vmia
Risk Management and Insurance

CLINICAL TRIALS

Risk and Insurance Guide

VICTORIA
State Government

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OVERVIEW

Clinical trials play a very important role in the Australian health sector, providing significant benefits to both the Australian community and the economy.

Clinical trials are essential for evaluating the effectiveness and safety of drugs, devices, services and interventions to help prevent, detect or treat illness and disease. It is through the research done in clinical trials that people gain access to better treatments sooner. Clinical trials also bring hundreds of millions of dollars each year into the Australian economy.

Australia is a leader in the governance of clinical trials and we continue to be competitive as a clinical trial host country. The speed and the efficiency by which proposed clinical trials are considered and approved ensures Australia continues to lead the way for clinical trials.

We support Victoria's efforts to maintain the highest standards of clinical trial and research governance and efficient approval processes for clinical trials.

The Clinical Trials Risk and Insurance Guide has been developed in consultation with the Victorian Department of Health and Human Services to ensure it is consistent with the Victorian Government's policies, current multi-state agreements and the overall governance framework for clinical trials in Victoria.

Using this guide

This guide provides a practical explanation of VMIA's role in supporting clinical trials in Victoria. It provides answers to frequently asked insurance and risk questions and directs you to additional resources.

OUR SUPPORT

Our purpose is to build a confident, resilient Victoria through world leading harm prevention and recovery. We form strategic partnerships with government departments and agencies to identify and mitigate harm and manage State significant risks. We understand your business and are experts in risk and insurance. We exist to support you to manage your risk and prevent harm to the Victorian Community.

Our risk advisers will work with you to meet your risk and insurance needs as well as assist you with embedding enterprise and insurable risk management into your organisational practices.

Our work is about:

- **Education**
  Building the skills and capabilities of your team to better respond to risks.
- **Advice**
  Providing expert advice and consulting services to assist you in tackling your issues, guiding action and decision making.
- **Insight**
  Helping you turn information into knowledge, to know what's important and guide your action.
- **Learn**
  Reflecting what's gone wrong to make changes for the future.

VMIA is here to support public health sector agencies involved in clinical trials and health and medical research.

INSURANCE

This section outlines the insurance policies which are available to public health sector agencies to help protect them from the financial risk of something going wrong arising from clinical trials and health and medical research.

VMIA provides insurance cover for key risks associated with clinical trials. These policies include a definition of 'clinical trials and health and medical research' and the definition of 'health care services' includes 'clinical trials and health and medical research'.

Medical Indemnity

Patient care can be complex and sometimes results in errors or omissions. As a health service provider you may be held liable for personal injuries resulting in costly settlements and legal expenses. Medical indemnity insurance covers claims seeking compensation for personal injuries, which may arise from the provision of health care services.

Medical Indemnity http://www.vmia.vic.gov.au/insure/policies/medical-indemnity

Combined Liability

VMIA has improved our Liability Insurance offering by combining both of VMIA's Public and Products Liability and Professional Indemnity insurance into one simpler policy wording.

Coverage for each of these policies will be specified across two sections within the policy, Section 1 - Public and Products Liability and Section 2 – Professional Indemnity.

With fewer definitions and simpler wording, the new single policy better reflects your current insurance requirements. We have also provided better coverage for your professional liability exposures by substantially increasing your Section 2 limit of liability.

Combined Liability – Section 1 Cover – Public and Products Liability

During the course of conducting business activities, you may receive a claim for personal injury or property damage from a client, member of the public or another organisation. Defending these claims, even if you are not at fault, can result in costly legal expenses. Public and products liability insurance covers legal liabilities arising from business activities that result in personal injury or property damage to third parties. To obtain full policy wordings, please refer to the following links on VMIA's website.

Combined Liability – Section 2 Cover – Professional Indemnity

If your organisation provides advice, specialised knowledge or expertise of any kind, it may be held liable for an error or omission. Professional indemnity provides cover for an alleged breach of professional duties arising out of the provision of health services which includes clinical trials and health and medical research.

Combined Liability https://www.vmia.vic.gov.au/insure/policies/combined-liability

CLINICAL TRIALS DOCUMENTATION

This section outlines the various types of clinical trials sponsorship agreements available. These agreements aim to ensure that obligations for both sponsors and institutions are fair and reasonable and provide a degree of certainty of application in the commercial clinical trial environment.

The sponsor of a clinical trial is the company, institution, organisation, body or individual that takes responsibility for the funding and conduct of the clinical trial.

The type of sponsorship agreement you enter will determine the agreement and indemnity forms you will need to complete.

Type of Sponsorship	Research Agreement Form	Indemnity Forms
	Commercial Trials	
Commercially Sponsored Trial of a Pharmaceutical	Clinical Trial Research Agreement – Standard Form Available on Medicines Australia website	Standard Indemnity Form on Medicines Australia website
	Clinical Trial Research Agreement Phase 4 Clinical Trial (Medicines) Available on Medicines Australia website	Standard Indemnity Form on Medicines Australia website
Commercially Sponsored Trial of a Device	Clinical Investigation Research Agreement – Standard Form Available on Medical Technology Association of Australia website	Standard Indemnity Form for a Clinical Investigation on Medical Technology Association of Australia website
Contract Research Organisation (CRO) acting as the local Sponsor	Clinical Trial Research Agreement – CRO specific Available on Medicines Australia website	Standard Indemnity Form on Medicines Australia website
	Research Studies	
Collaborative or Cooperative Research Group (CRG)	Clinical Trial Research Agreement – CRG specific Available on Medicines Australia website	Both the CRG and IIS standard agreements have the same general 'liability and insurance' clause. The intent of the clause is that each party is liable for its acts and omissions in relation to the conduct of the study.
Investigator Initiated Study (IIS)	Clinical Trial Research Agreement – IIS specific Available from the Coordinating Office for Clinical Trial Research, Department of Health and Human Services	

EXTERNAL EXPERT REVIEWS

This section outlines the requirements to ensure that external expert reviews are adequately protected by insurance.

An external expert reviewer is appointed to provide an independent review on the appropriateness of the clinical trials protocols and the risks and benefits to participants. The reviewer is not involved in the research and can be either an existing employee of a VMIA client or contracted to provide the service.

There are two types of reviewer:

1. An employee of a VMIA insured agency

The expert reviewer is covered under the VMIA Health Program, subject to any relevant policy exclusions, terms and/or conditions.

2. Not an employee of a VMIA insured agency

You should ensure that the reviewer provides you with a Certificate of Currency for a Professional Indemnity insurance policy covering the reviewer for the provision of these services.

If the reviewer does not have a current professional indemnity insurance policy or cannot provide confirmation that their professional indemnity insurance policy covers them for the review you must complete a 'Details of Independent Review' form and submit to VMIA via email at contact@vmia.vic.gov.au

Details of Independent Review

Please refer to the template 'Coverage for Independent Reviewer'.

Coverage for Independent Reviewer

RISK MANAGEMENT

This section outlines the concepts associated with managing risk with a focus on providing guidance in identifying research risk and research risk categories.

Effective risk management is an integral and essential part of ensuring participant safety in clinical trials. Risk management supports decision makers in understanding both the benefits of conducting a clinical trial as well as the clinical risks and/or associated hazards.

By definition, risk management describes the activities an organisation undertakes to manage the effect of uncertainty on its objectives. Importantly, risk management is not only concerned with responding to threats, but seizing opportunities as well.

As research is fundamentally concerned with deliberately exploring what is unknown and unpredictable, it is important that a realistic balance is maintained between risk management and the pursuit of knowledge. Risk management should add value to a research organisation, not stifle innovation and creativity.

Public sector agencies are required to maintain a risk management framework that aligns with:

- the principles and practices of the Australian/New Zealand Risk Management Standard (AS/NZSIS0 31000:2009);
- the Victorian Government Risk Management Framework; and existing legislation such as
- the *Financial Management Act 1994* and the *Victorian Managed Insurance Authority Act 1996*

Risk management should also be informed by and consistent with the requirements of the relevant legislation, regulations and guidelines under which clinical trials are conducted.

Risk management includes the structures, processes and activities undertaken to ensure that:

- adequate oversight, reporting, monitoring and assurance occurs
- risks are identified, assessed and action is taken
- controls are identified, assessed for effectiveness and sufficient investment occurs in ensuring the controls mitigate the risk
- people have the right capability and skills to manage risk.

Risk management, applied as a discipline within the organisation's prescribed risk management framework will:

- support successful execution of strategy, business plans and projects
- increase the chance of achieving objectives
- improve culture
- provide confidence to Government and the community
- promote the efficient allocation of resources
- reduce negative perceptions and impact on reputation
- empower people to make decisions with confidence
- determine how much risk can be taken and tolerated
- inspire others to follow examples and work collaboratively.

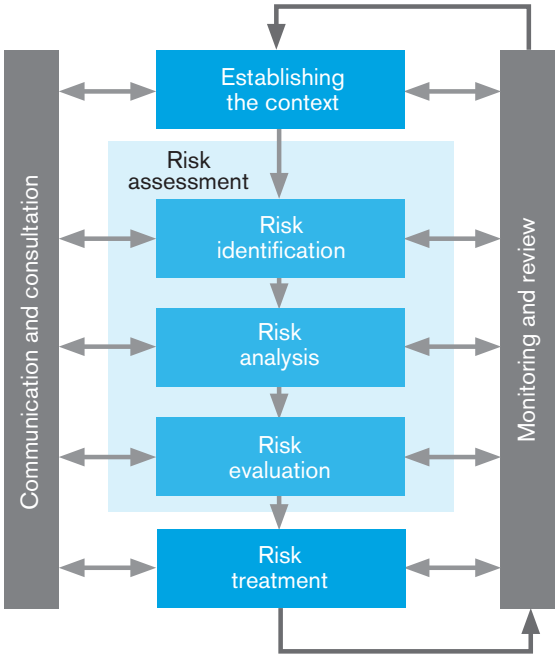
A **risk management framework** is the term used to describe the totality of all processes, procedures, documents, policies, resources, governance, and arrangements an agency has in place that contribute to risk management. A framework is essential to ensure there is an agreed approach to manage risk. It is required as part of overall governance arrangements and will also complement and support other frameworks.

A **risk management strategy** describes an organisation's future vision, direction and objectives for risk management. It incorporates key activities designed to achieve these objectives and the plan to build risk management capability and maturity. The risk management strategy ensures the organisation's Responsible Body and management have a common understanding and clear view of the purpose of risk management, the activities to be pursued to enhance the framework and the capability building requirements to achieve this.

Risk management process

The risk management process is a core component of the risk management framework. Having a documented risk management process is important as it will outline the steps about how to:

- establish the context
- understand what is uncertain and potential effects
- identify and assess what could happen
- make a decision about what needs to occur.



AS/NZS ISO 31000:2018

Process steps

Communicate and consult	Actively engage with stakeholders throughout each step of the process.
Establish context	Consider the organisation's 'culture', 'environment' and 'parameters' that influence how risks are managed.
Identify risks ***What could happen?***	Identify what can happen and then why, where, when and how it can occur. There are many sources to draw from including business plans, incidents, feedback, legislation, new trials and research.
Analyse risks ***What does that mean for us?***	What is currently in place (controls) to manage the risk? Taking into account the effectiveness of the current controls, what is the likelihood of the event happening and the consequences should it occur? Use your organisation's 'risk rating' matrix to calculate the level of risk.
Evaluate risks ***What are our priorities?***	Use the 'risk rating' to inform decision making about whether the risk is acceptable or not. Consider the degree of control possible for that risk, and the costs and benefits associated with treating it. Prioritise unacceptable risks and communicate the rationale for your decisions.
Treat risks ***What are we going to do to address the risk?***	Consider treatment options and action plans for controlling risks. Options include: ▪ Avoiding the risk by ceasing to perform the activity, function or service. ▪ Reducing the likelihood and/or impact of the risk by 'modifying' work practices, systems and processes. ▪ Sharing the risk with another party, such as an insurer or contractor. ▪ Retention of the remaining risks – but developing a plan for responding, should it occur.
Monitor and review	Monitor and review the effectiveness of actions taken to address the risk.

Research risks and risk categories

Below is a typical risk profile for a research organisation. Identifying risks using these categories (as potential sources of risk) will assist to ensure most risks have been considered.

Financial	Infrastructure	Commercial	Operational	Safety	Human Resources	Governance	Strategic
Liquidity – failure to secure timely/ adequate funding	Failure of key utilities – e.g. electricity	Breach of contract	Poor research outcomes	Laboratory hazards – serious staff injury	Failure to recruit and retain staff to critical roles	Failure to comply with regulatory requirements	Significant change in goverment research policy
Fraud – misappropriation of funds	Failure of key infrastructure – e.g. cooling	Failure to protect intellectual property	Serious errors in research data analysis	Failure to identify and treat adverse clinical outcomes	Failure to verify credentials and scope of practice	Undeclared conflicts of interest	Significant change in regulatory requirements
Over reliance on primary funding source	IT failure	Breach of intellectual property or patent	Damage/loss of key research specimens	Security threat to personnel	Breach of employment contract	Disruption to business continuity	Financial crisis – reduced opportunities for fund raising
Underfunding projects to ensure success rates	Loss of/inadequate communications	Breach of privacy or confidentiality	Lost, damaged or incomplete research records	Staff exposure to genetically modified organisms	Industrial dispute	Ineffective project management	Other?
Other?	Theft	Coercion of research participants	Inadequate consent of research participants	Other?	Other?	Breakdown of key internal or external relationships	
	Other?	Serious research misconduct	Inappropriate disposal of hazardous waste			Approval of a project with unjustified 'net research risk'	
		Publication of inaccurate or incomplete information	Inappropriate storage or use of hazardous materials			Other?	
		Other?	Failure to procure the right supplies within budget				
			Security breach of information systems				
			Other?				

Operational Risk Example (for demonstration purposes only) – Serious errors in research data analysis[1]

Description of risk

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

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

Likelihood of occurrence

Analysis of large data-sets requires considerable expertise with modern data-management packages. This expertise is obtained only from extensive experience gained under expert supervision. Modern statistical packages allow advanced analysis to be undertaken by junior researchers but at a high risk of inappropriate application.

Serious errors are more likely when the analysis of data is delegated to unsupervised junior researchers or research students. Mistakes are easy to make, and are more often difficult to detect because the intuitive feeling for data is less than with small paper based data-sets.

Likely consequences

If the study has been published it may require formal withdrawal at substantial cost to the reputation of the research team. If the study has influenced clinical practice, patients may be treated with ineffective interventions or not receive effective therapy. 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 organisation.

Risk treatment options to the occurrence of this risk

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.

[1] The above operational risk example was provided courtesy of the Monash University School of Public Health and Preventive Medicine.

FREQUENTLY ASKED QUESTIONS

When should YOU notify VMIA of an incident?

Notify us as soon as you are aware of the incident (and have stabilised the participant). Submit a copy of the Suspected Unexpected Serious Adverse Reaction Form to VMIA, at the same time it is submitted to the responsible Human Research Ethics Committee for the clinical trial.

What must YOU submit to VMIA?

- A copy of the Suspected Unexpected Serious Adverse Reaction Form that is completed for the responsible Human Research Ethics Committee for the clinical trial.
- Additional participant specific details such as name, date of birth, trial and/or identification number. The participant's identity is required in the event that a claim arises.
- You are only required to report in respect of your own participants.

What types of events do not require Suspected Unexpected Serious Adverse Reaction notification?

- Temporary and mild deterioration or change in a participant's condition
- Minor or short term events that have resolved
- Known adverse events/side effects of the trial drug
- Clearly identified events unrelated to the trial
- Events that have occurred to trial participants located overseas.

How do you notify VMIA?

The form should be submitted to VMIA by email at miclaims@vmia.vic.gov.au

Who is covered for clinical trials?

Medical Indemnity and Combined Liability insurance policies explicitly state the scope of insurance cover provided in relation to clinical trials and health and medical research conducted in Victoria. If you are a VMIA insured agency then you are covered for clinical trials.

Is approval from VMIA required for a clinical trial?

There is no requirement to seek approval from us for any aspect of a clinical trial.

When should VMIA be contacted regarding a clinical trial?

- To report a Suspected Unexpected Serious Adverse Reaction, or
- To request indemnity for an External Expert Reviewer in respect to a First Time In Human study.

Does VMIA have minimum insurance requirements for commercially sponsored clinical trials?

We do not set or recommend minimum insurance requirements for commercially sponsored clinical trials.

Do you need to provide VMIA insurance certificates of currency for commercially sponsored clinical trials?

You are not required to provide insurance certificates for commercially sponsored clinical trials.

Does the sponsor of a clinical trial in Australia have to be an Australian entity?

International pharmaceutical and biotechnology companies and groups of researchers can conduct clinical trials in Australia. Trials must be sponsored by an Australian entity. The entity can be an individual, company, institution or organisation that takes responsibility for the initiation, management, provision of insurance and indemnity, and/or financing of a clinical trial. Refer to: http://www.australianclinicaltrials.gov.au/industry-and-sponsors/sponsorship

What level of insurance coverage should a commercial sponsor provide?

We recommend that the commercial sponsors should provide insurance coverage for a minimum of AUD $10 million.

What clinical trial research agreement form should you use?

Refer to clinical trials documentation section, page 4.

Medicines Australia is the reference source for clinical trials research agreements and we recommend you refer to their website for advice on agreements.

Can clinical trial research agreements be amended?

Medicines Australia is the reference source for clinical trials research agreements and we recommend you refer to their website for advice on amendments to agreements. Refer to: https://medicinesaustralia.com.au/policy/ clinical-trials/clinical-trials-research-agreements/

RESOURCES

National Health and Medical Research Council

http://www.nhmrc.gov.au/research/clinical-trials

Australian Clinical Trials

http://www.australianclinicaltrials.gov.au/researchers

Therapeutic Goods Administration

http://www.tga.gov.au/

Medical Technology Association of Australia

http://www.mtaa.org.au/policy-initiatives/clinical-investigations

Medicines Australia

https://medicinesaustralia.com.au/policy/clinical-trials/

Clinical Trial Research (Victorian Department of Health and Human Services)

http://www.health.vic.gov.au/clinicaltrials/index.htm

Victorian Managed Insurance Authority

https://www.vmia.vic.gov.au/risk/risk-tools/risk-management-guide

International Standards Organisation

International Standard ISO 31000 Second Edition 2018-02. Risk Management Guidelines

For further guidance on risk management, please refer to VMIA's website.

The Victorian Government Risk Management Framework Practice Guide has been developed by VMIA to support the framework and to help agencies meet their risk obligations and accountabilities.

The guide aims to provide a practical explanation of key risk management concepts and practical tips to improve capability and it aligns with the Australian and New Zealand standard. You can adapt the guide to suit your organisation.

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