATEMENT

The PICF is an essential accompaniment of the consent process.

It is given to all study participants at the time when their participation in the research is first discussed with them. It must be made available in the language of study participants.

This document should be written in language appropriate to the participant group/s. Technical terms and concepts should be described in lay language. It should describe the reason the study is being conducted, the demands to be made of the participant and any risks that may occur as a result of their participation. It should also describe arrangements to ensure the privacy of the information collected.

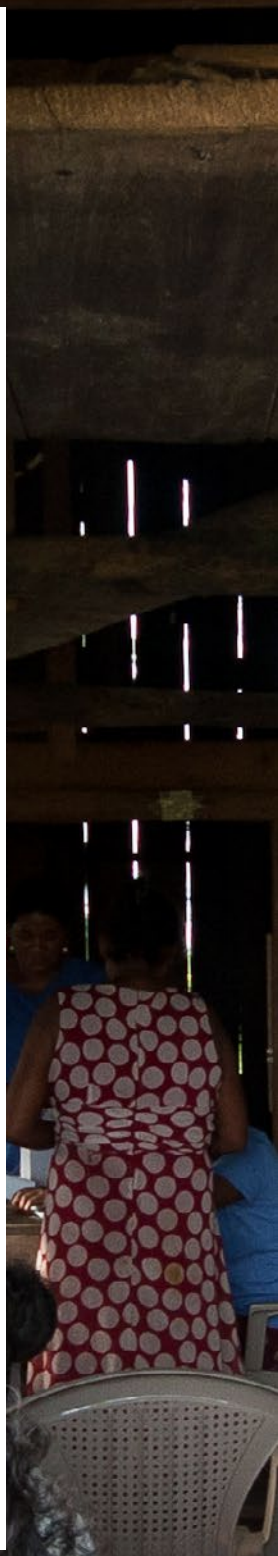
The PICF/Explanatory Statement must be updated if significant new information becomes available during the course of the study. The HREC should approve the update, and only the most recent approved version should be provided to potential participants.

Section 4.8.10 of the ICH GCP Guidelines[3] (See Appendix M) and section 2.2.6 of the National Statement[2] (See Appendix M) provides an outline of the information that should be included within a PICF.

Many institutions also require that specific wording covering local requirements (e.g. privacy legislation) be included in a PICF or Explanatory Statement.

Typically, the information to be included in a PICF includes:

1. An invitation to participate.
2. The fact that the study is a research project.
3. The nature and purpose of the project.
4. A description of any randomisation procedures and the use, if any, of placebos.
5. A description of any medical procedures to be undertaken.
6. A description of any drugs or isotopes to be used.
7. The availability of alternative treatments.
8. An explicit account of what is involved in participating including changes in lifestyle required, the expected number and timing of follow-up visits and any monetary costs likely to be borne by the participant.
9. The anticipated duration of the study.
10. The approximate number of patients treated similarly to date (when the research involves a new drug or device).
11. The possible benefits to the participant and others, stressing when appropriate, that these benefits are not assured.
12. Foreseeable risks, side-effects and discomforts.
13. The requirement that the participant must advise the researchers of any other research in which they are participating or drugs they are taking.
14. Any requirement that current treatment being taken by a participant may need to be suspended.
15. Steps to be taken in case of therapeutic failure or adverse events.
16. Insurance and other procedures for compensation in case of injury due to the study.
17. The fact that participation in the research project is entirely voluntary and that the participant is free to withdraw at any time without negative effects on his/her relationship with the researcher or influence on subsequent treatment.
18. The circumstances under which the participant's participation may be terminated.
19. The fact that the participant's records may be inspected for the purposes of source data audit by individuals from inside or outside the hospital.
20. The precautions that will be taken to protect the confidentiality of the participant's medical information.
21. The names and telephone numbers of the person to contact for further information about the study and the person to contact in case of emergency.
22. A statement about the funding of the study and any payments to study personnel.



HRECs require that participants be given time to properly consider the PICF (and discuss it with friends or relatives) before deciding whether to participate, particularly in long-term or invasive studies. Participants must also be given an opportunity to ask questions and should only be asked to provide consent when the researcher is confident that the participant understands what is required of them and is consenting willingly.

'Immediate consent' is increasingly restricted to those studies in which immediate treatment is required. When there is urgency in commencing an intervention (as with research in acute stroke or myocardial infarction), patients are often distressed and not receptive to detailed explanations of a research project. In such cases, an abbreviated discussion may be acceptable if approved by the HREC. However, wherever possible, it is also important to seek the assent of next of kin before any experimental interventions are commenced.

a. Documenting Informed Consent

The original, signed PICF/Explanatory Statement must be kept in the study document file (see section 4.6) and a copy should be provided to the participant. Where appropriate, another copy should be placed in the participant's medical record.

The PICF should be signed by the investigator, the participant and a witness (see below). The person who signs as investigator may be a delegate of the investigator (but should generally not be the participant's treating physician unless the project is relatively low risk).

b. Signature Witness

When required by the HREC, a witness should be asked to witness the participant's signature. In doing so, the witness signifies that they saw the participant sign the form freely. They are not verifying that the participant is competent, that the participant understands, that sufficient information has been provided or even that the participant is who they say they are.

Alternatively, the HREC may require a witness to the consent process; e.g. when the participant cannot read and needs to have the PICF/Explanatory Statement read to them. The witness must therefore be present for the entire consent process and must sign and date the PICF.

A witness is also required if the participant has temporary or episodic incapacity. The witness must therefore be independent of the research team, be able to understand the research and be able to confirm that the participant, at the time of consent, is able to provide consent for themselves. It is therefore recommended that the witness in this case be someone who knows the participant and is familiar with his/her condition.

c. Access to PICFs

Signed PICFs from every participant must be available for examination in case of an audit. They should be stored with study documentation after the completion of a study and where appropriate, another copy should be placed in the participant's medical record.

4.5 ADVERTISING FOR PARTICIPANTS

Advertising for participants to take part in studies must be undertaken with care and must receive HREC approval. This includes using the media, internet and flyers.

Advertising should be targeted to the appropriate audience. Local newspapers may have advantages over state-wide newspapers, particularly for studies with multiple visits. It is important that any public advertising avoids wording that might imply endorsement of other institutions (such as hospitals).

4.6 THE STUDY DOCUMENT FILE

A Study Document File should be kept by the study coordinator/investigator as a central repository of all significant documents and correspondence involving the study (See Appendix G).

5. SECURE MAINTENANCE OF STUDY RECORDS

5.1 PROPER DOCUMENT MANAGEMENT

All paperwork relating to a study must be maintained in a neat and orderly fashion. Clinical research requires meticulous record keeping. Study documentation may be audited at any time, even some years after it has been completed.

- All study documentation must be kept for at least 7 years after the completion of observational studies and a minimum of 15 years for interventional studies, although some institutions require indefinite archiving.
- It is recommended that, as a minimum, all relevant documents on the following list be kept in the study document file:

» HREC applications, including all correspondence and reports;
» Protocol and amendments;
» PICF/Explanatory Statement (all previous and current approved versions);
» Participant Identification List;
» Case report forms (CRFs) and/or questionnaires;
» Study brochures;
» Data dictionary;
» Correspondence with granting agencies;
» Contracts or agreements;
» Minutes of study meetings;
» Computer database specifications including data entry and verification procedures;
» A record of any changes to data on computer files after data collection;
» Drug dispensing records;
» Randomisation schedule;
» Adverse events reported;
» Progress reporting forms;
» Quality control and/or monitoring reports; and
» Study reports and publications.

5.2 MAINTAINING SECURITY OF STUDY RECORD

Study participants are often asked to provide information of a personal and private nature. Sometimes research involves extraction and collection of personal data from hospital records or records held by other bodies.

Confidentiality refers to the strict avoidance of disclosure of this information to anyone other than authorised individuals. SPHPM staff and students should take reasonable caution to avoid breaches of confidentiality.

a. Privacy Principles and Guidelines

State and Federal legislation is in place to ensure privacy standards for the handling of health information. In December 2001, the Commonwealth Privacy Act (1988)[9] was extended to cover all Australian private sector organisations. The Victorian Health Records Act (2001)[10] applies to both private and public sectors that handle health information and took effect in July 2002. Together, these Acts impose a series of Privacy Principles that regulate the collection, use, disclosure and handling of personal information, including health information[11].

Exemption from specific requirements of the Privacy Act may be allowed for health research. HRECs have the authority to grant such exemptions provided certain criteria are met. These criteria include that:

- The research is of major public health significance
- The research is being carried out by a bona fide researcher with appropriate experience.
- The data will be kept secure and adequate privacy protection is in place.
- The data are not of a highly sensitive nature; and
- Consent to access the information is obtained from each individual unless compelling reasons exist (typically that the requirement for consent would result in invalid results or cause distress).

If access to medical information is granted, it is the responsibility of the research team to ensure the participant's privacy is adequately safeguarded. The following requirements apply:

- Information collected must be used only for the study for which approval has been given.
- Personal identifying information must be removed from all data collection forms and computer files. Typically, if identifying information is recorded in a data collection form, it should be located on page 1, which is removed and stored separately from the rest of the form. Codes linking participant information to their data must be kept separately in a locked draw or filing cabinet. Access to data on computer should be under password control.
- Access to data should be available only to a limited number of individuals, directly responsible to the investigator(s).
- The principal investigator or head of the appropriate unit should take responsibility for the safe destruction of records containing personal information (after the required archival period, as described above).
- No data capable of association with a particular participant should be published.
- Research data containing identifying information must never be kept on USB sticks, laptop computers or home computers.

Notifiable Data Breaches

Where the data falls under the auspices of the Privacy Act 1988 a data breach is defined as personal information that is lost, accessed or disclosed without authorisation. When the breach is likely to cause serious harm to the individual to whom the information relates the breach is a Notifiable Data Breach. If an entity is able to act quickly and remedy the breach thus removing the likelihood that it will cause harm, the breach does not require notification. For all data breaches please contact the Monash University Data Protection Officer at the **Office of the General Counsel** on +61 3 9902 0117 or **adm-ogc@monash.edu**. The Data Protection Officer will determine if a notifiable breach has occurred and assist in managing the situation.

Vignette:
A researcher was undertaking data analysis in an airport lounge. The data was held on a USB stick which contained names, addresses and laboratory test data (including HIV test results). In the rush to leave, the investigator left the unprotected memory stick in the publicly accessible computer. This was found by the next computer user and given to a journalist colleague.

b. Medical Record Access

In general, clinical records can only be accessed by employees of the hospital and with the permission of the HREC of the institution. University staff conducting research in a hospital typically require an honorary position in the hospital to be allowed to access clinical records. External individuals (such as pharmaceutical company monitors) who require access to medical records will need to obtain written approval from the institution (usually via the HREC and the Medical Director's department). A statement that such access is likely should be included within the PICF provided at the commencement of the study.

c. Transfer of Data

Google Apps has been endorsed by Monash University as way of transmitting coded research data. Google Apps (including email and Google Drive) should not be used for the transfer of identified information. A list of approved services for the transfer and storage of data can be found at **intranet.monash/esolutions/security/approved-services/_nocache.**

SPHPM researchers are reminded to use password protection where ever possible and to communicate the password separately.

5.3 RISKS ASSOCIATED WITH SERIOUS BREACH OF CONFIDENTIALITY

A serious breach of confidentiality could have significant consequences for:

- The research participant (e.g. resulting in legal action);
- Future recruitment (e.g. fears about data security could significantly lessen the likelihood of future participants providing confidential information); and
- Future research (e.g. the likelihood of an HREC approving future projects requiring collection of personal data would be jeopardised).

To minimise this risk, the following requirements have been introduced:

- Staff must sign a privacy declaration when they commence (and will often be asked to resign if their role changes).
- New staff must complete Ethics/Good Research Practice training.
- Requirements for privacy and data security are emphasised to new staff by unit head and the Research Governance Officer.
- Data storage for all studies is reviewed periodically by the Research Governance Officer.

Vignette:
A research study was undertaken involving volunteers suffering from severe depression. They were recruited by advertising in the general community. The volunteers underwent nerve velocity testing, undertaken by a research assistant. One of the volunteers was the daughter of a neighbour of the research assistant's mother. The research assistant told her mother about the volunteer's illness ... who in turn mentioned the fact to the mother of the volunteer, commenting "I did not know your daughter was depressed." A complaint was made to the hospital administration and the researchers were reprimanded (the importance of maintaining the participants confidentiality was highlighted).

6. COLLECTING AND RECORDING RESEARCH DATA

Most clinical and epidemiological research requires a systematic gathering of information. This may be undertaken directly with the participant via data collection forms that are either paper based or electronic.

Collection may occur via data collectors or clinicians who fill in forms or enter directly into web-based systems. Alternatively, collection may be from the provision of a large administrative dataset or electronic medical records (EMRs) or it could be sent directly from a medical device. The sources of data are ever changing but regardless of the method used for collecting these data, the researcher has a responsibility to manage this data appropriately. This includes:

- Only collecting data in accordance with the approved study protocol;
- Collecting and recording these data as directly, promptly and accurately as possible;
- Verifying the data and ensuring its quality;
- Analysing the data so that they are reliable, accurate and valid; and
- Holding the data through their lifecycle, regardless of format (digital or physical) while meeting all data protection and privacy requirements.

Monash has developed a Data Governance Framework (DGF) (Appendix K) to better manage health data gathered for research. The DGF is a structured and well-defined description of these data activities and is used operationally to develop policy, procedures and data management tools, as well as providing a common language to be used across the university.

6.1 DATA ELEMENT MANAGEMENT AND DATA DICTIONARY

A data element is the piece of data collected to inform the research question. A data dictionary outlines the data elements that will be collected and their characteristics. More information on data dictionaries can be found in Appendix K. The selection of these data elements and their subsequent definition are important activities that will help researchers design the right tools for collecting their data. It is important that only those data elements outlined in the study protocol are collected and included in the data dictionary. This activity should be undertaken prior to any data being collected.

If the researchers hope to undertake data linkage at any point, it is important that they consider standard definitions used by the datasets to which they hope to link. There are a number of sources for standard definitions that can be used including (but not limited to):

- Meteor and SnowMed
- For disease coding – ICD108.
- For occupation coding – ASCO (Australian Standard Classification of Occupations) is available from the Australian Bureau of Statistics.
- For industry coding – ANZSIC (Australian & New Zealand Standard Industrial Classification) is available from the Australian Bureau of Statistics.
- For geographic and language codes – standard Australian Bureau of Statistics codes are also available.
- For clinical registries there may be standardised coding schemes already available, and, ideally, consistent across registries to enable easier linkage.

If during the research there is a change to the data elements (e.g. the definition needs to change, a new data element needs to be included or an existing data element is no longer relevant/ needed), a systematic process is required to ensure the variation does not impact subsequent analysis and reporting. This includes at a minimum:

1. Recording of the change and why it was made (including who approved the change).
2. Recording of the impact (including any data migration requirements or system change / data form/ procedure manual change requirements).
3. Updating the data dictionary with variation but not overwriting previous definition.

Vignette:
A new research assistant was engaged in a project involving telephone counselling after traumatic stress. The assistant strongly believed in the value of the study and the certainty (in her mind) of a positive result. When the actual result of a test she undertook was unfavourable, she recorded different data to make it appear that the result was positive in each patient. This was picked up during a routine quality control check, when it was found that her results were different to the results of the other research assistants employed. Fabrication of data in this way can have the most serious results for everyone involved and could be grounds for instant dismissal. The research assistant might well find it impossible to gain future employment in a health or research occupation.

6.2 DATA COLLECTION

No matter what method is used to collect data, researchers should always remember that this data is being gifted to the research by the patient, clinician and/ or health service, and thus there are principles that apply to its collection:

1. Data should be collected directly, promptly and as accurately as possible;
2. Data should only be collected that meets the purpose of the research by informing the research question and to which the researcher has obtained ethics approval to collect;
3. Data should be collected securely
4. Data should be collected in such a manner that the risks of error or fraud are minimised

6.2.1 Form Design

Whether electronic or paper based, badly designed data collection forms will impair the quality of research. All questions must be clear and simple. Whenever possible, it is advisable to create new forms by adapting others that have proven successful in other studies. Other points to note are:

Standard Questionnaires, Definitions and Coding.
Whenever possible, standard questions and definitions (see above re data dictionary) should be used. Examples are the SF36® health surveys for quality of life estimation, and the standard smoking questions adopted by the National Heart Foundation, Medical Research Council's Committee on Environmental and Occupational Health. Questionnaire on respiratory symptoms. London, Medical Research Council, 1986.

Questionnaire Elements.
Whenever new questions are developed for a questionnaire or data collection instrument, it is essential that:

- the options are comprehensive, i.e. they cover all possible responses; and
- the options are mutually exclusive, i.e. only one option can be chosen for any specific situation (unless it is designed as a multi value field).

Patient Identifiers.
All pages of paper-based data collection forms should be prominently labelled with a unique numerical identifier that allows identification of participant, if needed.

Collector Identifiers.
It is essential that the individuals responsible for collecting data, whether digital or paper based, should be identified. This means on paper forms ensuring the data collector's details are recorded. In digital systems, this requires that the identity of the creator or editor of records is noted.

Special instructions.
Special instructions should be provided in small print on the data collection form (e.g. how to interpret or code specific responses). These instructions require great thought and considerable pilot testing prior to the introduction of the completed form.

Pilot Testing.
Pilot testing is required for all data collection instruments. The nature and results of the piloting should be recorded in the study coordinator's log.

Easy coding of forms. Whenever possible, forms should be self-coding; i.e. those completing them should enter the data directly into coding boxes in the form. Decimal points should be clearly marked and each box must be large enough to allow legible recording. Particular care should be paid to having separate codes for 'missing', 'not known' and 'refused to answer' data. The values 99, 88, and 77 are often used for these, provided that they are not within the range of valid responses. Particular attention needs to be paid to the recording of the units of measurement, such as serum cholesterol in mmol/L or mg/dL. If different units are possible, a CRF field is needed to capture the units actually used.

Training of Data Collectors (If Being Used).
Study coordinators must carefully explain every question and every response to new staff involved in data collection. When the form is to be completed at interview, the study coordinator must personally supervise the initial interviews until he/she is confident that the information is being collected correctly

Erasure of Data (Paper).
Data collectors must be instructed not to erase any entry on a data collection form. If a mistake has been made, a line should be placed through the original entry so that it remains legible. The corrected value should be written in an adjacent space and a comment provided as to why the correction was made. Data collection forms should be checked for completion as soon as possible after they have been completed. A record should be kept of who checked which forms and when.

Erasure of Data (Electronic).
The system used to collect data should include a tracking system so that corrections/editing of any fields, are logged and can be retrieved if necessary.

Written Comments.
Data Collectors and interviewers should also be encouraged to record comments with the data whenever a new or unusual situation is encountered. This can be done on a paper or electronic form by providing a space for free form text. These can then be brought to the coordinator/investigator's attention at the regular study meetings.

6.2.2 Use of Electronic Systems to Capture and Transfer Research Data

There are a number of electronic systems now available to capture data directly from participants, clinicians or data collectors, rather than the researcher collecting the data in person and recording it on a paper form.

If there is still a need to collect data on a paper form, these can also be entered into the database with an electronic data collection tool such as REDCap or a custom-built web application.

a. REDCap

Monash University offers access to REDCap, a browser-based electronic data capture system with an underlying database that includes workflows for clinical and translational research purposes. It can be used to capture, transfer, report and to act as a repository of health data. Electronic Data Collection Forms and online surveys can be designed by Researchers without specialist programming assistance and allows:

- internal system checks to be built into the system (eg range checks, consistency checks);
- inbuilt auditing so it is clear who has created and altered the record;
- multi-user access securely across the internet for distributed participants/ clinicians/ data collectors to submit their data

There is also the ability to access some workflows such as consent. It is also well-supported by Monash with training courses and access provided by the Helix team.

b. Custom Built Web Applications

Some research has the need and the resources to develop a customised data solution that would incorporate a database and web applications to capture the data. These data may be captured via electronic web forms or in bulk via APIs or other data transfer mechanisms. This level of customisation can provide internal system checks beyond that offered in REDCAP by incorporating complex business rules. It can also incorporate more workflows and complex access requirements.

Monash has the capacity to host these solutions with the high level of security required to protect health data. If these higher end data solutions are required, Helix and the e-Research team are available to discuss needs and help customise a solution.

c. On-line Survey Tools

There are a number of on-line survey tools on the market that can be used to capture data. To ensure the security of the personal data that is being collected, only authorised products should be used. Monash currently has an enterprise agreement with Qualtrics to collect data via their on-line survey tool with sufficient security in place to protect health data. There are, however, conditions when using this mechanism that must be met (**intranet.monash/esolutions/security/approved-services/_nocache**).

d. Other Tools to Transfer Electronic Data

There are many other data transfer mechanisms such as Helix's Secure File Transfer Platform (SFTP) or commercial products for file transfer or other products that send readings directly from devices. Each of these mechanisms need to be secure in how they transfer and deal with the data that passes through them. A list of approved transfer mechanisms can be found at **intranet.monash/esolutions/security/approved-services/_nocache.** It should be noted that in some cases these mechanisms are approved for transfer of data but not storage (e.g. SFTP), so researchers need to ensure data is removed from these systems after transfer is complete. If researchers have a mechanism that is not on this list, they should contact Helix to confirm its suitability prior to its use.

e. Data Transfer via Fax

Medical data is often sent via fax machines. This remains an acceptable way to capture data or send data, although it should be noted that when Monash receives/ sends faxes, they re-direct them through the University's google mail system so the data does go off-shore to Google's servers in Singapore.

f. Data Transfer via Email

It is generally considered unacceptable to send medical/ health data via email in Australia unless it is via a secure, encrypted email system.

g. Data Transfer via Mail

It is generally considered acceptable to send paper medical/ health data via Australia Post in Australia. Care needs to be taken that return addresses do not reveal the membership of the individual in the study as well as supplying pre-addressed reply-paid envelopes to avoid return mail being misdirected.

Digital data contained on encrypted portable media (CDs, flash drive etc) should not be sent via Australia Post.

6.2.3 Database Management

Usually the data that is collected is input into a database. A database is a structured set of data held digitally. Some of the electronic capture mechanisms, such as REDCap and custom-built Web Applications, have a database that is integrated into the system. Other tools may be integrated into SQL Databases or ACCESS databases.

If there is not an option to do this, software packages such as Microsoft Excel and Microsoft Access are an option to hold and manage such data. While Microsoft (MS) Excel can be used as a database it is designed as a spreadsheet not a database product and so extreme care needs to be taken. Data from spreadsheets can be copied and managed in statistical software such as SPSS or Stata once it is complete and ready for cleaning or analysis. MS Access is well supported, easy to learn, has good security and data checking features and is recommended for studies that have limited need for multi-user access, customisation and the building of workflows by eSolutions. Monash runs several short courses on database management with MS Access

a. Database Documentation

Each database, large or small, should be accompanied by a folder, or have embedded in their system, documentation containing the following information:

- Copies of the questionnaire and/or other data collection instruments.
- Database information including an explanation of the various files, languages and data formats used, the directory structure and the key programs used to manipulate the data.
- The database or system data dictionary lists all variables, variable names, coding rules, relationships between variables and coding manuals (e.g. occupation and drug codes). This will contain more information than the data dictionary and it is essential that it is consistent. Templates can be accessed that provide the ability to maintain a large single data dictionary (covering both research and IT purposes) in MS Excel that can then be output to a more user-friendly MS Word format for data sharing.
- The database log used by the study coordinator and database manager to record the nature of, and reasons for, all modifications, data cleaning etc. Some areas in the School have procedures manuals that also record and manage this process.

b. Data Log

It is the responsibility of those with access to the database to ensure that a data log is maintained. For systems such as REDCap and custom-built Web Applications, these are generally built into the system and include:

- the identity of individuals entering (or correcting) data onto the main database,
- any changes made to questionnaires or data entry screens,
- any auditing or checking undertaken and any difficulties experienced.

Documentation of any change to the systems is also required and, at a minimum, should include:

1. Recording of the change and why it was made (including who approved the change)

2. Recording of the impact (including any data migration requirements or procedure manual change requirements)

6.3 DATA VERIFICATION

Data Verification can occur when data are being input into the data solution (e.g. enforcing range, consistency and other business rules as data is entered into the database) or it can happen following data entry, and before finalisation of a data set by running a series of data verification procedures. Such range (to identify values that are likely to be outside a valid range), consistency (e.g. checking that non-smokers do not have entries under “numbers of cigarettes smoked per day”) or business rule checks (e.g. treatment is considered stopped if device is removed and follow up will cease) will ensure that errors are identified and can be corrected prior to analysis.

To further avoid error, it may also be possible to check the dataset against a third-party dataset (e.g. via data linkage to Births, Deaths and Marriages) to verify if data is missing or incorrect.

If errors are found during these processes, record should be kept of what was corrected and why to provide an audit trail should the data be queried in the future.

6.4 DATA REPOSITORY MANAGEMENT

Researchers are responsible for how health data is to be held through its entire lifecycle (including storage, back up, archive, sharing) regardless of the form of the data i.e. paper, films, biospecimens or digital.

6.4.1 Storage of Paper Based Research Data

All paper work relating to a study must be maintained in a neat and orderly fashion. Clinical research requires meticulous record keeping. Study documentation may be audited at any time, even some years after it has been completed.

All study documentation must be kept for at least 7 years after the completion of observational cohort studies and a minimum of 15 years for interventional studies, although some institutions require indefinite archiving. Data of regulatory or community significance (e.g. of high public interest, impossible to reproduce, involving the use of an innovative technique for the first time) will also need to be stored indefinitely. This may include data from some registries.

All physical records (including paper-based, films or other physical media) must be correctly stored with a procedure to ensure the security of data. The exact procedures to be followed may depend on the sensitivity of the data set and on specific caveats imposed by the HREC. A storage site must be designated and security procedures established (e.g. responsibility for locking cabinets, location and access of keys).

To back up physical records, these can be converted to a digital format by scanning it into an image or a machine-readable format. Not all studies will require their physical records to be digitised. Further information can be found in Appendix G.

6.4.2 Storage, Back Up and Archiving of Digital Health Data

It is important that researchers understand where their digital health data are stored, backed up and archived, particularly when completing their protocol and other ethics applications. Digital health data are not limited to the database being used. It also includes digital files that may contain:

- PDFs of the paper forms
- Digital images of x-rays, MRIs, CT scans, ultrasounds, pathology samples
- Digital copies of radiology or other reports
- Extracts from EMRs
- Spreadsheets of results
- Digital recordings

Health data should be held on a secure Monash mechanism and not on individual computers, laptops and portable storage devices (e.g. USB sticks). Mechanisms for holding health data and the conditions under which they are approved (e.g. provision of passwords to key individuals and nomination of individuals with differing levels of access) need to be considered. Some mechanisms may be approved for data capture (e.g. Qualtrics) but not for data storage/ repository. This will generally be for risk mitigation purposes and will be outlined as a condition of their use.

The most common places for researchers to store their electronic health data are listed below, with details of how they are stored and backed up, including whether they are in the Monash University ‘Red Zone’. The ‘Red Zone’ is a highly secure computer network that is actively monitored for threats and is used to store highly sensitive data. It includes personally identifiable data collected for research purposes.

Researchers are advised that a new tool is being developed, called Strongbox, for the sharing and storage of sensitive (identified) research data. Strongbox automatically applies double encryption to the file or document that is upload and generates a password needed to access the file. At the time of writing this was being tested and should be available towards the end of 2020.

System:	Data Stored:	Regimen:	Backup deleted after:	Can be Retrieved by:	Recovery Time
S:/Drive	On Monash infrastructure	Overnight	30 days and then monthly held for 12 months, quarterly for 7 years, annually for 15 years	"Restore previous version" when right mouse click or contact eSolutions for assistance	Next business day
X:/drive	On Monash infrastructure	Snapshots taken regularly	30 days and then monthly held for 12 months, quarterly for 7 years, annually for 15 years	Request via eSolutions	
SQL Server	In Red Zone	Back up every 2 hours	30 days	Requests for data to be restored should come to helix-support@monash.edu	
REDCap	In Red Zone	Back up every 2 hours	30 days	Requests for data to be restored should come to helix-support@monash.edu	

At the completion of the study, digital data needs to be archived. Currently, researchers are responsible for archiving their own electronic data. This should be undertaken using approved mechanisms. In the case of SQL databases, Helix can be contacted to have these archived within the Red Zone. The S:/drive and X:/drive are suitable for archiving of this data.

6.4.3 Storage and Back Up of Human Bio-specimens

Many studies will collect and store bio-specimens such as blood, urine, saliva and other tissues. Samples are stored in biobanks and are often utilised for multiple analyses over many years. Things to consider when storing bio-specimens:

- Appropriate storage environment to ensure the samples are kept at the requirement temperature. The temperature should be monitored and a temperature log maintained so that any variation in temperature is identified and documented.
- Access to the storage of the samples should be restricted.
- Freezers should be fitted with alarms that will trigger if the temperature moved outside a predetermine range. The alarm needs to be able to send a message, preferably via text, to alter researchers of the issue. An alarm that is audible only is not helpful after hours. A protocol for responding to a freezer alarm must be established.
- Ideally, a back-up freezer should be available. Large biobanks will have a 'spare' freezer that is empty but running. This freezer is ready to receive samples if one of the freezers experience technical difficulties. An alternative to having a spare freezer on stand-by is to share facilities with other research groups. Researchers should be aware of who may have space in their freezer in an emergency and, like wise, let others know what space they have in case it is needed.
- It is preferable to create multiple aliquots from a single blood or urine sample or to collect more than one saliva and tissue sample. This is to ensure there is a backup if one perishes (large biobanks will store the samples in separate locations for additional security, small research groups can store each other's backups) and to protect the integrity of the sample which often degrades with repeated freezing and thawing between analyses.
- If multiple aliquots from the one sample are being shipped between locations, it is advisable that they are not shipped together. This will ensure that if a shipment is lost or thaws that not all everything is lost.
- Ensure all storage equipment is serviced regularly and is visually inspected for signs of wear.

6.4.4 Destruction of Digital Data

Destruction of research data may occur during a project (e.g. a participant requests their data be destroyed and this is permitted by the ethics approval) or after the archive period is complete. Researchers may also be requested to destroy data they hold from another data custodian after a certain period of time.

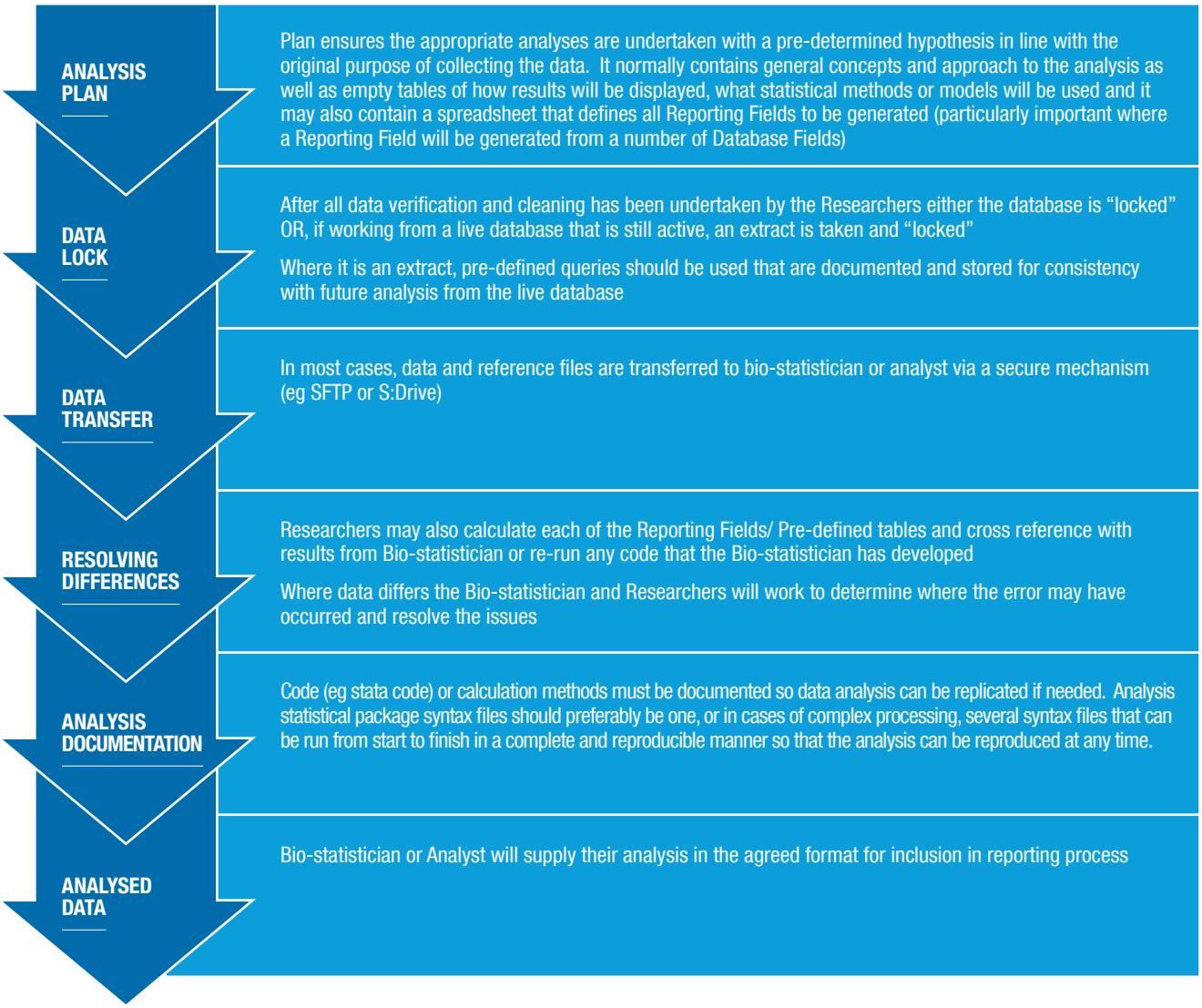
Destruction of paper records should be undertaken via the secure, locked bins provided by the School.

Destruction of electronic research data will depend on the repository system and on whether it is a single record or entire database/file. Consideration may need to be given to data held as back up and whether this may be written back if data needs to be recovered.

6.5 DATA ANALYSIS

Analysis of data is a vital step in the research process and must be undertaken so that results are replicable, accurate, consistent and valid.

A number of activities are required to ensure this, including:



6.5.1 Final 'Locked' Dataset

When final corrections have been made and the dataset is ready for analysis, either the entire database is locked and finished (e.g. at the end of the study) or an extract for analysis is taken (e.g. in a registry or for an interim analysis during a trial). Such a file should be labelled accordingly and date/time stamped. This final 'locked' dataset should be stored with its data dictionary and if a clinical trial, with its randomisation key. For extracts, it is particularly important to note the date/time of extract as the 'live' database will likely change and it should be clear that the analysis and findings are as at the time of extraction.

6.5.2 Statistical Analysis of Data

All data and statistical syntax files for an analysis should be contained in the one location. One or more, if processing is complicated, statistical syntax files should reproduce all key results. Although ad hoc work is required when exploring the dataset, one or more final syntax files should be created which contain all analyses which are being reported in the publication or paper. These should be accompanied by notations which explains what each syntax file does and what order they need to be run in.

- Participant or case ID numbers should never be hard coded within a syntax file as data can change. Any processing required should identify cases by a condition, not a list of ID numbers (e.g. drop all participants where ANALYSIS_FLAG= "X", rather than dropping a list of ID numbers).
- All statistical syntax files should write output to a log file. All ad hoc statistical work should also be logged accordingly.
- Log files should be maintained for all statistical work under an easily identified file path such as \Logs of the specific \Data\Analysis folder for this analysis.
- Syntax files should include comments to explain what the syntax is doing and what the results represent.
- Multiple syntax files should be named in such a way that is obvious what they produce if run and also explained in accompanying document. Preferably, multiple syntax file should be numbered in order in the name so it is obvious which order they should be run in.

6.6 DATA REPORTING

The final output of the research will be reported in one form or another. It may be a:

- thesis or publication:
- presentation or poster at a conference;
- report delivered to a funding body;
- publicly available annual report;
- reports to individual clinicians, hospitals or statutory body;

Regardless of the form reporting takes, there are four principles of reporting:

1. Whatever is reported, it must be in line with the original purpose of the study.
2. No reporting should be released without appropriate analysis and approvals.
3. Expectations should be set as to when it will be delivered – researchers may need to trade off the importance of the timeliness of their reporting versus the resources available to collect, verify and analyse the data.
4. Reporting must be done with data protection in mind, particularly in relation to stratification and ensuring minimum cell size obligations are observed.

7. STUDY MANAGEMENT

7.1 THE PRINCIPAL INVESTIGATOR

The Principal Investigator must be specified as having ultimate responsibility for the conduct of the study. He/she has responsibility for the design, conduct, analyses and reporting of the study and should:

- Ensure that all investigators are aware of their responsibilities and that they can conduct the study in accordance with the study protocol.
- Ensure that appropriate systems are in place to guarantee quality control of every aspect of the study.
- Ensure that all persons involved in implementing the study are adequately informed about the protocol, the nature of the intervention (if applicable) and their study-related duties.
- Ensure that clear lines of communications are present between all study investigators.
- Ensure that the Case Report Forms (CRF's) are adequately designed to capture the required data.
- Manage the resources for the study in a way that ensures that the study finishes within the available budget.
- Ensure that any contractual requirements, or other terms or conditions specified by a granting body or sponsor, are being met.
- Ensure that the results are analysed, written up, reported and disseminated appropriately.

Other key individuals fulfilling different roles in a study may include:

a. Co-investigator(s)

Each co-investigator has the responsibility for the conduct of the study within his/her participating centre and/or area of expertise.

b. Study Coordinator / Manager / Executive Officer

This role is often filled by a senior Research Fellow or senior administrator, who may be responsible for the day-to-day management of the study. This may include staff recruitment, purchasing, oversight of contact deliverables, engagement with sub-contractors and stakeholders, oversight of study timelines, HREC obligations, protocol development and reporting.

c. Study Documentation

The management and storage of research records should be undertaken in accordance with Section 5 of this document. At a minimum, the following should be stored on the Monash shared drive with more than one person having access to the folder:

- Grant application and/or letters of agreements/contracts between Monash and the granting body/sponsor and/or sub-contractors.
- Protocol and any Procedure or Data Management manuals.
- If applicable, most recent approved versions of the PICF and any additional letters or invitation materials given to participants.
- HREC approval and correspondence.
- Annual reports to granting bodies/sponsors and HRECs.
- Documentation showing where any relevant datasets and statistical analysis code/output can be found.
- Details of where the study has been archived, if applicable.

If there is an impediment to storing the research records on the shared drive, a copy of the above files should be provided to the School Research Manager.

If a senior member of the study team is departing SPHPM, please see Section 7.4.g of this document.

The School has responsibility for the conduct, management and monitoring of all research undertaken by staff and students, including adjunct staff and students conducting research in affiliated institutions. It is therefore necessary for the School to be able to access basic study documentation if and when needed.

7.2 FINANCES AND HUMAN RESOURCES

- Financial management of each study will be the responsibility of the Principal Investigator. He/she must keep accurate and timely records of all expenditure and inform the Head of School or School manager of any concerns or irregularities.
- Job descriptions based on a generic proforma will list staff responsibilities and will be provided for all staff associated with the project. These should be signed by the principal investigator and the staff member.

7.3 STUDY MEETINGS

a. Regular Meetings

The Principal Investigator and Study Manager must arrange for regular meetings of the study staff. In the early stages, such meetings should be at least fortnightly and in the later stages, at least every two months. Formal minutes should be kept and circulated to all involved parties.

b. Study Management Committee (For Larger Studies)

This committee should meet at specified intervals to review the progress of the study.

Decisions concerning changes to protocols, case report forms, key staff, budget, governance or stakeholder engagement must be ratified and recorded at meetings of this group. Any risks, or potential risks (as outlined further in Section 7.4), to staff or participants, or to the quality or reputation, of the study must be monitored by the committee and acted upon, including issues around staff safety, delays in the study timeline, obstacles to meeting study deliverables, sub-optimal data quality or reporting standards, participant complaints or sensitivities, budget overspend, staff-turnover etc.

Minutes of these meetings should be made and circulated as soon as possible after the meeting and stored in the Study Document File (see above).

Each member of the management committee should be provided with the meeting minutes and be able to easily access the study documentation as described in Section 7.1 c.

7.4 STUDY RISKS

The School's Risk Management Plan is provided in Appendix D. Here are some examples of risks that Study Management need to monitor.

a. Interviewer Safety

If interviews are undertaken in a participant's home or similar location away from the office, the Project Manager or delegate should be advised of the times and locations of those interviews. Ideally, a second staff member should attend the interview. The interviewer must have a charged mobile phone. To verify personal safety, interviewers should check-in (by phone) with the Project Manager or delegate after leaving the interview, regardless of time of day. The Project Manager should consider equipping interviewers with personal safety devices, such as a personal alarm or a personal safety mobile phone app (there are a number of free apps that, with the touch of a button, will send a message, including your GPS location, to selected individuals and some will also commence audio and video recording).

b. Participant Privacy, Including Deidentification, Randomisation and Blinding

Only a restricted list of study staff should have access to participant's identifying, and contact, details such as name, date of birth, address and phone number or email address. Health and other data collected from participants must be stored separately to the identifying, and contact, details, as per Section 5. Any randomisation or blinding codes must also be kept by a "restricted" staff member who is not involved in collecting, scoring, cleaning or analysing the data. It must be emphasised to all staff that under no circumstances must a randomisation or blinding code be broken until the final cleaned data set has been produced. Emergency unblinding methods must be developed and implemented and have the approval of the HREC.

c. Staff Management

It is the responsibility of the study investigator(s) and the study coordinator/manager, to provide appropriate training for staff and to monitor the work performance of all those involved in data collection, management and analyses. This supervision should include specific instructions concerning privacy, data handling, quality control, security during interviews, and adherence to these guidelines must be monitored. All staff must sign a document acknowledging their willingness to abide by privacy guidelines before commencing work.

d. If Things Go Wrong

If there is evidence of poor study practice, the study team should know how to deal with the problem in a positive way. Solving the problem at an early stage is the best way to reduce damage to study participants and researchers. Informal confidential advice from senior colleagues may be helpful in deciding what action to take. There may be times when it is not possible for the study team to deal with a problem alone. In these cases, they should share the problem with colleagues who are in a position to act. However, if there is a pattern of poor practice that could place participants at risk that would be the time to refer the problem to the Principal Investigator or the school Research Manager.

e. Follow Up of Abnormal Pathology Results

Many studies involve the measurement of physiological variables (such as blood pressure) and the undertaking of various pathology tests (such as full blood examinations or liver function tests). There is always a 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.

Each study must have a procedure to review the results of physical examinations and pathology tests and pass on important clinical information in a timely manner. If failure to pass on crucial clinical information meant that a potentially curable illness was not detected, it could lead to legal action for negligence. These procedures must be documented in the protocol and procedure manual and adherence monitored by the Research Governance Officer.

f. Emergency Procedures

Some clinical research projects, particularly those conducted on patients who are unwell, must pay particular attention to the monitoring of participant clinical status and access to 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 significant. If emergency care was not immediately available, repercussions could include the death or injury of a study participant, and legal action against the investigator and the department.

This risk is most likely to be encountered in drug trials and in physiological studies. The risk is greater when studies are supervised by inexperienced or junior staff and when senior clinical investigators are unavailable or unable to be contacted.

Management of this risk is handled by the development of standard operating procedures (SOPs) that cover as many emergency scenarios as possible. At a minimum, they should make sure each participant knows who to contact in case of an emergency. The Research Governance Officer will monitor the adequacy and functioning of these procedures via the self-audits and short face-to-face audits.

g. Staff Departing SPHPM

When a staff member leaves a study, important corporate knowledge, emails which document decisions, important documents kept on a personal computer server (and not the shared drive) and passwords to important spreadsheets or databases, can be lost. Staff who leave SPHPM must follow the instructions in the Induction guide (Resignation/Departure from the school) and ensure that an exit checklist is completed. In addition, if the staff member is responsible for one or more research projects which are ongoing in SPHPM, they must ensure appropriate handover and ongoing management of the research project(s).

If the project is not leaving with the staff member:

- Ensure an appropriate replacement researcher is identified. This person must agree to take responsibility for the project.
- Ensure the necessary documentation is submitted to the HREC, funding body, sponsor etc. of the project to inform them of this change.
- Ensure that copies of all-important emails, documents and passwords are handed over to the replacement researcher or the study manager.
- Ensure that NO copies of confidential study materials are retained by the staff member in their personal files or on their personal computer.

If the project is being relocated with the staff member:

- Ensure the HREC, funding body, sponsor and other relevant parties are notified.
- The departing researcher must discuss with the Head of School whether the researcher will be taking the original data or a copy. If the original data is being relocated, a full and complete copy of all Study Documentation, as described in Section 7.1c, must be retained by SPHPM. Alternatively, the departing researcher may take copies of the data and research records leaving the originals with SPHPM.

7.5 USE OF ELECTRONIC SIGNATURES

Staff and students are reminded that an electronic signature has the same power as a standard 'wet ink' signature and should always be used appropriately. Having access to someone's electronic signature does not mean you have authorisation to use it as you like.

Electronic signatures tend to fall into two broad categories:

- A pdf of a wet ink signature
- A true electronic sign-off of a document

PDF of a Wet Ink Signature

A pdf signature should only ever be used under one of the following conditions:

- The signature is attached to a document by the person who owns the signature.
- The signature is attached to a document by someone who has received authorisation from the owner of the signature. Documentation is required; e.g. email of authorisation.

Any document where a pdf signature is used must be converted to a pdf before being provided to another party. This is to protect the signature and its owner.

True Electronic Sign-Off

True electronic signatures are available in different formats. Some electronic systems (e.g. hospital medical records) have an in-built sign off system. By entering their username and password staff are signing off on an entry, request or referral.

Password protected electronic signatures can also be downloaded from the internet or come built in various programs.

Researchers are reminded to protect their electronic signature by ensuring they do not give others access to their password. If there is a reason why someone should have access to someone else's electronic sign-off, the above conditions should be adhered to.

Unauthorised use or misuse of a signature is unacceptable.

Vignette:
A senior academic staff member had access to the electronic signature of the Head of Department. In order to finalise a contract on time the staff member attached the Head of Department's signature (without their knowledge or consent). This contract had taken the Department in a direction that the Head had not intended and did not endorse. The staff member who had used the signature without authorisation lost their job.

7.6 SPECIFIC REQUIREMENT FOR CLINICAL TRIALS

a. Communication with a Participant's Doctors

When enrolling a patient into a clinical research project, it is essential to:

- Communicate with his/her treating physicians to ensure there is no reason why the participant may not be suitable.
- With the patient's permission, keep his/her general practitioner and other treating physicians informed regarding his/her involvement in the clinical trial.

b. Payments to Research Volunteers

Provision of appropriate reimbursement to research participants for expenses incurred is important. These payments should be disclosed to the relevant HREC(s). Other payments are sometimes approved, provided that it is judged that such payments are not an inducement for a person to participate against their better judgement.

c. Using Drugs and Other Therapeutic Agents During a Trial

When clinical trials of therapeutic agents are undertaken, preparation/dispensing of medication for participants should be undertaken by a Pharmacy Department. It is recommended that bulk medication be stored in the relevant pharmacy department, not in the School. Alternative arrangements are only acceptable with HREC and school approval.

d. Insurance Cover

Researchers conducting a clinical trial with MUHREC as the primary HREC, must complete the Clinical Trial Insurance Checklist available from Insurance Service by emailing **insuranceservices@monash.edu** and the Research Governance webpage (**intranet.monash/medicine/sphpm/research/governance**).

Insurance provided by Monash University covers damage to study participants resulting from professional negligence in the design of the research protocol. It will also provide cover for non-medical research staff involved in clinical activities outside public hospitals.

Insurance cover against actions for medical negligence involving a patient from a public hospital is the responsibility of the Victorian Managed Insurance Agency. It is critical that all medical practitioners participating in clinical research involving such patients have an appointment (or adjunct appointment) at a public hospital to qualify for this cover.

When the study is being conducted in a general practice setting, the University will not provide insurance for negligent acts on the part of participating general practitioners. Those doctors would be required to have cover for their research participation included within the policy provided by their medical defence organisation or purchase their own additional insurance. Alternatively, researchers may seek specific insurance to cover a particular research activity.

Externally sponsored studies are usually provided with an indemnity by the sponsor assuming liability for injury to participants in a clinical research project that they have initiated. Such arrangements agree to compensate injured participants on a no-fault basis in accordance with Medicines Australia's guidelines for compensation13. However, such indemnity may become void if the injury is sustained as a result of a protocol violation. However, if the study is investigator initiated, the employing institution takes on the role of sponsor and therefore the responsibility for providing insurance cover.

In some instances, injury to a research participant may result from the harmful effect of a product under investigation resulting from a defect in its manufacture[13] (see Appendix M). This is usually the responsibility of the sponsor or manufacturer of the investigational project and is covered by a product liability agreement.

It must be emphasised that insurance cover may not be valid unless:

- A HREC, constituted in accordance with NHMRC guidelines, has reviewed and approved the clinical trial in question.
- The clinical trial is conducted in accordance with the terms of any human research HREC approval, and
- The practitioner's involvement in the clinical trial comes within the category of practice for which the practitioner is insured[14] (see Appendix M)

e. The Study Report

Completed studies must be summarised in a final report that accurately and completely presents the study's objectives, methods, results and interpretation of the findings.

Funding agencies and/or sponsors must be informed of the study results in a manner that complies with applicable regulatory or contractual requirements. There is an ethical obligation to disseminate findings of public importance. Scientific peers should be informed of study results by publication in the scientific literature or presentation at scientific conferences, workshops or symposia. Potential conflicts of interest should be disclosed. Authorship of publications should be determined in accordance with the School's authorship guidelines (available from the 'Department' folder of the S: drive). Ideally, authorship should be discussed prior to the commencement of the study.

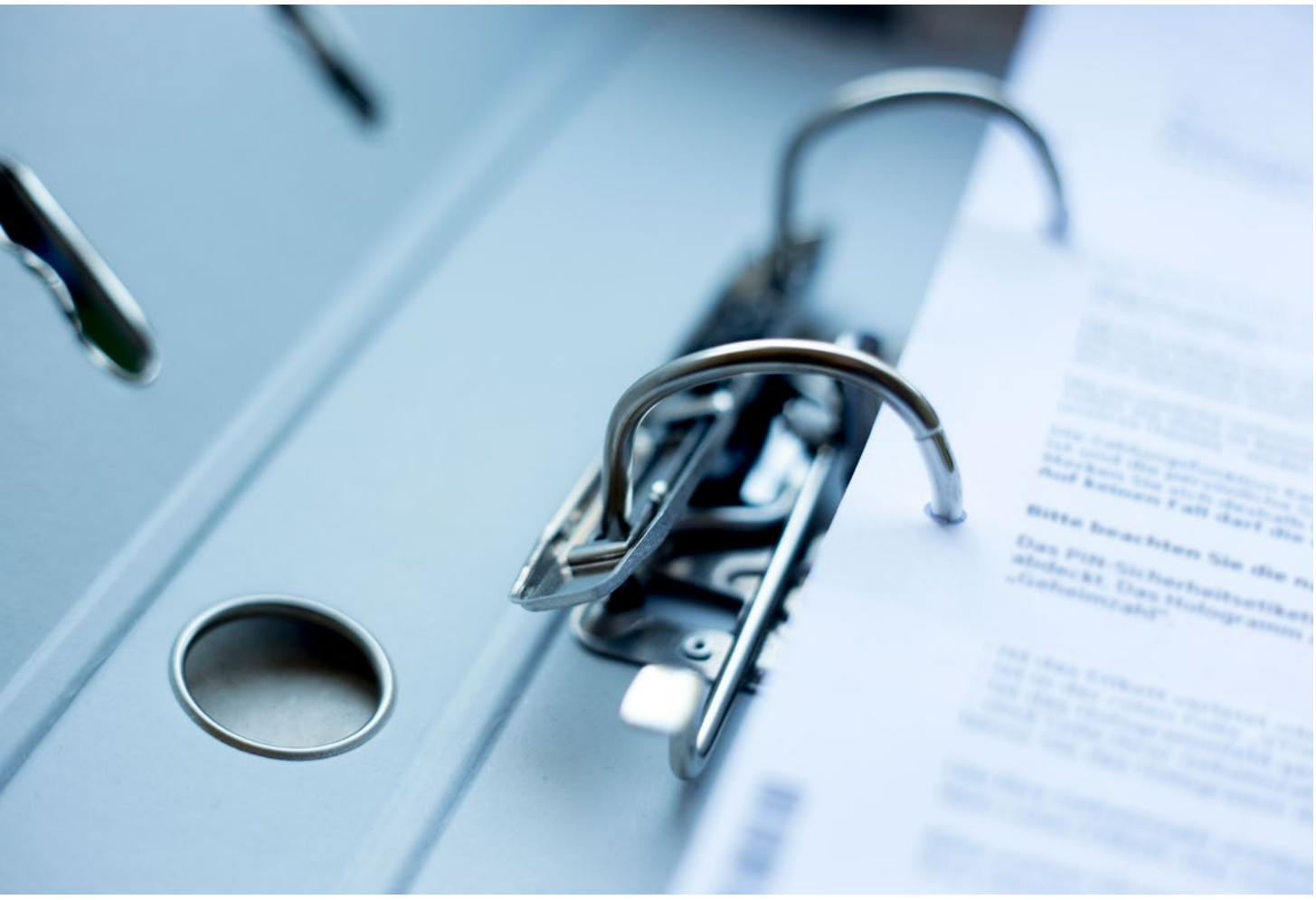
f. End of Study (Aarchiving)

All study documents should be archived at the end of the trial to ensure the study is archived as a whole and the study can be reconstructed if need be.

The length of time that a study should be archived for will depend on the type of study.

- Non-interventional studies must be archived for a minimum of 7 years;
- Interventional studies must be archived for a minimum of 15 years (some institutions have an indefinite archive policy);
- Studies involving children should be archived for a minimum of 25 years.

If in doubt, researchers should check with the ethics office to confirm the requirements for the study.



8. QUALITY ASSURANCE

8.1 QUALITY CONTROL (QC)

Quality control procedures should be conducted by the Principal Investigator or his/her nominee on a regular basis and will usually involve:

- adequate training to ensure full knowledge and understanding of protocol and study standard operating procedures
- verification of the availability of signed consent forms;
- verification that the protocol and standard operating procedures are being followed;
- recorded accreditation for any specialised study requirements (e.g, cognitive assessments)
- verification of appropriately secure data handling;
- source data verification (e.g. checking the study database against original pathology records);
- review of the completeness of Case Report Forms;
- regular monitoring of a proportion of a staff member's study activity for adherence to protocol and standard operating procedures verification of an appropriate audit trail accompanying data changes;
- verification of appropriate computer back up;
- retention all "returns" (e.g. pill bottles provided to participants), if a study involves administration of medication. These can later be used to verify the medication provided;
- verification that serious adverse reactions have been reported;
- off-site premises are reviewed regularly (e.g., for document security, medication storage conditions);
- regular checking of equipment (e.g., repair, calibration or safety); and
- verification that emergency procedures are in place and are operational.

8.2 AUDIT

An audit is a systematic and independent examination of study-related activities and documents to determine whether these activities were conducted according to the protocol, the applicable SOPs, good clinical practice and the applicable ethical and regulatory requirements.

SPHPM has a Research Governance Officer whose role, in part, is to conduct audits of the projects being undertaken within the School. In addition to randomly selecting projects for auditing, the Research Governance Officer will audit other projects on request of the Head of School or the Research Governance Committee.

Audits may also be undertaken after a request by an individual researcher. These requests are often helpful for inexperienced researchers, and/or those working in isolation.

The self-audit should be completed annually for each study. To facilitate this process, the school will email the self-audit tool and instructions for completion each year to the project manager of all current research projects. If a self-audit has been completed for the project for another institution less than 12 months previously, a copy of that self-audit can simply be upload in place of submitting the SPHPM self-audit tool.

The brief self-audits can be completed by the project manager, chief/principal investigator, or another representative of the project. However, the completed form must be reviewed and signed by the principal investigator before submission.

Encouragement is given to identify any areas where compliance with Good Research Practice requirements is less than ideal. Individual researchers are also encouraged to make use of this tool as a way of checking that their study procedures are in line with the School's guidelines.

During a formal audit, particular attention will be paid to the completion of PICFs. The audit will also ensure that the signed PICFs and other documentation are stored securely.

While the study co-ordinator is responsible for the day-to-day conduct of a research project, the ultimate responsibility lies with the principal investigator. Investigators are therefore reminded to oversee the conduct of their studies and to ensure all activities are undertaken appropriately. Study staff are reminded to keep their supervisors informed at all times.

Study closure

A definition of what constitutes the end of the study should be outlined in the study protocol before the study begins. The end of the study may vary; e.g. according to the end of participant involvement, end of ethics approval, database lock/data analysis or ready for archiving. The point at which unblinding can occur should also be outlined in the study protocol and/or should be the steering committee's decision. On completion of the study, procedures must be put in place to:

- notify participants and their doctors of the results, if applicable;
- provide reports to the HREC(s) and funding bodies;
- arrange storage of study documentation;
- label storage boxes clearly with the title of the study, the principal investigator, the completion date and the date on which records can be destroyed; and
- provide information about where documentation is stored to the office of the Head of School.

Vignette:
A PhD student finished her project, analysed the data and wrote her thesis. She then started looking for employment and found a new position, but her employment was contingent on successfully gaining the PhD. In the process of moving institutions, she disposed of anything she did not need, including her research documentation. Unfortunately, the examiners did have questions and asked for further analyses. With so much of the research documentation destroyed the student was faced with the need to repeat much of her project.

APPENDICES

APPENDIX A:
ETHICAL REVIEW OF RESEARCH PROJECTS

The term "ethics" refers to the principles of good, desirable and/or acceptable conduct that should govern interactions in all spheres of human activity. Ethical guidelines related to medical research have been developed primarily to establish standards for the protection of the welfare and the rights of participants in research projects. They also provide assistance to researchers by providing guidance in how to conduct research in an ethically responsible manner.

Ethical review of research is a relatively recent phenomenon. The Judgement of the Nuremberg Military Tribunal on War Crimes contained a series of principles describing acceptable medical research practice known as the Nuremberg Code. They were developed further by the World Medical Association in its 1964 publication 'The Declaration of Helsinki'. Subsequently many countries have adopted these principles into their own guidelines, modifying them when necessary to accommodate new problems such as genetic testing.

In Australia, the NHMRC has released its own publication entitled "National Statement on Ethical Conduct in Human

Research". This was released in 2007, updated in 2018 and can be downloaded from the NHMRC web site (**nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018**). Australian HRECs use this document to guide their decisions about the ethical acceptability of clinical research projects. The document has been supplemented by several other documents that give more detailed instructions about such matters as privacy, and Good Research Practice.

The NHMRC guidelines require that every institution in receipt of NHMRC funding must have an appropriately constituted HREC. As a result virtually all hospitals and universities and many research institutes have established HRECs.

In some cases, specific legislation has been introduced covering areas such as confidentiality of medical information. Naturally, HRECs will never (knowingly) approve a project that is in breach of the law or would place its home institution at legal risk. In the event that legal and ethical requirements both apply, the legal requirements will normally take precedence.

HREC Submissions

Membership of HRECs

To comply with NHMRC guidelines, HRECs must have a minimum of eight members including a chair, layman, laywoman, two health researchers, a clinical carer, a minister of religion and a lawyer. Most committees require more members to cope with the workload but retain a balance between non-researchers who can reflect community standards and researchers who can understand the clinical details.

Application Process

HRECs or their institutions may have simplified review processes for some low-risk projects. For example, a review of patient records, simple questionnaires or studies on discarded tissues can be notified to the HREC via a simplified "low-risk" application process. In most cases, however, a full application is needed. Many HRECs now only accept the Human Research Ethics Application (HREA) form, which is normally accompanied by a state Specific Module and an institution/site-specific assessment form.

There is an increasing move towards streamlined ethics review, both at a State and a Commonwealth level. Under these arrangements, projects are submitted to a single hospital for ethical review. When this step has been successfully completed, the application passes to individual research institutions for a governance review. The governance review looks principally at the willingness of each individual institution to be involved. It considers aspects such as impact on the institution's resources, the interest of staff, their workloads, the adequacy of the financial and insurance arrangements, conflicts of interest (if any) and whether staff are sufficiently trained.

Fees

Virtually all HRECs now charge commercial entities for processing their applications. Many charge a reduced fee (or no fee) for grant funded projects and amendments and investigator initiated research.

Modus Operandi

An increasing challenge for HRECs is the increasing workload and the possibility of letting something "slip through" because insufficient time has been spent on the review process. One common approach to addressing this problem has been to stratify projects into different levels of risk. Lowest risk projects may be sent to a small number (perhaps one or two) of members who provide comments that are reviewed (if necessary) at the main monthly committee meeting. The low risk group included most questionnaire studies, student projects, quality assurance projects and studies requiring only clinical record reviews.

The remaining studies are typically reviewed by a research committee that is often a subcommittee of the main HREC. This committee typically consists of several experienced researchers. Its role is to flag problems and attempt to resolve them prior to the main HREC meeting. Occasionally projects that raise special ethical issues may be flagged for interview. Typically, CTN and "first in human" trials, studies with devices or invasive procedures, and studies involving the collection of sensitive patient data may require an interview (along with those flagged for attention by subcommittee members).

Documentation

The first step in the review process is typically a review of the documentation provided to ensure it is complete. The majority of problems occur with:

1. failure to provide a non-technical description of the project; this frustrates lay members;
2. failure to provide a budget with sufficient explicit detail;
3. failure to provide resource utilisation forms signed by the clinical services to be used;
4. failure to include essential CTN documentation, particularly that related research approval in the US, UK or Sweden;
5. failure to include questionnaires; and
6. failure to provide details of an "after hours emergency contact".

APPENDIX B: **PROTOCOL OUTLINE**

Title Page

This page should include the following:

- Title of the research project;
- Names of the investigators;
- Version number of the protocol; and
- Date of completion of the protocol.

The title page should also include the signature of the Principal Investigator.

Background

This should include an explanation of why the study is being conducted and the specific question being addressed. This section will comprise:

- A Literature Review describing previous relevant literature summarised in a fashion which explains the rationale for the research;
- The Study Hypothesis or Study Objectives; and
- The Study Aims and Purpose.

Study Design

This should be a description of the design of the proposed study including (when appropriate) methods of treatment allocation and/or choices of controls.

Justification of Sample Size

This should be a description of sample size calculations demonstrating that the study will have adequate statistical power or statistical precision.

Inclusion and Exclusion Criteria

These should describe inclusion and exclusion criteria for participants.

Participants Recruitment

This should include the source of study participants, how participants will be recruited (advertisements in newspapers, notices around the institution, approached cold etc.), the anticipated approach to participants, procedures for establishing eligibility and confirming entry criteria, procedures for handling consent, and a description of any special measurements to be made (e.g. invasive and non-invasive measurements, questionnaires).

Interventions

This should describe the exact nature of the study intervention(s) and details relating to their preparation, stability, safety and, if necessary, a rationale for the choice of dose(s).

Randomisation

This is the process of assigning study participants to treatment or control groups using an element of chance to determine the assignments in order to reduce bias. Details should include how randomisation will be conducted, what allocation concealment will be used, who will be blinded, where the randomisation code will be stored, and the circumstances when unblinding is permitted.

Study Endpoints (Outcome measures)

This should be an outline of the primary and secondary variables to be measured to meet the study objectives.

Bias and Confounding Control

Predictable sources of bias, variability and confounders should be addressed, as well as measures taken to minimise them. Details of how blinding will be conducted and maintained and who is blinded should be included. All study staff must be informed that unblinding must never be permitted except according to the Protocol. The decision to unblind a participant or the whole study should only be made by the Principal Investigator, unless a contingecy plan has been established for emergencies.

Data Management

Include a description of how data will be handled, how privacy concerns will be addressed and how storage and back-up of data will be undertaken.

Quality Assurance and Control Procedures

Outline the quality assurance and control procedures to be employed to ensure integrity and validity of the data.

Data Analysis

A specification of any ‘a priori’ subgroup analyses and the statistical methods to be used for data analysis should be included. For some studies, interim analysis of data for safety monitoring and/or early study cessation will be required. Details of such analyses should be provided.

Study Time Lines

This should indicate the anticipated time line for each of the major stages of the study. Particular attention should be paid to participant recruitment.

Signature of the Principal Investigator

In all cases, the principal investigator should sign and date the title page of the final study protocol and any amendments to the protocol.

APPENDIX C: PROCEDURE MANUAL OUTLINE

Final Protocol

This is the Study Protocol as approved by the HREC(s) (see above).

Data Collection Documents

These include a copy of the approved PICF/Explanatory Statement and all data collection forms.

Study Staff

This describes all members of the study team including their roles, responsibilities and reporting arrangements. Members of various study committees, together with their contact details should also be provided. Also, an appropriate schedule of training for staff involved in the project should be included. The need to maintain strict confidentiality in relation to participants personal information should be stressed.

Funding Details

This details the sources of funding for the study as well as the expectation of funding bodies (e.g. timing of allocation of funds, deadlines for progress reports).

Study Flow Charts

A separate chart should be developed describing, in detail, the critical pathway for handling study participants and the sequence to be used in handling questionnaires, coding, data entry, data verification, cleaning and storage of hard copies and back-up of data files.

Clinical Measurements of the Study Endpoints

These describe detailed procedures to be followed for clinical measurement of the study endpoints, e.g. blood pressure.

Details of quality control of such measurements, maintenance of equipment, and methods of recording of results, calibration of equipment and the labelling and storage of biological specimens.

Compliance Measures

These describe details, when appropriate, of compliance tests (including plasma measurements) and who will perform them.

Adverse Events and Contingencies

These describe the nature of any adverse events that might occur together with the approach that should be taken to manage them. Contingency plans for these events should be documented. Such events must be reported to all necessary agencies.

These will vary from study to study but might include the HREC that originally authorised the study, other study personnel, the study sponsor, and the Therapeutic Goods Administration (TGA). In general, notification of serious adverse events should occur within 24 hours and should be in writing, signed by the Principal Investigator. Researchers should refer to the appropriate HREC for clarification of local requirements.

Clinical Abnormalities

This describes follow-up of abnormal laboratory investigations, or other issues that require further action (including liaison with the participant's medical practitioner).

Specific Procedures

These should enable the study to cope with sick leave, holidays, occasional duties (e.g. equipment maintenance, cleaning, office supplies and tidying). Emergency contact details should be documented.

Data Management

The procedure manual will also provide detailed information about data management as outlined in section 6.

APPENDIX D:
RISK MANAGEMENT PLAN

Introduction

Experience elsewhere has demonstrated that a serious misadventure in our research activities could have repercussions. This could result in disruption 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 Preventive 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 this Guide to Good Research Practice that is distributed to all staff and students, setting 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. Staff are required to pass the quiz associated with the training package.
- Development of Ethics and Good Research Practice training which usually runs twice a year and should be available online from March 2020. This course must be attended by all PhD students. Although not compulsory, it is recommended for all SPHPM staff.
- Establishment of a "Research Governance Committee" and appointment of a Research Governance Officer to assist in achieving/maintaining a high standard of research within the school by ensuring research projects comply with the 'Good Research Guidelines".
- Establishment of this "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. This plan also outlines approaches taken by supervisors and staff to reduce the likelihood of these risks eventuating. The Risk Management Plan is constantly updated as new risks are identified and new strategies are devised to counter them.

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.
- The sponsor of a trial offers financial incentives to the researchers for recruiting participants or for recruiting quickly
- Settings where there is high pressure to recruit within specific time frames e.g. PhD, postdoc.

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.
- If a change in clinical practice has resulted in the potential for harm to patients this may result in a police investigation which in turn could result in the person responsible for the fraud being brought up on criminal charges.
- 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 HRECs 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 ethical integrity. (All SPHPM staff must complete the "research governance induction" which is part of the onboarding process undertaken by all new staff and students).
- 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.
- Establish a routine practice of study auditing that includes random selection of projects for audit.

2. Carelessness or Errors in the Collection 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 with utmost care.

A serious error in the collection of research data may lead to retraction of a publication resulting to cost and reputational consequences. Most importantly patients and the generally public may be at risk if they are not receiving the best possible care.

Likelihood of Occurrence

Situations where mistakes when collecting data are more likely to occur may be similar to those listed above under ''Fraud'.

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 projects need to include quality assurance checks designed to identify errors that will occur in the collection of data.
- Study staff should be adequately trained to understand the need for care in data collection, the need to check data once collected and the specific requirements relating to data collection for their specific project.
- Database should be established with inbuilt warnings that are triggered by entering data outside the 'normal' or expected ranges.

3. Carelessness or Errors in the Analysis of Data

Description of Rrisk

As with collection of data, the analysis of data must also be undertaken with care for the same reason. The conclusion drawn from a published research project can alter clinical practice or public health policy and we need to ensure that the conclusions are accurate.

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.
- All basic frequencies should be checked prior to any analysis.

4. 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 (i.e. the latest) copy of the databases.
- Portable data storage devices such as laptops 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 must be stored and backed up according to University policy.
- 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.
- 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 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 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 predicable occurrence and must be addressed by security barriers on the device.

Data is less at risk when stored on a university server which is regularly backed up e.g. the S: drive.

By storing files on the S: drive there is a greater likelihood of continued access to the data in the future. Data stored on local and/or personal media e.g. floppy disks, may not be accessible in the future as technology changes. Portable hard drives can be damaged and the files rendered inaccessible.

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 with 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.
- Database managed outside the Red Zone should have patient identifiers stored separately from the remainder of 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 Database (under which circumstances it must be encrypted and code-protected).
- During the establishment phase of new projects staff from the relevant units must seek relevant advice and verification of appropriate storage and back-up procedures and review the construction of the database.
- A yearly review should be undertaken on data-management policies and testing of the data-recovery plan.
- It is not recommended that paper files containing data be taken off site as this can result in the loss of the data and can also lead to a breach of participant and/or sponsor confidentiality if the records are lost, stolen or damaged. If it is necessary to remove documents it is recommended that de-identified copies be used and the originals remain on site.
- Research records must be maintained in a way that not only ensures they are secure but also enables the tracking and retrieval of data and files. It is therefore important that computer files are named and stored in a consistent way as are paper documents and records. To assist with this the SPHPM has developed 'Maintaining Research Records'. See appendix G for a copy of this document.

5. Serious Breach of Protocol, Contract or HREC Conditions

Description of Risk

- The National Health and Medical Research Council (NHMRC) describe a deviation from GCP or the study protocol that significantly impact the safety or rights of the research participant or the reliability or robustness of the data as a 'serious breach'. Any serious breach must be reported to the unit head and/or to the Research Governance Committee/ Research Governance Officer.
- All research involving humans must be endorsed by an appropriate HREC. 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 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 adverse events 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 much be presented to the HREC 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.
- HRECs pay particular attention to circumstances of consent. They require all study participants to be provided with an approved PICF/ Explanatory Statement 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 HREC. Failure to do this may lead to sanctions by either of these agencies.
- Failure to adhere to contractual restrictions on the handling of study funding and/or restrictions regarding publication can result in the misuse of funds or restricted data e.g. commercial in confidence, entering the public domain.

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/interventional trials and invasive studies.
- The risk is higher in investigator-initiated research where there is no independent monitoring by a study sponsor.
- Failure to meet HREC requirements is usually a result of a lack of knowledge of an HREC'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 ethics and/or 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 results in the research being stopped by the HREC. The investigators may lose the protection of insurers. They may also lose the confidence of their HREC and the senior management of their institution. They may not be allowed to undertake further research.
- Adverse events that are not reported may also result in a study being suspended.

Barriers to Occurrence with 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 a strong research background should be required to attend courses in research methodology and complete the Research Training (**monash.edu/medicine/sphpm/study/professional-education**).
- 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.
- When embarking on a new project all staff and students are reminded to be mindful of contractual restrictions with regards to funding and publication.
- SPHPM staff are further reminded to check the expiry dates on contracts to ensure they remain current.

6. 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, HRECs 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.
- HRECs 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

- Communication with study participants (or potential participants) by phone can pose a risk to confidentiality in a couple of ways:

a. Conversations by phone can be overhead by others nearby. It is therefore not recommended that phone calls are made outside SPHPM e.g. from home, after hours. Caution is also advised when leaving mobile numbers and requesting a participant to call back as researchers have no control over where they will be when they receive the call. If this is necessary, thought needs to be given to maintain the participant's confidentiality.

b. If the research participant (or potential participant) is not the one to answer the phone when a researcher calls, leaving a message can reveal information that results in a breach of the participant's confidentiality. Strategies for minimising this risk should be discussed on a study by study basis and senior researchers need to ensure that staff making and receiving phone calls are appropriately briefed with regard to appropriate protocol.

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 the researcher will be required to notify each individual whose privacy may have been breached. This may be a major task.
- Transferring data or discussing a research participant via email can pose a risk to confidentiality. It is recommended that identified information should not be included in any email. However, protecting the participant identity can put the patient's safety at risk e.g. communicating with a colleague that they need to review a particular participant, visit a specific patient on the ward, administer a test to a participant etc. When using email the need for identified information needs to be considered and, if deemed necessary, kept to a minimum. Researchers are encouraged to consider alternative ways of communicating.
- A secure portal and operating in the 'red zone' reduces the need for data transfer. Researcher should contact eSolutions if they feel their project requires these measures.

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 with SPHPM

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 required to:

a sign declarations of confidentiality.

b undergo good research practice training if they are involved in research (the schools Ethics and Good Research Practice training is compulsory for all students and recommended for all new staff).

c complete the Research Governance Induction as part of the SPHPM 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 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 (**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
- Requirement for the development of standard scripts for leaving of messages on answering machines, voice mail or with people when trying to contact research participants (or possible participants). Consideration needs to be given to not only protecting the participants confidentiality but also to ensuring that distress is not caused to the person on the phone (or listening to the message) by what is said or not said.
- Research staff who regularly have identified patient information, particularly sensitive information, on their computer screen are encourage to install a privacy screen on their monitor. This screen fits to the front of the monitor and ensures that the screen is only visible from directly in front but not from the sides.

7. Failure to Identify and Follow-up and Abnormal 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 participant and/or the medical practitioner the participant may not receive the necessary treatment.
- This also applies to research projects that involve the collection of information around mental health issues such as depression and suicide. The implications and consequences of not following up on information pointing to a mental health issue are the same as for not following up on an abnormal pathology result. Consideration however, needs to be given to compliance with the Health Privacy act, duty of care and the approved study protocol. A distressed patient protocol is included in Appendix E.
- This also applies to results generated from screening tests. The same duty of care applies regardless of whether the participant qualifies for the study or not.
- Registries are becoming more common place and are repositories not only of individual data but also collectively, provide extensive information on particular populations (e.g. the patients who have undergone particular procedures as well as the doctors that performed them and the institutions where the procedures took place). As with any research, with the collection of data comes the responsibility of managing it appropriately and respectfully. This includes acting on group or individual data that may point to an issue.
- Therefore, custodians of registries have the same obligations as researchers in a clinical trial, to monitor their participants for abnormal outcomes and to have a process in place to act and/or manage this information as appropriate.
- All serious adverse events that occur in research participants must be promptly and appropriately reported. For details on reporting requirement please refer to ICH GCP[1]. An SAE template can be found in Appendix F.

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 with SPHPM

- All studies and registries involving physiological measurement, psychological measurements 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.
- All clinical information (e.g. blood pressure reading, pathology results etc) must be reviewed by a medical qualified member of the research team to ensure that no clinically relevant abnormalities are missed.
- Assessment of processes for reviewing abnormal results should be audited regularly by the Research Governance Officer.
- Procedures for reviewing and managing abnormal results should include instruction to ensure anyone (individual or department) involved in the analysis, collection or interpretation of physiological, psychological or laboratory data are aware of who to contact in the case of an abnormal result. It is standard practice for pathology departments to contact the requesting doctor with any abnormal results and this process should be implemented for all research data.
- Registries should have a policy/ procedure in place that outlines the steps to be taken with regards to practitioner outliers which should include the steps to be taken before it is reported and the reporting process.
- The existence of a procedure to manage abnormal results will be checked as part of the SPHPM audit process.

8. Failure of Emergency Procedures Leading to Death and Injury

Description of Risk

- Interventional clinical trials usually involve experimental treatments (either drugs or devices). These need to be stored, handles, dispensed etc in accordance with the study protocol. The intervention may result in adverse events that which may require medical care or, in some cases, emergency medical intervention.
- 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 develops serious complications both the investigator and the school may face legal action.
- This also applies to research projects that involve the collection of information around mental health issues such as depression and suicide. The implications and consequences of not following up on information pointing to a mental health issue are the same as for not following up on an abnormal pathology result. Consideration however, needs to be given to compliance with the Health Privacy act, duty of care and the approved study protocol. A distressed patient protocol is included in Appendix E.
- Registries are becoming more common place and are repositories not only of individual data but also collectively, provide extensive information on particular populations. As with any research, with the collection of data comes the responsibility of managing it appropriately and respectfully. This includes acting on group or individual data that may point to an issue. Therefore, custodians of registries have the same obligations as researchers in a clinical trial, to monitor their participants for abnormal outcomes and to have a process in place to act and/or manage this information as appropriate.
- All serious adverse events that occur in research participants must be promptly and appropriately reported. For details on reporting requirement please refer to ICH GCP[1]. An SAE template can be found in Appendix F.
- Emergency procedures may be difficult to implement if there isn't appropriate staff available e.g. someone to care for the patient and a second person to call 000 and, if necessary, let paramedics into the building. For this reason staff are advised that no clinical work is to be conducted after hours unless there is more than 1 staff member present and security has been notified.

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 researchers are required to call an ambulance on 000.

Likely Consequences

- Failure in providing emergency care to participants may results in Injury to the participant, legal action against researcher and/or adverse publicity for these involved in the study.

Barriers to Occurrence with SPHPM

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

9. 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 with 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 that will trigger not only based on temperature but will also trigger in the event of a power failure or if the power is turned off.
- An alarm protocol is established so that in the event of an alarm, four key staff are contacted by SMS to ensure the alarm is attended to. Alarm systems must be 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. Ideally the SOP should include options of where the samples can be moved to in the event of a freezer failure. All other staff handling biospecimens must have access to the SOPs and have received training on how to respond.
- Where possible, 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. For studies, units or groups where a second freezer is not practical, consider exchanging backup samples with another project. Even if the freezers are in the same location this provides a level of protection against loss of all samples due to freezer failure.
- Ensure the primary aliquot and the back-up aliquot are shipped separately. This will ensure that if something happens during shipping, the entire set of samples are less likely to be lost.
- All storage equipment is serviced in accordance with the manufacturer's recommendations and back-up batteries are installed where appropriate.
- Equipment should be visually inspected regularly for signs of wear, deterioration or problems and the outcome of this inspection should be logged.

10. Risks to Staff Safety

Description of Risk

- Several clinical trials and 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. Risks associated with home visits include travel risk such as car accidents or breakdowns (particularly after hours) and risks from the participant themselves or dangers in their environment such as a dog.
- From time to time research staff find themselves speaking with participants who have become upset or aggrieved. In some cases, this may be anticipated due to the nature of the research but may be unexpected. This can cause psychological distress to the staff member. There needs to be a system of support for staff working with distressed patients. Depending on the project and situation this could be anything from an informal debrief to access to formal counselling.
- Sometimes researchers are disappointed with the outcome of their project. They may be tempted to exclude data to achieve a particular result or put pressure on statisticians to exclude data. That can lead the researchers to encourage the statistician to delete some data e.g. outliers so that the results conform to the expectations. Putting pressure on statisticians is unacceptable and may constitute bullying. Bullying will not be tolerated within the SPHPM or Monash University. Deliberate exclusion of data may constitute fraud.
- In many cases the research undertaken by SPHPM involves the collection of biological samples. The collection, handling and processing of these samples can present a danger to researchers. Appropriate handling of the samples will minimise the risk to 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.
- With appropriate training the risk to staff of contracting a disease from biological samples is low.

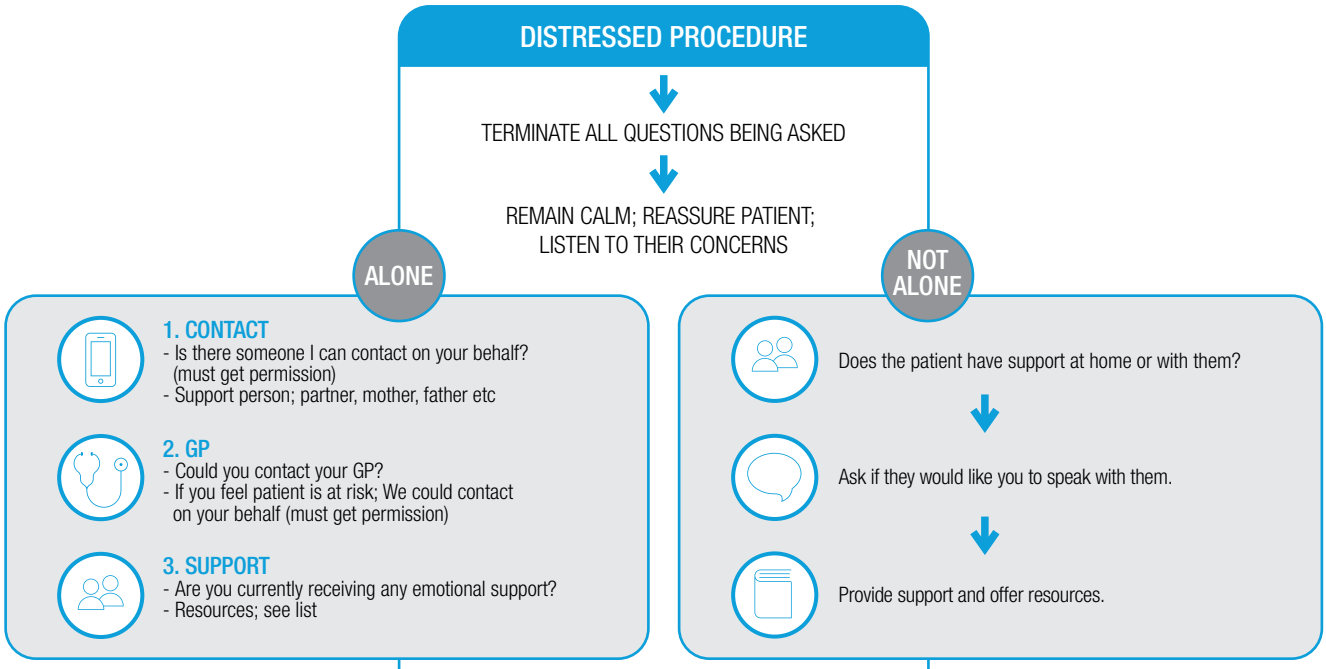
Likely Consequences:

- In the event of injury to a staff member, senior SPHPM management would be accountable for lack of appropriate preventive action.
- Mishandling of biological samples inappropriately can lead to infection of a staff member with a disease from the participant. Some diseases transmitted in this way are serious and/or may require lifetime treatment.

Barriers to Occurrence with SPHPM

- 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.
- SPHPM 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. Researchers are encouraged to consult with Monash University security to determine the best options.
- There are a number of mobile phone apps which claim to help in an emergency. The following Australian Government website provides relevant information: https://www.triplezero.gov.au/Pages/EmergencySmartphoneApp.aspx.
- Adherence to this protocol will be checked by the Research Governance Officer.
- All staff should have an understanding the minimum steps to take if they find themselves speaking with an aggrieved participant. When this is anticipated the project/unit/group should develop a "Distressed participant protocol" (see Appendix E for a template) and ensure all staff are familiar with it.
- For projects/registries where it is anticipated that interaction with aggrieved participants is likely, this should be made clear during the hiring process so that a potential staff member can make an informed decision as to whether this is something they are willing to deal with.
- Staff required to collect, process or handle biological samples in any way must be appropriately trained to enable them to fulfil their role safely.

APPENDIX E:
DISTRESSED PARTICIPANT PROTOCOL



THREATENING SELF HARM

Seek Senior Staff
Senior staff member will take over call (if appropriate)

If after hours
Insert appropriate after hours contact details

ASSESS NEED FOR:

Police
Abulance
Dial **000**
Inflicted self harm, dial **000**

Mental Health Crisis Assessment Teams
(7 days a week, 24 hours a day)

Zoned into Metropolitan Regions:
Western **1300 874 243**
South Western **1300 657 259**
Central and Outer East **1300 721 927**
Inner South East / Alfred **1300 363 746**
Dandenong **1300 369 017**
Inner Urban **1300 558 862**
Middle Southern / MMC **1300 369 012**
North Eastern **1300 859 789**
Peninsula**1300 792 977**
Barwon (Geelong) **1300 094 187**

DOCUMENT

Remember to document all issues raised by patient, all interventions that have been offered or actions taken (GOSE Text Box)

We can only **advise**; patient may not necessarily be receptive

RESOURCES

Lifeline: 24 Hour Counselling	13 1114
Lifeline Victoria Suicide 24 Hour Helpline	1300 651 251
Beyond Blue	1300 224 636
TAC Hotline	1300 654 329
Veterans Counselling Service	1800 011 046
Victims of Crime 24 Hour	1800 000 055
Road Trauma Suppport, can offer to send brochure	1300 367 797
Brain Link, can send information	1800 677 579
DDH Consumer Liaison	9554 8078
South West Victoria's Mental Health	1800 808 284

Alfred Hospital

Patient Advocate	9076 8001
Outpatient Department	9076 2038

Royal Melbourne Hospital

Patient Advocate / Consumer Liaiason Officer	9342 7806
Outpatient Department	9342 7393

Geelong Hospital / Barwon Health

Patient Advocate / Consumer Liaiason Officer	4215 1251
Outpatient Department	4215 1390

Northern Hospital

Outpatient Department	8405 8335
For Patient Advocate call switch and ask for #208	8405 8000

Austin Hospital

Outpatient Department	9496 4440
Fpr Patient Advocate call switch and ask for #208	9496 5000

Monash Medical Centre

Outpatient Department	1300 342 273
Patient Advocate / Consumer Liaiason Officer	9594 2702

APPENDIX F:
SERIOUS ADVERSE EVENT REPORT FORM

SERIOUS ADVERSE EVENTS REPORT FORM: (page 1 of 2)

Date of Birth	Gender (circle)	Ethnic Group	Weight	Height
_____/_____/_____	1 = Male 2 = Female	1 = White 2 = Black 3 = Asian 4 = Other (specify)	kg	cm

Study Title:

Study Sponsor:	Protocol No:	Project No:

SERIOUS ADVERSE EVENT DESCRIPTION:

SAE CATEGORY: circle all those relevant

1 = Death (date: ddmmyy) ____/____/____ 2 = Life Threatening 3 = Permanently Disabling
4 = Hospitalisation/prolongation 5 = Cancer 6 = Congenital Anomaly
7 = Overdose 8 = Other (specify)

Start Date dd,mm,yy ____/____/____ End Date dd,mm,yy ____/____/____	Intensity 1. Mild 2. Moderate 3. Severe (circle one) 1 2 3	Relationship to Study Drug or Study Procedure 0. Not suspected 1. Possible 2. Definite (circle one) 0 1 2	Study Drug Adjustment 0. None 1. Modified 2. Discontinued (circle one) 0 1 2	Treatment Required 0. No 1. Yes If YES, specify on conmed page (circle one) 0 1	SAE Resolution 1. Unresolved 2. Resolved 3. Resolved with sequelae 4. Fatal 5. Unknown (circle one) 1 2 3 4 5

Concomitant Drugs Generic Name	Indication	Total Daily Dose & Route	Start Date dd,mm,yy	Stop Date dd,mm,yy	Ongoing **Y** = yes **N** = no	Suspect Drug (to SAE) **Y** = yes **N** = no

SERIOUS ADVERSE EVENTS REPORT FORM: (page 2 of 2)

RELEVANT MEDICAL HISTORY. Include relevant diagnostic/investigational data.

_____

_____

_____

_____

_____

_____

_____

_____

_____

Report Information. Indicate when the following were notified.

Study Monitor	Date: _____/_____/_____
Study Sponsor	Date: _____/_____/_____
HREC	Date: _____/_____/_____
Therapeutic Goods Administration	Date: _____/_____/_____
Other: specify_____	Date: _____/_____/_____

_____	_____	_____/_____/_____
Principal Investigator's Signature	Name Printed	Date

APPENDIX G:
MAINTAINING RESEARCH RECORDS

PURPOSE OF THE GUIDE FOR MAINTAINING RESEARCH RECORDS

These guidelines have been developed to aid all School of Public Health and Preventive Medicine staff and students regarding the proper maintenance of research records. This document will provide guidance with regards to establishing a **Study Document File** (also known as a **Site File** or an **Investigator File**). It will also provide guidance with regards to the naming of electronic files.

It is hoped that in providing this guidance that we will achieve the following:

1. Research records will be set up and maintained in an orderly fashion from the onset of the study.
2. Implementation of these guidelines will enable necessary research documents to be easily identified.
3. All necessary documents will be locatable at the time of archiving ensuring that the study is archived as a whole and in a way that ensures easy retrieval of the study documents.

VERSION CONTROL

Study documents are often amended and updated during the course of the study. It is important to be able to identify which is the current version, which version has received HREC approval and what changes occurred in each version. Including a version number and/or date on each document is the recommended way of achieving this. The following are some suggestions for version control for research documents:

Hard Copy Documents:

- Each document should have a version number and/or date. This should be visible on the document when it is printed (i.e. not just a date in the file name.)
- Superseded documents should be marked as such. It is recommended that they be stamped “Superseded” and the version number and/or date of the new version be recorded (this assists during auditing).

Electronic Files:

- Each Document file should include a version number and/or date in the file name.
- This should be updated each time the document is changed (during the editing stage it is common to update the date while leaving the version number the same)
- It is recommended that a tracked version of the document be saved. This will make it clear what has changed from one version to the next.

Care should be taken when writing dates to ensure there is no confusion between the day and the month. The recommended format is DD/MMM/YYYY e.g. 01Dec2017 rather than 1/12/17.

STUDY DOCUMENT FILE

All documents associated with a study must be stored securely in an orderly fashion so that documents can be located as needed. A study document file is the recommended way of doing this. The ‘file’ can be a single folder, multiple folders or an entire filing cabinet, depending on the trial. The following is a template for a study document file. Each of the section headings below represents a new divider in the folder (or filing cabinet).

In some cases, addition information is provided. Researchers may find it useful to print this on to the dividers. This will give additional guidance regarding the contents of the section or actions that should be taking during the study or at the end of the study i.e. as part of the archiving process.

Following this template will ensure that no important documents are missed when maintaining the study records and will also ensure that others can locate documents as necessary.

REMEMBER – If the study document file contains identified information (signed PICF, subject identification list etc) then it is an ‘identified’ document and the whole file must be treated as such which means it must be stored securely (e.g. in a locked office or filing cabinet) at all times.

DIVIDERS

1. HREC Paperwork

1.1 Original HREC applications and all subsequent amendments

1.2 HREC approvals

1.3 Annual reports to HRECs, progress reports

1.4 All correspondence to and from the relevant HRECs

2. Research Protocol

The SPHPM Guide to Good Research Practice states that no research activities, even relatively minor ones such as pilot studies, should be undertaken except in accordance with a protocol that has been approved by an HREC.

A complete, signed and dated protocol should be filed in this section. Note any changes to the protocol should also be recorded and filed with appropriate version numbers.

3. Participant Information and Consent Form (PICF)

3.1 All approved versions of the PICF

3.2 Signed PICFs

During the Study:

Where practical, signed PICFs should be stored in this section.
WHEN NOT IN USE THIS FOLDER SHOULD BE STORED SECURELY

If it is necessary to store the signed PICFs elsewhere please complete the following:

Are signed PICFs stored in the Study Document File? yes/no

If No, where are PICFs stored?

At the Completion of the Study:

Unless there is enough identified information to fill an archive box, identified information such as signed PICFs will be archived with other study records. To reduce the accessibility of this information the signed PICFs should be placed in a sealed envelope before being placed in the archive box. The envelope should clearly state that it contains identified information (see section 18 - Archiving).

4. Subject Identification List

Where practical, subject identification lists should be stored in this section.

WHEN NOT IN USE THIS FOLDER SHOULD BE STORED SECURELY

If it is necessary to store the subject identification lists elsewhere please complete the following:

Are subject identification lists stored in the Study Document File? Yes/No

If No, where are subject identification lists stored?

At the Completion of the Study

Subject identification lists should be placed in a sealed envelope and archived (see section 18 - Archiving).

5. Completed Data Collection Forms (Case Report Forms) or questionnaires

5.1 Blank copy of the data collection form/questionnaire

5.2 Completed data collection forms/questionnaires

If it is necessary to store the data collection forms/questionnaires elsewhere please complete the following:

Are Data collection forms stored in the Study Document File? Yes/No

If No, where are data collection forms or questionnaires stored?

_____

_____

DO NOT STORE CODED/RE-IDENTIFIABLE DATA COLLECTION FORMS TOGETHER WITH SUBJECT ID LISTS OR OTHER INFORMATION THAT COULD IDENTIFY PARTICIPANTS

6. Study Brochure/Investigator Brochure/Product Information Sheet (If Applicable)

7. Data Dictionary

8. Correspondence (General)

File in this section all correspondence relating to the study, e.g. letters, faxes, memos, phone logs, emails etc.

9. Contracts or Agreements

Where practical, all contracts or agreements should be stored in this section

If it is necessary to store the contracts or agreements elsewhere please complete the following:

Are contracts or agreements stored in the Study Document File? Yes /No

If No, which contracts or agreements are not in the Study Document File:

Where are the above contracts or agreements stored?

_____

_____

10. Minutes of Study Meetings (these must be circulated to all study team members)

11. Data Management

11.1 Computer database specifications and details

Complete the Following

Study Computer File Nam _____

Database Name _____

Name of people with database access and password

11.2 Record and file of any changes to data on computer files after data collection

11.3 Record and file any Coding anomalies

12. Drug Dispensing Records (if applicable)

13. Randomisation schedule (if applicable)

14. Adverse events

All adverse event reports should be stored in this section

ALL SERIOUS ADVERSE EVENTS MUST BE REPORTED TO THE STUDY SPONSOR AND THE HREC

15. Quality assurance checks and documentation (if applicable)

16. Study Reports/publications

File in this section reports, audit reports, drug safety monitoring body reports and any publications resulting from the study

17. Additional Documentation

This may include:

CTN (Clinical trial notification scheme) form

Indemnity documents

Budgets

Advertising

18. Archiving

Visit the SPHPM intranet page for instructions on storage and retrieval of archiving.

LIST OF DIVIDERS TITLES

The following is a list of the divider titles only.

HREC Paperwork

Research Protocol

Participant Information and Consent Form (PICF)

Subject Identification List

Completed Data Collection Forms (Case Report Forms) or Questionnaires

Study Brochure/Investigator Brochure/Product Information Sheet (if applicable)

Data Dictionary

Correspondence (general)

Contracts or Agreements (if applicable)

Minutes of Study Meetings (these must be circulated to all study team members)

Data Management

Drug Dispensing Records (if applicable)

Randomisation Schedule (if applicable)

Adverse Events

Quality Assurance Checks and Documentation (if applicable)

Study Reports/Publications

Additional Documentation

Archiving

ELECTRONIC FILE NAMING POLICY

In order to ensure that electronic files can be identified and retrieved as necessary, it is useful to have some consistency in the way files are named. Below is a recommended file naming policy to be used as a guide.

All studies must have a folder on a Monash University shared drive which is backed up regularly, password protected and accessible by more than one person. The name of this folder should be an identifier easily associated with the study in question. The following folders should be located within the main study folder. These folders are suggestions. If a folder does not apply to the study researchers are not required to use it. If there is a component to the study not covered by the folders below researchers are welcome to add a folder and identify it accordingly.

It is recommended that file names begin with the identifier of the file e.g. 'Protocol', 'PICF' etc. rather than a study identifier. Starting file names with the study identifier when the files are in a folder labelled with the study identifier will make the files names unnecessarily long. It is also recommended that the file name end with the version date of the file. To avoid confusion with the American date system we suggest '01Jan15' or for 1st January, 2015.

Ethics

This folder should include the following document types:

Ethics Application

Whether researchers have used the NEAF, the Common application Form, the Monash University HREC Review form or a low risk application the application form should be stored here.

Study Protocol

All versions of the protocol should be stored here.

When a protocol is amended there should be a summary of changes document (stored in this folder) or a tracked version of the protocol.

The file name of the protocol should indicate the version number and date of the document.

Example:
Protocol V1 25Dec14.docx

Participant Information and Consent Form

All versions of the PICF should be stored here.

When the PICF is updated a tracked version of the document should be stored here.

Example:
PICF V1 01Jan15.docx

PICF V2 23June15 track.docx

PICF V2 23June15.docx

Request for Approval of Amendment Forms

It is recommended that an amendment number and or a date be included in the file name for easy tracking.

HREC Approval(s)

Most HRECs provide their approval certificates electronically. However, they often arrive with varying file names e.g. ethics approval certificate, project number approval certificate, amendment approval certificate, approval just to name a few. It is recommended that researchers use a consistent way to name the approvals particularly if there are many amendments in the project.

HREC Annual ProgressReport

Recommended naming:

Ethics progress report 2015.docx
Completed form

Ethics progress report 2015.pdf
Signed and scanned version of the word document. Researchers may wish to add 'signed' following the date.

Ethics progress report 2015 acknowledgement.pdf
Acknowledgement received back from the HREC

Additional Regulatory, Ethics, Governance Documents

Additional documents to be included in this section are:

CTN form

Indemnity form

Investigators brochure

Sponsor insurance certificate

Mutual Acceptance Studies

If the project is approved under one of the mutual acceptance schemes and the reviewing site will have numerous documents for other sites that will need to be store and keep track of. It is suggested that researchers generate a folder for each site in which to keep the relevant files.

For larger studies and/or long running studies where there are numerous IBs, annual report, amendments etc. it may be useful to create separate folders within the Ethics folder e.g. all annual reports may be stored in a folder called 'Annual Reports' that sits within the 'Ethics' folder.

CRF

A copy of the Case Report Form (CRF) or data collection form should be stored here. Ensure the version number and/or date is included in the file name.

Finance

Contract/Agreement

A copy of any agreement and a copy of any amendments to the original contract or agreement should be stored here.

Supporting Department Documentation

It is quite common to have written agreements from groups within the institution who will support a study either for a fee or in kind. Documentation of such arrangements should be stored here.

Study Budget

Financial Records

This includes documentation of invoices requested, bills paid and balances of funds.

Correspondence

All correspondence (letters, faxes, memos, files notes etc.) should be stored here.

Label documents consistently. One method is to label files with the recipient's name, the type of correspondence (if not a letter) and a date.

Examples:

- A letter sent to Rowan will be **Rowan 29Jun14.docx**
- A fax sent to her would be **Rowan fax 29Jun14.docx**

Database

Report

This folder should include the final report (Report date.docx) and draft versions as well as files containing tables, figures etc. used in the report. Statistics may also be stored here or may be stored in a separate folder (Stats) if this seems more appropriate.

SAEs

For interventional trials where Serous Adverse Events (SAEs) occur it may be useful to store these in this folder. Alternatively, SAEs can be stored in the Ethics folder or in an SAE folder that sits in the Ethics folder.

Misc

Use this folder for any files that do not fit into any of the above folders e.g. advertising.

Archive

If researchers prefer to keep superseded documents separately to the current versions they can create an Archive folder.

ARCHIVING

Once a study is complete all relevant documents should be archived. This includes not only paper records but electronic files also.

Archiving of Study Documents – Paper

All paper-based documents associated with the study which are not able to be scanned and stored electronically, need to be archived at the end of the trial. This includes everything listed in the “Study Document File” section of this document.

Visit the SPHPM intranet page for instructions on storage and retrieval of archiving.

Archiving of Study Documents – Electronic

At the completion of the study digital data needs to be archived. Currently each researcher is responsible to archive their own electronic data. This should be done on an approved mechanism. In the case of SQL databases, Helix can be contacted to have these archived within the Red Zone. The S:/drive and X:/drive are suitable for archiving of this data.

APPENDIX H:
STUDY CLOSURE CHECKLIST

Study Title:

Instructions: This document is a guide only. Anything that doesn't apply can be struck through or 'not applicable' recorded. Additional items can be added at the end. It is recommended that a copy of this document be files in the site file before archiving.

Task	Owner	Date Completed	Comments
Case Report Forms (CRFs)/Source Documents			
Confirm the last participant has done final tests			
Confirm that all forms/source data/CRFs have been completed, collected, and the proper legible copies are present in study files			
Ensure that all CRF pages requiring signature have been signed and dated by the investigator			
Data Management			
Confirm all data is entered into the database and is un-identifiable			
Appropriate data verification has occurred e.g. range checks, consistency checks, outlier checks, double data entry, independent checks			
All queries/errors have been rectified			
Perform database lock and store on S-drive with database dictionary			
Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting/Reconciliation			
Ensure that all AEs and SAEs have been captured, followed, and resolved per protocol, and reported to the appropriate parties			
Confirm that all required follow-up documentation has been retrieved, communicated to appropriate parties, and is present in the study files			

Task	Owner	Date Completed	Comments
Investigator Site Files			
Confirm that signed consent forms are on file for all participants			
Ensure all documents are files in the site file. These can include, but are not limited to: • protocols and amendments • approved Participant Information and Consent form / Explanatory statement and Consent form • ethics approvals • laboratory documentation • Correspondence • Legal documents			
Ensure reporting of study closure to the HREC (find progress report must be submitted) and supporting department (e.g. Pharmacy) and receipt/filing of study closure confirmation in the investigator site files			
Confirm notification of study outcome has been sent to all participants as appropriate			
Update status on online registry where protocol was registered (eg: clinicaltrials.gov)			
Collected Laboratory Specimens (Samples)			
Confirm that all specimens have either been analyzed or stored for future use			
Ensure that specimens collected for future use have been adequately processed, labeled/de-identified, and stored			
Analysis, Manuscripts, and Submissions/Publications			
Data analysis complete blinded (primary and secondary outcomes)			
Primary manuscript finalized			
Miscellaneous (add as required)			

APPENDIX I:
TRAINING LOG TEMPLATE

Page: _____

TRAINING LOG

{Insert Department/Unit name / Study name}: _____

Date of Training (DD/MM/YYYY)	**Description of Training** (include online or face-to-face) e.g. course title	**Certificate Received** (Y/N)	**Trainees Name**	**Trainee Role within the Study**	**Trainee's Signature**	**Signature of Head of Unit/ Supervisor** (only mandatory if certificate not received)

{insert version number and/or date}

APPENDIX J:
SIGNATURE AND DELEGATION OF RESPONSIBILITY LOG TEMPLATE

SIGNATURE AND DELEGATION OF RESPONSIBILITY LOG

Administrative Section		
Study Title:	Sponsor:	
	Principal Investigator name:	
	Site (name and address):	
	Site number:	

Although as Principal Investigator I remain responsible for the proper conduct of the Study at this site, I hereby authorize the following members of the participating institution's staff to perform the tasks assigned to him/her. I declare that each member is or will be appropriately trained and qualified before performing any task delegated.

Each person indicated below agrees by signing to comply with the study protocol named above and the regulations applicable to the study when performing his/her assigned tasks.

Research Personnel (columns below to be completed by the authorised designee)				**Principal Investigator** (columns below to be completed by the Principal Investigator)				
Name	Study Role (PI - Principal Investigator, Sub-I - Sub-Investigator, RC - Research Coordinator)	Initials	Signature	Delegated Tasks (See below)	Signature (Start Delegation)	Start Date (DD/MM/YYYY)	Signature (End Delegation)	End Date (DD/MM/YYYY)
	PI				Not Applicable		Not Applicable	

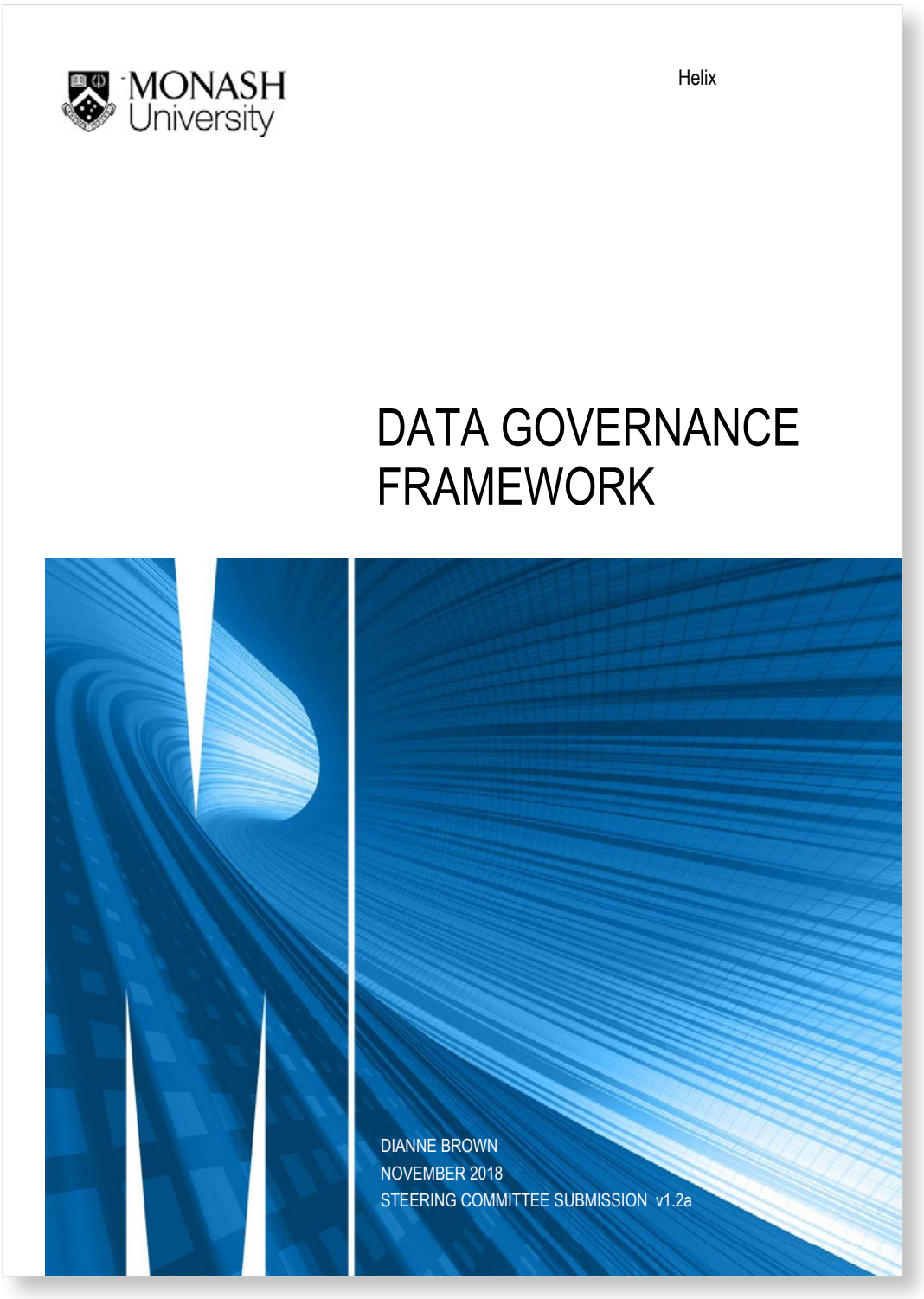
Task Key:

1: Informed Consent process
2: Participant selection/recruitment
3: Confirm eligibility
4: Conduct study visit
5: CRF completion
6: CRF approval
7: Assess AEs/SAEs
8: Dispense study medication
9: Perform drug accountability
10: Study drug storage and temperature monitoring
11: Other (specify task): _____

{include version number and/or date}

APPENDIX K:
DATA GOVERNANCE FRAMEWORK

Click here to link to the Data Governance Framework.



APPENDIX L:
DATA MANAGEMENT TOOLS

The Data Management Tool provides safe, centralised and structured information about SPHPM research projects. It provides quick and easy reporting on projects for the School, a repository of the storage pathways so that projects can always be located (even after the researchers have moved on) and is a way to increase awareness of data management for researchers and graduate research students.

A personalised link to the Data Management Tool is sent to the researchers soon after the project has been approved and graduate research students prior to confirmation. Staff and students are asked to complete the tool and are encouraged to update it during the life cycle of the research.

The SPHPM Data Management Tool is comprised of three parts:

Part 1 - Research Catalogue (compulsory for staff and graduate research students)

The information from the research catalogue will allow SPHPM to track where research data and documentation is located irrespective of staff changes.

Part 2 - Data Management Plan (compulsory for graduate research students)

The Australian Code for the Responsible Conduct of Research strongly encourages a data management plan to delineate research responsibilities from the beginning of a research project. Completing Part 2 of this Tool as well as the Research Catalogue (Part 1) will help move researchers toward compliance with the Code.

Part 3 - GDPR compliance (optional)

The General Data Protection Regulation places responsibility on researchers processing personal data on participants in Europe, or sending personal data to Europe. This short questionnaire will help clarify whether the project needs to consider GDPR compliance.

To create a Data Management Tool for the research project, email a request to the Research Governance Team (**researchgovernanceofficer@monash.edu**).

To accommodate different storage and reporting needs, two different versions of the tool have been created, one for graduate research students and one for researchers. An example of both tools is given below. Not all the information will be visible when the tool is commenced as the tool will expand based on the responses to questions.

SPHPM Graduate Research Data Management Tool

Please use this tool to record your research data management activity.

Please complete as many fields as possible now. You can return to this Tool as your research progresses.

Response was added on 13/11/2019 1:02pm.

The SPHPM Data Management Tool is comprised of three parts:

Part 1 - Research Catalogue (compulsory)
The information from the research catalogue will allow SPHPM to track where research data and documentation is located irrespective of staff changes.

Part 2 - Data Management Plan (compulsory)
The Australian Code for the Responsible Conduct of Research strongly encourages a data management plan to delineate research responsibilities from the beginning of a research project. Completing Part 2 of this Tool as well as the Research Catalogue (Part 1) will help move researchers toward compliance with the Code.

Part 3 - GDPR compliance
The General Data Protection Regulation places responsibility on researchers processing personal data on participants in Europe, or sending personal data to Europe. This short questionnaire will help clarify whether the project needs to consider GDPR compliance.

To start the Research Catalogue click Next Page >> below.

RESEARCH CATALOGUE (PART 1)

The information from the research catalogue will allow SPHPM to track where research data and documentation is located irrespective of staff changes.

1. What is the title of your thesis? _____

2. What is your name? _____

3. What is your student ID number? _____

4. What is your student email address? _____

5. What is your main (primary) supervisor's name? _____

6. What is your main (primary) supervisor's email address? _____

7. Does any part of your PhD require HREC approval?

This form can expand to cater for up to 6 HREC approvals. If more HREC approvals need to be added please email Research Governance at researchgovernanceofficer@monash.edu

⊗ Yes
◯ No

7.1A. What is your ethics approval number (if known)?

_____

7.1B. What is the title of the project?

_____

7.1C. Who is the Chief Investigator of the project?

_____

7.1D. Where will the data (excluding project documentation such as ethics applications) be stored?
For more information go to Monash University Library's Storage Guide
Identifiable data - contains direct identifiers
Re-identifiable data - direct identifiers have been removed but other indirect identifiers may be present
De-identified data - aggregate data with no identifying information included

	Identifiable data	Re-identifiable data	De-identified data
S: drive	☐	☐	☐
REDCap	☐	☐	☐
Google Drive	☐	☐	☐
Google Team Drive	☐	☐	☐
LabArchives	☐	☐	☐
Monash.Figshare	☐	☐	☐
SQL server	☐	☐	☐
Nectar	☐	☐	☐
Secure physical storage	☐	☐	☐
Other	☐	☐	☐

7.1E. Where will the project documentation such as ethics applications be stored?
For more information go to Monash University Library's Storage Guide

☐ S: drive
☐ Google Drive
☐ Google Team Drive
☐ LabArchives
☐ Monash.Figshare
☐ SQL server
☐ Nectar
☐ Other

7.1F. Does your project have another HREC ethics approval?

◯ Yes
◯ No

8. Please enter other information here such as the physical location of paper files or other explanatory text.

_____

DATA MANAGEMENT PLAN (PART 2)

For more information on research practices go to SPHPM's

1. What types of primary data will be collected?	☐ Direct measurement / collection - e.g., blood sample ☐ Participant survey ☐ Phone call collection ☐ Imaging and pathology collection ☐ Direct device collection ☐ Other ☐ None
2. What types of secondary data will be collected?	☐ Health care professionals - e.g., surveys, interviews, focus groups, etc ☐ Patient / hospital medical records ☐ Registries ☐ Data linkage ☐ Other ☐ None
3. Where will the project collect data from?	☐ Europe ☐ Oceania ☐ North America ☐ Central America and the Caribbean ☐ South America ☐ Middle East ☐ Africa ☐ Asia ☐ Australia
4. Will other copies of the data be kept elsewhere?	◯ Yes ◯ No ◯ I don't know
5. Will the data be shared with others during the project?	◯ Yes ◯ No ◯ I don't know
6. What is the minimum retention period of the data? For more information go to Monash Records Management's Retention and disposal of research data page or go to the Public Record Office Victoria's Higher and Further Education Functions page and select View PDF for the full documentation. For information on paper archiving go to SPHPM's intranet and select Archiving.	◯ 15 years after completion of research activity that involves an intervention ◯ 15 years after child reaches the age of 18 ◯ 7 years after completion of research activity for non-interventional research ◯ Other ◯ Permanent archive
7. Is there an expectation that any de-identified or coded data should be publicly accessible or available via open access?	◯ Yes ◯ No ◯ I don't know
8. Would a research team member like to speak with the Helix team about data management?	◯ Yes ◯ No

The General Data Protection Regulation places strict controls on the processing of personal data of research participants in Europe (whether citizens, permanent residents or short-term visitors) as well as sending personal data to Europe. To assess whether the GDPR applies please click on Next Page >> below.

GENERAL DATA PROTECTION REGULATION (GDPR) COMPLIANCE (PART 3)

The GDPR is new and complex European legislation relating to the processing of personal data. If you have any questions about whether it applies to your research please contact the Data Protection and Privacy Office.

The research will need to be GDPR compliant if any of the conditions below apply.

☐ You process personal data from participants in the European Union (irrespective of whether they are citizens, permanent residents or short-term visitors). For the definitions of 'processing' and 'personal data' please go to GDPR Article 4.
☐ You process or may process data from participants who are located in the European Union at the time of data processing (such as when monitoring the behaviour of individuals via email as part of follow up research).
☐ You send personal data about European Union residents to Europe.

SPHPM Data Management Tool

Please use this tool to record your research data management activity.

Response was added on 03/03/2020 2:58pm.

The SPHPM Data Management Tool is comprised of three parts:

Part 1 - Research Catalogue (compulsory)
The information from the research catalogue will allow SPHPM to track where research data and documentation is located irrespective of staff changes.

Part 2 - Data Management Plan
The Australian Code for the Responsible Conduct of Research strongly encourages a data management plan to delineate research responsibilities from the beginning of a research project. Completing Part 2 of this Tool as well as the Research Catalogue (Part 1) will help move researchers toward compliance with the Code.

Part 3 - GDPR compliance
The General Data Protection Regulation places responsibility on researchers processing personal data on participants in Europe, or sending personal data to Europe. This short questionnaire will help clarify whether the project needs to consider GDPR compliance.

To start the Research Catalogue click Next Page >> below.

RESEARCH CATALOGUE (PART 1)

The information from the research catalogue will allow SPHPM to track where research data and documentation is located irrespective of staff changes.
The Research Catalogue is compulsory for new projects but can be used for existing projects.

1. What is the ethics approval number? _____

2. Is this a Monash University ethics approval number?
◯ Yes
◯ No

3. What is the title of the research project? _____

4. Who is the Chief Investigator? _____

5. What is the Chief Investigator's email address? _____

6. Who is the the person with the ability and authorisation to provide access to the data (data custodian)? _____

7. What is the above person's email address? _____

8. Which SPHPM division is the project part of?
For more information go to

- ☐ ASPREE Research
- ☐ Cancer Research
- ☐ Clinical Epidemiology
- ☐ Research Methodology
- ☐ Health Services
- ☐ Occupational and Environmental Health Sciences
- ☐ Critical Care Research
- ☐ Teaching and Learning
- ☐ Social Sciences Research
- ☐ Metabolism, Ageing and Genomics
- ☐ Monash Centre for Health Research and Implementation (MCHRI)
- ☐ Department of Forensic Medicine
- ☐ Other

9. What are the funding sources for the project?

- ☐ Australian Competitive Grants (NHMRC, ARC, etc)
- ☐ Other Public Sector Research Income
- ☐ Industry and Other Research Income
- ☐ Cooperative Research Centre (CRC) Research Income
- ☐ Departmental funding
- ☐ Funding from consultation
- ☐ Other

10. Where will the data (excluding project documentation such as ethics applications) be stored?
For more information go to Monash University Library's Storage Guide
Identifiable data - contains direct identifiers
Re-identifiable data - direct identifiers have been removed but other indirect identifiers may be present
De-identified data - aggregate data with no identifying information included

	Identifiable data	Re-identifiable data	De-identified data
S: drive	☐	☐	☐
REDCap	☐	☐	☐
Google Drive	☐	☐	☐
Google Team Drive	☐	☐	☐
LabArchives	☐	☐	☐
Bridges (formerly Monash.Figshare)	☐	☐	☐
SQL server	☐	☐	☐
Nectar	☐	☐	☐
Secure physical storage	☐	☐	☐
Other	☐	☐	☐

11. Where will the project documentation such as ethics applications be stored?
For more information go to Monash University Library's Storage Guide

- ☐ S: drive
- ☐ Google Drive
- ☐ Google Team Drive
- ☐ LabArchives
- ☐ Bridges (formerly Monash.Figshare)
- ☐ SQL server
- ☐ Nectar
- ☐ Other

12. Please enter other information here such as the physical location of paper files or other explanatory text.

_____

13. Does the research have a data management plan?	◯ Yes ⊗ No

DATA MANAGEMENT PLAN (PART 2)

For more information on research practices go to SPHPM's

1. What types of primary data will be collected?	☐ Direct measurement / collection - e.g., blood sample ☐ Participant survey ☐ Phone call collection ☐ Imaging and pathology collection ☐ Direct device collection ☐ Other ☐ None
2. What types of secondary data will be collected?	☐ Health care professionals - e.g., surveys, interviews, focus groups, etc ☐ Patient / hospital medical records ☐ Registries ☐ Data linkage ☐ Other ☐ None
3. Where will the project collect data from?	☐ Europe ☐ Oceania ☐ North America ☐ Central America and the Caribbean ☐ South America ☐ Middle East ☐ Africa ☐ Asia ☐ Australia
4. Will other copies of the data be kept elsewhere?	◯ Yes ◯ No ◯ I don't know
5. Will the data be shared with others during the project?	◯ Yes ◯ No ◯ I don't know
6. What is the minimum retention period of the data? For more information go to Monash Records Management's Retention and disposal of research data page or go to the Public Record Office Victoria's Higher and Further Education Functions page and select View PDF for the full documentation. For information on paper archiving go to SPHPM's intranet and select Archiving.	◯ 15 years after completion of research activity that involves an intervention ◯ 15 years after child reaches the age of 18 ◯ 7 years after completion of research activity for non-interventional research ◯ Other ◯ Permanent archive
7. Is there an expectation that any de-identified or coded data should be publicly accessible or available via open access?	◯ Yes ◯ No ◯ I don't know

8. Who will own the intellectual property of the research outputs? For more information go to Monash University Library's Ownership and Rights page	◯ Monash University alone ◯ Monash University and at least one other institution ◯ Institutions other than Monash University ◯ I don't know
9. Would a research team member like to speak with the Helix team about data management?	◯ Yes ◯ No

The General Data Protection Regulation places strict controls on the processing of personal data of research participants in Europe (whether citizens, permanent residents or short-term visitors) as well as sending personal data to Europe. To assess whether the GDPR applies please click on Next Page >> below.

GENERAL DATA PROTECTION REGULATION (GDPR) COMPLIANCE (PART 3)

The GDPR is new and complex European legislation relating to the processing of personal data. If you have any questions about whether it applies to your research please contact the Data Protection and Privacy Office.

The research will need to be GDPR compliant if any of the conditions below apply.

☐ You process personal data from participants in the European Union (irrespective of whether they are citizens, permanent residents or short-term visitors). For the definitions of 'processing' and 'personal data' please go to GDPR Article 4.
☐ You process or may process data from participants who are located in the European Union at the time of data processing (such as when monitoring the behaviour of individuals via email as part of follow up research).
☐ You send personal data about European Union residents to Europe.

APPENDIX M:
REFERENCES / USEFUL RESOURCES

1. Medical Research Council "Guidelines for Good Clinical Practice in Clinical Trials 1998." **https://mrc.ukri.org/funding/guidance-for-applicants/applicants-guidance-update-history/**
2. National Statement on Ethical Conduct in Human Research. **nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018**
3. ICH/GCP Guidelines, an international ethical and scientific quality standard. **tga.gov.au/publication/note-guidance-good-clinical-practice**
4. Monash University Human Research Ethics Committee (MUHREC). **intranet.monash/researchadmin/start/ethics**
5. Alfred Hospital Research & Ethics Unit (Alfred Hospital Ethics Committee). **alfredhealth.org.au/research/ethics-research-governance**
6. Monash Health. **monashhealth.org/research/**
7. Guardianship and Administration Act 1986 (Act No.40/1999) 2011amendment. **austlii.edu.au/au/legis/vic/consol_act/gaaa1986304**
8. ICD10: available from the World Health Organisation website: **who.int/classifications/icd/icdonlineversions/en/**
9. Commonwealth Privacy Act. **legislation.gov.au/Details/C2020C00025**
10. Application of the Privacy Laws to Medical Records in Victoria. Your obligation under the Victorian Health Records Act 2001 and the Commonwealth Privacy Act 1988."Australian Medical Association (Victoria) publication. Melbourne 2002
11. Health Services Commissioner, Privacy Legislation. **ovic.vic.gov.au/privacy/for-agencies/information-privacy-principles/**
12. Ferris BG. Epidemiology Standardization Project (American Thoracic Society). Am Rev Respir Dis. 1978;118(6 Pt 2):1-120
13. **medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/09/CInical-Trials-Compensation-Guidelines-1.pdf**
14. **who.int/ictrp/en/**
15. Plagiarism tutorial **monash.edu/rlo/research-writing-assignments/referencing-and-academic-integrity/citing-and-referencing**
16. Academic integrity, plagiarism and collusion **intranet.monash/medicine/business-practices/academic-integrity-procedure**
17. Student academic integrity **monash.edu/__data/assets/pdf_file/0004/801841/Student-Academic-Integrity-Policy.pdf**
18. The Belmont Report **hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html**
19. National Mutual Acceptance: **health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/national-mutual-acceptance**

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AND PREVENTIVE
MEDICINE

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