

## Policy Directive Adoption Cover Sheet

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### Clinical Trials – Insurance and Indemnity

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**Links to Policy:** [http://www1.health.nsw.gov.au/PDS/pages/doc.aspx?dn=PD2011\\_006](http://www1.health.nsw.gov.au/PDS/pages/doc.aspx?dn=PD2011_006)

**Audience:** Research governance staff, risk management staff, researchers

**Classification:** Operational

**Date Introduced:** Jan 2011

**Date Adopted:** February 2016

**Endorsed by:** St Vincent's Hospital Management Committee

**Scheduled Review Date:** Jan 2016

**Responsible for Review:** Research Office Manager

**Key Words:** Clinical Academic, Commercially sponsored trial, Contracts of liability coverage, HREC, Lead HREC, NSW Health Staff, NSW Public Health System, Public Health Organisation, Services Contract, Sponsor-related liabilities, Treasury Managed Fund.

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**This policy directive has been adopted and endorsed by St Vincent's Health Network, Sydney.  
This cover sheet identifies variations specific to SVHNS.  
It is important that you read the cover sheet and the enclosed guideline in their entirety.**

#### 1. Scope

NSW Public Health Organisations must be satisfied that adequate insurance and indemnity arrangements are in place for clinical trials to be conducted at sites under their control. The arrangements must be reviewed as part of site specific assessment before trial commencement, in accordance with PD2010\_056: *Research – Authorisation to Commence Human Research in NSW Public Health Organisations*. This document sets out the insurance and indemnity requirements for the purpose of complying with this policy directive.

#### 2. Objective

To ensure that adequate insurance and indemnity arrangements are in place for clinical trials to be conducted at NSW Public Health Organisations.

#### 3. Definitions related to SVHNS

WORD	DEFINITION
Chief Executive	Chief Executive Officer

#### 4. Variation in areas of practice

#### 5. Mission Fit & Strategic Fit

SVHNS is a mission based organisation. SVHNS ensures that committee establishments and processes are provided in accordance with the Mission and Values of St Vincent's Health Australia (SVHA) as well as the frameworks of the Mary Aikenhead Ministries, Catholic teachings, the Code of Ethical Standards for Catholic Health and Aged Care Services in Australia and the NSW Ministry of Health.

#### 6. Compliance in SVHNS

Compliance with this policy will be monitored by the St Vincent's Hospital Director of Research and St Vincent's Hospital Research Office Manager. The Chief Executive Officer is provided with monthly site approval activity reports and with the Research Office Annual Report. Compliance will also be monitored by the NSW Ministry of Health Office of Health and Medical Research.

## **7. References**

- PD2010\_056 Research - Authorisation to commence human research in NSW Public Health Organisations*
- GL2011\_001 Research Governance in NSW Health Public Health Organisations*
- PD2005\_370 Intellectual Property Arising From Health Research*
- PD2005\_496 Visiting Practitioner Appointment*
- PD2007\_035 Human Research Ethics Committees: Standards for Scientific Review of Clinical Trials*
- PD2011\_028 Clinical Trial Research Agreements for use in NSW Public Health Organisations Public Health Orgs*
- PD2010\_036 Clinical Academics Employed in the NSW Health Service*
- PD2010\_055 Research – Ethical & Scientific Review of Human Research in NSW Public Health Organisations*
- PD2010\_056 Research – Authorisation to Commence Human Research in NSW Public Health Organisations*
- GL2011\_001 Research governance in NSW Public Health Organisations*

## Clinical Trials - Insurance and Indemnity

**Summary** This policy directive sets out the insurance and indemnity requirements for the conduct of clinical trials at sites under the control of NSW Public Health Organisations.

**Document type** Policy Directive

**Document number** PD2011\_006

**Publication date** 25 January 2011

**Author branch** Office for Health and Medical Research

**Branch contact** 9391 9920

**Review date** 30 September 2017

**Policy manual** Not applicable

**File number** 03/8605-11

**Previous reference** N/A

**Status** Review

**Functional group** Corporate Administration - Governance  
Clinical/Patient Services - Research

**Applies to** Local Health Networks, Board Governed Statutory Health Corporations, Chief Executive Governed Statutory Health Corporations, Specialty Network Governed Statutory Health Corporations, Affiliated Health Organisations, NSW Ambulance Service, Public Health Units, Public Hospitals

**Distributed to** Public Health System, NSW Ambulance Service, Ministry of Health

**Audience** Research governance staff; risk management staff; researchers

## CLINICAL TRIALS: INSURANCE AND INDEMNITY

### PURPOSE

The purpose of this policy directive is to ensure that adequate insurance and indemnity arrangements are in place for clinical trials to be conducted at NSW Public Health Organisations.

### MANDATORY REQUIREMENTS

NSW Public Health Organisations must be satisfied that adequate insurance and indemnity arrangements are in place for clinical trials to be conducted at sites under their control. The arrangements must be reviewed as part of site specific assessment before trial commencement, in accordance with PD2010\_056: *Research – Authorisation to Commence Human Research in NSW Public Health Organisations*.

The associated document, *Clinical Trials: Insurance and Indemnity*, sets out the insurance and indemnity requirements for the purpose of complying with this policy directive.

### IMPLEMENTATION

**NSW Public Health Organisations** are required to:

- a) ensure that sponsors of clinical trials meet the requirements set out for:
  - (i) commercial sponsors (section 2.2);
  - (ii) NSW Health Staff investigator-initiators (section 2.3.1); and
  - (iii) not-for-profit sponsors external to NSW Health (section 2.3.2).
- b) follow the processes set out in section 2.2.3 when a commercial sponsor is unable or unwilling to meet the insurance requirements outlined in section 2.2.2.
- c) ensure that individuals who are involved in conducting clinical trials are aware of the requirements set out under sections 3.2 and 3.3.
- d) ensure that it meets the requirements outlined in 2.3.1 (26) when sponsoring a clinical trial on behalf of a NSW Health Staff investigator-initiator.

**Visiting Medical Officers** and **Honorary Medical Officers**, to be indemnified by the Treasury Managed Fund for clinical trials (sections 2.3.1 and 3.2) are required to have a signed Services Contract and Contract of Liability Coverage for at least the period of the trial.

**Non-NSW Health Staff** who participate in clinical trials at a NSW Public Health Organisation and who are not covered by the Treasury Managed Fund for the conduct of clinical trials (section 3.3) are required to provide a certificate of currency or other document acceptable to the Public Health Organisation evidencing their clinical trial cover prior to the commencement of the clinical trial and thereafter, for the duration of the trial, on an annual basis or as otherwise requested by the Public Health Organisation.

**Chief Executives** are required to ensure that internal controls across the Public Health Organisation are understood and being observed to avoid the incurring of Treasury Managed Fund excess from failure to comply with this policy directive (section 4).

## REVISION HISTORY

Version	Approved by	Amendment notes
January 2011 (PD2011_006)	Director-General	Issue of new Policy Directive, <i>Clinical Trials: Insurance and Indemnity</i>

## ASSOCIATED DOCUMENTS

1. *Clinical Trials: Insurance and Indemnity, Procedures.*

## Clinical Trials: Insurance and Indemnity

**NSW**  **HEALTH**  
PROCEDURES

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**Issue date:** January 2011

PD2011\_006

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## 1 BACKGROUND

### 1.1 About this document

- (1) All proposals to conduct clinical trials on humans at a site under the control of a NSW Public Health Organisation (PHO) are required to
  - a) be scientifically reviewed according to the standards set by the Department of Health (PD2007\_035: *Human Research Ethics Committees: Standards for Scientific Review of Clinical Trials*);
  - b) have ethical and scientific approval following review that has been conducted in accordance with the *National Statement on Ethical Conduct in Human Research* (2007) of the National Health and Medical Research Council, Australian Research Council and Australian Vice-Chancellors' Committee (PD2010\_055: *Research – Ethical & Scientific Review of Human Research in NSW Public Health Organisations*); and
  - c) have received site authorisation from the PHO's Chief Executive or delegate following site specific assessment (PD2010\_056: *Research – Authorisation to Commence Human Research in NSW Public Health Organisations*).
- (2) Insurance and indemnity arrangements are matters of research governance and are to be reviewed as part of site specific assessment undertaken by each PHO at which a clinical trial is to be conducted.
- (3) This policy directive sets out the insurance and indemnity requirements for the conduct of clinical trials at sites under the control of a PHO. It outlines requirements relating to:
  - a) those responsible for sponsoring clinical trials, that is, commercial sponsors and non-commercial sponsors; and
  - b) those responsible for conducting clinical trials, including NSW Health employees and contractors, and other researchers.
- (4) It also sets out when Treasury Managed Fund coverage will apply, and when relevant parties must hold their own insurance. Section 4 provides details regarding the TMF excess amounts that apply to a PHO for failure to comply with the requirements set out in this policy directive.

### 1.2 Key definitions

**“Clinical Academic”** means staff of a university school of medicine who are also employed in the NSW Public Health System and provide clinical and associated administrative services for public patients in public hospitals. It excludes university staff who are medical practitioners but who do not become employees of the NSW Public Health System, as set out in policy directive PD2010\_036 *Clinical Academics Employed in the NSW Health Service*

**“Commercially sponsored trial”**, for the purpose of this policy directive, is a clinical trial where a commercial entity that is a pharmaceutical or device company:



- a) initiates the trial and makes an application to conduct the trial under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) Scheme administered by the Therapeutic Goods Administration;
- b) is directly funding the conduct of the trial, that is, making payments to the relevant hospital or investigator. This does not include trials where a commercial entity is providing in-kind support (e.g. provision of investigational product or funds) but has no other involvement in the conduct of the trial; and
- c) is the primary author or custodian of the clinical trial protocol.

**“Contracts of Liability Coverage”** means contracts of liability coverage that visiting practitioners enter into with the Public Health Organisation in accordance with section 9 of policy directive PD2005\_496 *Visiting Practitioner Appointment*

**“HREC”** is a committee constituted in accordance with the *National Statement on Ethical Conduct in Human Research (2007)* to review and where appropriate approve and monitor the ethical and scientific aspects of human research.

**“Lead HREC”** is a NSW Health HREC accredited by the Director-General of the NSW Department of Health to conduct ethical and scientific review of human research on behalf of the NSW Public Health System.

**“NSW Health Staff”** means a staff member of the NSW Health including:

- a) staff specialists;
- b) Visiting Medical Officers and Honorary Medical Officers with a signed, current Services Contract and Contract of Liability Coverage;
- c) Clinical Academics (defined above);
- d) employed non-specialist medical practitioners (interns, registrars, career medical officers);
- e) non-medical practitioner employees (employed nurses, allied health care workers etc), and
- f) nurses engaged by a PHO through an agency who are paid as NSW Health award employees through payroll.

**“NSW Public Health System”** under the *Health Services Act 1997 (NSW)* consists of all Local Health Networks, all statutory health corporations, all affiliated health organisations with respect to their recognised services, and the Director-General with respect to health support and ambulance services.

**“Public Health Organisation”** or **“PHO”** under the *Health Services Act 1997 (NSW)* is a Local Health Network, statutory health corporation or affiliated health organisation in respect of their recognised services.

“**Services Contract**” means a service contract between a visiting practitioner and a Public Health Organisation in accordance with section 9 of policy directive PD2005\_496 *Visiting Practitioner Appointment*.

“**Sponsor-related liabilities**” has the meaning given in section 2.1 (7).

“**Treasury Managed Fund**” or “**TMF**” refers to the NSW Treasury Managed Fund, which is the NSW Government’s self-insurance and risk management scheme.

### 1.3 Related Policy Directives and Guidelines

**PD2005\_370** Intellectual Property Arising From Health Research

**PD2005\_496** Visiting Practitioner Appointment

**PD2007\_035** Human Research Ethics Committees: Standards for Scientific Review of Clinical Trials

**PD2009\_032** Clinical Trial Research Agreement Public Health Orgs (Collaborative or Cooperative Research Groups)

**PD2009\_033** Clinical Trial Research Agreement for Public Health Organisations (Commercial entities)

**PD2010\_036** Clinical Academics Employed in the NSW Health Service

**PD2010\_055** Research – Ethical & Scientific Review of Human Research in NSW Public Health Organisations

**PD2010\_056** Research – Authorisation to Commence Human Research in NSW Public Health Organisations

**GL2011\_001** Research governance in NSW Public Health Organisations

## 2 SPONSORING CLINICAL TRIALS

### 2.1 Liabilities

- (5) The sponsor of a clinical trial is the company, institution or organisation, body or individual that takes overall responsibility for the conduct of the trial and usually initiates, organises and supports the clinical trial.
- (6) This section of the policy directive sets out the insurance and indemnity requirements in relation to Sponsor-related liabilities for the following:
  - a) commercial sponsors; and
  - b) non-commercial sponsors
    - (i) NSW Health Staff investigator-initiators.
    - (ii) Not-for-profit sponsors external to NSW Health.
- (7) Sponsor-related liabilities means claims made by or on behalf of clinical trial participants for personal injury that occurs as a result of their participation in the clinical trial. These injuries may be due to:
  - a) negligence in the design of the trial protocol, which may give rise to professional liability; or
  - b) the unintended, harmful effect of a product under investigation, which may give rise to products liability.

### 2.2 Commercial sponsors

- (8) Where a commercially sponsored clinical trial is proposed to be conducted at a site under the control of a PHO, the commercial sponsor must provide to the PHO:
  - a) an executed indemnity in the form of the most recent version of the Medicines Australia Form of Indemnity for Clinical Trials in accordance with section 2.2.1;
  - b) evidence of insurance arrangements that meet the requirements of section 2.2.2; and
  - c) an executed clinical trial agreement in the form of a standard Clinical Trial Research Agreement, or other clinical trial agreement approved by the PHO in accordance with PD2009\_033.

#### 2.2.1 Medicines Australia Standard Indemnity

- (9) Medicines Australia, in consultation with the Department and other key stakeholders, has developed two standard forms of indemnity in relation to clinical trials.
- (10) Where the trial is to be conducted at a site under the control of a PHO, whether or not the reviewing HREC is under the auspices of that PHO, the commercial sponsor must provide an indemnity in the form of *Medicines Australia Form of Indemnity for Clinical Trials: Standard* in favour of the PHO.

- (11) Where a Lead HREC is reviewing a trial and the trial is not being conducted at a site where the Lead HREC resides, the commercial sponsor must provide an indemnity in the form of *Medicines Australia Form of Indemnity for Clinical Trials: HREC review only* in favour of the PHO at which the Lead HREC resides.
- (12) The indemnities referred to in sections 2.2.1(10) and 2.2.1(11) must be given by an Australian corporate entity. This may be:
  - a) an Australian company;
  - b) an Australian company that is subsidiary of an overseas parent company; or
  - c) an Australian contract research organisation (CRO) that has been engaged by an overseas or Australian company to conduct the trial in Australia.

It is not acceptable for an indemnity to be provided by any company as an agent of an overseas entity; that is, the commercial sponsor must provide the indemnity in its own right.

- (13) Under the Medicines Australia indemnities, a sponsor agrees to compensate injured subjects on a no-fault basis in accordance with Medicines Australia *Guidelines for Compensation for Injury Resulting in Participation in a Company-Sponsored Clinical Trial*. The entitlement of an injured participant to claim compensation from a sponsor pursuant to the Guidelines does not displace a participant's right of action against a sponsor at common law.
- (14) Medicines Australia Standard Indemnity forms and Guidelines can be downloaded from: <http://www.medicinesaustralia.com.au/pages/page39.asp>

### 2.2.2 Insurance requirements

- (15) The commercial sponsor must provide evidence that it has appropriate and sufficient insurance with respect to its responsibilities as sponsor of the trial and its indemnity obligations under the Medicines Australia Indemnity that it provides in favour of the PHO, in accordance with section 2.2.2 (16).
- (16) The commercial sponsor must submit a certificate of currency of insurance that evidences current professional indemnity and products liability policy(s) (or equivalent) and must include clinical trials cover. A commercial sponsor may meet these insurance requirements by effecting a single policy or multiple policies. The certificate of currency must:
  - a) name the commercial sponsor as insured under the relevant policy. This requirement may also be satisfied where:
    - (i) the certificate of currency of insurance names the commercial sponsor's (Australian or overseas) parent company as insured and states that it also includes as insureds all subsidiaries of the parent company, provided that the parent company provides written confirmation that the Australian subsidiary acting as the commercial sponsor is a wholly owned, operated or controlled subsidiary company of the parent and that such subsidiary is also a named insured under the relevant insurance policy; and

- (ii) in the case of a CRO acting as commercial sponsor, the policy of insurance has been effected by a third party (usually an overseas based, international sponsor) and names the CRO as insured.
- b) evidence the existence of an insurance policy that covers the conduct of the relevant clinical trial in Australia;
- c) evidence a policy issued by an insurer either approved by the Australian Prudential Regulation Authority or an overseas insurer with a minimum credit rating of Standard and Poors (or equivalent) of A- or better;
- d) state that the policy will be current for at least the period during which the clinical trial will be conducted (that is, from time of trial commencement to trial close-out); and
- e) evidence a policy that contains insurance cover for a minimum amount of AUD20 million for any one occurrence and in the annual aggregate. The insurance policy must not contain an excess/deductible or self-insured retention amount greater than AUD25, 000 for each and every claim or series of claims arising out of one originating cause.

### 2.2.3 Commercial sponsors with insurance arrangements that do not meet the requirements

- (17) If a commercial sponsor of a clinical trial is unable or unwilling to meet the insurance requirements of this policy directive, it must provide the PHO with its reasons in writing.
- (18) PHOs are encouraged to negotiate with commercial sponsors, as far as possible, to obtain insurance arrangements that meet the requirements of this policy directive. Where after appropriate negotiation the commercial sponsor will only provide insurance cover that does not meet those requirements, the PHO must follow the procedure set out in section 2.2.3(19).
- (19) The PHO must conduct a risk assessment using the tool at **Attachment 1** and make a recommendation to the Department of Health's Chief Financial Officer as to whether it believes that the non-complying insurance arrangements should be accepted for the relevant trial, and the reasons justifying this recommendation. A request for advice must be set out in the Request for Advice on Insurance Coverage for Clinical Trial form at **Attachment 2** and emailed to the Department's Chief Financial Officer. The form must be accompanied by the completed risk assessment tool and site specific assessment form (see PD2010\_056).
- (20) The Department's Chief Financial Officer will provide advice within 15 working days of the receipt of a full request. The PHO must confirm with the office of the Chief Financial Officer that it has received its request for advice.
- (21) If the Chief Financial Officer advises that the non-complying insurance arrangements are acceptable for the relevant trial, the Chief Executive of a PHO may approve the commencement of the relevant clinical trial. In that case, the Chief Executive must authorise commencement of the trial personally, and not by their delegate.

## 2.3 Non-commercial sponsors

### 2.3.1 NSW Health Staff investigator-initiators

- (22) NSW Health, through TMF, provides cover for the Sponsor-related liabilities of clinical trials initiated by NSW Health Staff and conducted at a site under the control of a PHO, as specified in this section. (Note that “NSW Health Staff” is a defined term. Visiting Medical Officers who sponsor a clinical trial at a PHO are covered by TMF for Sponsor-related liabilities provided they have a current, signed Services Contract and Contract of Liability Coverage.)
- (23) TMF provides products liability cover for trials initiated by NSW Health Staff for:
- products still in development by a party that is not a NSW Health Staff investigator-initiator;
  - products still in development by a NSW Health Staff investigator initiator; or
  - an off label use of a registered product.

This cover excludes product warranty liabilities because these liabilities ordinarily attach to the manufacturer or supplier of the product.

- (24) When the product being trialled is being developed by a NSW Health Staff investigator-initiator, products liability cover is only provided where the PHO becomes the owner of any intellectual property rights in the product developed through the trial. Where a third party contributes to the development of the product and/or the conduct of the trial, the PHO must own intellectual property rights proportionally to its contribution to the research project in line with PD2005\_370.
- (25) To be indemnified by TMF for Sponsor-related liabilities for trials conducted under the control of a PHO, NSW Health Staff investigator initiator or PHO which takes on the role of sponsor on their behalf, must comply with all obligations and responsibilities of the sponsor under the *Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95): Annotated with TGA comments* or *ISO 14155 Clinical Investigation of Medical Devices*, whichever is appropriate, and to the extent relevant *Therapeutic Goods Act 1989 (Cth)*.

### 2.3.2 Not for profit sponsors external to NSW Health

- (26) Not for profit sponsors external to NSW Health include:
- research institutes external to NSW Health;
  - collaborative or cooperative research groups external to NSW Health; and
  - universities.
- (27) In order for the clinical trial to be classified as sponsored by a not for profit entity external to NSW Health, the trial must satisfy the following criteria:
- The research addresses relevant clinical questions and not pharmaceutical/device company or other commercial needs;
  - The not for profit entity declares the nature of any sponsorship/in-kind support (e.g. provision of medicines, devices, funds) from any organisation,

including a pharmaceutical/device company, that may benefit commercially from the research outcomes; and

- c) The not for profit entity is the primary author and custodian of the clinical trial protocol.

- (28) While this policy does not prescribe specific insurance requirements for external not for profit sponsors, PHOs must ensure that such sponsors have indemnity or insurance arrangements that are sufficient to cover their Sponsor-related liabilities associated with clinical trials to be conducted at sites under their control. This need not always take the form of a professional and products liability insurance policy issued by an insurer; it may, for example, take the form of self-insurance.
- (29) Where an external not for profit entity sponsors a trial that is required to be conducted under either the CTN or CTX Scheme, then that entity must be named as the sponsor on the CTN or CTX form.

### 3 CONDUCTING CLINICAL TRIALS

#### 3.1 Liabilities

- (30) This section of the policy directive sets out the insurance and indemnity requirements for individuals who are involved in conducting clinical trials at sites under the control of a PHO.
- (31) In the context of a clinical trial, liability may arise from the negligent acts and omissions of individuals in conducting a trial (professional liabilities). These liabilities are generally not covered by indemnities provided by sponsors. For instance, the Medicines Australia Standard Indemnity excludes application of the indemnity to the extent that injury to or death of a participant is caused by negligence on the part of individuals conducting the trial.
- (32) Accordingly any individual involved in conducting a clinical trial, whether commercially sponsored or otherwise, must be covered for their personal exposure to liabilities they might incur in connection with their involvement in conducting that clinical trial.

#### 3.2 NSW Health Staff

- (33) The TMF contract of coverage provides cover for the civil liabilities of NSW Health Staff that arise from their conduct in carrying out authorised clinical trials at a PHO in good faith, in the course of their employment or appointment and within their practice discipline. (Note that “NSW Health Staff” is a defined term. Visiting Medical Officers who participate in clinical trials at a PHO are covered by TMF, provided they have a current, signed Services Contract and Contract of Liability Coverage.)
- (34) The TMF cover that applies to NSW Health Staff described in section 3.2(33) extends to claims made or proceedings brought by any clinical trial participant, whether a healthy volunteer or patient.

#### 3.3 Non-NSW Health Staff

- (35) The TMF contract of coverage does not extend to professional liabilities of persons other than NSW Health Staff involved in conducting a clinical trial at sites under the control of PHOs. Individuals that are not covered include independent contractors and those conducting trials in their capacity as a member, agent or employee of:
- a) a research institute external to NSW Health;
  - b) a collaborative or cooperative research group external to NSW Health; or
  - c) a university (other than Clinical Academics who are NSW Health Staff).



- (36) In order to conduct clinical trials at a site under the control of a PHO these individuals must provide evidence that they hold separate insurance cover or are covered by their employer for liabilities that may arise in the course of their involvement in the conduct of the trial.
- (37) Unless covered by their employer, such as a university or a research institute, medical practitioners must hold a separate professional indemnity cover from a recognised organisation that includes cover for the conduct of clinical trials within the category of practice for which the practitioner is insured.
- (38) All relevant privately covered medical practitioners must provide a certificate of currency or other document acceptable to the Public Health Organisation, evidencing their clinical trial cover to the PHO on an annual basis, being the date of renewal of the policy or as otherwise requested by the PHO. The process should follow the provision of a certificate of currency or other acceptable document evidencing their professional cover to practise in NSW as a medical practitioner.

#### 4 TREASURY MANAGED FUND EXCESS

- (39) When the TMF is required to defend a claim involving a clinical trial conducted at sites under the control of a PHO, the following excess applies:
- a) Full compliance with all Department of Health policy directives (excess for public liability currently \$10,000 per claim);
  - b) Deficiencies in compliance with PD2005\_496 (excess currently \$250,000 per claim); and
  - c) Deficiencies in compliance with this policy directive (excess currently \$1 million)
- (40) Excess will be aggregated as appropriate. If both PD2005\_496 and this policy directive are not satisfied, the excess on current level is therefore \$1.26 million.

## **5 LIST OF ATTACHMENTS**

1. Risk Assessment Template for Clinical Trials
2. Request for Advice on Insurance Coverage for Clinical Trials

**Attachment 1: Risk Assessment Template for Clinical Trials - Variations to NSW Health Standard Requirements by Commercial Sponsors**

- 1. **Name of Public Health Organisation where the Trial is to be conducted:** .....
- 2. **Compiled By:** .....
- 3. **Date Risk Assessment Completed:** .....
- 4. **Study Title:** .....  
.....
- 5. **Protocol Number:** .....
- 6. **Brief Description of the Trial: (attach a copy of the HREC approved trial protocol)**  
.....  
.....  
.....  
.....
- 7. **Name of Sponsor:** .....
- 8. **Amount of Insurance Cover and type of Insurance Cover provided by Sponsor:** (A copy of the Sponsor claims history for the last five (5) years and a list of other clinical trials currently being undertaken by the Sponsor also needs to be attached).  
.....  
.....  
.....  
.....

**9. Risk assessment**

*Complete the Risk Assessment Template based on hazards identified for this trial, which could lead to events that are subject to a claim against the Sponsor. When completing the Template, refer to Annexure A which provides some examples of potential hazards for clinical trials and the NSW Health Risk Matrix, accessed through policy directive PD2009\_039 Risk Management – Enterprise-wide Policy and Framework – NSW Health for determining the risk level for each event.*

**Risk Assessment Template:**

<b>Hazards</b> (Anything from the trial that could lead to an incident or cause harm) <b>List all hazards which may be subject to a claim against the Sponsor</b>	<b>Event</b> (Incident or harm that could be caused by the hazard)	<b>Impact From Event Happening</b>		<b>Control Strategies</b>	<b>Effectiveness of Control Strategies</b>  (A) - Adequate (M) - Moderate (I) - Inadequate	Current Risk Level			
		NSW Health Risk Categories (e.g. Clinical Care & Patient Safety, Finance & Legal and Leadership & Management)	\$'000 (only where applicable)			Note 1  Likelihood	Note 2  Consequence	Note 3  Current Risk Rating	Note 4  Acceptability (A / U)

For each risk the following profile is to be used based on the NSW Health Risk Matrix accessed through policy directive 2009\_039 Risk Management – Enterprise-wide Policy and Framework – NSW Health:

**Note 1: Likelihood of Risk Occurring**

Apply the profile of likelihood in accordance with the criteria.

**Likelihood:** 1 – Rare 2 – Unlikely 3 – Possible 4 – Likely 5 – Almost Certain

**Note 2: Consequences if the Risk Occurs**

Apply the consequence criteria.

**Consequence:** 1 – Minimal 2 – Minor 3 – Moderate 4 – Major 5 – Catastrophic

**Note 3: Current Risk Rating** – Based on the mix of likelihood and consequences

**E** – Extreme Risk **H** – High Risk **M** – Medium Risk **L** – Low Risk

**Note 4:** The level of risk is to be assessed as acceptable **(A)** or unacceptable **(U)**.

**10. Reasons for reduced insurance cover:** *Provide the reasons why the commercial sponsor is unable or unwilling to provide the level of insurance cover required by NSW Health. Reduced cover may be considered if it can be substantiated in undertaking the risk assessment that it demonstrates the proposed level of insurance is commensurate with the risk profile.*

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**11. Assessor recommendation:** *Comment and make a recommendation based on the risk assessment as to whether the Sponsor's proposed insurance cover is supported with reasons stated.*

.....  
.....  
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.....

**11.1 Assessor's Name:** .....

**Signature** ..... **Date:** .....

**11.2 Chief Financial Officer: Review of Recommended Amount:**

**Signature** ..... **Date:** .....

**11.3 Chief Executive: Endorsement of insurance cover:**

**Signature** ..... **Date:** .....

**Annexure A: Some examples of potential hazards for clinical trials**

Hazard	Potential event	Points to consider
Intervention	<ul style="list-style-type: none"> <li>Expected and unexpected adverse events</li> </ul>	<ul style="list-style-type: none"> <li>Nature of intervention (e.g. drugs, devices, surgical procedures)</li> <li>Research clinician's previous experience of intervention</li> <li>Pre-trial training</li> <li>Unproven effectiveness or use for new indication?</li> <li>Development phase, licensing status, clinical experience, and (if drugs) pharmacology.</li> <li>Novel handling requirements of pharmacy/drug, tissues, equipment</li> <li>Susceptibility of participant population – disease state, genetics, age, and sex.</li> <li>Systems to monitor and review adverse events, and act on new information</li> </ul>
Clinical management of adverse events	<ul style="list-style-type: none"> <li>Effect on participant safety</li> </ul>	<ul style="list-style-type: none"> <li>Experience of clinician researchers and support available</li> </ul>
Clinical management of participant's underlying medical conditions	<ul style="list-style-type: none"> <li>Effect on participant safety</li> </ul>	<ul style="list-style-type: none"> <li>Experience of clinician researchers and support available</li> </ul>
Assessment methods	<ul style="list-style-type: none"> <li>Effect on participant safety</li> </ul>	<ul style="list-style-type: none"> <li>Invasive tests over and above routine care</li> <li>Increased radiological exposure</li> </ul>
Consent	<ul style="list-style-type: none"> <li>Participants entering the trial without fully informed consent</li> <li>Failure to act on withdrawal of consent</li> <li>Data or tissue samples being used or stored without fully informed consent</li> </ul>	<ul style="list-style-type: none"> <li>Vulnerability of the participant and capacity to give consent, e.g. children, incapacitated adults</li> <li>Consent process, e.g. timing relative to diagnosis, time to consider, signature</li> <li>Participant information provided</li> <li>Experience of those providing participant information and obtaining consent</li> </ul>
Privacy	<ul style="list-style-type: none"> <li>Failure to protect the privacy of participants</li> </ul>	<ul style="list-style-type: none"> <li>Data protection and security systems</li> <li>Anonymisation process</li> </ul>

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## Attachment 2: Request for Advice on Insurance Coverage for Clinical Trials

Name of Public Health Organisation where trial is to be conducted

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Title and protocol number of clinical trial

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Human Research Ethics Committee that has approved this trial

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Trial sponsor

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**Attach:**

- Completed clinical trial risk assessment tool
- Completed site specific assessment form
- Copy of the participant information sheet and consent form regarding the trial
- Copy of the clinical trial agreement and the indemnity provided
- Written reasons from commercial sponsor as to why they are unwilling/unable to provide insurance in accordance with Departmental policy
- A copy of the Sponsor claims history for the last five (5) years and a list of other clinical trials currently being undertaken by the Sponsor

**NOTE: The fifteen day period for provision of advice in response to this form may not start until the Public Health Organisation has confirmed that the Department of Health's Chief Financial Officer has received this form.**

Email to the Chief Financial Officer, NSW Department of Health

Email address:

Date emailed:

**After Department of Health Assessment, this form should be returned to:**

Name of contact:

Contact details:

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### FOR NSW HEALTH USE

Date received:

Assessed by:

Assessment:

Addressee for email assessment:

Date assessment emailed: