



# Life Sciences Liability Policy

Wording Document

## Your Award Winning Insurer



**Berkley**  
Insurance Australia  
| a Berkley Company

1300 800 772  
[berkleyinaus.com.au](http://berkleyinaus.com.au)

## Important Information

### Please read the following information

#### A. 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.

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.

#### B. Claims made and Notified Policy

Sections 1.1 Public Liability, 1.5 Clinical Trial Coverage, 1.8 Errors & Omissions Liability for Economic Injury, 1.9 Biological Agents Liability and 1.10 Data Breach Expense Coverage of this policy are issued on a 'claims made and notified' basis. This means that they respond to:

- (a) claims first made against the insured during the Policy Period and notified to Us during the Policy Period, provided that the Insured was not aware at any time before policy inception of facts, matters or circumstances which would have put a reasonable person in the Insured's position on notice that a claim may be made against the Insured; and
- (b) written notification of facts pursuant to section 40(3) of the Insurance Contracts Act 1984. If the Insured chooses to tell Us in writing about facts which might give rise to a claim against the Insured as soon as reasonably practicable after the Insured becomes aware of these facts but before insurance cover provided by the policy expires, then We are not relieved of liability under the policy for the claim, when made, by reason only that it was made after the expiration of the period of insurance cover provided by the policy.

After the policy expires, no new notification of facts may be made on the expired policy even though the event giving rise to the claim against the Insured may have occurred during the Policy Period. An exception to this is where an extended reporting period applies to the policy. If an extended reporting period applies, then cover may be available for notifications of facts or claims made up to expiry of the extended reporting period.

When completing the proposal the Insured is required to provide full details of all facts, matters and circumstances of which they are aware and which a reasonable person in the Insured's position would consider may give rise to a claim. It is important that the Insured make proper disclosure. Refer to the Duty of Disclosure above to understand the Insured's disclosure obligations.

#### Retroactive Date

Where coverage is provided on a claims made and notified basis, this policy does not provide cover for claims arising from or in connection with an act, error, omission or event occurring or alleged to have occurred before the policy's retroactive date, where such a date is specified in the Schedule.

**C. Subrogation Agreements**

Where another person would be liable to compensate you for any loss or damage otherwise covered by the insurance, but you have agreed with that person either before or after the loss or damage occurred that you would not seek to recover any monies from that person, We will not cover you under the insurance for such loss or damage.

**D. Privacy Statement**

We are a member of the W. R. Berkley Corporation, which We refer to as WRBC.

We take privacy seriously and are committed to handling and protecting your personal information in accordance with the Privacy Act 1988 (Cth) and Australian Privacy Principles (APPs). This Privacy Statement explains how We collect, hold, use and disclose your personal information and who We share it with. It should be read with Our Privacy Policy which provides more information about Our privacy practices.

Our Privacy Policy is available at [www.berkleyinaus.com.au](http://www.berkleyinaus.com.au). Alternatively, you can use the details in Contact Us at the end of this Privacy Statement to request a copy of Our Privacy Policy.

**Consent**

You agree to Us collecting, holding, using and disclosing your personal information as set out in Our Privacy Policy when you: (i) provide Us with your personal information; or (ii) apply for, use or renew any of Our products and services.

**Personal information about others**

If you provide Us with personal information about another person, then you must: (i) have their consent to do so; and (ii) tell them that you are disclosing their personal information to Us and provide them with a copy of this Privacy Statement.

**How we collect your personal information**

We collect your personal information directly from you, your agents and through others including the parties listed in Our Privacy Policy. This includes Our agents and service providers. We will use a variety of methods to collect your personal information from these parties, including written forms, telephone calls and electronic delivery.

**Not giving us your personal information**

You may choose not to give Us your personal information. However, this may affect Our ability to provide you with any, some or all of the features of Our products or services, including processing a claim.

**How we handle your personal information**

We will use your personal information for the purposes We collected it. This usually includes: (i) providing you with assistance, a product or service you have requested; (ii) handling claims and complaints you have made; and (iii) facilitating Our business functions and operations.

Your personal information may also be used for other purposes that are set out in Our Privacy Policy.

We may disclose your personal information to other members of WRBC, agents or service providers (either yours or Ours), other insurers, reinsurers, persons involved in a claim and other parties set out in Our Privacy Policy. These disclosures will be for the same purposes described above or as otherwise permitted by law.

**Overseas Disclosure**

Sometimes We need to provide your personal information to, or get personal information about you from, persons or organisations located overseas. We will do this for the same purposes as in the 'How we handle your personal information' section above.

The complete list of countries is contained in Our Privacy Policy.

From time to time, We may need to disclose your personal information to, and collect your personal information from, persons and organisations located in countries that are not on the list.

### Marketing

Every now and then We might let you know – including via email, telephone or online - about news, products and services that We think may be of interest to you.

We will engage in marketing unless you tell Us otherwise. We want you to be able to exercise your marketing preferences. Accordingly, you can contact Us to update your marketing preferences by using the details in Contact Us below. Alternatively, you can simply follow the unsubscribe instructions in the relevant communication. More information about Our marketing practices can be found in Our Privacy Policy.

### Access, correction and complaints

You have the right to request access and correct your personal information held by Us. Our Privacy Policy provides information about how you can: (i) access your personal information; (ii) ask Us to correct your personal information; and (iii) complain about a breach of the APPs and how We will deal with such a complaint.

### Contact Us



[www.berkleyinaus.com.au](http://www.berkleyinaus.com.au)



02 9275 8566



[privacy@berkleyapac.com](mailto:privacy@berkleyapac.com)



Berkley Privacy Officer, PO Box Q296, QVB NSW 1230

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## LIFE SCIENCES LIABILITY POLICY

The following coverage sections apply if purchased by the First Named Insured and shown as included on the Schedule.

### SECTION 1 - INSURING CLAUSES

In consideration of payment of the premium and in reliance on the proposal form and any other information submitted by or on behalf of the Insured We will indemnify the Insured in accordance with, and subject to, the terms, conditions and exclusions of this Policy.

To the extent that any part of an exclusion is found to be invalid or unenforceable, the remainder of such exclusion and all other exclusions shall remain in full force and effect.

#### 1.1 PRODUCTS LIABILITY

##### 1.1.1 Bodily Injury and Property Damage

We will pay all Damages the Insured becomes legally obligated to pay for Bodily Injury or Property Damage arising from Loss occurring away from premises owned, occupied by, loaned or rented to You and arising out of Your Product or Your Work, provided always that:

- a. a Claim for such Bodily Injury or Property Damage is first made against the Insured during the Policy Period or, if applicable, an Extended Reporting Period; and
- b. the Bodily Injury or Property Damage takes place on or after the Retroactive Date and before the end of the Policy Period.

##### 1.1.2 Medical Monitoring Expense

We will pay all Damages the Insured becomes legally obligated to pay for Medical Monitoring Expense arising from Loss occurring away from premises owned, occupied by, loaned or rented to You and arising out of Your Product or Your Work, provided always that:

- a. a Claim for such Medical Monitoring Expense is first made against the Insured during the Policy Period or, if applicable, an Extended Reporting Period;
- b. prior to the Claim, Your Product, or a product on which Your Work was performed, was the subject of a Class I Product Recall; and
- c. the exposure to the product requiring the claimant to incur Medical Monitoring Expense first takes place on or after the Retroactive Date and before the end of the Policy Period.

##### 1.1.2 Clauses 1.1.1 and 1.1.2 do not apply to Bodily Injury, Property Damage or Medical Monitoring Expense:

- a. caused by or directly resulting from participation in a Clinical Trial, or which is otherwise covered under clause 1.5 Clinical Trial Coverage; or
- b. based upon or arising out of Advertising Injury or Personal Injury, or which is otherwise covered under any coverage section covering such injury.

#### 1.2 PUBLIC LIABILITY

##### 1.2.1 We will pay all Damages the Insured becomes legally obligated to pay for Bodily Injury or Property Damage not covered under clause 1.1 Products Liability Insuring Clause caused by an Occurrence, which takes place during the Policy Period.

##### 1.2.2 Clause 1.2.1 does not apply to Bodily Injury or Property Damage:

- a. covered under clause 1.1.1;
- b. based upon or arising out of a Clinical Trial or otherwise covered under clause 1.5 Clinical Trial Coverage; or
- c. based upon or arising out of Advertising Injury or Personal Injury or which is otherwise covered by any coverage section covering such injury.

### 1.3 MEDICAL PAYMENTS

**1.3.1** We will pay Medical Expenses for Bodily Injury covered under clause 1.2.1 Public Liability caused by an accident:

- a. on premises You own or rent;
- b. because of Your operations.

**1.3.2** We will make these payments regardless of fault.

**1.3.3** Clause 1.3.1 applies only if:

- a. the accident takes place during the Policy Period;
- b. the expenses are incurred and reported to Us within one (1) year of the date of the accident;
- c. the injured person is not:
  - i) any Insured other than a Volunteer Worker; or
  - ii) a person hired to do work for or on behalf of any Insured or a tenant of any Insured;
- d. and is not injured:
  - i) on that part of premises You own or rent that the person normally occupies; or
  - ii) practicing, instructing or participating in any physical exercises or games, sports, or athletic contests; and
- e. the injured person submits to examination, at our expense, by medical practitioners of our choice, as often as We reasonably require.

### 1.4 ADVERTISING INJURY AND PERSONAL INJURY LIABILITY

**1.4.1** We will pay all Damages the Insured becomes legally obligated to pay for Advertising Injury or Personal Injury caused by an offence:

- a. arising out of Your business; and
- b. committed during the Policy Period.

**1.4.2** Clause 1.4.1 does not apply to:

- a. any Advertising Injury or Personal Injury based upon or arising out of a Clinical Trial or otherwise covered under clause 1.5 Clinical Trial Coverage; or
- b. any Loss covered under any other coverage section of this Policy.

### 1.5 CLINICAL TRIAL COVERAGE

#### 1.5.1 No Fault Compensation

- a. We will pay No Fault Compensation for Bodily Injury, Property Damage or Personal Injury caused by, or directly resulting from participation in, an Approved Clinical Trial.
- b. We agree the settlement of No Fault Compensation payable under clause 1.5.1a will be initiated in accordance with the conditions of the Compensation Protocol Guidelines and such amounts will be deemed to be Damages under the Policy.
- c. If an amount cannot be agreed in accordance with the terms and conditions of the Compensation Protocol Guidelines then We will pay Damages the Insured becomes legally obligated to pay in accordance with clause 1.5.2;

provided this clause shall only apply if the Clinical Trial Participant was not first exposed to the material tested in the Approved Clinical Trial prior to the Retroactive Date.

#### **1.5.2 Bodily Injury and Property Damage and Personal Injury**

We will pay all Damages the Insured becomes legally obligated to pay for Bodily Injury, Property Damage or Personal Injury caused by, or directly resulting from participation in, an Approved Clinical Trial.

This clause shall not apply to any Bodily Injury, Property Damage, Personal Injury, Medical Stop Loss Expense or Medical Monitoring Expense arising out of Advertising Injury.

Clauses 1.5.1 and 1.5.2 apply only if:

- a. a Claim for such Bodily Injury, Property Damage or Personal Injury is first made against the Insured during the Policy Period or, if applicable, an Extended Reporting Period;
- b. the Bodily Injury, Property Damage or Personal Injury takes place:
  - i) on or after the Retroactive Date; and
  - ii) before the end of the Policy Period

#### **1.5.3 Abuse or Molestation Liability**

We will pay all Damages the Insured becomes legally obligated to pay for Bodily Injury, Property Damage or Personal Injury caused by sexual abuse or sexual molestation of a Clinical Trial Participant during the course of an Approved Clinical Trial provided that:

- a. the Insured's liability is based upon negligent:
  - i) employment;
  - ii) investigation;
  - iii) supervision; or
  - iv) retention;of a person for whom the Insured was legally responsible at the time of the abuse or molestation;
- b. the Insured did not participate in the abuse or molestation; and
- c. the Insured reported the abuse or molestation to the appropriate government authorities as soon as the Insured became aware of it.

#### **1.5.4 Medical Stop Loss Coverage**

We will pay Medical Stop Loss Expense in excess of the Medical Payments Excess stated in the Schedule that the Insured pays as a result of all Approved Clinical Trials that take place during the Policy Period. We will pay such expenses:

- a. regardless of fault; and
  - b. even if the Clinical Trial Participant's health insurer or another person or entity is willing or obligated to pay such expenses, however, We will be subrogated to all rights the Insured has to recover such expenses;
- provided coverage under this clause shall only apply if such Medical Stop Loss Expense is:
- c. incurred to treat a Clinical Trial Participant during the course of, or subsequent to, an Approved Clinical Trial, for Bodily Injury incurred by the Clinical Trial Participant caused directly by the Clinical Trial Participant's participation in the Approved Clinical Trial; and
  - d. reported to Us in writing within three (3) years of the Bodily Injury or the conclusion of the Clinical Trial Participant's participation in the Clinical Trial, whichever takes place first.

In the event We are able to recover such expenses from a health insurer or any other entity or person willing or obligated to pay, then:

- a. if the Medical Payments Excess has not been exceeded, any such expenses recovered by Us shall be returned to the Insured and shall reduce the Medical Payments Excess

considered satisfied; and

- b. if the Medical Payments Excess has been exceeded, We shall be entitled to keep any such expenses recovered by Us.

#### **1.5.5 Medical Monitoring Expenses**

We will pay all Damages the Insured becomes legally obligated to pay for Medical Monitoring Expense caused by, or directly resulting from participation in, an Approved Clinical Trial, provided, this clause shall only apply if:

- a. a Claim for such Medical Monitoring Expense is first made against the Insured during the Policy Period or, if applicable, an Extended Reporting Period;
- b. the claimant was not first exposed to the product or material requiring claimant to incur Medical Monitoring Expense prior to the Retroactive Date or after the expiration of the Policy Period; and
- c. the Clinical Trial is placed on hold or is suspended by:
  - i) the Therapeutic Goods Administration;
  - ii) a comparable government entity outside of the Commonwealth of Australia having jurisdiction over the Clinical Trial; or
  - iii) the Named Insured;

for the sole reason, expressed in writing, that human subjects are or would be exposed to an unreasonable and significant risk of illness or injury if the Clinical Trial were continued

### **1.6 PRODUCT WITHDRAWAL EXPENSES COVERAGE**

**1.6.1** We will pay Withdrawal Expenses incurred by or on behalf of the Named Insured as a direct result of a Class I Product Recall.

**1.6.2** This Coverage Part applies only if the Class I Product Recall:

- a. commences during the Policy Period;
- b. is reported to us within ten (10) days of the expiration of the Policy Period; and
- c. the Withdrawal Expenses are incurred within one (1) year of the date the Class I Product Recall commenced.

### **1.7 GOODS OR PRODUCTS IN YOUR CARE, CUSTODY OR CONTROL**

**1.7.1** We will pay all Damages You become legally obligated to pay for Property Damage to the following tangible personal property of others in Your care, custody or control:

- a. personal effects of any visitor, director, partner or Employee of the Insured;
- b. premises (including their fixtures and fittings) leased or rented to the Insured;
- c. premises and their contents not belonging to, leased or rented to the Insured, at which the Insured is conducting work as part of their usual business;
- d. buildings (including contents therein) which are not owned leased or rented by the Insured but are temporarily occupied by the Insured for the purpose of maintenance alteration extension installation or repair;
- e. vehicles (and their contents) on the Insured's premises, but not in any car parks owned or operated by the Insured for reward; and
- f. all other property up to a limit of \$250,000 in the aggregate in any one Policy Period.

**1.7.2** We will also pay all Defence Costs to defend a Claim seeking such Damages.

**1.7.3** This coverage section applies only if the event giving rise to such Property Damage occurs during the Policy Period.

## **1.8 ERRORS AND OMISSIONS LIABILITY**

- 1.8.1** We will pay all Damages the Insured becomes legally obligated to pay for Economic Injury caused by an unintentional act, error or omission on the part of the Insured while conducting their Business Activity, if such error, act or omission causes any of the following:
- a. Your Product to become defective, deficient, inadequate or dangerous; or
  - b. Your Work to be performed in a manner inconsistent with, or Your Product to not function as required by the terms and conditions of a written agreement executed by the Named Insured prior to such error, act or omission.
- 1.8.2** Clause 1.8.1 applies only if:
- a. a Claim for such Economic Injury is first made against the Insured during the Policy Period or, if applicable, an Extended Reporting Period; and
  - b. the Economic Injury takes place on or after the Retroactive Date and before the end of the Policy Period.
- 1.8.3** This coverage section does not apply to any injury, damage, expense or cost otherwise covered under any other coverage section or endorsement attached to this Policy.

## **1.9 BIOLOGICAL AGENTS LIABILITY**

- 1.9.1** We will pay all Damages the Insured becomes legally obligated to pay for:
- a. Bodily Injury, Property Damage or Medical Monitoring Expenses caused by contact with or exposure to Biological Agents which:
    - i) are, or are in Your Product, or
    - ii) are, or are in materials used by the Named Insured in a laboratory setting or manufacturing process, provided that such product or materials are located on premises owned or occupied by, or rented or loaned to, the Named Insured, or migrated from such premises, at the time of such contact with or exposure to the Biological Agents; and
  - b. Clean-up Costs incurred by the Named Insured to remediate Biological Agents which have migrated beyond the boundaries of premises owned or occupied by, or rented or loaned to the Named Insured, provided that such Biological Agents:
    - i) originated on such premises;
    - ii) are, or are in Your Product or materials used by the Named Insured in a laboratory setting or manufacturing process; and
    - iii) were released from the area on such premises in which they were contained prior to the migration.
- 1.9.2** Clause 1.9.1 applies only if:
- a. a Claim for such Bodily Injury, Property Damage, Medical Monitoring Expense or Clean-up Costs is first made against the Insured during the Policy Period or, if applicable, an Extended Reporting Period; and
  - b. the Bodily Injury or Property Damage first takes place, or in the case of Clean-up Costs, the migration of Biological Agents requiring the Named Insured to incur Clean-up Costs first takes place, or in the case of Medical Monitoring Expense, the exposure to Your Product requiring claimant to incur Medical Monitoring Expense first takes place:
    - i) on or after the Retroactive Date; and
    - ii) before the end of the Policy Period.
- 1.9.3** Clause 7.15 Pollution does not apply to Bodily Injury, Property Damage, Medical Monitoring Expense or Clean-up Costs to the extent covered under clause 1.9.1.

## **1.10 DATA BREACH EXPENSES COVERAGE**

**1.10.1** We will pay Data Breach Expenses, not otherwise covered as Personal Injury or Advertising Injury under this or any other policy, incurred by or on behalf of the Named Insured caused by an unintentional act, error or omission on the part of the Insured, while conducting Your business, if such error, act or omission causes either:

- a. the disclosure of Protected Personal Information; or
- b. a failure to protect Protected Personal Information from access or use by any person or entity not authorised to have access or use;

Provided that:

- i) the disclosure of or access to or use of such Protected Personal Information is prohibited by a Privacy Law, or by contract executed between the Insured and an Insured Client prior to the error, act or omission; and
- ii) the Insured Client or Protected Person has not authorised disclosure, access or use.

**1.10.2** Clause 1.10.1 applies only if:

- a. the disclosure of such Protected Personal Information, or the discovery by the Insured of unauthorised access to or use of such Protected Personal Information:
  - i) first takes place on or after the Retroactive Date; and before the end of the Policy Period; and
  - ii) is first reported to us within ten (10) days of the expiration of the Policy Period; and
- b. The Data Breach Expense is incurred within one (1) year of the expiration of the Policy period.

**1.10.3** Clause 1.10.1 does not apply to any injury, damage, expense or cost otherwise covered under any other coverage section or endorsement attached to this Policy.

## SECTION 2 - DEFENCE COSTS

### 2.1 Defence Costs Insuring Clause

**2.1.1** We will pay all Defence Costs to defend a Claim seeking Damages under the following coverage sections:

- 1.1.1 Products Liability
- 1.2.1 Public Liability
- 1.4.1 Advertising Injury and Personal Injury Liability
- 1.5.2 Bodily Injury and Property Damage and Personal Injury (Clinical Trial)
- 1.5.3 Abuse or Molestation Liability (Clinical Trial)
- 1.5.6 Medical Monitoring Expenses (Clinical Trial)
- 1.7 Goods or Products in Your Care, Custody or Control
- 1.8 Errors and Omissions Liability
- 1.9 Biological Agents Liability
- 1.10.3 Data Breach Expense Coverage

### 2.2 Defence Obligations

**2.2.1** We may at Our discretion investigate any Claim, Occurrence or offence and settle any Claim that may result. We shall have the right to designate legal counsel for the investigation, adjustment or defence of any Claims.

**2.2.2** Our right to defend ends when We have exhausted the applicable Indemnity Limit as set forth in SECTION 3 –INDEMNITY LIMIT.

**2.2.3** Defence Costs payable under clause 1.2.1 Public Liability and 1.4.1 Advertising Injury and Personal Injury Liability shall be payable in addition to the Indemnity Limit applicable to those coverage sections.

**2.2.4** Defence Costs payable under the following sections:

- 1.1.1 Products Liability
- 1.5.2 Bodily Injury and Property Damage and Personal Injury (Clinical Trial)
- 1.5.3 Abuse or Molestation Liability (Clinical Trial)
- 1.5.6 Medical Monitoring Expenses (Clinical Trial)
- 1.7 Goods or Products in Your Care, Custody or Control
- 1.8 Errors and Omissions Liability
- 1.9 Biological Agents Liability
- 1.10.3 Data Breach Expense Coverage

shall form part of and not be payable in addition to the Indemnity Limit applicable to those sections.

## SECTION 3 - INDEMNITY LIMIT

The Indemnity Limit shown in the Schedule is to be applied as an Overall Policy Aggregate Limit regardless of the number of:

- a. Insureds;
- b. Claims made; or
- c. persons or organisations making claims or Claims.

Notwithstanding any other provision of this Policy, the purchase of an Extended Reporting Period shall not under any circumstances increase or reinstate the Indemnity Limit set forth in this Policy unless such increase or reinstatement is specifically provided for by endorsement.

### 3.1 Overall Policy Aggregate Limit

**3.1.1** The Overall Policy Aggregate Limit is the most We will pay for the sum of:

- a. all Damages for Loss;
- b. all Loss we must pay; and
- c. all Defence Costs which erode any other Indemnity Limit covered under this Policy.

**3.1.2** The Overall Policy Aggregate Limit applies regardless of the amount of any General or Individual Aggregate Limits or Individual Coverage Section Limits applicable to one or more coverage sections.

**3.1.3** The General Aggregate Limit, the Products Aggregate Limit, the Clinical Trial Aggregate Limit, the Errors and Omissions Aggregate Limit and all other aggregate or sub- limits set forth in this Policy or any endorsement attached thereto are subject to the Overall Policy Aggregate Limit. Any obligation we have under this Policy, ends once the Overall Policy Aggregate Limit has been satisfied by the payment of Damages for Loss, Loss We must pay, or Defence Costs.

### 3.2 General Aggregate Limit

The General Aggregate Limit is the most We will pay for the sum of:

**3.2.1** all Damages for Loss We must pay under clause 1.2 Public Liability and 1.4 Advertising Injury and Personal Injury Liability;

**3.2.2** all Loss We must pay under clause 1.3 Medical Payments for Public Liability;

**3.2.3** all Damages for Loss and Defence Costs We must pay under clause 1.7 Goods or Products in Your Care, Custody or Control;

**3.2.4** all Damages for Loss and associated Defence Costs We must pay under clause 1.9 Biological Agents Liability;

**3.2.5** all Damages for Loss and associated Defence Costs and all Loss We must pay under clause 1.10 Enhanced Privacy and Data Protection Coverage;

**3.2.6** all Loss we must pay under clause 4.3 Leased or Rented Premises; and

**3.2.7** all Damages, Loss or expense We must pay under any other coverages afforded under this Policy or by endorsement, unless a separate aggregate limit is established to apply to such other coverages.

The General Aggregate Limit is subject to the Overall Policy Aggregate Limit and any sub- limits.

### 3.3 Products Aggregate Limit

The Products Aggregate Limit is the most We will pay for the sum of:

- 3.3.1** all Damages for Loss and associated Defence Costs We must pay under clause 1.1 Products Liability;
- 3.3.2** all Damages for Loss, associated Defence Costs and Loss We must pay under clause 1.5 Clinical Trial Coverage; and
- 3.3.3** all Loss We must pay under clause 1.6 Product Withdrawal Expenses Coverage.

The Products Aggregate Limit is subject to the Overall Policy Aggregate Limit and any sub-limits.

### 3.4 Clinical Trial Aggregate Limit

**3.4.1** The Clinical Trial Aggregate Limit is the most We will pay for the sum of:

- a. all No Fault Compensation, Damages for Loss and associated Defence Costs covered under clauses 1.5.1, 1.5.2 and 1.5.4; and;
- b. Loss in the form of Medical Stop Loss Expense covered under clause 1.5.4.

**3.4.2** If a Medical Stop Loss Expense Aggregate Limit is stated in the Schedule for Medical Stop Loss Expense (if clause 1.5.4 Medical Payments Stop Loss Coverage is purchased), then the Medical Stop Loss Expense Aggregate Limit is the most We will pay for the sum of all Medical Stop Loss Expense We must pay under clause 1.5.4. The Medical Stop Loss Expense Aggregate Limit is subject to the Clinical Trial Aggregate Limit and any limit per Clinical Trial Participant or any other individual limit.

**3.4.3** The Clinical Trial Aggregate Limit is subject to the Overall Policy Aggregate Limit, the Products Liability Aggregate Limit and any applicable individual coverage section limits.

### 3.5 Errors and Omissions Aggregate Limit

**3.5.1** The Errors and Omissions Aggregate Limit is the most We will pay for the sum of all Damages for Loss and associated Defence Costs under clause 1.8 Errors and Omissions Liability and clause 4.14 Intellectual Property.

**3.5.2** The Errors and Omissions Aggregate Limit is subject to the Overall Policy Aggregate Limit.

### 3.6 Individual Coverage Sub-Limits

**3.6.1** If a sub-limit is stated in the Schedule for any coverage section, then the sub-limit is the most We will pay for the sum of all Damages for Loss, and, if applicable, associated Defence Costs, or Loss We must pay, whichever applies, under that coverage section. The sub-limit is subject to all applicable aggregate limits and the Overall Policy Aggregate Limit.

**3.6.2** Subject to Paragraph clause 3.2. above, the Personal Injury and Advertising Injury Limit is the most We will pay under clause 1.4 Advertising Injury and Personal Injury for the sum of all Damages for Loss sustained by any one person or organisation.

**3.6.3** Subject to clause 3.2 General Aggregate Limit above, the each Occurrence limit is the most We will pay for the sum of:

- a. Damages for Loss under clause 1.2 Public Liability; and
- b. Medical Expenses under clause 1.3 Medical Payments; for Loss arising out of any one Occurrence.

**3.6.4** Subject to clause 3.4 Clinical Trial Aggregate Limit, above, the Clinical Trial Participant limit is the most We will pay under clause 1.5.4 Medical Payments Stop Loss Coverage for all Medical Stop Loss Expense we must pay to a single Clinical Trial Participant.

### **3.7 Non-Cumulation of Limit of indemnity**

If any Loss or associated Defence Costs covered under this Policy are also covered in whole or in part under any other insurance policy issued by Us or an affiliated company prior to the inception date of this Policy, and both this Policy and such other insurance policy cover the Insured for any Loss or associated Defence Costs arising out of:

**3.7.1** substantially the same or related general harmful conditions or substances, or repeated or continuous exposure to substantially the same or related general harmful conditions or substances, or

**3.7.2** any Loss which extends over a period of days, weeks, months or longer;  
then the Indemnity Limit of this Policy shall be reduced by any amounts due to the Insured on account of such prior insurance policy. Such Indemnity Limit shall be reduced regardless of whether such Loss: (a) extends over more than one (1) Policy Period; or (b) arises as a result of one or more Occurrence or event. In no event shall we pay more for such Loss and associated Defence Costs, where applicable, covered under this Policy and all such other insurance policies than the Indemnity Limit set forth in the Schedule of this Policy reduced by any applicable Excess.

This provision shall not be construed as providing additional coverage under this Policy or providing coverage where excluded under any other provision of this Policy including any endorsements attached to it. All other terms, conditions, definitions and exclusions shall remain the same.

## SECTION 4 - GENERAL COVERAGE PROVISIONS

The following coverage provisions are applicable to one or more coverage sections.

### 4.1 Estates, Heirs and Legal Representatives

In the event of the death, mental disorder and/or other incapacity or insolvency or bankruptcy of the Insured, We will indemnify the estate, heirs, legal representatives or assignees of the Insured in respect of any civil liability of the Insured to the extent that the Insured would have been covered by under this Policy if the Insured was alive, had capacity or was not insolvent or bankrupt PROVIDED ALWAYS THAT such persons will observe and be subject to all the terms conditions and exclusions of this Policy insofar as they can apply.

### 4.2 Lessors of Equipment

We will indemnify the owner of equipment with whom the Insured has entered into a written contract or agreement for the hire of such equipment for the purpose of the Insured's business for Bodily Injury and/or Property Damage PROVIDED ALWAYS THAT:

- 4.2.1 coverage provided to the owner will be no more extensive than the coverage that would be provided to the Insured if they were held legally liable for the Bodily Injury and/or Property Damage; and
- 4.2.2 coverage will only be provided where the liability arises out the Insured's use of the equipment.

### 4.3 Leased or Rented Premises

4.3.1 We will indemnify the Insured for Property Damage to premises (including the fittings and fixtures) leased or rented to the Insured for the purpose of Your Work provided always that We will not provide indemnity against:

- a. any contractual liability; or
- b. the first \$1,000 of each and every occurrence of Property Damage caused other than by fire or explosion.

4.3.2 Notwithstanding clause 8.1.1, and clause 4.3.1a, We will indemnify a lessor with whom the Insured has entered into a written agreement for the rental or lease of premises (including the fittings and fixtures) for the purpose of Your Work for Property Damage PROVIDED ALWAYS THAT:

- a. coverage provided to the lessor will be no more extensive than the coverage that would be provided to the Insured if they were held legally liable for the Property Damage; and
- b. coverage will only be provided where the liability arises out the Insured's use of the premises.

### 4.4 Vendors

4.4.1 We will indemnify any person or organisation who is a vendor of Your Product for their liability for Loss in the form of Bodily Injury, Property Damage, Medical Monitoring Expense, Personal Injury, Advertising Injury or Clean-up Costs, but only if:

- a. You have agreed to add the vendor as an Insured for such Loss pursuant to a written contract You entered into with the vendor prior to the event which resulted in the Loss for which coverage is sought;
- b. the Loss arises out of Your Product distributed or sold in the regular course of the vendor's business; and
- c. the vendor is not a Life Science Contractor.

4.4.2 Such vendors are Insureds only to the extent, and for the Indemnity Limit, required by the contract; however, the following shall also apply:

- a. in no event shall the extent of coverage or the Indemnity Limit be greater than that provided for under this Policy; and
- b. if a vendor is an Insured under this clause 4.4, then the term "You" or "Your" as used in all exclusions applicable to this Policy shall also mean the vendor as Insured, and all exclusions applicable to a Named Insured shall also apply to the vendor.

**4.4.3** No vendor is an Insured for Loss:

- a. which the vendor is obligated to pay by reason of the assumption of liability in a contract or agreement; however, this limitation does not apply to liability for which the vendor would have in the absence of an agreement;
- b. based upon or arising out of:
  - i) any expressed warranty or representation unauthorised by You;
  - ii) any physical or chemical change in Your Product made intentionally by the vendor;
  - iii) repackaging of Your Product, except when unpacked solely for the purpose of inspection, demonstration, testing, or the substitution of parts under instructions from the manufacturer, and then repackaged in the original container;
  - iv) any failure to make such inspections, adjustments, tests or servicing that the vendor has agreed to make, or normally undertakes to make in the usual course of business, in connection with the distribution or sale of Your Product, or any failure to remove from sale or distribution Your Product once the shelf life or expiration date of such product has been reached;
  - v) demonstration, installation, servicing or repair operations regarding Your Product, except such operations performed at the vendor's premises in connection with the sale of Your Product;
  - vi) Your Product which, after distribution or sale by You, has been labelled or relabelled or used as a container, ingredient, part, or part or ingredient of any other thing or substance, by or for the vendor;
  - vii) the sale or distribution of Your Product under the name of the vendor;
  - viii) The sole negligence of the vendor for its own acts or omissions or those of its employees or anyone else acting on its behalf; however, this exclusion does not apply to the exceptions set forth in subparagraphs 4.4.3 b.iii) and 4.4.3 b.v) above, or to those inspections, adjustments, tests or servicing the vendor has agreed to undertake or normally undertakes in the usual course of business, in connection with the distribution or sale of Your Product;
- c. if the vendor is the same person or organisation from which You have acquired Your Product, or any ingredient, part or container, entering into, accompanying or containing Your Product; or
- d. if the vendor dispenses, distributes, furnishes or sells a drug, biologic, medical device, dietary supplement, cosmetic, cosmetic drug or medical food to any health care provider for the purpose of providing Healthcare Services to others.

**4.5 Life Science Contractors**

**4.5.1** We will indemnify the following Life Science Contractors;

- a. Clinical Trial Contractors,
  - b. Product Sales Contractors; or
  - c. Product Service Contractors (including scientific advisory boards),
- as an Insured for the Life Science Contractor's liability for Loss in the form of Bodily Injury, Property Damage, Medical Monitoring Expense, Personal Injury, Advertising Injury or Clean-up Costs, but only if:

- i) the Loss is caused, in whole or in part, by Your Work or Your Product;
- ii) You have agreed to add the Life Science Contractor as an additional Insured for such Loss pursuant to a written contract You entered into with the Life Science Contractor prior to the Loss.

- 4.5.2** Such Life Science Contractors are Insureds only to the extent, and for the Indemnity Limit, required by the contract; however, the following shall also apply:
- a. in no event shall the extent of coverage or the limits of insurance be greater than that provided for under this Policy;
  - b. no Life Science Contractor is an Insured with respect to liability for which the Life Science Contractor has agreed to assume the liability of another to pay Loss, unless the Life Science Contractor would have such liability in the absence of such agreement; and
  - c. if a Life Science Contractor is an Insured under clause 4.5, then the term "You" or "Your" as used in all exclusions applicable to this Policy shall also mean Life Science Contractors, and all exclusions applicable to the Named Insured shall also apply to Life Science Contractors.

## **4.6 Insured by Contract**

- 4.6.1** We will indemnify any person or organisation not otherwise identified as an Insured under any other provision of this Policy, or any endorsement attached thereto, as an Insured for liability for Loss in the form of Bodily Injury, Property Damage, Medical Monitoring Expense, Personal Injury, Advertising Injury or Clean-up Costs, but only if:
- a. You have agreed to add such person or organisation as an additional Insured for such Loss pursuant to a written contract You entered into with the person or organisation prior to the event which resulted in the Loss for which coverage is sought; and
  - b. such person or organisation is vicariously liable for Your Work or Your Product.

- 4.6.2** Such persons or organisations are additional Insureds only to the extent, and for the limits of insurance, required by the contract; however, the following shall also apply:
- a. in no event shall the extent of coverage or the limits of insurance be greater than that provided for under this Policy;
  - b. no such person or organisation is an additional Insured with respect to liability for which the person or organisation has agreed to assume the liability of another to pay Loss, unless the person or organisation would be liable in the absence of such agreement; and
  - c. if a person or organisation is an Insured under this clause 4.6, then the term "You" or "Your" as used in all exclusions applicable to this Policy shall also mean such person or organisation, and all exclusions applicable to You shall also apply to such person or organisation.

## **4.7 Ethics Committee**

- 4.7.1** We will indemnify Ethics Committees as an Insured for their liability for Loss in the form of Bodily Injury, Property Damage, Medical Monitoring Expense, Personal Injury, Advertising Injury or Clean-up Costs, but only if You have agreed to add such Ethics Committee as an additional Insured for such Loss pursuant to a written contract You entered into with the Ethics Committee prior to the event which resulted in the Loss for which coverage is sought; and

- 4.7.2** Such Ethics Committees are Insureds only to the extent, and for the Indemnity Limit, required by the contract; however, the following shall also apply:
- a. in no event shall the extent of coverage or the limits of insurance be greater than that provided for under this Policy;
  - b. no Ethics Committee is an Insured with respect to liability for which Ethics Committee

has agreed to assume the liability of another to pay Loss, unless the Ethics Committee would have such liability in the absence of such agreement; and

- c. if an Ethics Committee is an Insured under clause 4.5, then the term "You" or "Your" as used in all exclusions applicable to this Policy shall also mean Ethics Committee, and all exclusions applicable to the Named Insured shall also apply to Ethics Committee.

#### **4.8 Indemnity to Other Persons**

We will indemnify any officer or member of the Insured's catering, social, sports, educational, medical, dental and welfare organisations and fire, security, first aid and ambulance services in their respective capacity as such, but not any medical or dental practitioner in respect of medical or dental services, PROVIDED ALWAYS THAT such persons will observe and be subject to all the terms conditions and exclusions of this Policy insofar as they can apply.

#### **4.9 Acquired Organisations**

In the event You acquire or have in the past acquired the assets, business or organisation of another person or organisation, either directly or indirectly, then the following shall apply:

##### **4.9.1** no person or organisation is an Insured under this Policy with respect to:

- a. the ownership, maintenance or use of any such assets, business or organisation; or
- b. the conduct of any such person or organisation whose assets, business or organisation You acquire;

for any Loss that occurred, in whole or in part, or in the case of Advertising Injury or Personal Injury, arising out of any offence first committed, in whole or in part;

- i) before the date of acquisition of such assets, business or organisation; and
- ii) if the acquisition took place during the Policy Period, later than:
  - ninety (90) days after the date of acquisition; or
  - the end of the Policy Period; whichever comes first.

Coverage provided under this clause may be extended upon receipt and acceptance by Us of additional underwriting information and may be subject to payment of additional premium having regard to the nature of the risk to be assumed by Us.

#### **4.10 Newly Formed Organisation**

In the event You form a new organisation during the Policy Period, then no person or organisation is an Insured with respect to the conduct of such organisation for any Loss that occurred, in whole or in part, or in the case of Advertising Injury or Personal Injury, arising out of any offence first committed, in whole or in part, later than:

##### **4.10.1** ninety (90) days after the date the organisation was formed; or

##### **4.10.2** the end of the Policy Period; whichever comes first.

Coverage provided under this clause may be extended upon receipt and acceptance by Us of additional underwriting information and may be subject to payment of additional premium having regard to the nature of the risk to be assumed by Us.

#### **4.11 Loss of or Damage to Documents**

We will indemnify the Insured for reasonable and necessary costs and expenses incurred by the Insured (although not the Insured's own time) in replacing, restoring or reconstituting Documents due to a physical loss of or damage to such Documents that are the property of the Insured or are in the Insured's care, custody or control in the conduct of Your Work and where such loss or damage is discovered and is notified to Us during the Policy Period.

#### **4.12 Inquiry Costs**

We will indemnify the Insured for the reasonable and necessary legal costs and expenses incurred with Our prior written consent (not to be unreasonably withheld or unreasonably delayed) for representation of the Insured at any regulatory inquiry, disciplinary proceeding or other proceedings (other than in respect of a Claim) that the Insured first became aware of and was first initiated during the Policy Period.

#### **4.13 Joint Venture**

We will indemnify the Insured for any Claim made against the Insured arising out of the acts, errors or omissions of the Insured as part of any joint venture, but only where we have agreed to indemnify the Insured under Section 1 - Insuring Clauses and Section 2 - Defence Costs, provided always that no coverage shall be provided to any joint venture partner of the Insured.

#### **4.14 Intellectual Property**

We will pay, under Insuring Clause 1.8 Errors and Omissions Liability, all Damages the Insured becomes legally obligated to pay for Economic Injury caused by an unintentional breach of Intellectual Property.

Exclusion 7.12 Intellectual Property Rights shall not apply to this Extension.

## SECTION 5 - EXTENDED REPORTING PERIODS

### 5.1 When Extended Reporting Periods Apply

- 5.1.1** Extended Reporting Periods apply to all claims-made coverages where:
- this Policy is cancelled or not renewed by You or by Us; or
  - We renew or replace this Policy with insurance that:
    - has a Retroactive Date later than the date shown in the Schedule; or
    - does not apply to Loss covered on a claims-made basis.
- 5.1.2** Extended Reporting Periods do not extend the Policy Period or change the scope of coverage provided. They apply only to Claims for Loss provided that such Loss:
- is covered under a claims-made coverage section or claims-made endorsement; and
  - occurs before the end of the Policy Period, but not before the Retroactive Date, if any, shown in the Schedule.
- 5.1.3** Once in effect, Extended Reporting Periods may not be cancelled.
- 5.1.4** Extended Reporting Periods do not:
- apply to Claims that are covered under any subsequent insurance You purchase, or that would be covered but for exhaustion of the amount of insurance applicable to such Claims; or
  - reinstate or increase the Indemnity Limit.

### 5.2 Automatic Extended Reporting Period

- 5.2.1** An Automatic Extended Reporting Period is automatically provided without additional charge. This period starts with the end of the Policy Period and lasts for sixty (60) days.
- 5.2.2** Claims made against the Insured during the Automatic Extended Reporting Period are covered provided that:
- the Loss takes place before the expiration of the Policy Period;
  - Claims for such Loss are reported to Us, through written notice to Us, prior to the expiration of the Automatic Extended Reporting Period; and
  - the Loss is otherwise covered under this Policy.

### 5.3 Run-off Extended Reporting Period

A Run-off Extended Reporting Period is provided under the following circumstances:

- 5.3.1** The First Named Insured may purchase a Run-off Extended Reporting Period of up to seven (7) years duration which shall commence immediately following the expiration of the Policy Period.
- 5.3.2** A Run-Off Extended Reporting Period may only be purchased if the First Named Insured:
- notifies Us in writing prior to the expiration of the Policy Period that it has elected to purchase a Run-off Extended Reporting Period; and
  - the full premium for the Run-off Extended Reporting Period is paid and received by Us within thirty (30) days of:
    - providing such notice to Us; or
    - the expiration of the Policy Period, whichever is sooner.
- 5.3.3** Once the premium is fully paid and received by Us, the premium is fully earned, and the Run-off Extended Reporting Period may not be cancelled by You or Us.

- 5.3.4** The premium charged for a Run-off Extended Reporting Period of seven (7) years duration shall be no greater than two hundred percent (200%) of the premium for this Policy.
- 5.3.5** Claims made against the Insured during the Run-off Extended Reporting Period are covered provided that:
- a. the Loss takes place before the expiration of the Policy Period;
  - b. Claims for such Loss are reported to Us, through written notice to Our claims department prior to the expiration of the Run-off Extended Reporting Period; and
  - c. the Loss is otherwise covered under this Policy.
- 5.3.6** If a Run-off Extended Reporting Period is purchased, We shall issue an endorsement setting forth the terms, not inconsistent with this section, which shall apply to such period.

## SECTION 6 - KNOWN CRITICAL FACTS

### 6.1 Known Critical Facts

- 6.1.1** No coverage is afforded under this Policy for any Loss connected to a Critical Fact known by an Insured Representative prior to the inception date of this Policy unless:
- a. the Critical Fact is set forth in an endorsement listing covered known Critical Facts; or
  - b. if this is a Renewal Policy:
    - i) the Critical Fact first becomes known to an Insured Representative after the initial coverage date; and
    - ii) You have reported the Critical Fact to us prior to the inception date of this Renewal Policy.

Loss is connected to a Critical Fact if such Loss arises out of the Critical Fact, or if the facts and circumstances resulting in the Critical Fact also resulted in the Loss.

A Critical Fact set forth in a document in the possession of an Insured Representative shall be considered known by the Insured Representative.

- 6.1.2** This requirement applies to all coverage sections and any coverages added by endorsement.

### 6.2 Definition of Critical fact

Critical Fact means the following as it applies to the coverage sections stated below:

#### 6.2.1 ALL COVERAGE PARTS

A verbal or written demand for any Damages which would be covered under this Policy;

- 6.2.2** For any Loss covered under clause 1.1 Products Liability, Clause 1.5 Clinical Trial Coverage and Clause 1.8 Product Withdrawal Expenses, Critical Fact means the following:

- a. the suspension of a Clinical Trial for:
  - i) safety reasons; or
  - ii) non-compliance with the trial protocol, where there is a reasonable probability that non-compliance would place a person at increased risk of Bodily Injury;
- b. any of the following actions:
  - i) A Class I Product Recall regarding, or any banning or seizure of:
    - i. Your Product;
    - ii. any product containing Your Product; or
    - iii. any product where Your Work was performed in connection with such product;
  - ii) the addition of or change to a black box warning regarding any product referenced in clause 6.2.1b.i) above; or
  - iii) the issuance of a "Dear Healthcare Professional" letter regarding any product referenced in clause 6.2.1b.i) above advising that a Severe Adverse Event could occur;
- c. any criminal investigation of the Insured related to Your Product or Your Work;
- d. an Adverse Event concerning Your Product or Your Work provided that all of the following three (3) criteria below ((i), (ii) and (iii)) have been satisfied:
  - i) the Adverse Event has been reported to, or was required to be reported to, the Therapeutic Goods Administration or other appropriate governmental authority;
  - ii) the Adverse Event is a Severe Adverse Event; and
  - iii) in response to the Severe Adverse Event, the person at the Insured responsible for

monitoring, evaluating and reporting Adverse Events regarding Your Work or Your Product, or recommending label or product changes in response to a Severe Adverse Event for the Insured has recommended to an Insured Representative or the appropriate governmental authority that a product label should be changed or a product be redesigned or reconstituted; or

- e. a defect or malfunction in Your Product or error in Your Work set forth in a document in the possession of, or otherwise known by an Insured Representative of the Named Insured, where the continued use of, or exposure to, Your Product or Your Work, without correction, would potentially cause a Severe Adverse Event.

**6.2.3** For any Loss covered under any clause 1.2 Public liability, clause 1.3 Medical Payments, clause 1.7 Property Damage for Goods and Products in Your Care, Custody or Control or clause 1.9 Biological Agents Liability, where such Loss is covered under the Policy on a claims-made or claims-made and reported basis, Critical Fact means the following which has occurred prior to the inception date of this Policy:

- a. any event involving injury to a person resulting in hospitalisation or death which occurs on premises owned or occupied by or loaned or rented to an Insured, or during or as a result of operations performed by an Insured;
- b. any sickness or disease sustained by a person which is claimed to have resulted in whole or in part from the person's presence on or contact with premises owned or occupied by or loaned or rented to an Insured, or from operations performed by an Insured; or
- c. any event involving Property Damage to the property of a person or organisation in an amount in excess of fifty percent (50%) of any Excess applicable to this Policy, where such Property Damage is claimed to have resulted in whole or in part from conditions on premises owned or occupied by or loaned or rented to an Insured, or from operations performed by an Insured;
- d. any release or escape of, or contact with or exposure of a person to, or contamination of the real or personal property of a person or organisation with, Biological Agents, which release, escape, contact or exposure occurred at or from premises owned or occupied by, or rented or loaned to, an Insured;
- e. any notice that any person or organisation referenced in a. b. c. or d. above has obtained legal representation; or
- f. any criminal investigation of an Insured or an Insured's officers or agents related to:
  - i) any premises owned or occupied by or loaned or rented to an Insured; or
  - ii) an Insured's work.

**6.2.4** For any Loss covered under any clause 1.2 Public liability, clause 1.3 Medical Payments, clause 1.7 Property Damage for Goods and Products in Your Care, Custody or Control or clause 1.9 Biological Agents Liability, where such Loss is covered under the Policy on an Occurrence basis, Critical Fact means the following which has occurred prior to the inception date of this Policy:

- a. the discovery of a dangerous condition on any premises owned or occupied by or loaned or rented to an Insured, or any work improperly performed by the Insured, where the dangerous condition or work, if not addressed, would place a person or organisation at imminent risk of Loss;
- b. any safety or violation notice issued by a governmental body, or any known violation of an applicable regulation, regarding premises owned or occupied by or loaned or rented to an Insured, or any work performed by an Insured, which requires immediate corrective measures or which places a person or organisation at imminent risk of harm; or
- c. any criminal investigation of an Insured or an Insured's officers or agents related to:
  - i) any premises owned or occupied by or loaned or rented to an Insured; or
  - ii) an Insured's work.

**6.2.5** For any Loss covered under clause 1.4 Advertising Injury and Personal Injury Liability or clause 1.10 Enhanced Privacy and Data Protection Coverage, Critical Fact means the following which has occurred prior to the inception date of this Policy:

- a. An unauthorised breach of:
  - i) an entire computer system;
  - ii) any part of a system containing personally-identifiable information; or
  - iii) any other storage system containing private or privileged information; where the Insured:
    - (i) either owns or controls the system or the part from which the breach occurred;
    - (ii) was otherwise responsible for the breach; or
    - (iii) is required to give notice of the breach to any government entity;
- b. a known loss or theft of patient data or Personal Protected Information, or failure to keep such data or information private, where privacy is required;
- c. an Insured has received notice of a cease and desist order or other written notice alleging Advertisement infringement, or otherwise becomes aware that its Advertisement is infringing upon another's advertisement; or
- d. an Insured receives notice of a cease and desist order or other written notice alleging libel, slander, or invasion of privacy, or otherwise becomes aware that it is engaging or has engaged in such conduct.

**6.2.6** For any Loss covered under clause 1.8 Errors and Omissions Liability, Critical Fact means the following which has occurred prior to the inception date of this Policy:

- a. a client of an Insured has cancelled a contract with the Insured, or has requested a refund or withheld payment from the Insured due to the Insured's alleged:
  - i) non-performance;
  - ii) missed milestone or project deadline; or
  - iii) product or work defect;
- b. an Insured's client has invoked, or sent written notice of its intention to invoke, a liquidated damages or any penalty clause in a contract;
- c. payment from a client of the Insured is more than 120 days past due, or an Insured has initiated collection or other proceedings or a Claim against a client for delinquent payment;
- d. a product recall has been initiated by an Insured's client or others for products produced or worked on by the Insured, or that incorporate the Insured's product or work; or
- e. an Insured has received written notice of a contract dispute, alleging non-performance of an Insured's product or work in whole or in part.

## SECTION 7 - GENERAL POLICY EXCLUSIONS

The following exclusions apply to all Loss unless otherwise stated below. Where an exclusion applies to Loss, it shall also apply to any covered Defence Costs associated with such Loss.

This insurance does not apply to:

### 7.1 Abuse or Molestation

Loss arising out of any:

- 7.1.1** actual or threatened abuse or molestation, by anyone, of any person while in the care, control or custody of any Insured; or
- 7.1.2** employment, investigation, supervision, or reporting to or failure to report to the proper authorities, or hiring, retention, or discharge of or failure to discharge a person for whom any Insured is or ever was legally responsible and whose conduct would be excluded in subparagraph 7.1.1 above.

This exclusion does not apply to the extent coverage is provided under clause 1.5.3 Abuse or Molestation Liability.

### 7.2 Aircraft, Mechanically Propelled Vehicles and Watercraft

Loss arising out of:

- 7.2.1** the ownership, possession, maintenance, operation or use by or on behalf of the Insured of any:
  - a. airline, aircraft, aerodrome, airport, spacecraft, or launch sites;
  - b. hovercraft or watercraft other than hand propelled watercraft or other watercraft not exceeding eight (8) metres in length; or
  - c. Mechanically Propelled Vehicle.

- 7.2.2** This exclusion shall not apply to liability caused by or arising from;
  - a. the use of Mechanically Propelled Vehicles as a Tool of Trade at the Insured's premises or on any site at which the Insured is working; or
  - b. the loading or unloading of any vehicle or the bringing to or taking away of a load from any vehicle; or
  - c. damage to any building, bridge, weighbridge, road or to anything beneath caused by vibration or by the weight of any vehicle or its load.

PROVIDED ALWAYS THAT we will not provide indemnity against liability:

- i) in respect of which compulsory insurance or security is required under any legislation governing the use of the vehicle; or
- ii) for which indemnity is provided by any other insurance.

### 7.3 Antitrust/Unfair Competition/Consumer Fraud

Loss based upon, arising out of or in any way related to any actual or alleged:

- 7.3.1** antitrust violation, restraint of trade, price-fixing, or monopolistic practices;
- 7.3.2** unfair competition;
- 7.3.3** piracy;
- 7.3.4** false, deceptive, or unfair trade practices;
- 7.3.5** consumer fraud; or
- 7.3.6** violation of consumer protection laws.

In the event a Claim is made against the Insured alleging:

**7.3.7** any Loss excluded in 7.3.1 – 7.3.3 above; and

**7.3.8** any other Loss;

then this exclusion shall apply to preclude coverage for the entire Claim even if any portion of the Claim would have been covered in the absence of such allegations.

#### **7.4 Asbestos**

Loss based upon or arising out of or in connection with:

**7.4.1** the actual, alleged, threatened or suspected existence, presence, inhalation, absorption or ingestion of or the contact with, exposure to or use of asbestos in any form, in whole or in part; or

**7.4.2** any Claim by or on behalf of a governmental entity or others for Damages because of testing for, monitoring, cleaning up, removing, containing, treating, detoxifying, or neutralising, or in any way responding to or assessing the effects of asbestos.

As used in this exclusion, asbestos includes any form of the mineral known as asbestos, including any material, waste, equipment, device, product or good containing asbestos, or any dust or particles containing asbestos, whether or not the asbestos is friable and whether or not the asbestos is in or on any thing or structure or in the air, soil, or groundwater.

#### **7.5 Batch or Integrated Occurrences**

Loss, products or work covered under any “extended coverage”, “batch” or “integrated occurrence” language in any other policy, including language in any other policy designed to cover Claims, related Claims or other events which commenced or occurred prior to the Policy Period, unless We specifically agree to provide coverage for such Loss, products or work in an endorsement attached to this policy.

#### **7.6 Biological Agents (Including Mould and Other Fungi)**

**7.6.1** Loss which would not have occurred, in whole or in part, but for the actual, alleged or threatened contact with, exposure to, existence of, or presence of, any Biological Agents on or within a building or structure, or at or from any premises, site or location which is or was at any time owned or occupied by, or rented or loaned to, any Insured, regardless of whether any other cause, event, material or product contributed concurrently or in any sequence to such Loss; and

**7.6.2** Loss arising out of the abating, testing for, monitoring, cleaning up, removing, containing, treating, detoxifying, neutralising, remediating or disposing of, or in any way responding to, or assessing the effects of, Biological Agents by any Insured or by any other person or entity.

However:

- a. Clause 7.6.1 of this exclusion does not apply to Loss caused by Biological Agents that are on, or are contained in, a good or product intended for bodily consumption or use as a medical product or device; and
- b. Clauses 7.6.1 and 7.6.2 of this exclusion do not apply to Loss from Biological Agents for which coverage is afforded under clause 1.9 Biological Agents Liability Coverage.

#### **7.7 Contractual Liability**

Loss for which the Insured is obligated to pay by reason of the assumption of liability in a contract or agreement. This exclusion does not apply to liability to which this insurance otherwise applies for:

**7.7.1** any Loss that the Insured would have in the absence of the contract or agreement; or

**7.7.2** liability for Loss in the form of Bodily Injury, Property Damage, Medical Monitoring Expense, Personal Injury, Advertising Injury or Clean-up Costs otherwise covered under this Policy, where such liability for loss of another person or organisation is assumed in an Insured Contract, provided that the event, offence or Occurrence resulting in such Loss occurs after the execution of the Insured Contract.

However, coverage for such assumption of liability is subject to the following:

- 7.7.3** the liability assumed pursuant to an Insured Contract is assumed solely to the extent and for the amounts required in the Insured Contract, and in no event for greater than the Indemnity Limit applicable to the coverage section for which such liability is assumed;
- 7.7.4** if You have agreed to assume the liability of the following persons or organisations:
- i) lessors of equipment; or
  - ii) lessors of premises;
- then We will cover You for such assumption of liability only if the person or organisation is not solely negligent;
- 7.7.5** if You have agreed to assume the liability of a vendor then we will cover You for such assumption of liability only if the vendor is not solely negligent, or if solely negligent, was found liable based solely upon:
- a. the repackaging of Your Product when unpacked solely for the purpose of inspection, demonstration, testing or the substitution of parts under instructions from the manufacturer, and then repackaged in the original container;
  - b. demonstration, installation, servicing or repair operations regarding Your Product performed at the vendor's premises in connection with the sale of Your Product; or
  - c. those inspections, adjustments, tests or servicing the vendor has agreed to undertake or normally undertakes in the usual course of business, in connection with the distribution or sale of Your Product.
- 7.7.6** if You have agreed to assume the liability of any other person or organisation not otherwise identified above then We will cover You for such assumption of liability only if such person or organisation is vicariously liable for Your Work or Your Product; and
- 7.7.7** if Your assumption of liability under an Insured Contract also includes liability to a party other than an Insured for, or for the cost of, that party's defence, then reasonable legal fees and necessary litigation expenses incurred by or for such party are deemed to be Damages for Bodily Injury, Property Damage, Medical Monitoring Expense, Personal Injury, Advertising Injury, or Clean-up Costs otherwise covered under this Policy, provided that such legal fees and litigation expenses are for defence of that party against a Claim in which Damages to which this insurance applies are alleged.

## **7.8 Designated Products Exclusion**

- 7.8.1** Loss based upon, arising out of or in any way related to any good or product listed below, including but not limited to any product or substance containing such product or substance, or containing a similar chemical formula of such product or substance, or which is a derivative of such product or substance:
- a. Belladonna (Atropa belladonna), including but not limited to teething products, when used in or on a person under the age of 18;
  - b. Benzocaine when used either orally, or in or on the ear, nose or throat, to treat person under the age of 18;
  - c. Birth control or fertility goods or products;
  - d. Bisphosphonates;
  - e. Breast Implants;
  - f. Cold therapy products, meaning any device that operates by pumping liquid through a plastic bag or other receptacle and is applied to the body to reduce temperature;
  - g. Depakote (divalproex sodium);
  - h. Di-(2-ethylhexyl) Phthalate (DEHP neonatal goods or products, meaning any good or product containing DEHP used to treat neonatal patients or to which such patients are exposed;
  - i. Diethylstilbestrol (DES);

- j. Ephedra, Ephedrine or pseudoephedrine except where used in prescription products;
- k. Hormone replacement products approved for menopause treatment, or which is intended to be used for such treatment;
- l. Inferior vena cava filters (IVC filters);
- m. Isoretinoin;
- n. Kratom;
- o. Mesh Implants, meaning surgical mesh or other similar product or woven fabric either temporarily or permanently implanted into a human;
- p. Metal-on-metal implant meaning any knee, hip or other joint implant, replacement or resurfacing system and the component parts of any of the foregoing ("implant") where: (1) a part of the implant designed for motion is made of metal; and (2) the moving part, while either at rest or in motion, contacts another metal part of the implant that is designed for motion, or designed to meet or serve as a socket or contact surface against which the moving part comes to rest;
- q. Metoclopramide;
- r. Nitrosamines including but not limited to N-Nitrosodimethylamine (NDMA), N-Nitro-N-methyl-4-aminobutyric acid (NMBA), N-Nitrosodiethylamine (NDEA), N-N-Dimethylformamide (DMF);
- s. Phentermine used in combination with fenfluramine (including but not limited to Pondimin) or dexfenfluramine (Redux);
- t. Phospho soda, sodium phosphate, or any phospho soda or sodium phosphate based agents;
- u. Proton Pump Inhibitors;
- v. Rosiglitazone;
- w. Selective Serotonin Reuptake Inhibitors (SSRI);
- x. Silicone product (Implanted), meaning any good or product containing liquid or gel silicone which is intended to be, or which is implanted;
- y. Talc;
- z. Thalidomide;
- aa. Tianeptine;
- bb. Tobacco or tobacco-related products; or
- cc. Vaping products, meaning any product used in the act of inhaling or exhaling the aerosol, often referred to as vapor, which is produced by an e-cigarette or device similar in appearance or function, including but not limited to vapes, vaporizers, vape pens, hookah pens, electronic cigarettes, e-pipes, electronic nicotine delivery systems (ENDS), or tank or drip systems, whether or not any such devices contain or were designed to contain nicotine.

**7.8.2** This exclusion does not apply to Clause 1.5 – Clinical Trial Coverage (if afforded under this Policy), except, however, this exclusion shall continue to apply to the following:

- a. Loss concerning, or a Claim for Loss made by or on behalf of, any Clinical Trial Participant where:
  - i) the Insured knows or has reason to know at the inception of the Clinical Trial that the Clinical Trial Participant is a Vulnerable Class Member;
  - ii) the Clinical Trial Participant continues to participate in the Clinical Trial after the Insured learns that the Clinical Trial Participant is a Vulnerable Class Member; or
  - iii) the Clinical Trial does not have an Approved Protocol in place to identify whether the Clinical Trial Participant is a Vulnerable Class Member; or

- b. Loss directly or indirectly based upon, arising out of or in any way related to Nitrosamines as defined in clause 7.8.1r.

## **7.9 Employer's Liability**

- 7.9.1** Loss arising out of Bodily Injury, mental injury (including but not limited to mental stress and mental anguish), harassment, bullying, invasion of privacy, disease or death of any Employee of the Insured or damage to or destruction of any property of any Employee, including loss of use, arising out of, or in the course of, their employment or any dispute in connection with employment.
- 7.9.2** This exclusion does not apply to liability where otherwise covered under this Policy:
  - a. assumed by the Insured under an Insured Contract; or
  - b. arising out of the Employee's voluntary participation in an Approved Clinical Trial.

## **7.10 Employment Practices**

Loss to a person arising out of any:

- 7.10.1** refusal to employ that person;
- 7.10.2** termination of that person's employment; or
- 7.10.3** employment-related practices, policies, acts or omissions, including but not limited to coercion, demotion, evaluation, assignment or reassignment, transfer, discipline, hiring or the handling of employment references, defamation, harassment, humiliation, malicious prosecution, invasion or other violation of any right of privacy, occupancy or publicity, or discrimination directed at that person based upon race, colour, creed, religion, political belief, age, physical type, physical or mental limitation or handicap, medical condition, sex or sexual orientation, or upon any other basis directed at that person.

## **7.11 Healthcare Services**

Loss based upon or arising out of the rendering or failure to render Healthcare Services. This exclusion does not apply to the following where otherwise covered under this Policy:

- 7.11.1** Bodily Injury or Economic Injury, where applicable, caused by a defect, deficiency, inadequacy or dangerous condition in Your Product;
- 7.11.2** Bodily Injury caused by first aid services, including cardiopulmonary resuscitation, other than in connection with an Approved Clinical Trial;
- 7.11.3** Bodily Injury, Medical Monitoring Expense or Economic Injury, where applicable, resulting from services performed in connection with an Approved Clinical Trial provided that such services are within the scope of, and specifically described within, the applicable written protocol for such trial;
- 7.11.4** Economic Injury covered under clause 1.8 Errors and Omissions Liability caused by advice provided by You with respect to the use of Your Product;
- 7.11.5** Medical Expenses paid under clause 1.3 Medical Payments; or
- 7.11.6** Medical Stop Loss Expense paid under clause 1.5 Clinical Trial Coverage.

#### **7.12 Intellectual Property**

Loss based upon, arising out of or in any way related to any actual or alleged assertion, infringement or violation, by any person or entity including the Insured, of any Intellectual Property.

In the event a Claim is made against the Insured alleging a Loss concerning intellectual property rights as described above or any other Loss then this exclusion shall apply to preclude coverage for the entire Claim even if any portion of the Claim would have been covered in the absence of the allegations concerning intellectual property rights.

#### **7.13 Intentional, Fraudulent or Criminal Acts**

Loss based upon or arising out of:

- 7.13.1** any criminal or fraudulent acts committed by or at the direction of, or with the consent or knowledge of the Insured;
- 7.13.2** the Insured's intentional disregard of, or deliberate, wilful or intentional non-compliance with, any applicable, federal, state or local law, regulation or ordinance, or any legal or administrative complaint, notice letter, instruction or direction issued by any government entity; or
- 7.13.3** any other act intended by the Insured to cause Loss, in whole or in part; however, this clause does not apply to the known side effects of Your Product or a product on which Your Work was performed, so long as such side effects are reported to the appropriate government authority as soon as reasonably possible after they become known to the Insured.

In the event the Loss is based upon or arising out of the acts referenced in 7.13.1 – 7.13.3 by an Insured Representative of any Named Insured, then this exclusion shall apply to all Insureds; otherwise this exclusion shall apply only to the Insured responsible for such action.

#### **7.14 Listed Human Disease**

Loss arising directly or indirectly from, related to or in connection with a Listed Human Disease or any directly or indirectly related condition or threat or fear thereof (whether actual or perceived).

#### **7.15 Named Insured v. Named Insured**

Any Claim by a Named Insured against any other Named Insured.

#### **7.16 Nuclear or Radioactive Material**

- 7.16.1** Loss based upon or arising out of the "hazardous properties" of "nuclear material" if such material is:
  - a. at or has been discharged or dispersed from any "nuclear facility" owned by, or operated by or on behalf of, any Insured; or
  - b. contained in "spent fuel" or "waste" at any time transported, handled, stored, disposed of, processed, treated, possessed or used by or on behalf of any Insured;
- 7.16.2** Loss in any way related to the furnishing by any Insured of services, materials, parts or equipment in connection with the planning, construction, maintenance, operation or use of any "nuclear facility"; or
- 7.16.3** Loss based upon or arising out of the existence, required removal or abatement of radon or other naturally occurring radioactive materials present on or below the ground or emanating into a location owned, leased or under the care, custody or control of the Insured.
- 7.16.4** As used in this exclusion, the following definitions apply:
  - a. "Hazardous properties" includes radioactive, toxic or explosive properties.
  - b. "Nuclear material" means "source material", "special nuclear material", or "by-product material".
  - c. "Source material", "special nuclear material", and "by-product material" have the

meanings given them by the United States Atomic Energy Act of 1954 or in any law amendatory thereof.

- d. "Spent fuel" means any fuel element or fuel component, solid or liquid, which has been used or exposed to radiation in a nuclear reactor.
- e. "Waste" means any waste material (a) containing "by-product material" other than the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its "source material" content; and (b) resulting from the operation by any person or organisation of any "nuclear facility" included under the first two paragraphs of the definition of "nuclear facility".
- f. "Nuclear facility" means:
  - i) Any "nuclear reactor";
  - ii) Any equipment or device designed or used for separating the isotopes of uranium or plutonium; processing or utilising "spent fuel"; or handling processing or packaging "waste";
  - iii) Any equipment or device used for the processing, fabricating or alloying of "special nuclear material" if at any time the total amount of such material in the custody of the Insured at the premises where such equipment or device is located consists of or contains more than 25 grams of plutonium or uranium 233 or any combination thereof, or more than 250 grams of uranium 235; or
  - iv) Any structure, basin, excavation, premises or place prepared or used for the storage or disposal of "waste";

And includes the site on which any of the foregoing is located, all operations conducted on such site and all premises used for such operations.
- g. "Nuclear reactor" means any apparatus designed or used to sustain nuclear fission in a self-supporting chain reaction or to contain a critical mass of fissionable material.

## 7.17 PFAS

Loss, damages (including but not limited to punitive and/or exemplary damages), compensation, loss, liability, penalties, fines, fees, Defence Costs, expenses, or any other amount or relief, of any kind whatsoever directly or indirectly and regardless of any other cause contributing concurrently or in any sequence, originating from, caused by, arising out of, contributed to by, resulting from, or otherwise in connection with any PFAS, such as any perfluoroalkyl or polyfluoroalkyl substances for example, including, but not limited to, any cost to clean-up, detoxify, remove, monitor, contain, test for or in any way respond to or assess the effect of any PFAS.

## 7.18 Pollution

- 7.18.1** Loss directly or indirectly caused by, arising from or contributed to by the discharge, dispersal, release, seepage, migration or escape of Pollutants into or upon buildings or structures, water, land or the atmosphere;
- 7.18.2** any costs incurred in removing nullifying or cleaning up Pollutants;
- 7.18.3** any costs incurred in preventing the escape of Pollutants; or
- 7.18.4** Loss directly or indirectly caused by, arising from or contributed to by the discharge, dispersal, release, seepage, migration or escape of Pollutants caused by any products which have been discarded, dumped, abandoned or thrown away by others.
- 7.18.5** Provided clauses 7.18.1 and 7.18.2 shall not apply where the Loss arises from a sudden, identifiable, unintended and unexpected incident which takes place in its entirety at a specific time and place during the Policy Period and occurs outside the United States of America and Canada and their respective protectorates and territories.

#### **7.19 Products in Your Possession and Incomplete Work**

Bodily Injury or Property Damage arising out of or caused by:

**7.19.1** Your Products that are still in Your physical possession; or

**7.19.2** Your Work that has not yet been completed or abandoned. However, Your Work will be deemed completed at the earliest of the following times:

- a. when all of the work called for in Your contract has been completed.
- b. when all of the work to be done at the job site has been completed if Your contract calls for work at more than one job site.
- c. when that part of the work done at a job site has been put to its intended use by any person or organisation other than another contractor or subcontractor working on the same project.

Work that may need service, maintenance, correction, repair or replacement, but which is otherwise complete, will be treated as completed.

This exclusion shall only apply to clause 1.1 Products Liability Insuring Clause.

#### **7.20 Professional Liability other than Healthcare Services**

Loss based upon or arising out of the rendering of or failure to render any Professional Service by the Insured or on the Insured's behalf, whether or not such Professional Service is ordinary to the Insured's profession and regardless of whether or not a Claim is brought by a client or any other person or organisation.

However, this exclusion does not apply to:

**7.20.1** Loss in the form of Economic Injury covered under clause 1.8 Errors and Omissions Liability;

**7.20.2** Loss resulting from Your Work as a Life Science Contractor; or

**7.20.3** any other such Loss where we specifically agree to provide coverage for the Loss by endorsement attached to this Policy.

#### **7.21 Recall of Products, Work or Impaired Property**

Loss incurred by You or others for the loss of use, withdrawal, recall, inspection, repair, replacement, adjustment, removal or disposal of:

**7.21.1** Your Product or any property or product containing or incorporating Your Product;

**7.21.2** Your Work or any property on which Your Work is or was performed; or

**7.21.3** Impaired Property;

regardless of whether such use, withdrawal, recall, inspection, repair, replacement, adjustment, removal or disposal is performed by any Insured or others. However, this exclusion does not apply to:

- a. Withdrawal Expenses covered under clause 1.6 Product Withdrawal Expenses Coverage.
- b. Bodily Injury caused by:
  - i) the removal of a medical device implanted, or tissues, organs or biological material transplanted, into human beings where such removal is a result of a Class I Product Recall, including the Medical Expenses incurred to conduct the removal; or
  - ii) the removal of a medical device implanted into a Clinical Trial Participant at the direction of the Clinical Trial Participant where such removal is the result of a device malfunction, including the Medical Expenses incurred to conduct the removal.

- c. Economic Injury sustained by others, covered under clause 1.8 Errors and Omissions Liability resulting from the loss of use of:
  - i) Your Product;
  - ii) property containing or incorporating Your Product; or
  - iii) property on which Your Work was performed; in connection with the ownership, maintenance or use of Your Product or Your Work.

#### **7.22 Silica**

Loss arising directly or indirectly from or in connection with any actual, alleged, or threatened exposure to or ingestion, inhalation, absorption or presence of silica or silica dust in any form.

#### **7.23 Social Engineering**

Loss arising directly or indirectly from or in connection with any fraudulent or dishonest instruction to the Insured or its agents which purports to be from a legitimate or trusted source authorised to make such instruction and which results in the Insured:

- 7.23.1** transferring, paying or delivering any money or securities from an account maintained by the Insured to another person or entity;
- 7.23.2** transferring or delivering any property to another person or entity;
- 7.23.3** revealing confidential information; or
- 7.23.4** changing or altering bank account or payment details of any person or entity.  
Provided always that clause 7.23.3 shall not apply to coverage provided under Insuring Clause 1.10 Data Breach Expense Coverage.

#### **7.24 Specific Diseases**

Loss arising directly or indirectly from or in connection with:

- 7.24.1** human immunodeficiency viruses (HIV), Human T-Cell Lymphotropic Virus Type iii (HTLV iii) or Lymphadenopathy Associated Virus (LAV) or the mutants, derivatives or variations thereof or in any way related to Acquired Immune Deficiency Syndrome (AIDS) or AIDS related complex (ARC) or any syndrome or condition of a similar kind howsoever it may be named
  - 7.24.1** Transmissible Spongiform Encephalopathy (TSE), Creutzfeldt-Jakob Disease (CJD), variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease (nvCJD); or
- 7.24.2** Hepatitis.

#### **7.25 Transportation of property**

Bodily Injury or Property damage arising out of:

- 7.25.1** the transportation of property, unless the injury or damage arises out of a condition in or on a vehicle not owned or operated by You, and that condition was created by the loading or unloading of that vehicle by any Insured;
- 7.25.2** the existence of tools, uninstalled equipment or abandoned or unused materials.  
This exclusion shall only apply to clause 1.1 Products Liability Insuring Clause.

#### **7.26 Unapproved Clinical Trials**

Loss in connection with any Clinical Trial arising out of any exposure to material, upon or within human beings:

- 7.26.1** during the trial, unless the exposure has been approved by the government or regulatory authority having jurisdiction over the trial; or

- 7.26.2** after any government or regulatory authority having jurisdiction over the trial:
- a. places or imposes a hold on the trial;
  - b. withdraws approval of any authorisation applicable to the trial; or
  - c. directs or orders that the trial be discontinued.

## **7.27 Unapproved Goods or Products**

- 7.27.1** Loss based upon or arising out of any goods or products distributed, handled, manufactured or sold by, or disposed of by, the Insured:
- a. before such goods or products have been approved for such distribution, handling, manufacture, sale or disposal; or
  - b. after such goods or products have been declared unsafe; by the appropriate government authority having jurisdiction over such distribution, handling, manufacturing, sale or disposal.
- 7.27.2** This exclusion only applies to such distribution, handling, manufacture, sale or disposal in the country where such goods or products have not yet been approved or have been declared unsafe.

## **7.28 United States of America / Canada**

- 7.28.1** any Loss caused by, arising from or in connection with any occurrence in the United States of America or Canada and their respective protectorates and territories; or
- 7.28.2** any action brought in any court of the United States of America or Canada or their respective protectorates and territories or any judgment registered or lodged in any jurisdiction in connection with such an action.
- 7.28.3** Clause 7.28.1 shall not apply to Loss arising from or in connection with any occurrence in the United States of America or Canada and their respective protectorates or territories; provided that such Loss occurs outside the United States of America or Canada and their respective protectorates and territories.

## **7.29 War and Terrorism**

Loss, however caused, arising, directly or indirectly, out of:

- 7.29.1** war, invasion, acts of foreign enemies, hostilities or warlike operations (whether war be declared or not), civil war, mutiny, revolution, rebellion, insurrection, uprising, military or usurped power, confiscation by order of any public authority or government de jure or de facto, martial law; or
- 7.29.2** riots, strikes or civil commotion; or
- 7.29.3** any Act of Terrorism; or
- 7.29.4** any action taken in controlling, preventing, suppressing, retaliating against or responding to or in any way relating to those things in 7.29.1 to 7.29.3 above.

## **7.30 Workers' Compensation and Similar Laws**

Any obligation of the Insured under a workers' compensation, disability benefits or unemployment compensation law or any similar law.

## SECTION 8 - EXCLUSIONS APPLICABLE TO PROPERTY DAMAGE

This insurance does not apply to Loss (and any Defence Costs associated with such Loss) arising out Property Damage to:

### 8.1 Property Damage

#### 8.1.1 Owned or Controlled Property

- a. property You own, rent, lease or occupy, including any costs or expenses incurred by You, or any other person, organisation or entity, for repair, replacement, enhancement, restoration or maintenance of such property for any reason, including prevention of injury to a person or damage to another's property;
- b. property loaned to You; or
- c. personal property in the care, custody or control of the Insured unless covered under clause 1.7 Property Damage Liability for Goods or Products in Your Care, Custody or Control.

#### 8.1.2 Alienated Property

premises You sell, give away or abandon, if the Property Damage arises out of any part of those premises; however, this exclusion does not apply if the premises are Your Work and were never occupied, rented or held for rental by You.

#### 8.1.3 Other Real Property

that particular part of real property on which You or any contractors or subcontractors working directly or indirectly on Your behalf are performing operations, if the Property Damage arises out of those operations; however, this exclusion does not apply to liability assumed under a sidetrack agreement.

### 8.2 Property that must be Restored, Repaired or Replaced

that particular part of any property that must be restored, repaired or replaced because Your Work was incorrectly performed on it; however, this exclusion does not apply to:

**8.2.1** liability assumed under an agreement;

**8.2.2** Property Damage included within the Products Liability Insuring Clause; or

**8.2.3** goods or products of others while Your Work is being performed on them and which are covered under clause 1.7 Property Damage for Goods or Products in Your Care, Custody or Control.

### 8.3 Damage to Property Impaired or Property not Physically Injured

Impaired Property or property that has not been physically injured, arising out of:

**8.3.1** a defect, deficiency, inadequacy or dangerous condition in Your Product or Your Work; or

**8.3.2** a delay or failure by You or anyone acting on Your behalf to perform a contract or agreement in accordance with its terms.

This exclusion does not apply to the loss of use of other tangible property arising out of sudden and accidental physical injury to Your Product or Your Work after it has been put to its intended use.

### 8.4 Damage to Your Product

Your Product arising out of it or any part of it.

**8.5 Damage to Your Work**

Your Work arising out of it or any part of it and included in the Products Liability Insuring Clause.  
This exclusion does not apply if the damaged work or the work out of which the damage arises was performed on Your behalf by a subcontractor.

## SECTION 9 - EXCLUSIONS SPECIFIC ONLY TO PERSONAL INJURY AND ADVERTISING INJURY AND DATA BREACH EXPENSE

This insurance does not apply to Loss (and any Defence Costs associated with such Loss) in the form of Personal Injury, Advertising Injury or Data Breach Expense:

### 9.1 Breach of Contract

arising out of a breach of contract.

### 9.2 Internet Activities

arising out of:

- 9.2.1 controlling, creating, designing or developing another's internet site;
- 9.2.2 controlling, creating, designing, developing, determining or providing the content or material of another's internet site;
- 9.2.3 controlling, facilitating or providing, or failing to control, facilitate or provide, access to the internet or another's internet site; or
- 9.2.4 publication of content or material on or from the internet, other than material developed by You or at Your direction.

### 9.3 Insureds in Media and Internet Type Businesses

committed by or on behalf of an Insured whose business is:

- 9.3.1 advertising, broadcasting, publishing or telecasting;
- 9.3.2 designing or determining content or web-sites for others; or
- 9.3.3 an internet search, access, content or service provider.

However, this exclusion does not apply to clauses 11.4.1 – 11.4.3 under the definition of Personal Injury in SECTION 11 – DEFINITIONS.

### 9.4 Knowing Violation of Rights of Another

caused by or at the direction of the Insured with the knowledge that the act would violate the rights of another and would inflict Personal Injury or Advertising Injury.

### 9.5 Material Published Prior to Policy Period

arising out of oral or written publication of the same or similar material whose first publication took place before the beginning of the Policy Period.

### 9.6 Material Published with Knowledge of Falsity

arising out of oral or written publication of material, if done by or at the direction of the Insured with knowledge of its falsity.

### 9.7 Quality or Performance of Goods – Failure to Conform to Statements

arising out of the failure of goods, products or services to conform with any statement of quality or performance made in Your Advertisement.

### 9.8 Wrong Description of Prices

arising out of the wrong description of the price of goods, products or services.

## SECTION 10 - EXCLUSIONS SPECIFIC ONLY TO ECONOMIC INJURY

This insurance does not apply to Loss (and any Defence Costs associated with such Loss) in the form of Economic Injury:

### 10.1 Delay

based upon or arising out of any delay in:

- 10.1.1** delivery of, or failure to deliver, Your Product; or
- 10.1.2** performance of, or failure to commence, Your Work; or any part or phase of Your Product or Your Work.

### 10.2 Disappearance, Theft or Security Breach

based upon or arising out of any actual, alleged or threatened:

- 10.2.1** burglary, inventory shortage or shrinkage, mysterious disappearance, robbery or theft;
- 10.2.2** security breach of, unauthorised access to or unauthorised use of:
  - a. Your Product;
  - b. any property containing or incorporating Your Product;
  - c. any property on which Your Work is or was performed;
  - d. any software, data or other information in electronic form; or
  - e. any equipment, parts, programs or systems involving the use of computers, the internet, or any networks or websites, or which are designed or used for communication or information;by any person or organisation (including any Insured), regardless of whether this insurance would otherwise apply to all or part of any such actual or alleged injury in the absence of any such actual, alleged or threatened breach, access or use.

### 10.3 Financial Impairment of Insureds

based upon or arising out of any bankruptcy, insolvency or other financial impairment of any Insured.

### 10.4 Governmental Claims or Proceedings

based upon, arising out of or in any way related to any Claim, proceeding, investigation, order or regulation made by or on behalf of any governmental entity.

This exclusion does not apply to Economic Injury sustained by a governmental entity resulting from such entity's ownership, maintenance or use of Your Product or Your Work.

### 10.5 Liquidated Damages

in the form of liquidated damages to the extent such liquidated damages exceed the actual damages to the Insured's client.

### 10.6 Maintenance of Contracts or Licenses

based upon or arising out of any actual, alleged or threatened:

- 10.6.1** failure to effect, maintain, procure or secure, in whole or in part; or
- 10.6.2** cancellation, lapse, modification, nonrenewal, revocation, suspension or other impairment, in whole or in part:  
of any bond, insurance, lease, license, order, permit or other contract or agreement that any Insured is obligated to maintain, procure or secure in connection with Your Product or Your Work.

**10.7 Product or Work Support**

based upon or arising out of any actual, alleged or threatened decision by any Insured not to provide or support Your Product or Your Work, or to cease such provision or support.

**10.8 Securities Laws**

based upon or arising out of the actual or alleged violation of any law, whether created or imposed by a legislative or regulatory body or by a court, either in whole or in part, and which is designed to address certain activities in connection with any offering, selling, purchasing, registration or trading of any instrument or other evidence of credit or ownership, including but not limited to such activities designed to prevent or prohibit fraudulent, unfair or other similar such practices or require the disclosure of information.

**10.9 Value of Money**

based upon or arising out of the loss of value of money that is commingled, injured or damaged, incorrectly processed, lost, misappropriated or misplaced in connection with any actual or failed processing, receipt, retention or transmission of such money, whether by electronic means or otherwise.

## SECTION 11 - DEFINITIONS

The following definitions of each word, words or phrase appearing in the title are applicable to all sections of the Policy. All words in the title also include the plural or singular versions.

### 11.1 Act of Terrorism

Means an activity that:

- 11.1.1 involves a violent act or the unlawful use of force or an unlawful act dangerous to human life, tangible or intangible property or infrastructure, or a threat thereof; and
- 11.1.2 appears to be intended to:
  - a. intimidate or coerce a civilian population, or
  - b. disrupt any segment of the economy of a government de jure or de facto, state or country; or
  - c. overthrow, influence, or affect the conduct or policy of any government de jure or de facto by intimidation or coercion; or
  - d. affect the conduct of a government de jure or de facto by mass destruction, assassination, kidnapping or hostage taking.

### 11.2 Adverse Event

Means any incident where the use of a drug, biologic, medical device, dietary supplement, cosmetic, cosmetic drug or medical food is suspected to have resulted in an adverse outcome in a person or animal, whether or not such incident must be reported to any applicable governmental authority in accordance with applicable law.

### 11.3 Advertisement

Means a notice that is broadcast or published to the general public or specific market segments about Your goods, products or services for the purpose of attracting customers or supporters. For the purposes of this definition:

- 11.3.1 notices that are published include material placed on the internet or on similar electronic means of communication; and
- 11.3.2 regarding web-sites, only that part of a web-site that is about Your goods, products or services for the purposes of attracting customers or supporters is considered an advertisement.

### 11.4 Advertising Injury

Means injury caused by any unintentional:

- 11.4.1 infringement of copyright or passing off of title or slogan;
- 11.4.2 breaches of the misleading and deceptive conduct provisions of the Competition and Consumer Act 2010 (Cth) or any State or Territory Fair Trading Act or similar legislation of any country, state or territory;

in any advertisement, publicity article, broadcast, telecast or via an internet website, and caused by or arising out of the Your advertising activities in connection with the Your Products or Your Work.

### 11.5 Approved Clinical Trial

Means a Clinical Trial performed upon or within human beings, provided that the sponsor of the trial makes all filings that are required to be made under all applicable laws and regulations and receives all necessary authorisations in connection therewith, including the approval of the applicable institutional review board, Ethics Committee or other similar body.

#### **11.6 Approved Protocol**

Means a protocol for the conduct of a Clinical Trial approved by the institutional review board, Ethics Committee or other governmental or other entity delegated by law with the obligation to determine whether a trial may proceed or continue.

#### **11.7 Automatic Extended Reporting Period**

Means the period of time commencing immediately following the Policy Period and lasting for sixty (60) days.

#### **11.8 Biological Agents**

Means any microorganisms or biological organisms identified as, or having the same characteristics as those identified as, viral, bacterial, fungal, parasitic or rickettsial agents, or prions or arboviruses, set forth in Section VII of the fourth edition of *Biosafety in Microbiological and Biomedical Laboratories*, published by the National Institutes of Health, Bethesda, Maryland.

#### **11.9 Bodily Injury:**

Means physical:

**11.9.1** injury;

**11.9.2** sickness; or

**11.9.3** disease

sustained by a person, including death, mental anguish, shock or humiliation where resulting from such injury, sickness or disease at any time.

#### **11.10 Claim**

Means:

**11.10.1** any writ, application, summons or other originating legal process, cross claim or counter claim issued against or served on the Insured claiming Damages because of Loss to which this insurance applies are alleged; or

**11.10.2** the positive assertion in writing of a legal entitlement to Damages because of Loss to which this insurance applies are alleged, in terms evincing an intention to pursue such legal entitlement;

#### **11.11 Class I Product Recall**

Means:

**11.11.1** a Class I Product Recall as defined by the applicable government authority in the Commonwealth of Australia or New Zealand; or

**11.11.2** the equivalent recall provision outside of the Commonwealth of Australia or New Zealand, which provision addresses the removal of Your Product, or a product in which Your Product is a component or on which Your Work was performed, from the market, or a correction of such product, because there is a reasonable probability that the continued use of, or exposure to, such product, without correction, will cause serious adverse health consequences or death.

Such recall or removal may be taken voluntarily by or on behalf of the Insured, or required by a government entity acting in accordance with applicable federal, state, regional or local law.

#### **11.12 Clean-up Costs**

Means the cost of abating, testing for, monitoring, cleaning up, removing, containing, treating, detoxifying, neutralising, remediating or disposing of, or in any way responding to, or assessing the effects of, Biological Agents to the extent required by applicable law.

#### **11.13 Clinical Trial**

Means the testing of material to establish the effectiveness or safety of such material as a drug, biologic, medical device, dietary supplement, cosmetic, cosmetic drug or medical food, including the taking of all steps to obtain the informed consent of any human beings participating in such tests, and the performance of all other activities taken in connection with such testing.

#### **11.14 Clinical Trial Contractor**

Means any person other than Your Employees, or any organisation other than Your subsidiary, engaged to provide service, advice or instruction in connection with:

**11.14.1** clinical, laboratory or research testing activities, within the scope of and in accordance with the applicable written protocol; or

**11.14.2** the planning monitoring or review; of an Approved Clinical Trial.

#### **11.15 Clinical Trial Participant**

Means a human being participating as a test subject in an Approved Clinical Trial.

#### **11.16 Compensation Protocol Guidelines**

Means guidelines which set forth the manner and rules by which to determine if, and to what extent a Clinical Trial Participant should be paid compensation and related expenses by the Insured for Bodily Injury, Property Damage or Personal Injury sustained as a result of their participation in an Approved Clinical Trial.

#### **11.17 Damages**

Means a monetary judgment, award or settlement of:

**11.17.1** compensatory damages; and

**11.17.2** claimants' costs and expenses.

Damages does not include:

**11.17.3** fines, taxes or penalties;

**11.17.4** punitive, exemplary and multiplied damages

**11.17.5** injunctive or equitable relief except in the form of Medical Monitoring Expense otherwise covered under this Policy;

**11.17.6** the return of fees or charges for services rendered or the return of the cost of Your Product or Your Work;

**11.17.7** expenses incurred by the Insured for redesign, changes, additions or remedies to Your Product or Your Work necessitated by a Claim; or

**11.17.8** the time and expense incurred by the Insured in assisting in resolving a Claim.

#### **11.18 Data Breach Expense**

Means the following expense where incurred with our prior written consent in order to comply with any Privacy Law or to minimise any Loss otherwise covered under this Policy:

##### **11.18.1 Notification Expense**

The required amount of necessary expenses incurred by You or by others on Your behalf to comply with any Privacy Law that requires a person or organisation storing Protected Personal Information, either in paper or electronic format, to provide notice to a Protected Person of any actual or potential disclosure of or unauthorised access to Protected Personal Information;

#### **11.18.2 Credit Monitoring and Data Recovery Expense**

Costs incurred by You or on Your behalf:

- a. to provide credit monitoring expenses to protected persons to the extent required by Privacy Law or to minimise any Loss otherwise covered under this Policy; or
- b. to recover information which has been accessed without the Protected Person's permission where the costs of recovery would minimise any Loss otherwise covered under this Policy.

#### **11.18.3 Cyber Investigation Expense**

Costs incurred by You or on Your behalf, with Our prior approval, to pay a third party to conduct an investigation of a computer system from which Protected Personal Information has been accessed in order to determine the manner in which and the date and time such information was accessed. Such costs do not include compensation, fees, benefits, overhead or the charges or expenses of any Insured or any Employee of an Insured; and

#### **11.18.4 Crisis Management Expense**

Costs incurred by You or on Your behalf, with Our prior approval, to pay a public relations firm, law firm or crisis management firm, hired with Our prior written consent, to perform crisis management services to minimise the potential harm to a Protected Person resulting from unauthorised disclosure or access to Protected Personal Information.

Such costs may include extortion amounts paid to a person demanding such payment in return for a promise not to disclose Protected Personal Information which has been wrongfully accessed, but only if the law enforcement authorities having jurisdiction over the theft of the information have been advised of and do not object to such payment.

Such costs do not include compensation, fees, benefits, overhead or the charges or expenses of any Insured or any Employee of an Insured.

### **11.19 Defence Costs**

Means all reasonable and necessary litigation expenses incurred by Us, and by the Insured at Our request, to investigate or settle any Claim against an Insured including the following:

- 11.19.1** expenses paid to lawyers, their staff and any necessary consultants or experts to defend the Claim; provided, however, that if We are required by law to allow the Insured to select his, her or its own counsel, such expenses shall be no greater than that generally charged for such services by Our panel counsel in the jurisdiction where the lawsuit is being litigated;
- 11.19.2** all reasonable expenses incurred by the Insured at Our request to assist us in the investigation or defence of the Claim, including actual loss of earnings up to \$250 a day because of time off from work;
- 11.19.3** all court costs taxed against the Insured in the Claim; however, these payments do not include solicitors' fees or solicitors' expenses taxed against the Insured;
- 11.19.4** prejudgment interest awarded against the Insured on that part of the judgment We pay. If We make an offer to pay the applicable Indemnity Limit, We will not pay any prejudgment interest based on that period of time after the offer; and
- 11.19.5** all interest on the full amount of any judgment that accrues after entry of the judgment and before We have paid, offered to pay, or deposited in court the part of the judgment that is within the applicable Indemnity Limit.

**11.20 Documents**

Means project models or displays, deeds, wills, agreements, maps, plans, records, photographs or negatives, written or printed books, letters, certificates or written or printed documents of any nature whatsoever and will include computer software and systems records (electronic data will be deemed to be physical property for the purposes of this insurance). This definition excludes bearer bonds, coupons, bank or currency notes and other negotiable paper.

**11.21 Economic Injury**

Means monetary loss sustained by a person or organisation.

**11.22 Employee**

Means:

- 11.22.1** any person under a contract of service or apprenticeship with the Named Insured;
  - 11.22.2** any person under a contract of service or apprenticeship with another employer who is hired to or borrowed by the Named Insured;
  - 11.22.3** any self-employed person working under contract with and under the direction of the Named Insured; or
  - 11.22.4** any person or student undertaking work for the Named Insured under a work experience agreement, government training or similar scheme;
- whilst they are engaged in connection with Your business.

**11.23 Ethics Committee**

Means a board, committee, group or similar organisation constituted, designated, directed or requested by an institution or other person or organisation to review an Approved Clinical Trial (including any approval or periodic review) of such Approved Clinical Trial.

**11.24 Excess**

Means the amount shown as such in the Schedule and shall be the first amount payable of each Claim made against the Insured.

**11.25 Executive Officer**

Means a person holding any of the officer positions created by constitution, by-laws or any other similar governing document.

**11.26 Extended Reporting Period**

Means an Automatic Extended Reporting Period or a Run-Off Extended Reporting Period.

**11.27 First Named Insured**

Means the first Named Insured noted in the Schedule.

**11.28 Healthcare Services**

Means:

- 11.28.1** the provision of:
  - a. medical, surgical, dental, x-ray or nursing service, treatment, advice or instruction, or the related furnishing of food or beverages, including clinical testing performed in connection with the foregoing services;
  - b. any health or therapeutic service, treatment, advice or instruction; or
  - c. any service, treatment, advice or instruction for the purpose of appearance or skin enhancement, hair removal or replacement or personal grooming;

- 11.28.2** the furnishing or dispensing of drugs or medical, dental or surgical supplies or appliances;
- 11.28.3** clinical testing performed in connection with the services, treatment, advice or instruction, or the furnishing or dispensing activities described in clause 11.28.1 a. and b. above; and
- 11.28.4** the handling or treatment of dead bodies, including autopsies, organ donation or other procedures.

### **11.29 Impaired Property**

Means tangible property, other than Your Product or Your Work, that cannot be used or is less useful because:

- 11.29.1** it incorporates Your Product or Your Work that is known or thought to be defective, deficient, inadequate or dangerous; or
- 11.29.2** You have failed to fulfil the terms of a contract or agreement; if such property can be restored to use by the repair, replacement, adjustment or removal of Your Product or Your Work or Your fulfilling the terms of the contract or agreement.

### **11.30 Indemnity Limit**

Means the amount specified as such in the Schedule and includes the Overall Policy Aggregate Limit, the General Aggregate Limit, the Products Completed Operations Aggregate Limit, the Clinical Trial Aggregate Limit, the Errors and Omissions Aggregate Limit and any other or sub-limits.

### **11.31 Initial Coverage Date**

Means the Initial Coverage Date stated in the Schedule.

### **11.32 Insured**

Means:

- 11.32.1** the Named Insured;
- 11.32.2** any entity which is a subsidiary of the Named Insured at the beginning of the Policy Period and the time of the Loss;
- 11.32.3** any person who is during the Policy Period, a principal, partner or director of the Named Insured but only in respect of work performed while a principal, partner or director of the Named Insured;
- 11.32.4** any person who is during the Policy Period an Employee of the Named Insured but only in respect of work performed while an Employee of the Named Insured and on behalf of the Named Insured;
- 11.32.5** any former principal, partner, director or Employee of the Named Insured but only in respect of work performed while a principal, partner, director or Employee of the Named Insured; and
- 11.32.6** any person who is during the Policy Period a Volunteer Worker of the Named Insured.
- 11.32.7** Except to the extent set forth in clauses 4.1, 4.2, 4.3.2, 4.4, 4.5 and 4.6, no person or organisation is an Insured with respect to the conduct of any person or organisation that is not designated as a Named Insured in the Schedule.

### **11.33 Insured Client**

Means Your client or the client of a person or organisation acting on Your behalf.

#### **11.34 Insured Contract**

Means any of the following if in writing:

- 11.34.1** a contract for a lease of premises;
- 11.34.2** any easement or license agreement;
- 11.34.3** that part of any other contract or agreement pertaining to Your business (including an indemnification of a government entity in connection with work performed for a government entity) under which You assume the tort liability of another party to pay Loss otherwise covered under this Policy to a third person or organisation. Tort liability means a liability that would be imposed by law in the absence of any contract or agreement.  
This clause 11.34.4 does not include that part of any contract or agreement that indemnifies an architect, engineer or surveyor for injury or damage arising out of:
  - a. preparing, approving, or failing to prepare or approve, maps, shop drawings, opinions, reports, surveys, field orders, change orders, designs, drawings or specifications; or
  - b. giving directions or instructions, or failing to give them, if that is the primary cause of the injury or damage.

#### **11.35 Insured Representative**

Means the Insured's Executive Officers; the members of the legal department and risk management departments of the Insured; and any person(s) designated by the Insured as responsible for Claims reporting or insurance matters.

#### **11.36 Intellectual Property**

Means;

- 11.36.1** a copyright, patent, trademark, intellectual design right, collective trademark, certification mark or service mark or any similar such protections or rights (whether or not any of the foregoing are registered);
- 11.36.2** a trade secret or other type of formula, practice, process, design, instrument, pattern or compilation of information regarded by a business as confidential or proprietary;
- 11.36.3** trade dress or any right protecting any interest in a name, symbol, slogan, style of doing business, or any similar such expression, likeness or idea; or
- 11.36.4** the use of another's name or product in Your e-mail address, domain name or metatag, or any other similar tactics to mislead another's potential customers.

#### **11.37 Listed Human Disease**

Means:

- 11.37.1** any disease identified or listed at any time as a human disease under the Biosecurity Act 2015 (Cth) or its current equivalent, as amended or replaced from time to time, or
  - 11.37.2** any disease identified or listed in a state of emergency, public health emergency or pandemic declared by any governmental authority or identified by the World Health Organisation or its current equivalent as amended or replaced;
- regardless of when the disease is so listed or identified.

#### **11.38 Life Science Contractor**

Means a Clinical Trial Contractor, Product Sales Contractor or Product Service Contractor.

**11.39 Loss**

Means, wherever applicable, Bodily Injury, Property Damage, Medical Monitoring Expense, Economic Injury, Personal Injury, Advertising Injury, Withdrawal Expenses, Medical Stop Loss Expense, Clean-up Costs or Data Breach Expense or any other Loss, injury, damage or expense covered by this Policy or any endorsement attached thereto.

**11.40 Mechanically Propelled Vehicle**

Means any type of machine on wheels, skis or on self-laid tracks made or intended to be propelled other than by manual or animal power.

**11.41 Medical Expenses**

Means reasonable medical expenses for:

- 11.41.1** first aid administered at the time of an accident;
- 11.41.2** necessary medical, surgical, x-ray and dental services, including prosthetic devices; and
- 11.41.3** necessary ambulance, hospital, professional nursing and funeral services.

**11.42 Medical Monitoring Expense**

Means expenses incurred to conduct medical testing on or medical monitoring of a claimant in the absence of physical injury, illness or disease:

- 11.42.1** where the claimant has been exposed to Your Product or a product on which Your Work was performed;
- 11.42.2** such exposure creates a substantial, increased risk that the claimant will sustain Bodily Injury in the future;
- 11.42.3** medical testing or monitoring expenses are medically warranted because the prospect of early diagnosis of such Bodily Injury will improve the chance of beneficial medical intervention; and
- 11.42.4** the expense provides no other material benefit to the claimant.

**11.43 Medical Payments Excess**

Means the amount set forth in the Schedule.

**11.44 Medical Stop Loss Expense**

Means Medical Expenses incurred for treatment administered at the time of or after an Approved Clinical Trial in order to treat a Clinical Trial Participant; however, such expenses do not include any amounts incurred for planned concurrent treatment of side effects set forth in the Clinical Trial protocol.

**11.45 Named Insured**

Means the person(s), partnership, company, corporation or other entity noted as the Named Insured in the Schedule.

**11.46 No Fault Compensation**

Means the amounts the Insured is obligated to pay in accordance with agreed Compensation Protocols.

**11.47 Occurrence**

Means an accident, including continuous or repeated exposure to substantially the same general harmful conditions.

#### **11.48 Personal Injury**

Means injury, including consequential Bodily Injury, caused by one or more of the following offences:

- 11.48.1** false arrest, detention or imprisonment;
- 11.48.2** malicious prosecution;
- 11.48.3** the wrongful eviction from, wrongful entry into, or invasion of the right of private occupancy of a room, dwelling or premises that a person occupies, where committed by or on behalf of its owner, landlord or lessor;
- 11.48.4** discrimination, harassment or segregation based on a person's age, colour, national origin, race, religion or sex; or
- 11.48.5** oral, written, electronic or other publication, in any manner, of material that:
  - a. slanders or libels a person or organisation; or
  - b. violates a person's right of privacy.

#### **11.49 PFAS**

Means any organic molecule, salt, free radical or ion, the composition of which includes at least one:

- 11.49.1** perfluorinated methyl group (-CF<sub>3</sub>); or
- 11.49.2** perfluorinated methylene group (-CF<sub>2</sub>).

#### **11.50 Policy**

Means:

- 11.50.1** all terms (including without limitation the insuring clauses, definitions, extensions, conditions, exclusions, coverage provisions and Indemnity Limit) set out in this document;
- 11.50.2** the Schedule; and
- 11.50.3** all endorsements applied to and issued from time to time for application to this document; all of which shall be read together and constitute the contract of insurance.

#### **11.51 Policy Period**

Means the period shown in the Schedule.

#### **11.52 Pollutants**

Means any solid, liquid, gaseous or thermal irritant or contaminant, including smoke, vapour, soot, fumes, acids, alkalis, chemicals and waste. Waste includes materials to be recycled, reconditioned or reclaimed.

#### **11.53 Privacy Law**

Means the Privacy Act 1988 (Cth) as amended and any other similar state, regional or national identity theft and privacy protection laws requiring commercial entities that collect personal information to post privacy policies, adopt specific privacy controls, or notify individuals in the event that personal information has potentially been compromised.

#### **11.54 Product Sales Contractor**

Means any person or organisation other than your Employees or subsidiaries engaged to provide service, advice or instruction in connection with the dispensing, distribution, furnishing for sale of a drug, biologic, medical device, dietary supplement, cosmetic, cosmetic drug or medical food, other than in connection with a Clinical Trial.

#### **11.55 Product Service Contractor**

Means any person or organisation other than your Employees or subsidiaries engaged to provide clinical; design or development review; laboratory; or research service, advice or instruction in connection with a drug, biologic, medical device, dietary supplement, cosmetic, cosmetic drug or medical food, other than in connection with a Clinical Trial.

#### **11.56 Professional Service**

Means or refers to any service, advice, or instruction specialised to the Insured's vocation and requiring the Insured's specialised knowledge, skill, experience or training, regardless of whether the Insured needs a license or other formal certification to perform such service, advice or instruction.

#### **11.57 Property Damage**

Means:

**11.57.1** physical injury to tangible property, including all resulting loss of use of that property. All such loss of use shall be deemed to occur at the time of the physical injury that caused it; or

**11.57.2** loss of use of tangible property that is not physically injured. All such loss of use shall be deemed to occur at the time of the Occurrence that caused it, or in the case of claims-made coverage, the event which precipitated the Claim.

For the purposes of this insurance, electronic data is not tangible property. As used in this definition, electronic data means information, facts or programs stored as or on, created or used on, or transmitted to or from, computer software, including systems and applications software, hard or floppy disks, CD-ROMS, tapes, drives, cells, data processing devices or any other media which are used with electronically controlled equipment.

#### **11.58 Protected Person**

Means a person whose non-public personal information is protected from unauthorised disclosure or access by a Privacy Law. Such person shall not be either an Employee or Temporary Worker of any Insured unless the Employee or Temporary Worker is participating in an Approved Clinical Trial and the information was collected for the purpose of the person's participation in the trial.

#### **11.59 Protected Personal Information**

Means protected personal information as described in the Privacy Act 1988 (Cth) as amended and any other similar state, regional or national identity theft and privacy protection laws requiring commercial entities that collect personal information to post privacy policies, adopt specific privacy controls, or notify individuals in the event that personal information has potentially been compromised.

#### **11.60 Renewal Policy**

Means a life science liability Policy issued to You by Us where We have provided continuous, uninterrupted, substantially similar coverage to You from the Initial Coverage Date to the commencement of the Policy Period.

#### **11.61 Retroactive Date**

Means the retroactive date stated in the Schedule.

#### **11.62 Run-off extended reporting period**

Means the period of time commencing upon the expiration of the Policy Period and lasting until the end of the Run-off Extended Reporting Period as set forth in the Policy or by endorsement.

#### **11.63 Schedule**

Means the document entitled Schedule that relates to this insurance.

**11.64 Severe Adverse Event**

Means the following:

- 11.64.1** death;
- 11.64.2** a life-threatening event;
- 11.64.3** hospitalisation;
- 11.64.4** disability or permanent damage;
- 11.64.5** a congenital anomaly or birth defect; or
- 11.64.6** required intervention to prevent permanent impairment or damage.

**11.65 Temporary worker**

Means a person who is furnished to you to substitute for a permanent Employee on leave or to meet seasonal or short-term workload conditions.

**11.66 Tool of Trade**

Means any Mechanically Propelled Vehicle which has mechanical digging, scraping, drilling equipment or any tool or plant attached but only when it is being used by the Insured on any worksite at which work is performed for or in connection with the Insured's business.

**11.67 Volunteer worker**

Means a person who is not your Employee, and who donates his or her work and acts at the direction of and within the scope of duties determined by You, and is not paid a fee, salary or other compensation by You or anyone else for their work performed for You.

**11.68 Vulnerable Class Member**

means any of the following:

- 11.68.1** a person under the age of 18;
- 11.68.2** a prisoner;
- 11.68.3** a person in an inpatient facility because of a mental health condition;
- 11.68.4** a person who is pregnant; or
- 11.68.5** a person whose decision-making capacity is reduced to the extent that a legal authorised representative is necessary for the potential Clinical Trial Participant to give informed consent to participation in an Approved Clinical Trial.

**11.69 We, Us, Our**

Means Berkley Insurance Company (limited company incorporated in Delaware, USA) ABN 53 126 559 706 | AFSL 463129 t/as Berkley Insurance Australia.

**11.70 Withdrawal Expenses**

Means the following reasonable expenses where necessarily incurred to accomplish a Class I Product Recall and which would not have been incurred had such recall not taken place:

- 11.70.1** expenses incurred to prepare and issue communications regarding the recall (in whatever format is required), including but not limited to notices to or communications with direct accounts, the public or the appropriate regulatory authorities;
- 11.70.2** fees paid following or in conjunction with a Class I Product Recall to public relations or other consultants to develop and implement the recall in a manner designed to minimise the financial impact of the recall to the Insured;

- 11.70.3** fees paid to law firms and consultants to challenge a governmental communication requesting or directing a Class I Product Recall, where such fees are paid with Our prior written consent, which consent shall not be unreasonably withheld;
- 11.70.4** transportation, storage and disposal costs necessarily incurred in connection with the recall; and
- 11.70.5** costs incurred over and above the salaries and expenses of Employees of the Insured where necessary:
  - a. to ensure that the recall is accomplished within a reasonable period of time; or
  - b. to remove Your Product from:
    - i) a specific location; or
    - ii) a product in which Your Product is a component part;

where it is reasonably probable that the failure to remove Your Product will cause serious adverse health consequences or death.

Withdrawal Expenses do not include the cost of removing Your Product from a person in which such product has been medically implanted, but does include expenses incurred to prepare and issue communications to any such person. To the extent Withdrawal Expenses includes fees paid to law firms or consultants, such fees shall not be greater than the fees normally charged by our panel counsel or consultants for similar services.

#### **11.71 You, Your**

Means the Named Insured.

#### **11.72 Your Product**

Means:

- 11.72.1** any goods or products manufactured, sold, handled, distributed or disposed of by:
  - a. You;
  - b. others trading under Your name; or
  - c. a person or organisation whose business or assets You have acquired;
- 11.72.2** containers (other than vehicles), materials, parts or equipment furnished in connection with such goods or products;
- 11.72.3** vending machines or other property loaned or rented to or located for the use of others by:
  - a. You;
  - b. others trading under Your name; or
  - c. a person or organisation whose business or assets You have acquired;
- 11.72.4** warranties or representations made at any time with respect to the fitness, quality, durability, performance or use of Your Product, including the supervision or failure to supervise persons or organisations with respect to the making of such warranties or representations; and
- 11.72.5** the providing of or failure to provide warnings or instructions.

#### **11.73 Your Work**

Means:

- 11.73.1** work or operations performed by You or on Your behalf; and
- 11.73.2** materials, parts or equipment furnished in connection with such work or operations;
- 11.73.3** warranties or representations made at any time with respect to the fitness, quality, durability, performance or use of Your work, including the supervision or failure to supervise persons or organisations with respect to the making of such warranties or representations; and
- 11.73.4** the providing of or failure to provide warnings or instructions.

## SECTION 12 - Claims Conditions

The following conditions apply to this insurance:

### 12.1 Duties in the Event of Occurrence, Offence, Claim

**12.1.1** You or Your legal personal representatives shall give notice in writing to Us as soon as possible after any Occurrence or event which may give rise to liability under the following Coverage Sections of this Policy:

- 1.2 Public Liability;
- 1.3 Medical Payments;
- 1.4 Advertising Injury and Personal Injury Liability;
- 1.6 Product Withdrawal Expenses Coverage;
- 1.7 Property Damage for Liability for Goods or Products in Your Care, Custody or Control;
- 1.10 Data Breach Expenses Coverage

with full particulars of such Occurrence or event. Full particulars shall include:

- a. how, when and where the Occurrence, offence or Loss took place;
- b. the names and addresses of any injured persons and any witnesses; and
- c. the nature and location of any injury or damage arising out of the Occurrence, offence, Critical Fact or Loss.

Notice of an Occurrence, offence, Critical Fact or Loss is not notice of a Claim.

**12.1.2** If a Claim is received by any Insured, You must:

- a. immediately record the specifics of the Claim and the date received; and
- b. notify Us as soon as practicable by sending written notice of the Claim to Our claims department:

National Head of Claims  
australiacclaims@berkleyinaus.com.au  
Berkley Insurance Australia  
PO Box Q296  
QVB NSW 1230

**12.1.3** You and any other involved Insured must:

- a. send Us copies of any demands, notices, summonses or legal papers received in connection with the Claim as soon as practicable;
- b. authorise Us to obtain records and other information;
- c. cooperate with Us in the investigation or settlement of the Claim or defence against the Claim; and
- d. assist Us, upon Our request, in the enforcement of any right against any person or organisation which may be liable to the Insured because of Loss to which this insurance may also apply.

## **12.2 Admission of Liability**

**12.2.1** The Insured shall not admit liability or settle any Claim without Our consent.

**12.2.2** No Insured will, except at that Insured's own cost, voluntarily make a payment, assume any obligation, or incur any expense, other than for first aid, without Our prior written consent.

## **12.3 Right to Defend**

**12.3.1** We shall have the right to assume the investigation, adjustment or defence of any Claim. In the event We assume the defence of a Claim, and it is later determined that a Claim is not covered under the Policy, We have the right to seek reimbursement of Defence Costs paid to the extent permitted by law.

**12.3.2** The Named Insured will not be required to contest any legal proceedings unless a Senior Counsel (to be mutually agreed upon by the Named Insured and Us or failing agreement to be appointed by the President of the Bar Association of the State or Territory of Australia where this Policy is issued) advises that, taking due account of the interests of both the Named Insured and Us, the defence of such proceedings has reasonable prospects of being successful and should be contested having regard to the alternative to contesting the proceedings.

**12.3.1** If the Named Insured wishes to continue to contest any Claim which We wish to settle, the Named Insured may do so. However, Our maximum liability in respect of that Claim will thereafter be limited to the amount for which the Claim could have been settled plus Defence Costs incurred with Our prior written consent up to the date upon which it would have reasonably settled the Claim, less any unpaid Excess or the final amount of the Claim including Defence Costs.

**12.3.2** We shall have the right to select counsel wherever We are obligated or have the right to defend the Insured, or where We are required to pay defence costs under this Policy. In the event We are obligated by law to allow the Insured to select counsel, Our obligation to pay Defence Costs is limited to the amount generally charged for such services by our panel counsel in the jurisdiction where the lawsuit is being litigated for the type of case for which counsel is being retained. In addition, such counsel selected by the Insured shall have substantially similar qualifications and expertise as Our panel counsel in the jurisdiction where the lawsuit is being litigated for the type of case for which counsel is being retained.

## **12.4 Excess**

**12.4.1** In respect of any Claim or Loss covered by this Policy the Named Insured is liable for any Excess stated in the Schedule. We will have no liability for any such Excess.

**12.4.2** Where We exercise Our right to assume the investigation, adjustment or defence of any Claim, the Named Insured, on demand by Us, shall promptly reimburse Us for any element of Loss or Defence Costs falling within any Excess applicable to this Policy.

## **12.5 Allocation**

Where the Insured is entitled to indemnity pursuant to clause 2.1 Defence Costs in circumstances where a Claim is made and part of that Claim for compensation arises out of, is in connection with or is related to facts or matters that are not covered by this Policy then, Our liability under this Policy is limited to that proportion of the Defence Costs which represents a fair and equitable allocation between the Insured and Us, taking into account the relative legal and financial exposures attributable to covered allegations and allegations that are not covered under this Policy.

In circumstances where We and the Insured cannot agree on an allocation between covered allegations and allegations that are not covered, the dispute shall be submitted to binding opinion from a Senior Counsel agreed between the parties or, failing agreement, appointed by the President of the Bar Association of the State or Territory of Australia where this Policy is issued.

## SECTION 13 - GENERAL CONDITIONS

The following conditions apply to this insurance:

### 13.1 Premium Audit

**13.1.1** We will compute all premiums for this Policy in accordance with Our rules and rates.

**13.1.2** Premium shown in this Policy as advance premium is a deposit premium only. At the close of each audit period We will compute the earned premium for that period and send notice to the First Named Insured. The due date for audit and retrospective premiums is the date shown as the due date on the invoice. If the sum of the advance and audit premiums paid for the Policy Period is greater than the earned premium, We will return the excess to the First Named Insured.

**13.1.3** The First Named Insured must keep records of the information We need for premium computation, and send Us copies at such times as We may request.

### 13.2 Representations

By accepting this Policy, You represent and agree that:

**13.2.1** all of the information provided and statements made to Us by You, including the information contained in the application and any other supplemental materials and information submitted by You or on Your behalf, are true, accurate and complete, and each shall be deemed to constitute material representations made by all of the Insureds;

**13.2.2** We have issued this Policy in reliance upon such representations; and

**13.2.3** the misrepresentation of any material matter by You or Your agent will render this Policy null and void and relieve us from all liability.

### 13.3 Jurisdiction and Service

In the event of a dispute arising under or in connection with this Policy, We at the request of the Insured will submit to the jurisdiction of competent courts in the Commonwealth of Australia. The dispute shall be determined in accordance with the law and practice of that jurisdiction, as applied in those courts.

### 13.4 Legal Action Against Us

No person or organisation has a right under this Policy:

**13.4.1** to join Us as a party or otherwise bring Us into a suit asking for damages from an Insured; or

**13.4.2** to sue Us on this insurance unless all of its terms have been fully complied with.

A person or organisation may sue us to recover on an agreed settlement or on a final judgment against an Insured; but we will not be liable for Damages that are not payable under the terms of this Policy or that are in excess of the applicable Indemnity Limit.

As used in this paragraph, an agreed settlement means a settlement and release of liability signed by Us, the Insured and the claimant or the claimant's legal representative.

### 13.5 Bankruptcy

Bankruptcy or insolvency of the Insured or of the Insured's estate will not relieve us of our obligations under this Policy.

### 13.6 Terms of Payment

All premiums due to Us under this Policy will be paid within thirty (30) days from the Policy's inception.

### 13.7 Cancellation

The circumstances and manner in which We may cancel this insurance is governed by the Insurance Contracts Act 1984 (Cth).

The Insured may cancel this Policy at any time by giving fourteen (14) days' notice and provided there have been no notifications made by the Insured under this Policy the Insured will be entitled to a pro rata refund. If the Insured has made a notification under the Policy then the Insured is not entitled to any refund.

### 13.8 Subrogation

If the Insured has rights to recover all or part of any payment we have made under this Policy, the Insured shall grant those rights to Us. The Insured must do nothing after Loss to impair their right of recovery and must take all reasonable steps to preserve such rights. At Our request, the Insured will bring suit or transfer those rights to Us and help Us enforce them.

### 13.9 Claims Aggregation

**13.9.1** The following provision applies to all claims-made coverage sections.

- a. All Claims for Damages because of:
    - i) Bodily Injury to the same person, including Damages claimed by any person or organisation for care, loss of services, or death resulting at any time from the Bodily Injury;
    - ii) Medical Monitoring Expense applicable to the same person;
    - iii) Property Damage to the same person or organisation;
    - iv) Personal Injury or Advertising Injury to the same person or organisation; or
    - v) Clean-up Costs applicable to the same person or organisation;
- will be deemed to have been made at the time the first of those Claims is made against any Insured.

**13.9.2** The following provision applies to all coverage sections applicable to Bodily Injury:

- a. Damages because of Bodily Injury to any one person include Damages claimed by any person or organisation for care, loss of services or death resulting at any time from such Bodily Injury to that person.

### 13.10 Alteration to Risk

The Insured will give Us written notice as soon as reasonably practicable of any material alteration to the risk during the Policy Period including but not limited to:

- 13.10.1** an Insured going into voluntary bankruptcy, receivership, liquidation or any other form of external administration or an Insured failing to pay debts or breaching any other obligation which could give rise to the appointment of a receiver or bankruptcy or winding-up proceedings;
- 13.10.2** any cancellation or suspension, or loss of or condition imposed, upon any licence, registration or other authority required by the Insured to conduct their business; and/or
- 13.10.3** any material change in Your Product or Your Work.

Where the Insured fails to notify Us as required under this clause or there is any material alteration to the risk during the Policy Period, We may be entitled to cancel this Policy in accordance with the Insurance Contracts Act 1984 (Cth).

Where such notice is not provided by the Insured before the happening of a Claim or a notification giving rise to a Claim under this Policy, We may refuse to pay a Claim either in whole or in part or We may reduce Our liability to pay a Claim in accordance with the Insurance Contracts Act 1984 (Cth).

### **13.11 Cross Liability**

Except with respect to the Indemnity Limit, and any rights or duties specifically assigned in this Policy to the First Named Insured, this insurance applies:

**13.11.1** as if each Named Insured were the only Named Insured; and

**13.11.2** separately to each Insured against whom Claim is made.

### **13.12 GST**

Where We are required to indemnify the Insured and the Insured is entitled to claim an input tax credit in relation to GST the amount of such input tax credit will be deducted from any amount payable by Us.

Where the Insured is entitled to claim an input tax credit in relation to GST for a payment required to be made by the Insured as an Excess then the monetary limit of the Excess shall be deemed to be net of the Insured's entitlement to the Input tax credit.

### **13.13 Sanctions**

We are not liable to make any payment under this Policy where such payment would be in violation of any sanction, prohibition or restriction with which We are required to comply, including but not limited to United Nations resolutions or the trade or economic sanctions, laws or regulations of the European Union, Australia, United Kingdom or the United States of America.

### **13.14 Headings**

Headings and notes are for information purposes only and are not be construed as part of this Policy. This clause shall not apply to Section 11 – Definitions.