



**No Fault Compensation Insurance Policy
for Human Clinical Trials**

Claims Made

v12.15



Pen Underwriting Pty Ltd
ABN 89 113 929 516 AFSL 290518

Our name comes from the expression 'to pass the pen'. It reflects what we do and what we bring to the insurance industry – specialist expertise and quality underwriting. We strive to exceed the expectations of brokers by providing professional and flexible solutions for their clients' risks across a wide range of major and boutique general insurance products.

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Contact Details:

Current as at December 2015

BRISBANE

Level 9, 60 Edward St P: +61 7 3056 1400
Brisbane Qld 4000 F: +61 7 3056 1477
GPO Box 541
Brisbane Qld 4001

MELBOURNE

Level 3, 333 Collins St P: +61 3 9810 0600
Melbourne Vic 3000 F: +61 3 9810 0650
PO Box 230
Collins St West Vic 8007

SYDNEY

Level 19, 347 Kent St P: +61 2 9323 5000
Sydney NSW 2000 F: +61 2 9323 5077
GPO Box 4431
Sydney NSW 2001

E: info.au@penunderwriting.com

W: www.penunderwriting.com.au

Important Information

This Policy

This Policy is an important document and should be kept in a safe place. Please read it carefully so that you understand the insurance provided.

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.

Claims Made Policy

This Policy is issued on a Claims made and notified basis. This means that the Policy only covers the Insured for Claims first made against the Insured during the Period of Insurance and notified to the insurer during the Period of Insurance.

Section 40(3) of the *Insurance Contracts Act 1984* may provide additional rights at law. That section provides that where the insured gave notice in writing to the insurer of facts that might give rise to a Claim against the insured as soon as was reasonably practicable after the insured became aware of those facts but during the period of insurance, the insurer is not relieved of liability under the contract in respect of the Claim, when made, by reason only that it was made after the expiration of the period of insurance.

Retroactive Date

This Policy is limited by a Retroactive Date. This means that the Policy excludes liability arising out of an occurrence which happened prior to the Retroactive Date.

Good and Services Tax

The Premium may include an amount for GST.

Underwriters' liability to indemnify the Insured under this Policy is calculated less any Input Tax Credit to which the Insured is entitled for any relevant Acquisition, or to which the Insured would have been entitled had it made a relevant Acquisition. The Insured must inform Underwriters of the extent to which it is entitled to an Input Tax Credit for that GST, and any GST liability arising from the Insured's provision of incorrect advice is payable by the Insured.

GST, Input Tax Credit and Acquisition have the meaning given to those words in *A New Tax System (Goods and Services Tax) Act 1999*.

Privacy

Pen Underwriting handles your personal information with care and in accordance with the Privacy Act 1988 and the Australian Privacy Principles. We collect personal information about you to provide you with insurance and insurance related services. We may disclose your personal information to third parties for the purposes described in our Privacy Policy, including related entities, insurers, reinsurers, agents and service providers, some of whom may be located in the United Kingdom and India. By asking us to provide you with insurance and insurance related services, you consent to the collection, use and disclosure (including overseas disclosure) of your personal information for the purposes described in our Privacy Policy. Where you provide personal information about others, you represent to us that you have made them aware of that disclosure and of our Privacy Policy and that you have obtained their consent. If you do not consent to provide us with the personal information that we request, or withdraw your consent to the use and disclosure of your personal information at any stage, we may not be able to offer you the products or provide the services that you seek. For information about how to access and or correct the personal information we hold about you or if you have any concerns or complaints, ask us for a copy of our Privacy Policy or visit www.penunderwriting.com.au.

Complaints Handling

If you are dissatisfied with a decision Pen Underwriting makes, our service, the service of others we appoint to discuss insurance matters with you, or a claim settlement, we have an internal dispute resolution process to assist you. For further information, ask for a copy of our Complaints and Disputes Resolution Policy or visit www.penunderwriting.com.au.

General Insurance Code of Practice

Pen Underwriting and Underwriters at Lloyd's proudly support the General Insurance Code of Practice. The Code commits general insurers to uphold high standards of service and practice. A copy of the Code can be obtained from us upon request or from www.codeofpractice.com.au.

Australian Terrorism Insurance Act

The Underwriters have treated this insurance (or part of it) as an insurance to which the Australian Terrorism Insurance Act 2003 (ATIA) applies.

ATIA and the supporting regulations made under the Act deem cover into certain policies and provide that the Terrorism Exclusion to which this Policy is subject shall not apply to any "eligible terrorism loss" as defined in ATIA.

Any coverage established by ATIA is only in respect of any "eligible terrorism loss" resulting from a "terrorist act" which is a "declared terrorist incident" as defined in ATIA. The Terrorism Exclusion to which this Policy is subject applies in full force and effect to any other loss and any act or event that is not a "declared terrorist incident".

All other terms, conditions, insurance coverage and Exclusions of this Policy including applicable limits and excesses remain unchanged.

If any or all of the Underwriters have reinsured this insurance with the Australian Reinsurance Pool Corporation, then any such Underwriters will not be liable for any amounts for which they are not responsible under the terms of ATIA due to the application of a “reduction percentage” as defined in ATIA which results in a cap on the Underwriter’s liability for payment for “eligible terrorism losses”.

Further Information

Your insurance broker has arranged this insurance on your behalf. If you have any questions or need further information concerning your insurance, you should contact your insurance broker to assist you with your enquiry. You should direct all of your correspondence to us through your insurance broker as he is your agent for this insurance.

1. Cover

The Underwriters will indemnify the Insured against all sums in excess of the Deductible that the Insured shall become liable to pay as damages or compensation and claimants costs and expenses in respect of any Claim made by Research Subjects for Bodily Injury caused by an Occurrence happening after the Retroactive Date within the Policy Territory and arising out of the insured Trial or Trials.

Provided that:

- 1.1. such Claim is first made in writing against the Insured during the Period of Insurance and is notified to the Underwriters during the Period of Insurance;
- and
- 1.2. all Bodily Injury resulting or alleged to have resulted from the same Trial shall be considered as resulting from one Occurrence and as having occurred during the Period of Insurance in which the first Claim is made against the Insured irrespective of the number of claimants or the period over which such Bodily Injury is likely to result in a Claim or Claims being made against the Insured at some future date;
- and
- 1.3. the Insured has offered and the Research Subject has agreed to abide by the Conditions of Compensation.

The Underwriters will also pay Legal Costs in addition to the Limits of Indemnity.

2. Definitions

- 2.1. The Insured shall mean any person or company named in the Schedule and shall include:
 - 2.1.1. at the request of the Insured, any director or partner whilst acting in their respective capacities for the Insured;

- 2.1.2. at the request of the Insured, any employee of the Insured including Medical Persons but only whilst acting within the scope of their duties;
- 2.1.3. at the request of the Insured, any past employee who acted for the Insured and who agrees to be bound by the terms of this Policy;
- 2.1.4. subject to the prior written agreement of the Underwriters, any sub-contractor, doctor, consultant, physician, hospital or contract research organisation or nurse who will be performing work for the Insured in respect of a Trial covered by this Policy;
- 2.1.5. subject to the prior written agreement of the Underwriters, any Ethics Committee or its members that has approved a Trial which is the subject of this Policy,

but only in respect of Claims arising out of a Trial covered by this Policy.

- 2.2. Bodily Injury shall mean personal injury, sickness, disease or death and shall include, but not by way of limitation, mental injury, mental anguish and shock.
- 2.3. Occurrence shall mean an accident or event including continuous or repeated injurious exposure to substantially the same general conditions which results during the Period of Insurance in Bodily Injury neither expected nor intended from the standpoint of the Insured.
- 2.4. Legal Costs shall mean all the costs and expenses (including any fees or disbursements of any Independent Lawyer) incurred by or on behalf of the Insured with the written consent of the Underwriters in relation to any Occurrences which may be the subject of indemnity under this Policy.
- 2.5. Medical Persons shall mean Licensed Physicians, Doctors, Medical Nurses and Dentists.
- 2.6. Deductible shall mean the amount(s) stated in the Schedule which the Insured shall pay in respect of all damages, compensation, claimant’s costs and expenses and Legal Costs before the Underwriters shall be liable to make any payment.
- 2.7. Claim shall mean:
 - 2.7.1. the receipt by the Insured of any written demand for compensation made against the Insured by or on behalf of a

- Research Subject;
- 2.7.2. any writ, statement of claim, summons, application or other originating legal or arbitral process, cross-claim, counter claim or third or similar party notice served upon the Insured containing a demand for compensation made by or on behalf of a Research Subject.
- 2.8. Research Subject shall mean any person participating in a Trial and shall include their dependants, heirs, executors, administrators and legal representatives.
- 2.9. Trial or Trials shall mean any Clinical Trial or Healthy Volunteer Study which complies with the statutory requirements or guidelines of the relevant person, authority, department or public or private body in the country in which the Trial occurred.
- 2.10. Independent Lawyer shall mean a judge, retired judge, barrister or solicitor.
- 2.11. The Underwriters shall mean certain Underwriters at Lloyd's of London participating in this Policy.
- 2.12. Pen Underwriting shall mean Pen Underwriting Pty Ltd ABN 89 113 929 516 AFSL 290518.
- 2.13. Serious Adverse Event shall mean any untoward medical occurrence that at any dose:
- 2.13.1. results in death;
- 2.13.2. is life-threatening;
- 2.13.3. requires in-patient hospitalisation or prolongation of existing hospitalisation;
- 2.13.4. results in persistent or significant disability/incapacity; and or
- 2.13.5. is a congenital anomaly or birth defect
- 2.14. Life-threatening shall mean an event in which the patient was at risk of death at the time of the event; it does not mean an event which hypothetically might have caused death if it were more severe.
- 2.15. Schedule shall mean the Certificate of Insurance and Schedule issued and signed by Pen Underwriting or the Underwriters.
- 2.16. Policy shall mean this policy wording, the Schedule, any endorsements attaching to this policy wording and the Proposal.
- 2.17. Premium shall mean the total amount stated as Premium in the Schedule and in any endorsement to this Policy.

3. Extensions

Unless otherwise stated the following Extensions are subject always to the terms, Conditions and Exceptions contained in this Policy:

3.1. Manslaughter Defence Costs (Ethics Committee)

The Underwriters will indemnify the Ethics Committee or any member thereof in respect of legal costs and expenses incurred with the Underwriters written consent in the defence of any criminal proceedings brought (or in an appeal against conviction arising from such proceedings) as a result of alleged manslaughter arising from any event which may be the subject of indemnity under this Policy.

PROVIDED THAT

- 3.1.1. the proceedings relate to an offence alleged to have been committed during the Period of Insurance and in the course of the insured Trial or Trials;
- 3.1.2. the Underwriters will not provide indemnity:
- (a) for fines or penalties of any kind;
- (b) in respect of proceedings consequent upon:
- (i) any deliberate act or omission;
- (ii) Bodily Injury sustained by any employee of the Insured.
- (iii) the ownership, possession or use by or on behalf of the Insured or any person entitled to indemnity of any mechanically propelled vehicle while being used in circumstances where insurance or security is required by law.

4. Exceptions

The Underwriters shall not be liable for

- 4.1. any loss, damage or injury, cost or expense of whatsoever nature directly or indirectly caused by or resulting from or in connection with any of the following regardless of any other cause or event contributing concurrently or in any other sequence to the loss:
- 4.1.1. war invasion acts of foreign enemies hostilities or warlike operations (whether war be declared or not) civil war,

rebellion, revolution, insurrection, civil commotion assuming the proportions of or amounting to an uprising military or usurped power; or

4.1.2. any act of terrorism.

For the purpose of this Exception, an act of terrorism means an act including but not limited to the use of force or violence and/or the threat thereof of any person or group(s) of persons whether acting alone or on behalf of or in connection with any organisation(s) or government(s) committed for political religious ideological or similar purposes including the intention to influence any government and/or to put the public or any section of the public in fear.

This Exception also excludes loss damage bodily injury cost or expense of whatsoever nature directly or indirectly caused by or resulting from or in connection with any action taken in controlling preventing suppressing or in any way relating to 5.1.1 and/or 5.1.2 above.

If the Underwriters allege that by reason of this exclusion any loss damage injury cost or expense is not covered by this insurance the burden of proving the contrary shall be upon the Insured.

In the event any portion of this Exception is found to be invalid or unenforceable the remainder shall remain in full force and effect.

4.2. any legal liability of whatsoever nature directly or indirectly caused by or contributed to by or arising from:

4.2.1. ionising radiations or contamination by radioactivity from any nuclear fuel or from any nuclear waste from the combustion of nuclear fuel;

4.2.2. the radioactive toxic explosive or other hazardous properties of any explosive nuclear assembly or nuclear component thereof.

4.3. any Claim arising from Hepatitis or any condition directly or indirectly caused by or associated with 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 or any syndrome or condition of a similar kind howsoever it may be named.

4.4. any Claim arising from any condition directly or indirectly caused by or associated with Transmissible

Spongiform Encephalopathy (TSE), Creutzfeldt-Jakob Disease (CJD), variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease (nvCJD).

4.5. liability arising from any Occurrence happening prior to the Retroactive Date.

4.6. any:

4.6.1. claim made against the Insured prior to the Period of Insurance;

4.6.2. circumstance disclosed by the Insured to the Underwriters prior to the inception of this Policy;

4.6.3. circumstance disclosed by the Insured to any prior insurer; or

4.6.4. any Claim arising out of any Claim or circumstance of which the Insured was aware prior to the inception of this Policy and which the Insured knew, or ought reasonably to have known might give rise to a Claim or loss under this Policy.

4.7. any legal liability of whatsoever nature directly or indirectly caused by or contributed to by or arising from asbestos, asbestos fibres, asbestos dust or any materials containing asbestos.

4.8. any Claim which arises out of any act, error or omission outside of the terms or instructions of the Trial protocol.

4.9. any Claim, judgement, award or settlement made within any country or territory which operates under the laws of the United States of America or Canada or to any order made anywhere in the world to enforce such judgement, award or settlement, either in whole or in part.

4.10. Biological or Chemical Materials Loss, Damage cost or expense of whatsoever nature directly or indirectly caused by, resulting from or in connection with the actual or threatened malicious use of pathogenic or poisonous biological or chemical materials regardless of any other cause or event contributing concurrently or in any other sequence thereto.

4.11. any claim or any benefit to the extent that the provision of such cover, payment of such claim or provision of such benefit would expose the Underwriters or any member of the Underwriters' group to any sanction, prohibition or restriction under United Nations resolutions or the trade or economic sanctions, laws or regulations of any country.

5. Conditions of Compensation

5.1. The Research Subject shall be entitled to

- compensation in accordance with the following:
- 5.1.1. prior to the determination of the Research Subject's Claims or the decision of an Independent Lawyer, the Insured by way of agreement or court ruling offers the Research Subject the option of having the Research Subject Claim determined in accordance with these Conditions of Compensation; and
 - 5.1.2. the Research Subject must agree within three months to the amount of compensation offered by these Conditions of Compensation.
- 5.2. In the event of 5.1.1, but no agreement between the Insured and the Research Subject after three months the amount of compensation payable under these Conditions of Compensation shall be determined by an Independent Lawyer experienced in Medical Litigation and acting as an Arbitrator. The choice of Independent Lawyer shall be with the agreement of the Underwriters and Research Subject and in the absence of such agreement the appointment shall be made by the President for the time being of the Law Society of New South Wales and/or the equivalent body of the State or country in which the Claim is made.
 - 5.3. In the event of the appointment of an Independent Lawyer such person:
 - 5.3.1. shall allow the parties a reasonable opportunity to present their cases with both oral and written evidence;
 - 5.3.2. shall be entitled to obtain independent expert advice;
 - 5.3.3. shall exercise any power conferred upon an Arbitrator by an Arbitration Statute or other law application in the country in which the Claim is made;
 - 5.3.4. shall otherwise determine the procedure in order to arrive at a just settlement.
 - 5.4. In the event that the Insured and the Research Subject agree to be bound by the decision of the Independent Lawyer and the Research Subject accepts the amount of compensation (if any) in full and final settlement of all causes of action against the Insured or any other person in connection with the Trial, the Underwriters will pay the reasonable costs of the Research Subject including the legal costs and expenses.
 - 5.5. If the Research Subject does not accept the decision and award of the Independent Lawyer within three months, the Research Subject shall have no further entitlement pursuant to these Conditions of Compensation but shall be able to pursue such rights as the Research Subject may otherwise have.
 - 5.6. If the Research Subject accepts by agreement with the Insured or the award (if any) of an Independent Lawyer then the Research Subject is bound by the following:
 - 5.6.1. the Research Subject waives all rights of action against the Insured other than under these Conditions of Compensation; and
 - 5.6.2. in the event of any payment under this Policy, the Insured (and the Underwriters) shall be subrogated to all the rights of recovery which the Research Subject may have against any third party and shall receive all help and assistance as the Insured (or the Underwriters) may reasonably require from the Research Subject in exercising and enforcing these rights, provided that any recovery over and above any compensation paid or payable to the Research Subject (after deduction of all costs incurred in effecting such recovery) shall accrue to the Research Subject.
 - 5.6.3. the Research Subject shall sign such release or other documents as the Insured may reasonably require to give effect to Conditions 5.6.1 and 5.6.2.
 - 5.7. Compensation will only be paid if, on the balance of probabilities, the Bodily Injury (including exacerbation of an existing condition) was caused by the administration to or use by the Research Subject of any drug or product involved in the Trial or was directly attributable to participation in the Trial.
 - 5.8. Subject to Condition 5.11 below, compensation will not be refused solely on the basis that the Bodily Injury arose from a foreseeable adverse reaction or that the Research Subject was warned of the risk but still signed a consent form agreeing to participate in the Trial.
 - 5.9. Compensation will not be paid for the failure of a drug or product under Trial to perform its intended purpose.
 - 5.10. Where the Research Subject has not

received the drug or product under Trial, compensation will not be unreasonably withheld from the Research Subject if treatment or other drugs normally used in relieving any conditions for which the Research Subject was undergoing treatment were withheld or rendered ineffective by the administration of a placebo.

- 5.11. The amount of compensation payable shall be made with reference to the amount of damage awarded in similar cases by the courts of the country where the Trial took place and shall be commensurate with the nature and severity and persistence of the Bodily Injury.

The amount of compensation may be reduced, denied or affected by the following circumstances:

- 5.11.1. negligence of the Research Subject or (where the Research Subject is under the age of majority) the Research Subject's parents or legal guardian;
- 5.11.2. the seriousness of the injury treated in the Trial and the degree of probability that adverse reactions would occur and any warning the Research Subject received;
- 5.11.3. the comparison of risk between established treatments and those that are used or researched in a Trial;
- 5.11.4. the availability and efficacy of alternative treatments which would have been available to a Research Subject had that person not agreed to participate in the Trial.

- 5.12. The amount of compensation shall be paid as a lump sum.

6. Conditions

- 6.1. Any word or expression to which a specific meaning has been attached in any part of this Policy shall bear such specific meaning wherever it may appear.
- 6.2. The Insured has a duty of disclosure under the Insurance Contracts Act 1984 and should the Insured fail to comply with that duty of disclosure or make a misrepresentation to the Underwriters before this Policy was entered into and such failure was fraudulent then the Underwriters may refuse payment of a claim and or issue notice of cancellation of this insurance subject to the provisions of the Insurance Contracts Act 1984. Upon receipt of this Policy the Insured

agrees that it has been issued upon the truth of his declarations and representations made to the Underwriters or any of its agents relating to this Insurance.

- 6.3. The terms of this Policy shall not be waived, altered or changed in any way except by endorsement issued by Pen Underwriting or the Underwriters. As soon as practicable within the Period of Insurance, the Insured must notify Underwriters of every change that materially varies any of the facts or circumstances existing at the commencement of this Policy including but not limited to any merger or acquisition of another business and material change to the services offered or the entering into voluntary or involuntary bankruptcy, receivership or liquidation.
- 6.4. If any part of the Deposit Premium is based on estimates furnished by the Insured, the Insured shall keep an accurate record containing all relative particulars and shall allow the Underwriters to inspect such record. Within one month of the expiry of the Period of Insurance the Insured shall furnish such information as the Underwriters may require. The Deposit Premium shall thereupon be adjusted and the difference paid by or allowed to the Insured, subject to the retention by the Underwriters of any Minimum Premium.
- 6.5. The Insured shall take reasonable precautions to prevent any event which may give rise to liability under this Policy and to maintain all buildings, furnishings, ways, works, machinery, plant and vehicles in sound condition and, as soon as possible after discovery, cause any defect or danger to be made good or remedied and, in the meantime, shall cause such additional precautions to be taken as the circumstances may require.
- 6.6. The Insured shall as a condition precedent to their right to be indemnified under this Policy and regardless of any Deductible give immediate written notice to the Underwriters of any Claim. Every Claim shall be forwarded to the Underwriters immediately upon receipt.
- 6.7. No admission, offer, promise, payment or indemnity shall be made or given by or on behalf of the Insured without the written consent of the Underwriters. The Underwriters shall be entitled to conduct in the name of the Insured the defence or settlement or any Claim or to prosecute in the name of the Insured for its own benefit any Claim and shall have sole discretion in the conduct of any proceedings and in the settlement of any

- Claim save as hereinafter provided in Conditions 6.8 and 6.9.
- 6.8. The Insured shall give all such assistance to deal with Claims and the conduct of legal proceedings as the Underwriters and/or its legal advisers and consultants may require.
- 6.9. In connection with any Claims against the Insured, the Underwriters may at any time pay to the Insured the Limit of Indemnity or any lesser amount for which such Claims can be settled and thereupon the Underwriters shall relinquish the control of such Claims and be under no further liability in connection therewith except for costs and expenses which the Underwriters have already agreed to bear in respect of matters prior to the date of such payment.
- 6.10. The insurance afforded by this Policy is excess over and reduced by any other valid and collectable insurance available to the Insured. Valid and collectable insurance includes any self-insurance plan which would be applicable to the loss.
- 6.11. Premium Payment and Policy Cancellation:
- 6.11.1. indemnity under this Policy is in consideration of the payment of the Premium. The Premium shall be paid within forty-five (45) days of inception of this Policy. In the event of non-payment, this Policy may be cancelled.
- 6.11.2. the Insured may cancel this Policy at any time by providing written notice to Pen Underwriting.
- 6.11.3. the Underwriters may cancel this Policy in accordance with the provisions of the Insurance Contracts Act 1984.
- 6.11.4. in the event of Policy cancellation, Pen Underwriting and the Underwriters will calculate the earned Premium at pro-rata to the number of days that the Policy is in effect subject to Pen Underwriting and the Underwriters retaining a minimum amount of thirty percent (30%) of the Premium. Pen Underwriting's fee and commission shall be deemed fully earned at Policy inception.
- 6.11.5. where any circumstance, Claim or loss has been notified to the Underwriters under this Policy, the Premium shall be deemed fully earned.
- 6.12. Where any Claim arises from an Occurrence outside Australia:
- 6.12.1. the Insured will be required to handle the defence and investigation of any Claim where the Underwriters are by law or circumstance prevented from indemnifying the Insured locally;
- 6.12.2. the Underwriters will indemnify the Insured in Australia in respect of any Claim where the Underwriters are by law or circumstance prevented from indemnifying the Insured locally.