

Chubb Clinical Trials Liability Policy Wording - Australia

Insured Name:

<HIDDEN_FirstLocalInsuredName>

Policy Period: <InceptionDate> to <ExpiryDate>

CHUBB®

Contents

Important Notices.....	3
Complaints and Dispute Resolution	6
Clinical Trials Liability Policy Wording	8
About Chubb in Australia	32
Contact Us.....	32

Chubb Clinical Trials Liability

Policy Wording



Important Notices

“We”, “Our” and “Us” means Chubb Insurance Australia Limited (**Chubb**).
“You” and “Your” refers to the **Named Insured**.

Duty of Disclosure

Your Duty of Disclosure

Before you enter into an insurance contract, you have a duty to tell us anything that you know, or could reasonably be expected to know, may affect our decision to insure you and on what terms.

You have this duty until we agree to insure you.

You have the same duty before you renew, extend, vary or reinstate an insurance contract.

What You do not need to tell Us

You do not need to tell us anything that:

- reduces the risk we insure you for; or
- is common knowledge; or
- we know or should know as an insurer; or
- we waive your duty to tell us about.

If you do not tell us something

If you do not tell us anything you are required to, we may cancel your contract or reduce the amount we will pay you if you make a claim, or both.

If your failure to tell us is fraudulent, we may refuse to pay a claim and treat the contract as if it never existed.

General Insurance Code of Practice

We are a signatory to the General Insurance Code of Practice (the Code). The objectives of the Code are to further raise standards of service and promote consumer confidence in the general insurance industry. Further information about the Code and your rights under it is available at www.codeofpractice.com.au and on request.

Parts of this policy provide cover on a claims made or claims made and notified basis, and for such parts the following two provisions will apply.

Claims-Made and Claims-Made and Notified Coverages

These coverages apply only to claims that are either:

- first made against you during the Policy Period; or
- both first made against you and notified to us in writing before the expiration of the Policy Period of the insurance cover provided by the Policy.

If your Policy does not have a continuity of cover provision or provide retrospective cover, then your Policy may not provide insurance cover in relation to events that occurred before the contract was entered into.

Notification of Facts that might give rise to a claim

Pursuant to Section 40(3) of the Insurance Contracts Act 1984, and only pursuant to that section, if you give notice in writing to us of facts that might give rise to a claim against you as soon as reasonably possible after you become aware of such facts but before the insurance cover provided by the Policy expires, then we are not relieved of liability under the Policy in respect of the claim, when made, by reason only that it was made after the expiration of the period of the insurance cover provided by the Policy.

Section 40(3) of the Insurance Contracts Act 1984 only applies to the claims made and the claims-made and notified coverages available under the Policy.

Privacy Statement

In this Statement “We”, “Our” and “Us” means Chubb Insurance Australia Limited (**Chubb**).

“You” and “Your” refers to Our customers and prospective customers as well as those who use Our Website.

This Statement is a summary of Our Privacy Policy and provides an overview of how We collect, disclose and handle Your Personal Information. Our Privacy Policy may change from time to time and where this occurs, the updated Privacy Policy will be posted to Our [website](#).

Why We collect Your Personal Information

The primary purpose for Our collection and use of Your Personal Information is to enable Us to provide insurance services to You. Sometimes, We may use Your Personal Information for Our marketing campaigns, in relation to new products, services or information that may be of interest to You. If You wish to opt out of Our marketing campaigns, You can contact Our customer relations team on 1800 815 675 or email CustomerService.AUNZ@chubb.com.

How We obtain Your Personal Information

We collect Your Personal Information (which may include sensitive information) at various points including but not limited to when You are applying for, changing or renewing an insurance policy with Us or when We are processing a claim. Personal Information is usually obtained directly from You but sometimes via a third party such as an insurance intermediary or Your employer (e.g. in the case of a group insurance policy). Please refer to Our Privacy Policy for further details.

When information is provided to Us via a third party We use that information on the basis that You have consented or would reasonably expect Us to collect Your Personal Information in this way. We take reasonable steps to ensure that You have been made aware of how We handle Your Personal Information.

When do We disclose Your Personal Information?

We may disclose the information We collect to third parties, including service providers engaged by Us to carry out certain business activities on Our behalf (such as claims assessors and call centres in Australia). In some circumstances, in order to provide Our services to You, We may need to transfer Your Personal Information to other entities within the Chubb group of companies such as the regional head offices of Chubb located in Singapore, UK or USA (Chubb Group of Companies), or third parties with whom We (or the Chubb Group of Companies) have sub-contracted to provide a specific service for Us, which may be located outside of Australia (such as in the Philippines or USA). These entities and their locations may change from time to time. Please contact us, if you would like a full list of the countries in which these third parties are located.

Where access to Our products has been facilitated through a third party (for example: insurance broker, online marketing agency etc) We may also share Your information with that third party.

In the circumstances where We disclose Personal Information to the Chubb Group of Companies, third parties or third parties outside Australia We take steps to protect Personal Information against unauthorised disclosure, misuse or loss.

Your Consent

If you'd like a copy of your Personal Information or wish to correct or update it, want to withdraw Your consent to receiving offers of products or services from Us or persons We have an association with, or You would like a copy of Our Privacy Policy, please contact Our customer relations team on 1800 815 675 or email CustomerService.AUNZ@chubb.com.

To request access to, update or correct your personal information held by Chubb, please complete Our Personal Information Request Form online or download it from www.chubb.com/au-en/footer/privacy.aspx and return to:

Email: CustomerService.AUNZ@chubb.com

Fax: + 61 2 9335 3467

Address: GPO Box 4907 Sydney NSW 2001

How to Make a Complaint

If You have a complaint or would like more information about how We manage Your Personal Information, please review Our Privacy Policy for more details, or contact:

Privacy Officer
Chubb Insurance Australia Limited
GPO Box 4907 Sydney NSW 2001
+61 2 9335 3200
Privacy.AU@chubb.com.

Complaints and Dispute Resolution

We take the concerns of our customers very seriously and have detailed complaint handling and internal dispute resolution procedures that you can access. Please note that if we have resolved your initial complaint to your satisfaction by the end of the 5th business day after we have received it, and you have not requested that we provide you a response in writing, the following complaint handling and internal dispute resolution process does not apply. This exemption to the complaints process does not apply to complaints regarding a declined claim, the value of a claim, or about financial hardship.

Stage 1 – Complaint Handling Procedure

If you are dissatisfied with any aspect of your relationship with Chubb including our products or services and wish to make a complaint, please contact us at:

The Complaints Officer
Chubb Insurance Australia Limited
GPO Box 4065
Sydney NSW 2001
O 1800 815 675
E Complaints.AU@chubb.com

The members of our complaint handling team are trained to handle complaints fairly and efficiently.

Please provide us with your claim or policy number (if applicable) and as much information as you can about the reason for your complaint.

We will investigate your complaint and keep you informed of the progress of our investigation. We will respond to your complaint in writing within fifteen (15) business days provided we have all necessary information and have completed any investigation required. In cases where further information or investigation is required, we will work with you to agree reasonable alternative time frames and, if We cannot agree, you may request that your complaint is taken to Stage 2 and referred to Our internal dispute resolution team. We will otherwise keep you informed about the progress of our response at least every ten (10) business days, unless you agree otherwise.

Please note if your complaint relates to Wholesale Insurance (as defined in the General Insurance Code of Practice), we may elect to refer it straight to Stage 2 for review by our Internal Dispute Resolution team.

Stage 2 – Internal Dispute Resolution Procedure

If you advise us that you wish to take your complaint to Stage 2, your complaint will be reviewed by members of our internal dispute resolution team, who are independent to our complaint handling team and are committed to reviewing disputes objectively, fairly and efficiently.

You may contact our internal dispute resolution team by phone, fax or post (as below), or email at:

Internal Dispute Resolution Service
Chubb Insurance Australia Limited
GPO Box 4065
Sydney NSW 2001
O +61 2 9335 3200
F +61 2 9335 3411
E DisputeResolution.AU@chubb.com

Please provide us with your claim or policy number (if applicable) and as much information as you can about the reason for your dispute.

We will keep you informed of the progress of our review of your dispute at least every ten (10) business days and will respond to your dispute in writing within fifteen (15) business days, provided we have all necessary information and have completed any investigation required. In cases where further information or investigation is required, we will work with you to agree reasonable alternative time frames. If we cannot agree, you may refer your dispute to the Australian Financial Complaints Authority (AFCA) as detailed under Stage 3 below, subject to its Rules. If your complaint or dispute falls outside the AFCA Rules, you can seek independent legal advice or access any other external dispute resolution options that may be available to you.

Stage 3 – External Dispute Resolution

If you are dissatisfied with our internal dispute determination, or we are unable to resolve your complaint or dispute to your satisfaction within forty-five (45) days, you may refer your complaint or dispute to AFCA, subject to its Rules.

AFCA is an independent external dispute resolution scheme approved by the Australian Securities and Investments Commission. We are a member of this scheme and we agree to be bound by its determinations about a dispute. AFCA provides fair and independent financial services complaint resolution that is free to consumers.

You may contact AFCA at any time at:

Australian Financial Complaints Authority
GPO Box 3
Melbourne VIC 3001
O 1800 931 678 (free call)
F +61 3 9613 6399
E info@afca.org.au
W www.afca.org.au

Time limits may apply to complain to AFCA and so you should act promptly or otherwise consult the AFCA website to find out if or when the time limit relevant to your circumstances expires.

Clinical Trials Liability Policy Wording

Introduction

The documents comprising this **Policy** are to be read together and any word or expression that is defined has that meaning throughout this **Policy**.

Capitalised words and phrases refer to the corresponding titles and fields shown in the **Schedule**. Words and phrases that appear in **Bold Print** have special meanings and are defined in the Definitions section of this **Policy**.

In consideration of the payment of the premium and in reliance upon all statements and declarations made and information provided to Chubb Insurance Australia Limited (ABN 23 001 642 020) (**Chubb**) and subject to all the terms, conditions and limitations of this **Policy**, **Chubb** agrees with the **Insured** as follows:

Section 1. Clinical Trials Liability Coverage

1.1 Clinical Trials Liability Coverage

- a) **Chubb** shall indemnify the **Insured** against all:
- amounts that are agreed pursuant to applicable **Compensation Guidelines**; or
 - sums which the **Insured** shall become legally liable to pay, including liability assumed by the **Named Insured** in a **Contract Indemnity**;

as **Compensation** in respect of **Bodily Injury** which happens:

- after the Retroactive Date; and
- before the end of the Policy Period, except as described in extension 1.2.6 Extended Liability;

as a result of an **Occurrence** in connection with a **Clinical Trial** that is sponsored by the **Named Insured** or on the **Named Insured's** behalf.

- b) Provided that the **Claim** to which the indemnity relates is first made against the **Insured** during:
- the Policy Period, except as described in Extension 1.2.6 Extended Liability; or
 - any Extended Reporting Period, as described in Extension 1.2.7 Extended Reporting Period.

1.2 Clinical Trials Liability Coverage Extensions

Each of the following Extensions automatically applies unless otherwise stated in the endorsements. Each Extension is, unless otherwise stated, subject to the Coverage provisions and all other terms, exclusions and limitations of this **Policy**, including any applicable Limits of Liability.

1.2.1 Adverse Event Reporting

Coverage 1.1 is extended to note that reporting an **Adverse Event** to a governmental or regulatory authority, in itself, does not constitute:

- a conclusion that the **Clinical Trial Product** being used or the procedure or service that is provided within the scope of and in accordance with the applicable **Clinical Trial Protocol** caused or contributed to such event;
- an admission or assumption of liability;
- knowledge of **Bodily Injury** or a **Circumstance** as described in exclusion 2.10; or
- a conclusion that such **Bodily Injury** was expected or intended by the **Insured**.

1.2.2 Clinical Trial Product Recall Expenses

This **Policy** is extended to reimburse or pay on behalf of the **Named Insured** for **Product Recall Expenses** incurred because of a **Product Recall Defect** to which this extension applies.

This extension applies only:

- a) to a **Clinical Trial** covered by this **Policy**.
- b) if the **Named Insured** notifies **Chubb** in writing of such **Product Recall Defect** as soon as practicable, but not later than sixty (60) days from expiry of this **Policy**.
- c) to **Product Recall Expenses** that are incurred by the **Named Insured** and notified to **Chubb** in writing as soon as possible, but not later than one (1) year after expiry of this **Policy**.
- d) to **Clinical Trial Products** that are supplied for use in a **Clinical Trial** after the Retroactive Date shown in the **Schedule**.

This extension shall not apply to any:

- cost or expense to replace any **Clinical Trial Product**;
- cost or expense to correct any **Product Recall Defect**;
- cost or expense to adjust, inspect or repair any goods, products or other property;
- cost or expense to remove any **Clinical Trial Product** from any good, product or other property or the body of any human being;
- cost or expense to install any replacement goods, products or other property;
- refund to any person or organisation, including any cost or expense in connection with any refund;
- cost or expense in connection with any actual, alleged or threatened malicious alteration or contamination of any goods, products or other property;
- cost or expense in connection with the maintenance, recovery or realisation of goodwill, market share, profit, reputation or revenue;
- **Crisis Response Expenses**; or
- cost or expense that would have been incurred or paid regardless of the discovery of any **Product Recall Defect**.

The most **Chubb** will pay under this extension is subject to the applicable Sub-Limit shown in the **Schedule**.

1.2.3 Crisis Response Expenses

This **Policy** is extended to reimburse or pay on behalf of the **Named Insured** for **Crisis Response Expenses** incurred due to **Bodily Injury** to a **Research Subject** arising out of participation in a **Clinical Trial** covered by this **Policy**.

This extension applies only if such:

- a) **Bodily Injury** is first reported to **Chubb** in writing as soon as practicable and during the Policy Period or within sixty (60) days from expiry of this **Policy**;
- b) **Crisis Response Expenses** are incurred by the **Named Insured** during a period not exceeding 12 consecutive months from date of first reporting the **Bodily Injury** to **Chubb**; and
- c) **Bodily Injury** is not otherwise excluded by this **Policy**.

This extension shall not apply to any:

- cost or expense to replace any **Clinical Trial Product**;
- cost or expense to correct any **Product Recall Defect**;
- cost or expense to adjust, inspect or repair any goods, products or other property;
- cost or expense to remove any **Clinical Trial Product** from any good, product or other property or the body of any human being;
- cost or expense to install any replacement goods, products or other property;
- refund to any person or organisation, including any cost or expense in connection with any refund;

- cost or expense in connection with any actual, alleged or threatened malicious alteration or contamination of any goods, products or other property;
- **Product Recall Expenses**; or
- cost or expense that would have been incurred or paid regardless of whether or not any **Bodily Injury** happened.

The most **Chubb** will pay under this extension is subject to the applicable Sub-Limit shown in the **Schedule**.

1.2.4 *Damage To Personal Property of Research Subjects*

This **Policy** is extended to include **Damage** which happens during the Policy Period to **Research Subjects'** personal property at a clinical site caused by or resulting from an **Occurrence** not otherwise excluded by this **Policy**.

At **Chubb's** option, **Chubb** shall either:

- pay the value of the personal property (or any part of it that sustains **Damage**) at the time of the **Damage** having regard to physical deterioration, physical depreciation, obsolescence or depletion; or
- reinstate or replace the personal property (or any part of it that sustains **Damage**).

The most **Chubb** will pay under this extension is subject to the applicable Sub-Limit shown in the **Schedule**.

Unless otherwise specified, no deductible will apply to this coverage extension.

1.2.5 *Expected or Intended Bodily Injury*

Coverage 1.1 is extended to include **Bodily Injury** that may be intended by the **Insured** or expected from the standpoint of a reasonable person in the circumstances of the **Insured**, but only if such **Bodily Injury** results from:

- use of a **Clinical Trial Product** or performance of a procedure in accordance with a **Clinical Trial Protocol**; or
- a procedure or service to:
 - remove a **Clinical Trial Product** from; or
 - repair or replace a **Clinical Trial Product** that has been put inside;

a **Research Subject's** body if:

- such **Clinical Trial Product** is a **Medical Device** that has caused **Bodily Injury** to such **Research Subject** before such procedure or service; and
- such removal, repair or replacement is necessary to prevent any further **Bodily Injury** from happening to the **Research Subject**.

1.2.6 *Extended Liability*

- The limitations described in Coverage 1.1 under:
 - sub-paragraph a) 2. (regarding the timing of **Bodily Injury**); and
 - sub-paragraph b) i. (regarding the timing of **Claims**);

do not apply to a **Claim** or series of **Claims** that correlates with a:

- **Claim** previously made; or
- **Circumstance** previously notified to **Chubb** by the **Insured**;

during the Policy Period.

- b) All such **Claims** or series of **Claims** notified under this extension will be deemed to have been made at the earliest of the following times:
 - i. when such **Claims** or the first of such series of **Claims** (covered by this **Policy**) is first made against the **Insured**; or
 - ii. when notice of a **Circumstance** (covered by this **Policy**) is first made to **Chubb**.

1.2.7 Extended Reporting Period

If this **Policy** is not renewed or is cancelled it will nevertheless apply to **Claims** first made against the **Insured** during the Extended Reporting Period immediately following the date of such non-renewal or cancellation.

Automatic Extended Reporting Period

The Extended Reporting Period shown in the **Schedule** as Automatic will be automatically provided without additional premium.

Optional Extended Reporting Period

If an Extended Reporting Period is shown in the **Schedule** as Optional then:

- a) such Extended Reporting Period is available, but only for an additional premium. Only the **First Named Insured** has the right to purchase the Extended Reporting Period.
- b) the **First Named Insured** must give **Chubb** a written request to purchase the Extended Reporting Period within thirty (30) days after the Policy Period expires.
- c) **Chubb** will determine the additional premium for the Extended Reporting Period in accordance with **Chubb's** rates and rules.
- d) the Extended Reporting Period will not go into effect unless **Chubb** receives the additional premium due.
- e) the Extended Reporting Period is additional to the Extended Reporting Period shown in the **Schedule** as Automatic.

Any Extended Reporting Period provided by this **Policy**:

- a) does not increase or reinstate the Limits of Liability;
- b) shall not apply unless the **Named Insured** agrees to pay any additional premium required by **Chubb** for the Extended Reporting Period.
- c) shall only apply if no material misrepresentation by the **Insured** nor any material failure by the **Insured** to comply with the terms or conditions of this **Policy**, including failure to pay any premiums when due.
- d) may not be cancelled by the **Insured** or **Chubb** (other than for reasons referred to in Section 60 of the Insurance Contracts Act 1984 (Cth)) once in effect.

If this **Policy** is extended or renewed then the Extended Reporting Period will commence at the end of the revised Policy Period.

1.2.8 Legal Costs – Coroner Inquests Or Regulatory Inquiries

This **Policy** is extended to indemnify the **Insured** for legal costs, expenses and fees incurred with **Chubb's** prior written consent (but only in connection with **Bodily Injury** arising out of activities during a **Clinical Trial** covered by this **Policy**) for representation of the **Insured** at:

- a) coroner's inquest or similar inquiry or court proceedings; or
- b) formal administrative or formal regulatory inquiry by a governmental, regulatory, self-regulatory, professional, statutory or other official body or institution that is empowered by law to investigate the affairs of the **Insured**.

This extension only applies if the:

- **Insured's** legal obligation to participate in such inquiry or proceedings is first commissioned and ordered after the beginning of the Policy Period; and
- **Insured** notifies the **Chubb** of such inquiry or proceeding in writing as soon as practicable but not later than sixty (60) days after the end of the Policy Period.

The most **Chubb** will pay under this extension is subject to the applicable Sub-Limit shown in the **Schedule**.

1.2.9 Medical Expenses

Coverage 1.1 is extended to reimburse the **Named Insured** for **Medical Expenses** for **Bodily Injury** to a **Research Subject** arising out of participation in a **Clinical Trial** covered by this **Policy**.

This extension applies only if such:

- a) **Bodily Injury** is not otherwise excluded by this **Policy**;
- b) **Medical Expenses** are incurred by the **Named Insured** and notified to **Chubb** in writing as soon as possible but no later than twelve (12) months after the end of the Policy Period; and
- c) **Research Subject** that sustained the **Bodily Injury** submits to examination by healthcare professionals of **Chubb's** choice as often as **Chubb** reasonably requires.

Chubb will indemnify the **Named Insured** regardless of fault. The most **Chubb** will pay is subject to the applicable Sub-Limit shown in the **Schedule**.

Unless otherwise specified, no deductible will apply to this coverage extension.

1.2.10 Medical Monitoring

Coverage 1.1 is extended to indemnify the **Insured** against all sums which the **Insured** shall become legally liable to pay for **Medical Monitoring Expenses** in connection with a **Clinical Trial** covered by this **Policy**.

This extension applies only if:

- a) the **Claim** to which the indemnity relates is first made against the **Insured** during the Policy Period or any Extended Reporting Period;
- b) the **Research Subject** was not first exposed to the **Clinical Trial Product** requiring them to incur **Medical Monitoring Expenses** before the Retroactive Date or after the suspension of the **Clinical Trial**; and
- c) the **Clinical Trial** is placed on hold or suspended by;
 - i. any governmental, statutory or regulatory authorities having jurisdiction over the **Clinical Trial**;
 - ii. any Data Safety Monitoring Board monitoring the **Clinical Trial**; or
 - iii. the **Insured**;

for the sole reason, given in writing, that **Research Subjects** are or would be exposed to a significant risk of **Bodily Injury** if the **Clinical Trial** was continued.

The most **Chubb** will pay under this extension is subject to the applicable Sub-Limit shown in the **Schedule**.

1.2.11 Privacy Data Breach

This **Policy** is extended to indemnify the **Named Insured** for **Privacy Data Breach Expenses** and related **Regulatory Costs** incurred by the **Named Insured** and resulting from a **Privacy Data Breach** that is caused by an **Act** in connection with a **Clinical Trial** that is sponsored by the **Named Insured** or on the **Named Insured's** behalf, which happens after the Retroactive Date and before the end of the Policy Period.

This extension will apply only if such:

- a) **Clinical Trial** is covered by this **Policy**;
- b) **Act**:
 - i. is described in the definition of **Privacy Injury** to which Extension 1.2.12 applies; and
 - ii. is notified to **Chubb** as soon as practicable during the Policy Period or not later than sixty (60) days after the end of the Policy Period; and
- c) **Privacy Data Breach Expenses** are incurred and notified to **Chubb** in writing as soon as practicable but not later than twelve (12) months after the end of the Policy Period.

The most **Chubb** will pay under this extension is subject to the applicable Sub-Limit shown in the **Schedule**. Payments under this extension will also reduce the Sub-Limit applicable for extension 1.2.12.

1.2.12 Privacy Injury

This **Policy** is extended to indemnify the **Named Insured** against all sums which the **Named Insured** shall become legally liable to pay as **Compensation** for any **Claim** made in respect of **Privacy Injury** or **Reputational Injury** caused by an **Act** in connection with a **Clinical Trial** covered by this **Policy**, which first happens after the Retroactive Date and before the end of the Policy Period.

Provided that the **Claim** to which the indemnity relates is first made against the **Insured** during;

- a) the Policy Period; or
- b) any Extended Reporting Period, as described in the extension titled Extended Reporting Period.

Chubb will also indemnify the **Named Insured** for:

- related **Defence Costs**; and
- **Regulatory Costs** related to **Privacy Injury**;

provided they are incurred with **Chubb's** prior written consent.

The most **Chubb** will pay under this extension is subject to the applicable Sub-Limit shown in the **Schedule**. Payments under this extension will also reduce the Sub-Limit of Liability applicable for extension 1.2.11.

1.2.13 Third Party Insureds

- a) This **Policy** is extended to indemnify any:
 - i. principal, person or organisation that the **Named Insured** is obligated pursuant to a written contract or agreement to provide insurance as is afforded by this **Policy**, but only to the extent and limit required by such contract or agreement and subject to the terms and conditions of this **Policy**;
 - ii. persons or organisations who are **Controlling Interests**, but only with respect to their liability in connection with their financial control of the **Named Insured**;
 - iii.
 - 1. **Clinical Trial Contractor**; or
 - 2. **Contract Research Organisation**;whilst engaged in the performance of work for or on behalf of the **Named Insured** in respect of a **Clinical Trial** covered by this **Policy**;
 - iv. any **Ethics Committee** or its members in respect of a **Clinical Trial** covered by this **Policy**; and

- v. any data safety monitoring board and its members in respect of a **Clinical Trial** covered by this **Policy**.
- b) The indemnification provided by this extension to any person or organisation described in subparagraphs a) iii., a) iv., or a) v. above shall only apply to liability for **Bodily Injury** caused by any **Clinical Trial Risk**.

1.2.14 Transfer Or Waiver Of Rights Of Recovery or Subrogation

This **Policy** is extended to note that **Chubb** will waive the right of recovery **Chubb** would otherwise have had against another person or organisation, for loss to which this **Policy** applies, if the **Named Insured** has waived their rights of recovery against such person or organisation in a contract or agreement that is executed before such loss.

To the extent that such **Named Insured's** rights of recovery have not been waived, such rights are transferred to **Chubb** and the **Named Insured** shall execute and deliver any appropriate instruments and papers and do whatever else is necessary to secure the rights. Any amount so recovered shall be applied in accordance with the provisions of s.67 of the Insurance Contracts Act 1984 (Cth).

1.3 Limits of Liability

Chubb's liability to indemnify the **Insured** under this **Policy** shall not exceed the applicable Limits of Liability, including any applicable Sub-Limit, stated in the **Schedule**.

Where stated in the **Schedule** any Aggregate Limit of Liability is the maximum aggregate **Chubb** shall indemnify the **Insured** in respect of **Compensation** or other amounts as may be payable. Unless stated to the contrary, such other amounts shall not include **Defence Costs**.

Any Sub-Limit shall also reduce the applicable Aggregate Limit of Liability as stated in the **Schedule**. If the applicable Aggregate Limit of Liability has been reduced to an amount less than the Sub-Limit then such amount is the most that will be available for any payment.

Any Aggregate Limit of Liability stated in the **Schedule** as an Annual Aggregate applies separately to the first twelve (12) months of the Policy Period and to each subsequent twelve (12) month period or part thereof.

1.4 Defence Costs

In respect of any liability for **Compensation** indemnifiable under this **Policy**, **Chubb** will pay **Defence Costs**, subject to the following:

- a) **Chubb** is not obliged to pay any **Defence Costs** or to defend any **Claim** or suit after the Limits of Liability have been exhausted;
- b) if a payment exceeding the Limits of Liability has to be made to dispose of a **Claim**, the liability of **Chubb** for **Defence Costs** is limited to the proportion that **Chubb's** liability to indemnify the **Insured** for **Compensation** under this **Policy** bears to that payment; and
- c) in the event of a **Claim** being made against the **Insured** in any Court or before any other legally constituted body in the United States of America, Canada or their respective protectorates and territories, the total amount payable by **Chubb** in respect of any one **Occurrence** including **Defence Costs** will not exceed the applicable Limits of Liability.

1.5 Additional Claim Expenses Incurred by Insured

Subject to all of the terms and conditions of this **Policy**, **Chubb** will pay, with respect to a **Claim** or suit that **Chubb** investigates or settles, reasonable expenses (other than **Defence Costs**) incurred by the **Insured** at **Chubb's** request to assist **Chubb** in the investigation of or defence against such **Claim** or suit, including actual loss of earnings up to \$1,000.00 a day because of time off work.

1.6 Deductible

The Deductible stated in the **Schedule** is the amount that shall be borne and payable by the **Named Insured**. Unless otherwise stated, the Deductible shall apply to all **Claims** made under this **Policy**.

The Deductible is payable by the **Named Insured** at such time as is required by **Chubb**. The Deductible applies to **Defence Costs** as well as **Compensation** and any other amounts indemnifiable under this **Policy**. **Chubb's** liability to indemnify the **Insured** under this **Policy** applies only in respect of the amount of **Defence Costs**, **Compensation** and other amounts that exceed the Deductible.

Section 2. Exclusions

This **Policy** does not indemnify the **Insured** or any third party beneficiary for any liability directly or indirectly caused by, arising out of or in any way connected with:

2.1 *Asbestos*

asbestos or materials containing asbestos

2.2 *Contractual Liability*

liability assumed by the **Insured** in any contract, agreement or warranty unless such liability:

- a) would have been implied by law in the absence of such contract, agreement or warranty; or
- b) has been assumed in a **Contract Indemnity**, provided any **Bodily Injury** or **Damage** giving rise to such liability happens after the execution of such contract or agreement.

2.3 *Damage To Clinical Trial Products*

any **Damage** to any **Clinical Trial Product** or any part of it.

2.4 *Deterioration*

any:

- a) expiration of any normal industry or statutorily recognised "use by" date or similar date;
- b) expiration of any normal shelf life;
- c) normal decomposition or deterioration; or
- d) normal perishability;

of any **Clinical Trial Products** but this Exclusion 2.4 shall only apply to Extension 1.2.2.

2.5 *Employment Liability*

any:

- a) liability in respect of which the **Insured** is or would be entitled to indemnity under any fund, scheme, policy of insurance or self-insurance pursuant to or required by any legislation relating to workers' compensation whether or not such insurance has been effected;
- b) industrial award or agreement or determination where such liability would not have been imposed in the absence of such industrial award or agreement or determination; or
- c) **Employment Practices**;

but this Exclusion 2.5 does not apply to **Bodily Injury** of an employee arising from such employee's voluntary participation in a **Clinical Trial** covered by this **Policy** as a **Research Subject**.

2.6 *Intentional Or Reckless Acts*

any intentional or reckless acts or omissions on the part of the **Insured** or the risk of which the **Insured** deliberately courted but this Exclusion 2.6 shall not apply to Extension 1.2.5.

2.7 *Kindred Clinical Trial Products*

any **Product Recall Expenses** for **Clinical Trial Products** from any lot or batch for which it can be readily determined that none of such **Clinical Trial Products** from that lot or batch have a **Product**

Recall Defect, even if **Clinical Trial Products** from another lot or batch or kindred **Clinical Trial Products** have been determined to have a **Product Recall Defect**.

This Exclusion 2.7 shall only apply to Extension 1.2.2.

2.8 Pollutants

- a) the discharge, dispersal, release, seepage, migration or escape of **Pollutants**, including the cost of testing, monitoring, treating, detoxifying, removing, neutralising or cleaning up **Pollutants**; or
- b) the cost of preventing the escape of **Pollutants**.

2.9 Prior Bodily Injury Or Damage

any **Bodily Injury** or **Damage** happening before the Retroactive Date.

2.10 Prior Claims Or Circumstances

any:

- a) **Claim** first made against the **Insured** before the beginning of the Policy Period;
- b) **Claim** or **Circumstance** notified, in whole or in part, to **Chubb** or any other insurer before the beginning of the Policy Period; or
- c) **Claim** or **Circumstance** of which the **Insured** was aware or ought reasonably to have been aware prior to the commencement of the Policy Period.

2.11 Prior Known Defects

any **Clinical Trial Product** or other property that has a defect, deficiency, inadequacy or dangerous condition, if such defect, deficiency, inadequacy or dangerous condition was known by the **Insured**, or ought reasonably to have been known by the **Insured** before:

- a) the beginning of the Policy Period; or
- b) delivery of such **Clinical Trial Product** or other property by any **Insured** or any person or organisation acting on any **Insured's** behalf;

whichever is the later, but this Exclusion 2.11 shall only apply to Extension 1.2.2.

2.12 Medical Professional Liability

the rendering of or failure to render medical professional advice or service by the **Insured**, but this Exclusion 2.12 does not apply to any **Clinical Trial Risk**.

2.13 Product Recall

- a) the withdrawal, recall, inspection, repair, adjustment, removal, replacement or loss of use of any **Clinical Trial Product** and / or the withdrawal or recall of any property of which such **Clinical Trial Product** forms a part, except to the extent such cover is available under Extension 1.2.2 of this **Policy**.
- b) this Exclusion 2.13 does not apply to the liability for damages for **Bodily Injury** that results from a procedure or service to:

- i. remove a **Clinical Trial Product** from; or
- ii. repair or replace a **Clinical Trial Product** which has been put inside:

a **Research Subject's** body if:

- such **Clinical Trial Product** is a **Medical Device** that has caused **Bodily Injury** to such **Research Subject** before such procedure or service; and
- such removal, repair or replacement is necessary to prevent any further **Bodily Injury** from happening to the **Research Subject**.

Paragraph b) above does not apply (and therefore this **Policy** does not apply) to the cost of the **Clinical Trial Product** or any product that replaces the **Clinical Trial Product**.

2.14 *Publications With Knowledge Of Falsity*

any electronic, oral, written or other publication of content, information or material by or with the consent of the **Insured**:

- a) with knowledge of its falsity; or
- b) if, from the standpoint of a reasonable person in the circumstances of such **Insured**, such content, information or material would be have been known to be false;

but this exclusion 2.14 shall only apply to Extension 1.2.12.

2.15 *Sanctions*

Chubb shall not be deemed to provide cover and **Chubb** shall not be liable to pay any **Claim** or provide any benefit hereunder to the extent that the provision of such cover, payment of such **Claim** or provision of such benefit would expose **Chubb**, or its parent to any sanction, prohibition or restriction implemented pursuant to resolutions of the United Nations or the trade and economic sanctions, laws or regulations of Australia, the European Union, United Kingdom, or United States of America.

2.16 *Specific Diseases*

any:

- a) **Specific Disease**, including any similar or other condition, injury, sickness or disease related thereto, by whatever name known;
- b) causative agent of such condition, injury, illness or disease, regardless of whether such agent gives rise to any such condition, injury, sickness or disease or any other condition, injury, sickness or disease, by whatever name known; or
- c) actual or attempted counselling or testing for, or containing, detoxifying, mitigating, monitoring or neutralising of, or responding to, or assessing the effects of any:
 - i. condition, injury, illness or disease; or
 - ii. causative agent;

described in paragraph a) or b) above, including any:

- actual or attempted cure, diagnosis, prevention of treatment of any such condition, injury, illness or disease;
- actual or attempted cleaning-up, disposing, handling and removing of any such causative agent; or
- failure to perform any of the foregoing.

This exclusion 2.16 shall not apply to **Bodily Injury** resulting from the use of any **Clinical Trial Product** (or comparator) that is specifically designed or intended to be used for the treatment of a **Specific Disease**.

2.17 *Terrorism*

any **Act of Terrorism** regardless of any other cause or event contributing concurrently or in any other sequence to the loss or any action taken in controlling, preventing, suppressing or in any way relating to any **Act of Terrorism**.

2.18 *Unapproved Clinical Trials*

any unapproved exposure to material in connection with any **Clinical Trial** that happens after:

- a) a hold has been placed on the **Clinical Trial**;
- b) any authorisation applicable to the **Clinical Trial** has been withdrawn; or
- c) the **Clinical Trial** has been ordered to be discontinued;

by the applicable government or regulatory authority having jurisdiction.

2.19 War

war, invasion, act of foreign enemy, hostilities or warlike operations (whether war be declared or not), civil war, mutiny, civil commotion assuming the proportions of or amounting to a popular rising, military rising, insurrection, rebellion, revolution, military or usurped power, or any act of any person or persons acting on behalf of or in connection with any organisation the objects of which are to include the overthrowing or influencing of any de jure or de facto government by terrorism or by any violent means.

Section 3. Conditions

3.1 Applicable Law

Should any dispute arise concerning this **Policy**, the dispute will be determined in accordance with the law of Australia and the States and Territories thereof. In relation to any such dispute the parties agree to submit to the exclusive jurisdiction of any competent court in a State or Territory of Australia.

3.2 Assignment

Assignment of an interest under this **Policy** does not bind **Chubb** until its consent is endorsed on the **Policy**. If the **Insured** dies or is adjudged bankrupt or insolvent, this insurance will cover:

- a) the **Insured's** legal representative acting on behalf of the **Insured** or the **Insured's** estate;
- b) any person or corporation having lawful temporary custody of property which is or was before the **Insured's** death owned or possessed by the **Insured** until the appointment of a legal representative.

3.3 Cancellation

- a) The **First Named Insured** may cancel this **Policy** by giving notice in writing to **Chubb**. If such notice is given, the cancellation will take effect on the day notice is received by **Chubb**.
- b) **Chubb** may cancel this **Policy** in any circumstances set out in the Insurance Contracts 1984 (Cth). Such cancellation is to take effect thirty (30) days from the time notification is received by the **First Named Insured**.
- c) Upon cancellation by the **First Named Insured** or **Chubb** the **First Named Insured** will receive a refund of premium in accordance with the following:
 - i. if the reason for cancellation is because the **Clinical Trial** covered by this **Policy** did not commence, **Chubb** will retain \$2,000 (or Premium currency equivalent) for administration costs and refund the balance of premium remaining in full to the **First Named Insured**.
 - ii. if this **Policy** is cancelled for any other reason **Chubb** will retain \$2,000 (or Premium currency equivalent) for administration costs and provide a pro rata refund of the remaining premium for the unexpired Policy Period.
- d) In the event of any **Circumstance** or **Claim** having been notified to **Chubb** prior to a request to cancel this **Policy** there will be no refund of premium.

3.4 Conformance

In the event any term or condition of this **Policy** is found to be invalid, illegal or unenforceable, in whole or in part, such term or condition or part thereof will be deemed not to apply to this **Policy**.

However, the validity, legality and enforceability of all other terms and conditions remains unchanged.

3.5 Cross Liability

Each of the parties comprising the **Insured** is considered a separate legal entity and the word "**Insured**" applies to each party as if a separate policy had been issued to each of the said parties but nothing contained in this clause will operate to increase **Chubb's** liability under this **Policy**.

3.6 *Currency*

Unless otherwise stated in the **Schedule**, all amounts under this **Policy** are expressed and payable in Australian currency. However, at **Chubb's** discretion **Chubb** may pay such amounts in another currency.

In the event any **Compensation, Defence Costs** or any other amounts paid under this **Policy** involve another currency, conversion into such currency will be computed as follows:

- a) with respect to awards or settlements, amounts will be computed at a free rate of exchange as soon as practicable following the date of entry of final awards or the date of settlement.
- b) with respect to all other elements of loss, amounts will be computed at a free rate of exchange as soon as practicable following the date of **Chubb's** agreement to release payment for such element of loss.

In no event will any conversion into or from another currency result in any increase in any Limits of Liability shown in the **Schedule**.

3.7 *First Named Insured*

In addition to the obligations of the **First Named Insured**, as set forth in any other provision of this **Policy**, the following provisions apply.

- a) The **First Named Insured** is primarily responsible:
 - i. for the payment of all premiums, deductibles, self-insured amounts and other amounts that become payable by any **Insured** under this **Policy**.
 - ii. To act on behalf of all other **Insureds** or other interests under this **Policy** for the giving and receiving of notice of cancellation or non-renewal and the receiving of any return premiums under this **Policy**.
 - iii. To act on behalf of any person or organisation (other than **Chubb**) having rights or duties under this **Policy**.
- b) **Chubb's** communications under this **Policy** will be principally through the **First Named Insured**. The inclusion of any other **Insured** or other interest under this **Policy** will not obligate **Chubb** to provide any notice or other specific information to any such interest.
- c) **Chubb** has no obligation to apportion or provide any **Claim**, premium or other information separately among or to any specific **Insured** or other interest under this **Policy**.

3.8 *Foreign Entity Loss*

Notwithstanding anything contained herein to the contrary:

- a) **Chubb** will indemnify the **First Named Insured** for an **Insured Loss**, the value of which is conclusively agreed and shall be equal to:
 - i. where at the time of the **Foreign Entity Occurrence** the **Ownership Interest** is a **Controlling Interest**, the **Foreign Entity Loss**; or
 - ii. subject to b) i. below, where at the time of the **Foreign Entity Occurrence** the **Ownership Interest** is not a **Controlling Interest**, the **Ownership Interest** multiplied by the **Foreign Entity Loss**.
- b) if, at the date of the **Foreign Entity Occurrence**:
 - i. the **First Named Insured** does not have an **Ownership Interest** or has an **Ownership Interest** which is not a **Controlling Interest** but, in either case, the **First Named Insured** or an intervening subsidiary is responsible:
 1. for reimbursing the **Foreign Entity** for the **Foreign Entity Loss**; or
 2. for obtaining liability insurance for the **Foreign Entity** pursuant to some form of responsibility which the **First Named Insured** or an intervening subsidiary has in relation to the **Foreign Entity**; or

- ii. the **First Named Insured** has an **Ownership Interest** which is not a **Controlling Interest** and the **First Named Insured** or an intervening subsidiary is responsible for obtaining liability insurance for the **Foreign Entity**, (an "Obligation");

Chubb will indemnify the **First Named Insured** for the **Insured Loss**, the value of which is agreed and shall be deemed conclusively to be equal to the **Foreign Entity Loss** to the extent that the **First Named Insured** has an Obligation to pay.

- c) **Chubb** will treat any **Foreign Entity Loss** in accordance with all of the terms and conditions of this **Policy**, including, but not limited to, exclusions and other limitations in this **Policy**, as if the **Foreign Entity Loss** occurred to the **First Named Insured**.
- d) information material to this insurance which is known to the **Foreign Entity** shall be deemed to be known to the **First Named Insured**.
- e) the **First Named Insured** shall, when directed by **Chubb**:
 - i. retain in its own name, but at **Chubb's** expense, a loss adjusting expert ("loss adjuster"), authorized in the jurisdiction in which the **Foreign Entity Loss** occurred and approved by **Chubb**, to adjust the **Foreign Entity Loss**;
 - ii. where permitted by applicable law, grant **Chubb** the full right to collaborate with such loss adjuster;
 - iii. grant **Chubb** full access to any records produced by such loss adjuster; and
 - iv. obtain the right to control the investigation, adjustment, defence and settlement of a **Foreign Entity Loss**, including access to books, records, bills invoices, vouchers and other information.
- f) the **First Named Insured** shall make best endeavours to ensure that the **Foreign Entity** shall, to the extent permitted by the laws and/or regulations to which the **Foreign Entity** is subject, do and concur in doing and permit to be done all such acts and things as may be necessary or reasonably required by **Chubb** for the purpose of enforcing any rights and remedies, or of obtaining relief, indemnity or settlement sums from other parties in each case in priority to the insurer with whom the **Local Policy** is written.

In the event any such recovery is subsequently received by the **Foreign Entity** in respect of which a payment or settlement is or has been made by **Chubb** to the **First Named Insured** in relation to the **Foreign Entity Loss**, the **First Named Insured** shall immediately pay to **Chubb** a sum equivalent to such payment or settlement.

3.9 *Goods And Services Tax (GST)*

If an **Insured** is entitled to an input tax credit for the premium, that **Insured** must inform **Chubb** to the extent of that entitlement at or before the time a **Claim** is made under this **Policy**. **Chubb** will not be liable for amounts based upon, arising from or in consequence of any **Insured's** misstatement or failure to inform **Chubb** of the extent of its entitlement to an input tax credit.

The amount of any deductible or retention payable will be less any input tax credit that is or may be available to the **Insured**.

3.10 *Insurance Contracts Act 1984 (Cth)*

Nothing contained in this **Policy** is to be construed to reduce or waive either the **Insured's** or **Chubb's** privileges, rights or remedies available under the Insurance Contracts Act 1984 (Cth).

3.11 *Insured's Duties In Event Of Act, Occurrence, Circumstance or Claim*

- a) The **Named Insured** must ensure that **Chubb** is notified as soon as reasonably practicable, but in no event later than the time frames set forth in the applicable Coverage or Extension, of any **Act, Occurrence, Circumstance or Claim** that would reasonably be expected by the **Named Insured** to result in any **Claim**. Notice must include:

- i. how, when and where the foregoing happened;
 - ii. the names and addresses of any injured persons and organisations and any witnesses;
 - iii. the nature and location of any injury or damage in connection with the foregoing; and
 - iv. any other information **Chubb** may require.
- b) If a **Claim** is made or suit brought against any **Insured**, the **Named Insured** and any other involved **Insured** must:
- i. immediately record the specifics of such **Claim** or suit and the date received;
 - ii. notify **Chubb** as soon as possible;
 - iii. ensure **Chubb** receive written notice of the **Claim** or suit as soon as possible.
- c) The **Named Insured** and any other involved **Insured** must:
- i. immediately send **Chubb** copies of any demands, notices, summonses or other legal papers received in connection with a **Claim** or suit;
 - ii. authorise **Chubb** to obtain records and other information if requested;
 - iii. cooperate with **Chubb** in the investigation of, defence against or settlement of a **Claim** or suit;
 - iv. allow **Chubb** all reasonable access to the **Named Insured's** premises, records and other information; and
 - v. assist **Chubb**, upon request, in the enforcement of any right against any person or organisation that may be liable to an **Insured** because of loss which is also covered by this **Policy**.
- d) No **Insured** may settle any **Claim** or suit, incur any **Defence Costs**, assume any contractual obligation or admit liability with respect to any **Claim** or suit without **Chubb's** written consent. **Chubb** will not be liable for any settlement, **Defence Costs**, assumed obligation or admission to which **Chubb** has not consented.
- e) Notice to **Chubb** under this **Policy** must be given in writing and addressed to the following.
- i. Notices of **Claims**, suits or **Circumstances**:

*Claim Manager at the address of the Issuing Office shown in the **Schedule**.*
 - ii. Other notices:

*Underwriting Manager at the address of the Issuing Office shown in the **Schedule**.*
- f) If **Claims**, suits or **Circumstances** involve any other insurers that may provide insurance coverage, then the **Named Insured** must ensure that such other insurers are notified in writing as soon as practicable. Further the **Named Insured** must cooperate with such other insurers and **Chubb** in the investigation of, defence against or settlement of the **Claim**, suit or **Circumstance**.

3.12 *Insured's Duties in Event of Clinical Trial Product Recall Or Crisis Response*

Further to Condition 3.11 above, the following provisions apply to Extensions 1.2.2 and 1.2.3.

- a) All **Insureds** must ensure that **Chubb** and any other insurers are notified in writing as soon as possible (and in strict conformance with all time frames set forth in this **Policy**) upon discovery by any **Insured** or upon notification by any governmental or regulatory authority of any **Product Recall Defect** that may make it necessary to regain control over any **Clinical Trial Product** covered by this **Policy**.
- b) As soon as reasonably possible, but no later than ninety (90) days after reporting to **Chubb** of a **Product Recall Defect**, the **Named Insured** must ensure that **Chubb** receives a sworn written statement containing the following information:

- i. copy of any notification from a governmental or regulatory authority directing that control be regained over the **Clinical Trial Product**.
 - ii. documentation that supports the **Named Insured's** decision to regain control over the **Clinical Trial Product**.
 - iii. a complete description and proof of such **Bodily Injury** or **Product Recall Defect**, including its cause.
 - iv. a listing that identifies the applicable **Clinical Trial Product**, including any batch or lot numbers, serial numbers and dates of manufacture and sale.
 - v. an itemised estimate of amounts claimed.
- c) As often as **Chubb** may reasonably require, all **Insureds** must permit **Chubb** to:
- i. inspect and make copies of records that support all amounts claimed.
 - ii. examine any person under oath, outside the presence of any other person and at times as may be reasonably required, about any matter relating to this insurance, including any **Insured's** books and records. Answers of the persons examined must be signed by each person.
- d) All **Insureds** must, at their own cost, immediately make every reasonable effort to stop any delivery of any:
- i. **Clinical Trial Product** that is known or suspected to have a **Product Recall Defect**; and
 - ii. kindred **Clinical Trial Products** until it is determined that such **Clinical Trial Products** do not have **Product Recall Defects**.
- e) **Insureds** must not, except at their own cost, make any payment, assume any obligation or incur any cost without **Chubb's** prior written consent.
- f) Subject to the foregoing, notification must be in writing and addressed to **Chubb's** Claims Department in accordance with Condition 3.11.

3.13 Loss Determination And Loss Payment

In making any loss determination under Extensions 1.2.2 and/or 1.2.3 **Chubb** will utilise relevant sources of information, including financial records and accounting procedures, bills, invoices and other vouchers.

The amount of loss will be determined based on:

- a) **Crisis Response Expenses** and/or **Product Recall Expenses** that exceed normal operating expenses; and
- b) other necessary expenses that reduce **Crisis Response Expenses** and/or **Product Recall Expenses** which otherwise would have been incurred.

Chubb will deduct from the total of such expenses the salvage value for any property bought for temporary use in connection with a **Product Recall Defect** to which this **Policy** applies.

Chubb will indemnify for covered amounts after receiving a sworn written statement, as described under Condition 3.11, provided that the **Insured** has complied with all of the terms and conditions of this **Policy** and **Chubb** has reached agreement on the amount of loss with the **Named Insured**.

3.14 Policy Changes

This **Policy** can only be changed by a written endorsement that becomes part of this **Policy**. The endorsement must be signed by one of **Chubb's** authorised employees.

3.15 Reduction of Expenses

All **Insureds**, at their own cost, must take all necessary and reasonable steps to minimise or prevent any loss which would otherwise be covered under this **Policy**.

3.16 Representations And Material Changes

It is a provision of this **Policy** that, in accepting it, the **Insureds** agree that the representations and statements contained in any **Application**:

- a) are accurate and complete;
- b) were made to induce **Chubb's** reliance upon them;
- c) were made on behalf of all **Insureds**;
- d) are material to **Chubb's** decision to provide coverage; and
- e) are considered as incorporated in and constituting part of this **Policy**.

Furthermore, every change materially affecting the representations and statements contained in the **Application** after the commencement of this **Policy**, or at any subsequent renewal date, must be notified to **Chubb** in writing immediately after such change comes to the notice of the **Insured's** officer responsible for insurance.

3.17 Right To Defend, Assistance And Co-Operation of the Insured

- a) In respect of any **Act** or **Occurrence** covered under this **Policy**, **Chubb** has the right, if it so elects, to defend any **Claim** or suit against the **Insured** seeking **Compensation** or reimbursement of expenses for **Bodily Injury, Damage, Personal Injury or Reputational Injury** and to bring any cross claim in the name of the **Insured** even if any of the allegations of the **Claim** or suit are groundless, false or fraudulent, and may make such investigation and settlement of any **Claim** or suit as it deems expedient; but **Chubb** is not obligated to pay any **Claim** or judgment or to defend any **Claim** or suit after **Chubb's** liability under this **Policy** in respect of the **Claim** has been exhausted.
- b) Notwithstanding any duties described in 3.11, if the cost of any **Claim** is not likely to exceed the Deductible, **Chubb** may elect not to defend the suit. In these circumstances and, subject to the provisions of this **Policy**, the **Insured** is responsible for the handling and payment of the **Claim** and its **Defence Costs** up to the amount of the Deductible.
- c) The **Insured** must co-operate with **Chubb** and comply with the terms and conditions of this **Policy**, and assist as necessary in enforcing any right to contribution or indemnity from any person, corporation or organisation.

3.18 Statutory and Regulatory Requirements for Clinical Trials

The **Insured** must:

- a) at all times be in receipt of all necessary authorisations in connection with **Clinical Trials** covered by this **Policy**;
- b) takes reasonable measures to ensure that such **Clinical Trials** are conducted in accordance with all applicable agreements, contracts, laws, procedures, protocols and regulations (including all applicable filing requirements); and
- c) take reasonable measures to comply with any other statutory obligations and regulations imposed by any statutory or governmental authority.

3.19 Titles of Paragraphs

The titles of various paragraphs of this **Policy** and endorsements, if any, attached to this **Policy** are inserted solely for convenience of reference and are not deemed to limit or affect the provisions to which they relate.

3.20 Transfer of Rights and Duties

The **Insured's** rights and duties under this **Policy** may not be transferred without **Chubb's** written consent.

4. Definitions

Wherever appearing in this **Policy**, the following definitions apply:

4.1 **Act** means

an act, error or omission. All acts, errors or omissions of a series consequent on or attributable to one source or original cause are deemed one **Act**.

- 4.2 **Act of Terrorism** means
any act, including but not limited to the use of force or violence and/or threat thereof, of any person, people or group of people, whether acting alone or on behalf of or in connection with any organisation or government which from its nature or context is done for, or in connection with, political, religious, ideological or similar purposes or reasons, including the intention to influence any government or to put the public, or any section of the public, in fear.
- 4.3 **Adverse Event** means
any of the following requiring notification to a governmental or regulatory authority:
- a) an outcome of the following types, regardless of whether or not such outcome is expected or intended:
 - i. congenital anomaly or birth defect;
 - ii. death;
 - iii. disability or incapacity;
 - iv. hospitalisation; or
 - v. life threatening injury, illness or disease;of any person;
 - b) an intervention to prevent any outcome described above; or
 - c) a condition that may give rise to any outcome described above.
- 4.4 **Application** means
any information or representation submitted to **Chubb** by the **Insured** or by any person or organisation on behalf of any **Insured** in applying for this **Policy** or prior **Policies** that this replaces.
- 4.5 **Bodily Injury** means
physical:
- a) injury;
 - b) illness; or
 - c) disease;
- sustained by a person, including resulting death, mental anguish, mental injury or shock at any time. All such resulting loss shall be deemed to happen at the time of the physical injury, illness or disease that caused it.
- Bodily Injury** does not include **Privacy Injury** or **Reputational Injury**.
- 4.6 **Circumstance** means
any facts, situation, matters or circumstances which gives rise to a **Claim** or has the potential to give rise to a **Claim**.
- 4.7 **Claim** means
any:
- a) i. written demand for **Compensation**; or
ii. originating process for recovery of **Compensation**.

issued against the **Insured**.
 - b) claim against this **Policy** made by the **Named Insured** pursuant to an Extension of this **Policy** that indemnifies amounts incurred by such **Named Insured**.

4.8 Clinical Trial:

- a) means any research study that prospectively assigns **Research Subjects** or groups of **Research Subjects** to one or more health-related interventions to evaluate the effects on health outcomes;
- b) includes:
 - i. testing of a **Clinical Trial Product** upon or within **Research Subjects** to establish the effectiveness or safety of such product;
 - ii. testing of a **Medical Device** to establish or validate the effectiveness of such device to provide clinical data;
 - iii. observation of disease progression in **Research Subjects**;
 - iv. providing the information necessary to obtain the informed consent of **Research Subjects** (or their legal guardian or representatives) to participate in such testing;
 - v. testing of a **Research Subject** as part of their enrolment; and
 - vi. any other activities in connection with the testing.
- c) does not include Phase IV studies or other post-marketing surveillance studies unless otherwise stipulated by **Chubb**.

4.9 Clinical Trial Contractor means

a person or organisation engaged to provide service, advice or instruction in connection with:

- a)
 - i. clinical;
 - ii. laboratory; or
 - iii. research;

testing activities, within the scope of and in accordance with the applicable **Clinical Trial Protocol**.

- b) the planning, monitoring or review of a **Clinical Trial**.

4.10 Clinical Trial Product means

any **Drug** or **Medical Device** being tested in a **Clinical Trial** covered by this **Policy**.

4.11 Clinical Trial Protocol means

the protocol under which the **Clinical Trial** covered by this **Policy** is to be conducted that has been approved by all relevant authorities, including the appropriate **Ethics Committee**.

4.12 Clinical Trial Risk means

any:

- a) defect, deficiency, inadequacy or dangerous condition in a **Clinical Trial Product** that is used within the scope of and in accordance with the applicable **Clinical Trial Protocol** of a **Clinical Trial** covered by this **Policy**; or
- b) procedure or service that is provided within the scope of and in accordance with the applicable **Clinical Trial Protocol** of a **Clinical Trial** covered by this **Policy**.

4.13 Compensation means

monies paid or payable by judgment or settlement together with any liability on the **Insured's** part to pay legal costs and expenses (other than **Defence Costs**).

4.14 Compensation Guidelines means

- a) the Medicines Australia ("MA") Compensation Guidelines version 160104 issued 16 January 2004 or subsequent revisions;
- b) the Medical Technology Association of Australia ("MTAA") Compensation Guidelines (Version 1) issued 8 April 2010 or subsequent revisions;
- c) the Researched Medicines Industry Association of New Zealand Inc. Guidelines On Clinical Trials Compensation For Injury Resulting From Participation In An Industry-Sponsored Clinical Trial (issued August 2008) or subsequent revisions;

- d) the Association of British Pharmaceutical Industries (“ABPI”) Clinical Trial Compensation Guidelines (Issued 1991) or subsequent revisions;
- e) the ABPI Guidelines for Phase 1 Clinical Trials (2007 Edition) or subsequent revisions;
- f) the Association of British Health-Care Industries Medical Devices Clinical Investigation Compensation Guidelines (1995) or subsequent revisions;
- g) compulsory guidelines that are imposed by government or regulatory authority; or
- h) written guidelines that are voluntarily agreed to by the **Named Insured** and accepted by **Chubb** as described in a Certificate of Insurance that is issued by **Chubb**;

which set forth the manner and rules by which to determine if, and to what extent, a **Research Subject** in a **Clinical Trial** should be paid compensation and related expenses by the **Insured** for **Bodily Injury** sustained by such **Research Subject** as a result of their participation in a **Clinical Trial** covered by this **Policy**.

- 4.15 **Contract Indemnity** means
a written contract or agreement pertaining to a **Clinical Trial** covered by this **Policy** in which the **Named Insured** assumes the tort liability of another person or organisation for damages sustained by a third person or organisation.
- 4.16 **Contract Research Organisation** means
a person (other than a **Research Subject**) or organisation that provides professional services in connection with or that organises or runs **Clinical Trials** within the scope of and in accordance with its applicable **Clinical Trial Protocol**.
- 4.17 **Controlling Interest** means
an ownership interest which is either:
- a) greater than fifty (50) percent; or
 - b) greater than fifteen (15) percent provided that is the largest shareholding;
- in a **Foreign Entity** (in respect of Condition 3.8) or a **Named Insured** (in respect of 1.2.13).
- 4.18 **Coverage Relationship** means
the period of time which lasts until the end of:
- a) the Policy Period of this **Policy**;
 - b) the Policy Period of a subsequent, continuous renewal or replacement of this **Policy** that is provided by **Chubb** to the **First Named Insured**; or
 - c) any Extended Reporting In Effect under the insurance described in in a) or b) above;
- whichever is latest.
- 4.19 **Crisis Response Expenses** means
necessary and reasonable expenses which are necessary, reasonable and devoted exclusively to the specific purpose of regaining the confidence of the general public or of a specific market segment following **Bodily Injury** covered by this **Policy** including, but only in connection with the foregoing:
- a) advice or service provided by a communications, public relations or other crisis response firm.
 - b) broadcast, electronic, printed, telecast and telephonic announcements, communications and notices.
 - c) overtime remuneration, transport and accommodation of the **Named Insured's** employees.
 - d) procurement, remuneration, transportation and accommodation of persons other than the **Named Insured's** employees.

4.20 Cyber And Security Breach:

- a) means an unauthorised access to or unauthorised use of an **Information Communication Technology Product**.
- b) includes an unauthorised access to or unauthorised use of software, data or other information in electronic form (including in connection with a **Medical Device**) that:
 - i. copies;
 - ii. corrupts;
 - iii. deletes;
 - iv. destroys;
 - v. discloses;
 - vi. distorts; or
 - vii. manipulates;

such software, data or other information or slows down an **Information Communication Technology Product** or **Medical Device**.

4.21 Damage means

- a) physical damage to, destruction of or loss of tangible property including the loss of use of thereof at any time resulting therefrom; or
- b) loss of use of tangible property which has not been physically damaged or destroyed, provided such loss of use is caused by physical damage of other tangible property.

4.22 Defence Costs means

the reasonable costs, fees and expenses incurred in the investigation, defence and settlement of that part of a specific **Circumstance, Act, Occurrence, Claim** or suit covered by this **Policy**.

In respect of Extension 1.2.12 only, **Defence Costs** also includes related reasonable costs, expenses and fees in connection with a **Claim** for injunctive relief to prevent such **Privacy Injury** or **Reputational Injury** from continuing or resuming.

Defence Costs does not include any **Regulatory Costs** or any salaries or expenses of the **Insured's** partners, directors, officers or employees.

4.23 Drug means

a biologic or synthetic article, other than conventional food, that is intended to achieve a chemical action upon or within the body of a human being:

- a) for use in the cure, diagnosis, mitigation, prevention or treatment of disease, injury or sickness in human beings;
- b) to affect any function or structure of the body of such human being; or
- c) which is recognised as such by the applicable governmental or regulatory authority having jurisdiction.

4.24 Employment Practices means

any wrongful or unfair dismissal, denial of natural justice, defamation, misleading representation or advertising, harassment (sexual or otherwise) or discrimination in respect of employment or prospective employment by the **Insured**.

4.25 Ethics Committee means

the members of any committee or similar group which is appointed to supervise or review the conduct of a **Clinical Trial** in accordance with the ethical standards applying in the jurisdiction in which the **Clinical Trial** is undertaken.

4.26 First Named Insured means

the first person or organisation named as a **Named Insured** in the **Schedule**.

- 4.27 **Foreign Entity** means
an entity (located in a country or territory in which **Chubb** is not lawfully permitted to insure that entity) in which the **First Named Insured** has an economic interest as a result either of benefiting financially from the continued operation of the **Foreign Entity** or of being prejudiced by loss or damage to or liability of a **Foreign Entity** or its business or for which the **First Named Insured** is responsible for arranging liability insurance.
- 4.28 **Foreign Entity Loss** means
the **Compensation, Defence Costs** and expenses that a **Foreign Entity** has incurred or become legally obligated to pay because of injury, damage, loss, or liability to which this insurance would apply if the **First Named Insured** were directly liable for such amounts.
- 4.29 **Foreign Entity Occurrence** means
means an event which may result in a **Foreign Entity Loss**.
- 4.30 **Information Communication Technology Product** means
- a) communication, computer, data security, electronic information, Internet, network or website:
 - i. equipment or parts; or
 - ii. programs or systems.
 - b) software, data or other information in electronic form.
- 4.31 **Insured** means
- a) the **First Named Insured**;
 - b) any **Named Insured**; and
 - c) any **Third Party Insured**.
- 4.32 **Insured Loss** means
the decrease in the value of the economic interest of the **First Named Insured** in the **Foreign Entity** as a result of the **Foreign Entity Loss**.
- 4.33 **Local Policy** means
means a clinical trials liability insurance policy (or equivalent) purchasable by a **Foreign Entity** from an insurer licenced and authorised to issue and make payments under such policy in the jurisdiction of the **Foreign Entity**.
- 4.34 **Medical Device** means
means an apparatus, contrivance, implant, implement, instrument, in vitro reagent, machine or other similar or related article, including an accessory, component, software or part, that is:
- a) intended for use in the cure, diagnosis, mitigation, prevention or treatment of disease, injury or sickness in human beings;
 - b) intended to affect any function or structure of the body of such human being; or
 - c) recognised as a medical device by the applicable governmental or regulatory authority having jurisdiction.
- 4.35 **Medical Expenses** means
to the extent permitted by law, reasonable expenses for necessary:
- a) ambulance, hospital or professional nursing services;
 - b) dental, medical, surgical or x-ray services, including prosthetic devices;
 - c) first aid administered at the time of an accident; or
 - d) funeral services.
- 4.36 **Medical Monitoring Expenses** means
to the extent permitted by law, reasonable expenses incurred to conduct medical testing on or medical monitoring of a **Research Subject** in the absence of **Bodily Injury**:

- a) where the **Research Subject** has been exposed to a **Clinical Trial Product** that caused **Bodily Injury** to another **Research Subject**;
- b) where such exposure described in a) above creates a **Substantial** risk that such **Research Subject** will sustain **Bodily Injury** in the future;
- c) such medical testing or monitoring is medically warranted because the prospect of early diagnosis of such **Bodily Injury** will improve the chance of beneficial medical intervention; and
- d) the expense provides no other material benefit to the **Research Subject**.

4.37 Named Insured means

- a) the **Insured** named in the **Schedule**;
- b) any subsidiary company (including subsidiaries thereof) of the **Insured** named in the **Schedule** and any other organisation under the control of the **Insured** named in the **Schedule** and over which it is exercising active management; or
- c) any director, officer, employee, partner or shareholder of the **Insured** named in the **Schedule**, but only whilst acting within the scope of their duties and in connection with a **Clinical Trial** covered by this **Policy**.

4.38 Occurrence means

an event including continuous or repeated exposure to substantially the same general conditions which results in **Bodily Injury** or **Damage** neither expected nor intended from the standpoint of the **Insured**. All events of a series consequent on or attributable to one source or original cause are deemed one **Occurrence**.

4.39 Ownership Interest means

the percentage ownership interest that the **First Named Insured** has in the **Foreign Entity**, either directly or through intervening subsidiaries.

4.40 Policy means

this **Policy** wording including the **Application**, **Schedule** and any endorsement attached hereto.

4.41 Pollutants means

any solid, liquid, gaseous or thermal irritant or contaminant, including but not limited to smoke, vapours, soot, fumes, acids, alkalis, chemicals and waste. Waste includes material to be recycled, reconditioned or reclaimed.

4.42 Privacy Data Breach means

a **Cyber And Security Breach** or other unauthorised access to or unauthorised use of information about a person, that is non-public personal information as established by applicable statute or regulatory or supervisory authority.

4.43 Privacy Data Breach Expenses means

necessary and reasonable expenses incurred following the discovery of a **Privacy Data Breach**:

- a) to notify a person or organisation as may be required by applicable statute or a regulatory or supervisory authority ("notification expenses");
- b) for determining the cause and extent of such **Privacy Data Breach** ("forensic expenses"); or
- c) for "remediation expenses" comprising:
 - i. credit monitoring services; or
 - ii. public relations services.

4.44 Privacy Injury means

injury sustained by a person or organisation that results from electronic, oral, written or other publication, disclosure or other use of content, information or material about a person that is:

- a) a breach of confidence;
- b) a **Privacy Data Breach**; or
- c) an invasion of privacy.

Privacy Injury does not include **Bodily Injury** or **Reputational Injury**.

4.45 Product Recall Defect:

- a) means an actual harmful condition in the **Clinical Trial Product** being tested that:
 - i. results from the actions of the **Named Insured** or the actions of a person or organisation acting on the **Named Insured's** behalf to formulate, manufacture or supply such **Clinical Trial Product**;
 - ii. causes or presents a **Substantial** likelihood of causing **Bodily Injury** to a **Research Subject**;
 - iii. is not intended by any **Insured**; and
 - iv. would not be expected from the standpoint of a reasonable person in the circumstances of any **Insured**.
- b) does not include any actual, alleged or threatened condition arising out of any malicious alteration or contamination of any goods, products or other property.

4.46 Product Recall Expenses:

- a) means that part of the following expenses which are necessary, reasonable and devoted exclusively to the specific purpose of regaining control over **Clinical Trial Products**:
 - i. broadcast, electronic, printed, telecast and telephonic announcements, communications and notices.
 - ii. transportation and storage of **Clinical Trial Products** or replacements thereof.
 - iii. destruction and disposal of **Clinical Trial Products**.
- b) includes, but only in connection with the expenses described in paragraph a) above:
 - i. overtime remuneration transportation and accommodation of the **Named Insured's** employees.
 - ii. procurement, remuneration, transportation and accommodation of persons other than the **Named Insured's** employees.

4.47 Regulatory Costs means

necessary and reasonable costs, expenses and fees incurred to investigate or defend against a regulatory action taken by a supervisory authority following a **Privacy Data Breach**.

Regulatory Costs do not include any salaries or expenses of any of the **Named Insured's** employees, partners, directors or officers or costs, expenses or fees incurred on compliance requirements necessitated in the usual course of the **Named Insured's** business as a sponsor of a **Clinical Trial** covered by this **Policy**.

4.48 Reputational Injury means

injury sustained by a person or organisation that results from:

- a) electronic, oral, written or other publication of material on the Internet or in other media that libels or slanders, or otherwise defames a person or organisation to the extent recognised by law.
- b) false arrest, false detention or other false imprisonment.
- c) malicious prosecution.
- d) discrimination, harassment or segregation based on a person's age, colour, national origin, race, religion or sex.

Reputational Injury does not include **Bodily Injury** or **Privacy Injury**.

4.49 Research Subject means

any person, including any child in utero in such person, participating in a **Clinical Trial**.

- 4.50 **Schedule** means
the **Schedule** issued with this **Policy** wording or any subsequent or amended version of that schedule issued by **Chubb**.
- 4.51 **Specific Disease** means
any of the following:
- a) Acquired Immune Deficiency Syndrome (AIDS).
 - b) Transmissible Spongiform Encephalopathy (TSE).
 - c) Viral Hepatitis.
- 4.52 **Substantial** means
considerable in extent and degree and not illusory or imaginary.
- 4.53 **Third Party Insured** means
any person or organisation described in Extension 1.2.13.

