Research Risk Register

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This document is relevant to all WH sites, including Bacchus Marsh, Melton and Caroline Springs

Contents

1. Overview

This procedure describes the manner by which research related risks that can impact on the delivery of the Best Research for Best Care - Research Strategy Plan 2021-2026 will be identified, captured and appropriate mitigation strategies implemented to reduce either their consequence or likelihood or both.

2. Applicability

This procedure is relevant to all Office for Research staff at Western Health and who may be involved in helping facilitate aspects of the Research Strategy development and implementation.

The Research Risk Register is not to be used for the capture of incident risk but operational, strategic and reputational risks across a number of identified categories that could have the potential to impact on the achievement of research strategic objectives.

3. Responsibility

The Office for Research has the responsibility for introducing and implementing the procedure into operational practice and to ensure that all relevant staff are aware of their obligations in relation to risk identification and reporting. Risk identification and reporting remains the responsibility of all Office for Research staff and more broadly WH staff engaged in research.

4. Authority

Exemptions to the practices described in this procedure can be authorised by the Research Program Director and/or the Chief Medical Officer.

The escalation of risks that exceed the defined risk appetite as defined by the Board will reside through collective consultation and agreement with the Research Program Director, Director of Clinical Research and the Chief Medical Officer.

5. Associated Documentation

- WH Clinical Trial Governance Framework
- WH Risk Management Framework
- WH Risk Management Policy
- WH Risk Management Procedure

6. Definitions

For purposes of this procedure, unless otherwise stated, the following definitions shall apply:

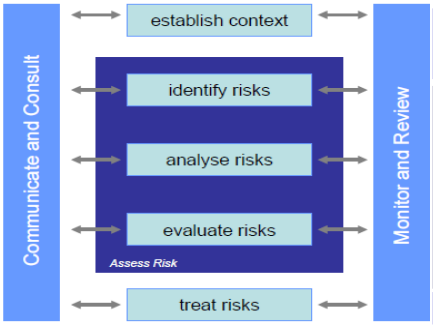
Risk	A risk is the potential of a situation or event to impact on the achievement of specific objectives.
Consequence	Impact or result of a particular event, action or situation expressed as: negligible, minor, moderate, major, severe.
Likelihood	The chance of something will happen expressed as: rare, unlikely, likely, possible and almost certain.
Inherent Risk	Risk state measured in terms of its likelihood and impact without the operations of any controls or risk mitigation strategies.
Control	The risk mitigation measure implemented to try to affect the likelihood and consequence of the risk and therefore the risk factor. Control measures may encompass risk: reduction, avoidance, transfer or acceptance.
New Consequence and Likelihood	The updated Consequence and Likelihood rating based on the impact that a control may exert on these elements.
Residual Risk	The risk measured in terms of its likelihood and impact after the operation of controls or risk mitigation strategy.

Procedure Detail

Risks that may impact the achievement of the Research Strategic objectives need to be identified, captured and monitored on the Research Risk Register. The Research Program Director and Manager of the Office for Research will review and update the risk register bi-monthly.

The Risk Management Guidelines AS/NZS ISO 31000:2018 provides the step-by-step process to manage risks in a structured and systematic way (please refer to the diagram below).

Explanatory procedures are set out within the framework in respect of the key steps of the Risk Management Guidelines ISO 31000:2018, for undertaking risk assessment activities across Western Health.



Identify Risks	Analyse Risks	Evaluate Risks	Treat Risks
Identify all Key Points, Risks & Opportunities that may impact/affect WH Strategic Objectives/Statement of Priorities	Determine what controls or risk mitigation strategies are in place	Determine what the residual risk position is and evaluate whether this position is acceptable	If not acceptable, make decisions or take additional action to reduce the residual risk position

Risks should be evaluated against the terms specified in the WH Risk Management Framework.

Risk identified under any of the above categories outside of any schedule risk review process will need to be validated and entered onto the Research Risk Register after endorsement by the Research Program Director.

Action 1: Identifying Research Risks

Research risks can be identified by the Office for Research or with relevant stakeholders in clinical trial. Identified research risks will be reviewed and captured in the register by the Research Program Director and/or Manager of the Office for Research if they are deemed to potential impact on achievement of research strategic objectives.

Clinical risks are not to be captured in the research risk register and are to be reported as per WH Enterprise Procedure, Policy and Framework.

- Risks should be identifiable under the respective categories such as: Strategic, Operational, Project, Reputational.
- Risks should be assessed for their likelihood and consequent to ascertain the inherent risk.
- Subject to the determination of the Inherent Risk, controls will need to be identified and considered. Control measures may encompass risk reduction, avoidance, transfer or acceptance.

Action 2: Controls

Risk mitigation strategies (controls) will need to consider the cost of their implementation and the anticipated impact on the identified risk.

Action 3: Residual Risk and Monitoring

Once controls are identified and approved for implementation, new risks with Likelihoods and Consequences should be updated regularly to reflect the impact of controls that have provided the residual risk.

Residual risk rating will determine the frequency that risks will need to be monitored and/or further actions to be taken.

Action 4: Reporting to the Executive and Board

The Risk register and status of risks should be reported to the executive on a quarterly basis with the exception of new risks or risks which have deteriorated that will require immediate attention.

7. Document History

Number of previous revisions: New

Previous version dates: Not applicable to this version

Minor amendment: Not applicable to this version

8. References

The external frameworks, standards & programs informing this procedure include:

- ACSQHC National Safety and Quality Health Service Standards
- ACSQHC National Clinical Trials Governance Framework
- AS/NZS Standard ISO 31000:2018 Risk Management – Guidelines

9. Sponsor

Research Program Director

10. Authorisation Authority

Chief Medical Officer