Policy Wording

Clinical Trials

vero liability insurance limited

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Contents

Preamble and Insuring Clause

Whereas the Insured named in the Policy Schedule herein has made to Vero Liability Insurance Limited (hereinafter called the Company) a written proposal and declaration which is the basis of this contract and incorporated herein and in consideration of the payment of the premium to the Company, the Company shall indemnify the Insured against all sums which the Insured shall be liable to pay as Compensation (including claimant's costs and expenses) arising out of claims which:

1. are made by Research Subjects arising out of Clinical Research; and

   are either:

   (i) first made in writing against the Insured during the Period of Insurance; or

   (ii) arise out of circumstances notified in writing by the Insured to the Company during such period (as a result of which notification such a claim, although made after the expiry of the Period of Insurance, shall be deemed for the purpose of this Policy to have been first made during such period);

   and

2. the Insured has offered and the Research Subject has agreed to determination of Compensation in accordance with the Compensation Conditions and the Research Subject has by agreement with the Insured or by acceptance of the determination of the Independent Lawyer agreed on the amount of the Research Subject's Compensation entitlement.

Further, the Company hereby agrees to pay Defence Costs, incurred by or on behalf of the Insured in connection with any claim in respect of which the Insured is entitled to indemnity under this Policy.

The Company's total aggregate liability for Compensation (including claimant's costs and expenses) and Defence Costs shall not exceed the Limit of Indemnity stated in the Policy Schedule.

Legal Liability Extension

If this Extension is specified in the Policy Schedule as INCLUDED then, in the event of a Research Subject first making a claim in writing against the Insured during the Period of Insurance but not being offered or not agreeing to any Compensation being determined in accordance with this Policy, or not agreeing to accept the award of the Independent Lawyer, the Company shall indemnify the Insured against all sums for which the Insured shall become legally liable to pay to the Research Subject (including costs and expenses awarded to the Research Subject) as damages for death, bodily injury, physical or mental illness, disease or impairment caused to the Research Subject by the Research Subject's participation in the Clinical Research.

Provided that this Extension:

(a) excludes liability arising out of any obligation assumed by the Insured under any warranty, guarantee, indemnity, agreement or other arrangement to the extent that the Insured's liability exceeds the Insured's liability in the absence of such obligation; and

(b) is in accordance with the law of New Zealand; and

(c) does not increase the Company's total aggregate liability under the Policy beyond the Limit of Indemnity stated in the Policy Schedule.

Exclusions

The Company shall not indemnify the Insured:

1. Accident Compensation Act 2001

any claim for which compensation or any other benefit is available to the Research Subject in terms of the Accident Compensation Act 2001 or any amendments thereto.

2. Asbestos

any actual or alleged liability whatsoever for any claim or claims in respect of loss or losses directly or indirectly arising out of, resulting from or in consequence of, asbestos in whatever form or quantity.

3. Dishonest, Fraudulent or Criminal Act

any claim directly or indirectly caused or contributed to or by any dishonest, fraudulent or criminal act of the Insured.

4. Excess

the amount of the excess stated in the Policy Schedule.

5. External Jurisdiction

any claim or claims made where the action for damages and all subsequent proceedings are not brought in a court of law within New Zealand and subject to the laws of New Zealand or any protectorate thereof.

6. Late Reporting

any claim or any circumstances which may result in a claim reported to the Insured if such claim or circumstances is not reported as soon as possible to the Company.

7. Non-approved Research

any claim arising in respect of any Clinical Research that has not been approved by the Health Research Council of New Zealand, Health Department, or any public or private statutory body which is authorised to approve such Clinical Research and which has not been notified to and approved by the Company.

8. Other Insurance

any claim in respect of which the Insured are entitled to indemnity under any other insurance except in respect of any excess beyond the amount which would have been payable under such insurance had this Policy not been effected.

9. Prior Circumstances

any claim arising out of any circumstance(s) or occurrence(s) which has been or would have been notified under a "No Fault Compensation" insurance policy (howsoever called) attaching prior to the inception of this Policy.

10. Prior Litigation

liability arising out of any litigation in existence at the commencement of the Period of Insurance.

11. Punitive & Exemplary Damages

any claim for punitive and/or exemplary damages

12. Radioactivity, War

any claim directly or indirectly caused by or contributed to by or arising from:

(a) ionising radiations, other than X-Ray equipment; or

(b) contamination by radioactivity from any nuclear fuel or from any nuclear waste from the combustion of nuclear fuel or from the radioactive, toxic, explosive or other hazardous properties of any explosive nuclear assembly or nuclear component thereof; or

(c) war, invasion, acts of foreign enemies, hostilities (whether war be declared or not), civil war, rebellion, insurrection, military or usurped power or confiscation or nationalisation.

Conditions

1. Claims

The Insured shall as a condition precedent to their right to be indemnified under this Policy give to the Company immediate notice in writing:

(a) of any claim made against it;

(b) of the receipt of notice from any person of an intention to make a claim against it;

(c) of any circumstance(s) likely to give rise to a claim against it of which it shall become aware during the Period of Insurance.

2. Control and Conduct

No liability shall be admitted or costs or expenses incurred and no admission, arrangement, offer, promise or payment shall be made by the Insured without the written consent of the Company which shall be entitled at its own choice to take control of the defence of any claim or prosecute in the name of the Insured (which shall be a condition precedent to the Insured's right to indemnity under this Policy) for its own benefit any claim for indemnity, contributions, damages or otherwise against any third party (including any right pursuant to Condition 6 of the Compensation Conditions) and shall have full discretion in the conduct of any negotiations or proceedings, and in the settlement of any claim.

Nevertheless, the Company shall not exercise its subrogated rights of recovery against any principal, partner, director or employee of the Insured as in Definition 6) if the conduct of the said principal, partner, director or employee that gave rise to the loss occurred in the course of or arose out of the employment or contract of service and it was not serious or wilful misconduct.

3. Disclosure

The Insured shall not at any time disclose the terms of this Policy to any person without the Company's written consent, (other than to any Ethics Committee that approved the Clinical Research in question).

4. Disputed Settlement

In the event of any claim, complaint or threat of action being made against the Insured which, in the opinion of the Company should be compromised or otherwise settled but which claim, complaint or threat of action the Insured insists on defending or resisting, the Company shall not be liable for any Compensation, damages, costs and/or expenses incurred from the date of such refusal to compromise as a result of such insistence on the part of the Insured.

5. Full and Final Settlement

In connection with any claims against the Insured the Company may at any time pay the Insured the Limit of Indemnity or any lesser amount for which such claims can be settled and thereupon the Company shall relinquish the control of such claims and be under no further liability in connection therewith except for costs and expenses which the Company has already agreed to bear in respect of matters prior to the date of such payment.

6. Policy Jurisdiction

Any dispute between the Company and the Insured concerning this Policy, its validity or the interpretation of the terms, condition, limitations and/or exclusions contained herein shall be decided in accordance with the law of New Zealand. The Courts of New Zealand shall have jurisdiction in any dispute arising under this Policy to which jurisdiction the parties hereto hereby submit.

7. Premium Adjustment

If the premium for this Policy is based wholly or in part on estimates furnished by the Insured, then the Insured shall as soon as possible after the expiry of the Period of Insurance stated in the Policy Schedule furnish such information as the Company may reasonably require to adjust the premium accordingly.

8. Release from Liability

On any payment by the Company to the Insured under this Policy or in settlement of any claim under this Policy, the Insured will release the Company from all further liabilities and claims under this Policy in relation to the subject matter of the Insured's claim and the Insured will use his best endeavours to procure a release of the Insured by the Research Subject.

9. Subrogation

Compensation shall not be denied or reduced by reason of any wrongful act (actual or alleged) of an Insured as in Definition 6), but an award having been made the Company shall be subrogated to the Research Subject's rights against such defined Insured. Recoveries over and above any compensation paid or award made by the appointed Independent Lawyer (after the deduction of costs incurred in such recovery) shall accrue to the Research Subject.

10. Waiver of Privilege

If the Company instructs any lawyer to investigate or defend any claim against the Insured, the Insured authorises the lawyer to provide to the Company any documents, information or advice in respect of the claim, including in relation to indemnity; and the Insured waives any privilege to the extent necessary to give full effect to the Company's entitlement in this respect.

Compensation Conditions

1. The Research Subject shall be entitled to Compensation in accordance with the principles and conditions set out in these Compensation Conditions if:
   (a) the Insured at any time prior to determination of the Research Subject's claim by agreement or court adjudication offers to the Research Subject the option of having the Research Subject's entitlement to Compensation determined in accordance with these Compensation Conditions; and
   (b) within three (3) months the Research Subject agrees to determination of the Research Subject's entitlement to Compensation in accordance with these Compensation Conditions; and
   (c) either:
      (i) agreement is reached between the Research Subject and the Insured as to the entitlement of the Research Subject to Compensation in accordance with these Compensation Conditions and the amount thereof; or
      (ii) such entitlement and the amount thereof is determined by an Independent Lawyer in accordance with Compensation
      (iii) 2. below and the Research Subject within three (3) months after receiving notice of such determination by written notice to the Insured elects to accept such determination.
2. In the event of the offer and agreement referred to in (a) and (b) of Compensation Condition 1. but no agreement being reached between the Research Subject and the Insured on the Research Subject's entitlement to Compensation under the Compensation Conditions within three (3) months after such agreement, the entitlement of the Research Subject arising out of these Conditions (including but not limited to the cause of the injury suffered by the Research Subject or the amount of compensation payable in accordance with these Conditions) and the amount of the award shall be determined by an Independent Lawyer with experience in medical negligence litigation acting as an expert and not as an Arbitrator. Such Independent Lawyer shall be agreed by the Insured and the Research Subject or in the absence of agreement be appointed by the President for the time being of the Law Society of New Zealand.
3. The Independent Lawyer in making his/her determination:
   (a) shall afford the parties a reasonable opportunity to present their cases to him/her;
   (b) shall in addition to taking into account such written and oral evidence as they may place before

him/her be entitled to obtain independent expert advice (medical or otherwise) of his/her own;

(c) shall be entitled to exercise any power conferred upon an Arbitrator by an Arbitration Statute or other law applicable in New Zealand;

(d) shall otherwise be entitled to determine the procedure which he/she should follow in order to achieve a just and expeditious determination.

4. The Insured agrees to be bound by the decision of the appointed Independent Lawyer and if the Research Subject also agrees to accept the award (if any) of the Independent Lawyer in full and final settlement of all causes of action that the Research Subject may have against the Insured or any other person connected with the performance of the Clinical Research the Company will pay the reasonable costs (including the legal and expert witness costs and expenses) of the Research Subject in presenting his/her case to the Independent Lawyer.
5. If the Research Subject does not elect within the three (3) month period referred to in Compensation Condition 1. to accept the award (if any) of the Independent Lawyer then the Research Subject shall have no further entitlement pursuant to these Compensation Conditions but shall be entitled to pursue such rights as the Research Subject may have other than pursuant to these Compensation Conditions.
6. If the Research Subject by agreement with the Insured or by accepting the award (if any) of the Independent Lawyer becomes entitled to Compensation in accordance with these Conditions:

(a) the Research Subject waives all rights of action against the Insured in respect of the injury otherwise than pursuant to the Compensation Conditions;

(b) the Insured shall be subrogated to and entitled to the Research Subject's rights against any third party and shall receive all help and assistance as the Insured may reasonably require from the Research Subject in enforcing those rights;

(c) however, any recovery over and above any Compensation paid or payable pursuant to the Compensation Conditions (after the deduction of costs incurred in such recovery) shall accrue to the Research Subject;

(d) the Research Subject shall execute and sign such releases, assignments, authorities and other documents as the Insured may be reasonably require to give effect to (a), (b) and (c) herein.

7. Compensation shall only be paid when there is a balance of probability that the injury (including exacerbation of an existing condition) was caused by the administration to or use by the Research Subject of any drug or other product involved in the Clinical Research or was otherwise directly attributable to participation in the Clinical Research.
8. Subject to the Compensation Condition 11., compensation shall not be refused solely on the grounds that the injury arose from an adverse reaction that was foreseeable and/or that the Research Subject was warned of the risk of such adverse reaction occurring but still agreed in writing or otherwise to participate in the Clinical Research.
9. Compensation shall not be paid for the failure of a drug or other product under research to have its intended or any other beneficial effect.
10. In any case where the Clinical Research involves the testing of a drug, compensation shall not be payable to a Research Subject not receiving the drug under the Clinical Research unless the withholding of other drugs or treatment normally used in relieving any condition for which the Research Subject was undergoing therapy or the administration of a placebo to the Research Subject, makes denial of compensation unreasonable.
11. The amount of Compensation payable shall be appropriate to the nature, severity, and persistence of the injury assessed by reference to the measure and quantum of entitlements that would have been available at the date when the claim was made under the Accident Compensation Act 2001 or any amendments thereto, had such entitlements been available to the Research Subject. The amount of Compensation may be reduced to such an extent as may be just and equitable or appropriate in the circumstances in the light of the following factors:

(a) negligence of the Research Subject (or in the case of a Research Subject under the age of 18 at the time consent to participate in the Clinical Research was given by the Research Subject's parent(s) or legal guardian(s)) being a contributory cause of the injury;

(b) the seriousness of the illness being treated in the Clinical Research, the degree of probability that adverse reactions will occur and any warnings given to the Research Subject;

(c) the risk associated with established treatments when compared with those that are known or suspected with the product being researched in the Clinical Research;

(d) the availability and efficacy of alternative treatments that the Research Subject would have had if he/she had not agreed to participate in the Clinical Research.

12. Any Compensation payable shall be awarded in the form of a lump sum.

Definitions

1. Clinical Research

means any Clinical Trial and/or Healthy Volunteer Study as defined in the Business Description in the Policy Schedule which complies with:

(a) the statutory requirements of New Zealand; and

(b) any approved research activity with human beings involving volunteer research and study; and

(c) has been approved by and follows the guidelines, if any, for the time being in force applicable to the Trial or Study, of the Health Research Council of New Zealand, or any successor or replacement authority or any government department, public or private statutory body, which regulates or controls health or medical research in New Zealand,

and is not a Clinical Trial for which approval is required under Section 30 of the Medicines Act 1981 or any amendment thereto, unless otherwise agreed by the Company.

2. Compensation

means the entitlements, that the Research Subject would have been entitled to in terms of the Accident Compensation Act 2001 or any amendments thereto, but for the application of Section 32.(6)(a)(ii) of that Act, to be determined in accordance with the Compensation Conditions herein.

3. Compensation Conditions

means the Compensation Conditions herein.

4. Defence Costs

means all the costs and expenses (including claims handling expenses and the charges, fees or disbursements of any Independent Lawyer appointed under the Compensation Conditions) incurred by the Company in investigating, defending or settling any claim made against the Insured and for which the Insured is entitled to indemnity under this Policy.

5. Independent Lawyer

Means a judge or retired judge or barrister or solicitor of the Courts of New Zealand.

6. Insured

means:

(a) the firm, partnership, institution, company or other Insured named in the Policy Schedule

(b) any person who is, has been or may become during the Period of Insurance a principal, partner, director or employee of the Insured named in the Policy Schedule (the Named Insured) but only in respect of claims arising out of Clinical Research which may be indemnified by this Policy

(c) any person who is engaged as a sub-contractor or consultant or agent to perform work on behalf of the Insured, but only in respect of Clinical Research which may be indemnified by this policy and being undertaken or sponsored by the Named Insured.

(d) any Ethics Committee (the members collectively and/or singly) that approved the Clinical Research, but only in respect of the indemnity provided by the Legal Liability Extension herein.

7. Period of Insurance

means period stated in the Policy Schedule.

8. Research Subject

means any person participating in any Clinical Research or in the pre-Clinical Research assessment including their assigns, spouse or dependants.