Life Sciences Liability - Proposal Form

Your Award Winning Insurer

IMPORTANT INFORMATION: PLEASE READ THE FOLLOWING INFORMATION BEFORE COMPLETING THIS PROPOSAL

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 that 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 Products-Completed Operations Liability, 1.5 Clinicial 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 the policy responds 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, matters or circumstances pursuant to section 40(3) of the Insurance Contracts Act 1984. The facts, matters or circumstances the insured may decide to notify are those which might give rise to a claim against the insured. Such notification must be given as soon as reasonably practicable after the insured becomes aware of the facts, matters or circumstances and before expiry of the policy period. If the insured gives this written notification, the policy will respond even though a claim arising from those facts, matters or circumstances is made against the insured after the policy has expired.

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After the policy period expires, no new notification of facts, matters or circumstances or claims may be made on the expired policy even though the event giving rise to the claim against you 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, matters, circumstances 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, the Insurer will not cover you under the insurance for such loss or damage.

D. Privacy Statement

Berkley Insurance Australia handles your personal information in a responsible manner and in accordance with the Privacy Act 1988 (Cth).

Consent

By requesting us to provide you with insurance and insurance related services, you consent to the collection, use and disclosure of personal information you have provided to us for the purposes set out in our Privacy Policy.

How we collect your personal information

Generally, we collect personal information from you or your agents. Personal information may also be collected by us from our agents and service providers; other insurers and insurance reference bureaus; third parties who may claim under your policies; service providers who assist us in investigating, processing and settling claims; third parties who may be arranging cover for a group that you are part of; statutory, regulatory and law enforcement bodies and from publicly available sources.

Why we collect personal information

The personal information we collect enables us to provide our products and services. This may include processing and settling claims; offering products and services that may be of interest to you and conducting market research for products and services that may be relevant to you.

You can choose not to receive product or service offering from us by calling (02) 92758500 Eastern Standard Time 9am to 5pm Monday to Friday inclusive. For further information, you can access our Privacy Policy at www.berkleyinaus.com.au

Who we disclose your personal information to

Your personal information may be disclosed to other parties with whom we have business arrangements for purposes set out in the paragraph above. These parties may include insurers, intermediaries, reinsurers, related companies, our advisers and parties involved in claims assessment, processing, investigation and settlement. Where required by law, we may also disclose information to government, law enforcement, dispute resolution and statutory or regulatory bodies.

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Personal information about others

Where you provide personal information about others, you represent to us that you have made them aware that you will do so, the types of third parties we may disclose it to together with the purposes we and our third parties use it for, how they can access such information and how complaints can be made Where you provide sensitive information about others, you represent to us that you have obtained their consent. If you have not, and will not do so, you must tell us before you provide the sensitive information.

Overseas Disclosure

Your personal information may be disclosed to other companies in the Berkley group, reinsurers and service providers that may be located in Australia and overseas. The countries this information may be disclosed may vary from time to time but may include the United States of America and other countries where the Berkley group has a presence.

Any information disclosed may only be used for the purposes detailed above.

Accessing your personal information and dealing with complaints

You may request access to the personal information we hold about you by calling us at any time.

Our Privacy Policy details how you can make a complaint about a breach of the privacy principles as set out in the Privacy Act 1988 (Cth) and our complaints process.

Our Privacy Policy is available at www.berkleyinaus.com.au

Contact Details

Berkley Insurance Australia

Level 7, 321 Kent Street

SYDNEY NSW 2000

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LIFE SCIENCES PROPOSAL FORM

1. Full Name of the Organisation				
2. Trading Names				
3. Type of Organisation	☐ Private Company	☐ Public Company	☐ Trust	☐ Not for Profit
	☐ Partnership	☐ Sole Trader	☐ Other(specify)	
4. ABN				
5. Principal Address				
6. Website Address				
7. Contact Person and E-mail address				
8. Country of Registration				
9. Date of Incorporation				

10. Gross Turnover	Last Financial Year	Current Financial Year	Coming Financial Year
Financial Year Ending	/	/	/
Australia			
Elsewhere			
Total			

If elsewhere, please breakdown income and specify location below:

11. Please provide a breakdown of your activities below:

Type of work	% of income last financial year	% of income next financial year
Biotech / Pharmaceutical		
Contract Manufacturing		
Contract Research		
Dietary Supplement		
Medical Device		
Other (please detail below)		

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12. Have you acquired or sold any companies or product lines in the last 5 years in which you have or had 50% or greater ownership interest? If yes, please explain	☐ No	☐ Yes
13. Have you discontinued any product lines in the last 5 years? If yes, please explain	☐ No	☐ Yes
14. What percentage of your sales are generated from license agreements, cooperation or collaboration agreements, or royalty agreements? If greater than 25% please provide copies of the 2 largest agreements in terms of revenue		
15. Are any of your products approved for use in a user population of less than 200,000 or a medical device approved or otherwise eligible for the Orphan Drug Designation Program or the Humanitarian Use Device (HUD) Program (or equivalent programs outside of the U.S.)?	☐ No	☐ Yes
16. Do you have any new products, active pharmaceutical ingredients (APIs) or dietary supplement ingredients that have been on the market less than 3 years? If yes, please describe them, and if applicable, please list those that include new APIs.	☐ No	☐ Yes
CLINICAL TRIALS INFORMATION		
17. Please provide the total number of human clinical trial participants enrolled in the last 3 years.	☐ No	☐ Yes
18. Have any of your clinical trials been approved by an Institutional Review Board (IRB) or Ethics Committee that were previously rejected by a different IRB or Ethics Committee? If yes, please explain.	☐ No	☐ Yes
19. Please provide data per year for each of the last 5 years indicating total medical expenses incurred to treat participants for adverse events that occurred during your clinical trials.		
20. Have any of your Clinical Investigators been cited for regulatory violations associated with any clinical trials?	☐ No	☐ Yes
21. Are you aware of any serious regulatory non-compliance or fraud by Clinical Investigators and/or their staff in the past 3 years involving your trials? If yes, please provide details	☐ No	☐ Yes

REGULATORY / SAFETY SURVEILLANCE INFORMATION		
22. Have you received any warning letters from, or have you been cited for any GMP, GLP, GCP, QS, or Advertising & Promotion violations by, the TGA, ACCC, or any equivalent governmental authority in the last year? If yes, please describe.	☐ No	☐ Yes
23. Other than the TGA or ACCC, have you been investigated or cited by a regulatory or governing body for violation of or non-compliance with any local, state, provincial, regional or federal law in the last five (5) years? If yes, please explain.	☐ No	☐ Yes
24. Have any of your directors, officers, partners or members been investigated for alleged criminal violations relating to your business in the last five (5) years? If yes, please explain	☐ No	☐ Yes
25. Has your product, any product containing your product, or any product on which your work was performed, been banned, seized, or discontinued for safety reasons by the TGA or any equivalent regulatory agency or government entity? If yes, please provide details	☐ No	☐ Yes
26. How many product recalls have you had in the last year? How many were Class I recalls? Please list and identify any recalls not yet classified that you expect to be classified as Class I Recalls.	☐ No	☐ Yes

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27. Identify any safety surveillance team or member recommendations requiring remedial actions that have yet to be implemented (e.g. additional studies, black box warning label / updates, "Dear Healthcare Professional" letter, expanded product monitoring, product recall / withdrawal, etc.)	

ERRORS & OMISSIONS		
28. What is your average contract size?		
29. What is your largest contract size? (If possible please attach a copy of your contract template)		
30. What is the average term of your contracts?		
31. What is the longest contract term?		
32. Do you hold any customer supplied materials as part of any service you provide? **33.** If yes, what is the average value and the largest value?	☐ No	☐ Yes

Average Value		Largest Value	

34. How often in the past 3 years have you accepted changes to your contract template, or agreed to use your customer's template?		
35. Do you have any contracts past due or any active contract disputes? If yes, please explain.	☐ No	☐ Yes

CYBER LIABILITY		
36. Please estimate the number of unique individual records in the care, custody or control of you and your subsidiaries and proposed insured entities.		
37. Do you encrypt data in transit, at rest or stored on laptops or other portable media?	☐ No	☐ Yes
38. Have you implemented a network and data security policy and/or an Incident Response Plan?	☐ No	☐ Yes
39. Do you have a formal business continuity/disaster recovery plan and/or back up critical data on a regular basis?	☐ No	☐ Yes

HISTORICAL AND LOSS INFORMATION		
40. Has any insurance company cancelled, rescinded, or refused to renew your insurance coverage for Products Liability, General Liability, Errors & Omissions / Professional Liability, or Cyber Liability? If yes, please explain.	☐ No	☐ Yes
41. Have any of your products or services ever been involved in class action? If yes, please provide details	☐ No	☐ Yes
42. How many times in the last five (5) years has a claim, demand for damages, or loss or expense exceeded your deductible or retention? Please provide details.		
43. In the last 12 months, have there been any:		
a. Suspension of a clinical trial or changes made to trial documents for safety reasons	☐ No	☐ Yes
b. Class I Product Recall	☐ No	☐ Yes
c. Boxed Warning label additions or changes	☐ No	☐ Yes
d. "Dear Healthcare Professional" letter advising of a serious adverse event	☐ No	☐ Yes
e. Criminal investigation of the insured	☐ No	☐ Yes

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f. Serious Adverse Event reported to the TGA which resulted in recommendations being made that a product label be changed or product be redesigned or reconstituted	☐ No	☐ Yes
g. Actual defects, malfunctions or errors that without correction, would potentially cause a serious adverse event	☐ No	☐ Yes
h. Mass litigation risk (three (3) or more claims first made against the insured in the past 12 months each of which alleges that the same or a substantially similar defect or malfunction in your product or error in your work caused a serious adverse event)	☐ No	☐ Yes
i. Incidents of unauthorised access to or use of a computer system, a denial of service attack or introduction of malicious code or computer virus	☐ No	☐ Yes
j. Theft, loss or unauthorised public disclosure of confidential information	☐ No	☐ Yes
k. Violations of intellectual property or privacy rights due to content on the insured's website or in social media	☐ No	☐ Yes
44. Do you have any reason to expect that any of the events listed in 43. a-k above will occur during the upcoming policy term? If "yes", please explain in detail	☐ No	☐ Yes
45. Are you aware of:		
a. Any fact, circumstance or situation which one might reasonably expect to give rise to a claim, loss or expense that would fall within the scope of the insurance being requested?	☐ No	☐ Yes
b. Any claim, demand for damages, loss or expense not yet reported to any prior or current insurance carrier?	☐ No	☐ Yes
c. Any claim that has become part of multi-district litigation, multi-claimant litigation, or part of a class action?	☐ No	☐ Yes
d. Any multi-district litigation, multi-claimant litigation or class action involving any product on the market that contains the same ingredient as is contained in your product, or is in the same device family as your product, or in which your product was incorporated or on which you performed a service?	☐ No	☐ Yes

NSW	VIC	QLD	SA	WA	TAS	NT	ACT	O/S

If income is generated in NSW, please answer the following additional questions:

a. Is the proposer a Capital Gains Tax small business entity (within the meaning of section 152-10(1AA) of the *Income Tax Assessment Act 1997* (Cth))? No ☐ Yes ☐

b. Is the proposer a small business individual, partnership, company and/or trust, which is carrying on a business, and the business has an aggregated turnover of less than $2,000,000? (Aggregated turnover is your Australia wide annual turnover plus the annual turnovers of any business entities that are your affiliates or are connected with you).
No ☐ Yes ☐

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CURRENT INSURANCE DETAILS

1. Does the proposer currently have insurance in force for the activities for which cover is being sought?

No ☐ Yes ☐ If yes, please provide the following details:

Insurer:	
Limit:	
Excess:	
Renewal date:	
Retroactive Date:	

INSURANCE REQUIRED

Please indicate the limit of indemnity you require and the excess you would prefer (Note: an excess will apply).

Coverage Section	Limit 1	Limit 2	Limit 3
Products Completed Operations and Clinical Trials			
Product Withdrawal Expenses			
Errors & Omissions Liability			
Clinical Trials Only			

Coverage Section	Excess	Excess	Excess
Products Completed Operations and Clinical Trials			
Product Withdrawal Expenses			
Errors & Omissions Liability			
Clinical Trials Only			

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DECLARATION

I declare that I am authorised to complete this Proposal Form (Proposal) on behalf of the Company and that to the best of my knowledge and belief the statements and particulars in this Proposal are true and correct and no material facts have been omitted or misrepresented. I undertake to inform Berkley Insurance Australia (BIA) of any change to any material fact which occurs before any insurance based on this Proposal is entered into (up to an including the policy inception date).

By completing and signing this Proposal you acknowledge, accept and agree that in underwriting and issuing a policy (including replacement policies) BIA does and will rely on all disclosures, proposals, declarations and representations made by you to BIA.

		/			/	2	0		

Date

Name of authorised individual/partner/principal/director

Signature of authorised individual/partner/principal/director

ADDITIONAL INFORMATION - THE FOLLOWING ADDITIONAL QUESTIONS ARE OPTIONAL TO ANSWER HOWEVER BY ANSWERING THESE QUESTIONS IT MAY ALLOW US TO PROVIDE MORE FAVOURABLE TERMS.

ADDITIONAL CLINICAL TRIALS INFORMATION			
1.	Do you require all informed consent documents to be readable at an 8th grade level or below? If no, please explain your reasons.	☐ No	☐ Yes
2.	Do you have, or plan to have, expanded access or compassionate use patients? If yes, please describe any formalised policies for expanded access or compassionate use.	☐ No	☐ Yes
3.	How do you ensure compliance with applicable local, state and federal laws and IRB or Ethics Committee requirements regarding human clinical trials?		
4.	Please describe your process for selecting, training and monitoring your Clinical Investigators including how you audit your Clinical Investigators.		
5.	How do you determine if there may be a conflict of interest with any Clinical Investigators or employees? If such risk is identified, how do you address and manage the risk?		
6.	Are there any duties of the principal investigator that you do not allow to be delegated to investigator support staff? If yes, please identify.	☐ No	☐ Yes

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REGULATORY / SAFETY SURVEILLANCE INFORMATION		
7. Who are the members of your safety surveillance team? How many years of experience do you require a member of the team to have? To whom does the team report?		
8. Does your safety surveillance team have contact with and/or report to your outside board of directors (if applicable)?	☐ No	☐ Yes
9. Who has the authority to suspend a trial, approve a label change, or withdraw a product from the marketplace? Do you have written procedures to address and communicate these actions?		
10. Under what circumstances do you use independent parties to analyse your processes or data?		
11. What steps, if any, would you take if you became aware of a pervasive off- label use of any of your products?		

RISK MANAGEMENT INFORMATION		
12. Provide an overview of your audit procedures. To whom does the audit team report? Who receives a copy of the audit report?		
13. Do you have a Compliance Officer? If yes, to whom does the position report?	☐ No	☐ Yes
14. Do you have an Enterprise Risk Management program? If yes, please describe it.	☐ No	☐ Yes
15. How do you prequalify and monitor foreign suppliers?		
16. What is your internal procedure for change control?		
17. If you use contract production vendors, do you require sign-off on vendor change orders that can impact product quality or performance?	☐ No	☐ Yes
18. Do any of your employees have direct patient contact? If yes, please provide details.	☐ No	☐ Yes
19. Do you follow trade or industry guidelines as respects interactions with Healthcare Professionals?	☐ No	☐ Yes
20. Please describe your claims escalation procedures.		
21. Do you have formalised information privacy policies and procedures that are compliant with applicable local, state and federal laws?	☐ No	☐ Yes
22. Do you have a written information security policy?	☐ No	☐ Yes
23. Do you have a code of conduct and annual training / certification for employees?	☐ No	☐ Yes
24. Do you have a system for documenting compliance violations and corrective actions?	☐ No	☐ Yes
25. Is there a method for employees to report compliance issues anonymously? What is the escalation process for such reports?		
26. How do you communicate that new employees should not bring intellectual or personal property with them from former employers?		

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27.	If you perform work on behalf of others, how do you evaluate the risk to you associated with your customers design / formulation, labelling & marketing of that product?		
SALES & MARKETING INFORMATION			
28.	Please describe the extent of your direct to consumer advertising, if any. How do you ensure your advertisements to consumers are both balanced and informative?		
29.	How do you ensure that your internal and external sales and marketing representatives conform to product safety, label indication and adverse event information when communicating with customers		
30.	How do you manage and conform to approved methods for communicating off-label information regarding your products?		
31.	Do you allow employees to advertise direct product comparisons against competitors' products? If yes, which employees are authorised to make these comparisons?	☐ No	☐ Yes
32.	How often do you train your sales and marketing staff on how to insulate your company from products liability exposures?		
33.	To what extent is your marketing group involved with scientific educational programs? Is your grant-giving function independent of your sales and marketing department?		
34.	Do any of the individuals or entities to which you sell your product have an ownership or other financial interest in your company or any of your products or services? (For purposes of this question, ownership or other financial interest does not include ownership of an immaterial amount of stock) If yes, please describe.	☐ No	☐ Yes
CONTRACT MANAGEMENT INFORMATION			
35.	Describe how you monitor your contractual obligations for confidentiality agreements and granting of additional insured status.		
36.	Under what circumstances does someone other than a senior officer or an attorney in your legal department have the authority to sign contracts?		
37.	Do you have a standard contract template that you utilise? If yes, please attach	☐ No	☐ Yes
38.	If applicable, who has the authority to deviate or make changes to the standard template wording? Does your legal department sign off on any and all changes?	☐ No	☐ Yes
39.	Are all contract changes required to be in writing and signed by both parties?	☐ No	☐ Yes
CYBER LIABILITY			
40.	Do you use firewalls at the perimeter of your network?	☐ No	☐ Yes
41.	Do you utilise antivirus/anti-malware software on all computers?	☐ No	☐ Yes
42.	Do you require employee passwords of at least eight characters that include at least one number and a special character?	☐ No	☐ Yes
43.	Do you deploy critical (software/firmware) updates, patches/hot-fixes or Service Packs on a regular basis?	☐ No	☐ Yes

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44.	Do you use any software or hardware that has been officially retired (end-of-life) that the manufacturer or developer is no longer supporting with updates and/or software patches?	☐ No	☐ Yes
45.	Do you revoke employee computer access when an employee is terminated?	☐ No	☐ Yes
46.	Do you have physical security controls of the Insured's Premises where computers, networking equipment, written and electronic records are kept?	☐ No	☐ Yes
47.	Have you implemented a network-based Intrusion Detection System?	☐ No	☐ Yes
48.	Do you perform vulnerability scanning/penetration testing on a regular basis?	☐ No	☐ Yes
49.	Do you provide security awareness training for employees?	☐ No	☐ Yes
50.	Are you currently compliant with Payment Card Industry Data Security Standards (PCI DSS) based on your merchant level? Check Here if you do not store, maintain or process credit card data ☐	☐ No	☐ Yes
51.	Do you comply with local, state, federal and international security and privacy laws affecting your business?	☐ No	☐ Yes
52.	Do you review content prior to posting on your website or your controlled social media site to ensure it does not contain any defamatory or libellous material or infringes on another's copyright, trademark, service mark or collective mark?	☐ No	☐ Yes

OTHER

53.	Describe or detail any information not previously included in this application which you feel would help us to better evaluate your company.

ADDITIONAL INFORMATION DECLARATION

I declare that I am authorised to complete this Proposal Form (Proposal) on behalf of the Company and that to the best of my knowledge and belief the statements and particulars in this Proposal are true and correct and no material facts have been omitted or misrepresented. I undertake to inform Berkley Insurance Australia (BIA) of any change to any material fact which occurs before any insurance based on this Proposal is entered into (up to an including the policy inception date).

By completing and signing this Proposal you acknowledge, accept and agree that in underwriting and issuing a policy (including replacement policies) BIA does and will rely on all disclosures, proposals, declarations and representations made by you to BIA.

		/			/	2	0		

Date

Name of authorised individual/partner/principal/director

Signature of authorised individual/partner/principal/director

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