SURA TECHNOLOGY RISKS

Level 14 / 141 Walker St
North Sydney NSW 2060
Po Box 1813
North Sydney NSW 2059

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Life Science Proposal Form

Important Information

In this application:

You/Your refers to all firms to be insured under this arrangement, including any predecessor or previous business for which cover is required.

Firm means any business, whether a sole trader, partnership or company, limited in liability or otherwise.

Principal means any Director, Partner, Member or Sole Trader.

The information You provide in this document and through any other documentation, either directly or through Your insurance broker, will be relied upon by the Insurer to decide whether or not to accept Your insurance as proposed and if so, on what terms.

Every question must be answered fully, truthfully and accurately. If space is insufficient for Your answer, please use additional sheets, sign and date each one and attach them to this document.

If You do not understand or if You have any questions regarding any matter in this document, including the Important Information, please contact Us or Your insurance broker before signing the Declaration at the end of this document.

Unless We have confirmed in writing that temporary cover has been arranged, no insurance is in force until the risk proposed has been accepted in writing by Us and You have paid or agreed to pay the premium.

Duty Of Disclosure

This Policy is subject to the Insurance Contracts Act 1984 (Act). Under that Act You have a Duty of Disclosure.

Before You take out insurance with Us, You have a duty to tell Us of everything that You know, or could reasonably be expected to know, may affect Our decision to insure You and on what terms. If You are not sure whether something is relevant You should inform Us anyway.

You have the same duty to inform Us of those matters before You renew, extend, vary, or reinstate Your contract of insurance. The duty applies until the Policy is entered into, or where relevant, renewed, extended, varied or reinstated (Relevant Time). If anything changes between when the answers are provided to Us or disclosures are made and the Relevant Time, You need to tell Us.

Your duty however does not require disclosure of matters that:

- reduce the risk;
- are common knowledge;
- We know or, in the ordinary course of Our business, ought to know; or
- We have indicated We do not want to know.

If You do not comply with Your duty of disclosure, We may be entitled to:

- reduce Our liability for any claim;
- cancel the contract;
- refuse to pay the claim; or
- avoid the contract from its beginning, if Your non-disclosure was fraudulent.

Claims Made Policy

Sections 2 – Products and Services Liability, Section 3 – Clinical Trials Liability, Section 4 – Professional Indemnity, Section 5 – Medical Professional Liability and Section 6(2) – Third Party Cyber Liability are issued on a "claims made" basis. This proposal is for a Claims Made Policy. This means that the policy only responds to:

- claims first made against You and notified to the Insurer during the policy period arising from events after any retroactive date on the policy, and
- events of which You first become aware during the policy period that could give rise to a future claim provided that You notify the Insurer during the policy period of the circumstances of such events and they arose after any retroactive date on the policy.

When the policy expires, no claims can be made on the policy even though the event giving rise to the claim may have occurred during the policy period.

Privacy Statement

We are committed to protecting Your privacy in accordance with the Privacy Act 1988 (Cth) and the Australian Privacy Principles (APPs), which will ensure the privacy and security of Your personal information.

The information provided in this document and any other documents provided to Us will be dealt with in accordance with Our Privacy Policy. By executing this document You consent to collection, use and disclosure of Your personal information in accordance with Our Privacy Policy. If You do not provide the personal information requested or consent to its use and disclosure in accordance with Our Privacy Policy, Your application for insurance may not be accepted, We may not be able to administer Your services/products, or You may be in breach of Your duty of disclosure.

Our Privacy Policy explains how We collect, use, disclose and handle Your personal information including transfer overseas and provision to necessary third parties as well as Your rights to access and correct Your personal information and make a complaint for any breach of the APPs.

A copy of Our Privacy Policy is located on Our website at www.sura.com.au

Please access and read this policy. If You have any queries about how We handle Your personal information or would prefer to have a copy of Our Privacy Policy mailed to You, please ask Us.

Agent Of Insurers

In arranging this insurance, SURA Professional Risks Pty Ltd is acting under an authority given to it by insurers, and is acting as the agent of the insurer and not as Your agent.

General Insurance Code Of Practice

We proudly support the General Insurance Code of Practice.

The purpose of the Code is to raise the standards of practice and service in the general insurance industry. For further information on the Code, please visit www.codeofpractise.com.au

Not a Renewable Contract

The Life Science Package Policy is not a renewable contract so the Policy will terminate on the expiry date indicated. If you therefore require a subsequent Policy, you will need to complete and submit a new proposal form for assessment prior to the termination of the current policy.

1. Applicant details

Company Name (Include names of all subsidiaries or affiliated companies to be insured)

Name

ABN

Indicate company type

☐ Individual ☐ Corporation ☐ Joint Venture ☐ Partnership Other

2. Address of firm

Address

Postcode

City

Date Established / /

Email

Website

3. Period of insurance required

Insurance required from / / expiring at 4pm on / /

4. Geographical area in which you operate

Is Your Business represented outside Australia? ☐ Yes ☐ No

If 'yes' please give details

Does the Business provide any Products or Services in:

☐ Cuba ☐ Iran ☐ North Korea ☐ Syria ☐ the Crimea Region of Ukraine

☐ any territory subject to any sanction, prohibition or restriction under United Nations resolutions or the trade or economic sanctions, laws or regulations of the European Union, the Commonwealth of Australia, United Kingdom or the United States of America?

If "Yes" to any of the above, We may require additional information to be provided to Us.

5. Financial Information

What is Your Annual Turnover broken down by Territory?

	Last Year	Current Year	Next Year
Australia and New Zealand	$	$	$
USA/Canada	$	$	$
Rest of the World	$	$	$
Total	$	$	$

Please provide a percentage breakdown of turnover by location

NSW	VIC	QLD	SA	WA	TAS	NT	ACT	Overseas
%	%	%	%	%	%	%	%	%

Limits of insurance/excess requested

Section	Max Limit Available	Limit Requested	Excess Requested
Section 1 – Public Liability	AUD20,000,000	$	$
Section 2 – Products and Services Liability	AUD20,000,000	$	$
Section 3 – Human Clinical Trials Liability	AUD20,000,000	$	$
Section 4 – Professional Indemnity	AUD20,000,000	$	$
Section 5 – Medical Professional Liability	AUD5,000,000	$	$
Section 6 – First and Third Party Cyber	AUD250,000	$	$

Product/Service Profile

Source/Potential Source of Revenues	% of T/O	Product/Service Description
Blood/Plasma/Tissue Banks	%	
Manufacturing – Pharmaceuticals	%	
Manufacturing – Medical Devices	%	
Contract Manufacturing – Pharmaceuticals	%	
Contract Manufacturing – Medical Devices	%	
Clinical Research Organisation	%	
Distributor – Pharmaceuticals	%	
Distributor – Medical Devices	%	
Diagnostic Laboratories	%	
Equipment Rentals/Leasing	%	
Research	%	
Repair/Installation/Service	%	
Other (Please explain)	%	

Product/Service Types

Pharmaceuticals	% of T/O
Proprietary Pharmaceuticals	%
Diet Aids	%
Generic Pharmaceuticals	%
Vaccines	%
Clinical Research	%
Infusions	%
Imaging / Diagnostic Agents	%
Nutraceuticals	%
Other (Please explain)	%

Medical Devices	% of T/O
Cardiac Devices	%
Therapy/Rehabilitation	%
Anaesthesia/Respiratory	%
Dialysis Equipment	%
Implants (Active)	%
Drug Delivery Systems	%
Implants (Non-Active)	%
Non-Cardiac Catheters	%
Lasers	%
Analytical Instruments	%
Surgical Devices	%
Diagnostic Kits	%
Dental Instruments	%
Durable Medical Equipment	%
Monitoring Devices	%
Hospital Products/Supplies	%
Imaging Devices	%
Other (Please explain)	%

Are any products manufactured and/or sold under others' labels? Yes No

If 'yes', please explain

Are any products sold as components for other products? ☐ Yes ☐ No

If 'yes', please indicate the likely end product

Do You subcontract/utilize independent contractors for product development, manufacturing, sales, and/or distribution services? ☐ Yes ☐ No

If 'yes', please indicate activities contracted

Professional Services

Contracted Professional Services	% of T/O	Contracted Professional Services:	% of T/O
Preclinical Testing	%	Biostatistics	%
Pharmacodynamics	%	Submission of Regulatory Filings	%
Pharmacokinetics	%	Bioequivalency/Bioavailability Testing	%
Study Participant Selection or Monitoring	%	Quality Control Monitoring	%
Clinical Investigations (Please indicate phase.)	%	Manufacturing	%
Clinical Staff Recruitment	%	Repackaging/Assembly	%
Clinical Staff Training	%	Product/Equipment Sterilization	%
Case Report Form Design	%	Marketing	%
Data Entry/Database	%	Sales Management	%
Publications/Software Design	%	Distribution	%
Other (Please explain)	%		

Do any of Your employees provide direct patient care? ☐ Yes ☐ No

Do they carry their own individual medical professional liability coverage? ☐ Yes ☐ No

Do You operate an inpatient facility? ☐ Yes ☐ No

Do any of Your employees participate on an institutional review board/independent ethics board? ☐ Yes ☐ No

Do You or Your employees have a financial interest in the products of Your clients? ☐ Yes ☐ No

Products/Product Classes/Diseases

Do You have any products, services or studies involving any of the following (include past and future activities)?

(Please note that some of these specific products may be excluded within the policy. These exclusions may be partially deleted subject to appropriate and satisfactory information.)

Products

- ☐ Acetaminophin
- ☐ Adalimumab
- ☐ Aprotinin
- ☐ Carbamazepine
- ☐ Cisapride
- ☐ Dasatinib
- ☐ Dexfenfluramine
- ☐ Diethylstilbestrol (DES)
- ☐ Divalproex Sodium
- ☐ Estrogen
- ☐ Fenfluramine
- ☐ Fentanyl
- ☐ Gadolinium-based Contrast Agents (GBCAs)
- ☐ Heparin
- ☐ Isotretinoin
- ☐ Norepinephrine
- ☐ Omalizumab
- ☐ Ondansetron
- ☐ Phentermine
- ☐ Phenyl proxyphene
- ☐ Phenytoin
- ☐ Protease Inhibitors
- ☐ Quetiapine
- ☐ Sibutramine
- ☐ Thimerosal
- ☐ Topiramate
- ☐ Varenicline
- ☐ Zolpidem

Product Class

- ☐ 5-Alpha Reductase Inhibitors
- ☐ Agonist/Antagonist [EPC]
- ☐ Alpha-Adrenergic Blocker [EPC]
- ☐ Angiotensin 2 Receptor Blocker [EPC]
- ☐ Angiotensin Converting-Enzyme (ACE) Inhibitors
- ☐ Anti-coagulant [EPC]
- ☐ Antidepressants
- ☐ Anti-epileptic Agent [EPC]
- ☐ Anti-fibrinolytic Agent [EPC]
- ☐ Anti-IgE [EPC]
- ☐ Atypical Antipsychotic [EPC]
- ☐ Beta2-Adrenergic Agonist [EPC]
- ☐ Bisphenol A (BPA)
- ☐ Bisphosphonates
- ☐ Botulinum Toxin Products
- ☐ COX-2 inhibitors
- ☐ Di-(2-ethylhexyl) Phthalate ("DEHP")
- ☐ Dipeptidyl Peptidase 4 (DPP-4) Inhibitors
- ☐ Efalizumab CD11a-directed Humanized IgG1 Antibody [EPC]
- ☐ Fertility goods or products
- ☐ Gamma-Aminobutyric Acid-ergic Agonist [EPC]
- ☐ Gene Therapy Products
- ☐ GI Prokinetic Agent
- ☐ Giltazones (TZDs)/ Thiazolinediones
- ☐ Glucagon-like Peptide-1 (GLP-1) Receptor Agonist [EPC]
- ☐ Gonadotropin Releasing Hormone Receptor Agonist [EPC]
- ☐ Gonadotropin-Releasing Hormone Agonists (GnRH-As)
- ☐ Hemotherapeutic Antibiotics/ Vaccines
- ☐ Hormone Replacement Products
- ☐ Human Immunoglobulin G [EPC]
- ☐ Incretin Mimetics
- ☐ Kinase Inhibitor [EPC]
- ☐ Long-acting Beta Agonists
- ☐ Metoclopramide Dopamine-2 Receptor Antagonist [EPC]
- ☐ Non-steroidal Anti-inflammatory drugs (NSAIDs)
- ☐ Opioid Agonist [EPC]
- ☐ Oral Sodium Phosphates
- ☐ Paramagnetic Contrast Agent [EPC]
- ☐ Partial Cholinergic Nicotinic Agonist [EPC]
- ☐ Peroxisome Proliferator Receptor alpha Agonist [EPC]
- ☐ Retinoid [EPC]
- ☐ Selective Serotonin Reuptake Inhibitors (SSRI)
- ☐ Serotonin and Dopamine Reuptake Inhibitor Anorectic [EPC]
- ☐ Serotonin-3 Receptor Antagonist [EPC]
- ☐ Standardized Chemical Allergen [EPC]
- ☐ Sympathomimetic Amine Anorectic [EPC]
- ☐ Thiazolidinedione [EPC]
- ☐ Tumor Necrosis Factor (TNF) Inhibitors
- ☐ Tumor Necrosis Factor Blocker [EPC]

Diseases

- ☐ Acquired Immune Deficiency Syndrome (AIDS)
- ☐ Transmissible Spongiform Encephalopathy (TSE)
- ☐ Transmissible Spongiform Encephalopathy (TSE)
- ☐ Coronavirus disease (COVID-19)

List any new products expected to be introduced in the next 12 months.

List any discontinued products. (Please indicate reason(s)).

Contract Management

Details of Your three (3) largest contracts (only applicable for contacts over $250k).

Name of customer	Value of contract	Description	Duration
	$		Months
	$		Months
	$		Months

Contract Terms

1. What is the value of Your largest contract? $
2. What is the maximum contract length?
3. Do You always have a written contract in place with Your customers? ☐ Yes ☐ No
4. How often do You use Your own standards and conditions of trade %?
5. Do the standard customer contract terms and conditions:
   - a) Exclude Consequential / indirect losses? ☐ Yes ☐ No
   - b) Limit the Insureds liability to the contract value? ☐ Yes ☐ No
   - c) Limit the Insureds liability to a fixed amount? ☐ Yes ☐ No
6. What % of all customer contracts include a limitation of liability? %
7. Who approves any deviation from Your standard terms and conditions of trade with Your customers?

8. Are You able to confirm that:

a) Contracts are always drafted by legal professionals or vetted by legal advisors? ☐ Yes ☐ No

b) Written procedures or checklists are used for the professional services provided? ☐ Yes ☐ No

c) Contracts or terms of acceptance are evidenced in writing, specify the work to be undertaken and the extent of the insureds responsibility? ☐ Yes ☐ No

d) Records are kept of all contracts, letters of engagement, client meetings and telephone calls? ☐ Yes ☐ No

e) All variations from the initial scope of works are documented in writing, with client acceptance? ☐ Yes ☐ No

f) Diary systems or other procedures are in operation to ensure that deadlines are met? ☐ Yes ☐ No

g) Working papers are retained for at least 3 years? ☐ Yes ☐ No

Clinical Trials

Sponsored Clinical Trials (Please attach approved protocols and informed consent documents for active clinical trials).

Product	Phase	No. of new subjects over next policy period	Indications	Country/State

No. of expanded access/compassionate use subjects anticipated in the coming policy period?

Total number of human subjects enrolled in the last three (3) years?

Have there been any clinical trials during the past three (3) years involving Your product which have been discontinued or suspended in whole, or in part, because of safety reasons? ☐ Yes ☐ No

If 'yes' to above, please provide details below:

Have any clinical investigators been cited during the past three (3) years for regulatory violations in connection with Your trials? ☐ Yes ☐ No

If 'yes' to above, please provide details below:

Have You provided material or product for investigator-sponsored trials in the past twelve (12) months? ☐ Yes ☐ No

Have You provided material or product for another organisation's clinical study / trial the past twelve (12) months? ☐ Yes ☐ No

During the past twelve (12) months, have You agreed to use any new clinical trial compensation guidelines to compensate participants injured in Your clinical trial(s)? ☐ Yes ☐ No

If 'yes' to above, please provide details below:

Regulatory

Have You provided material or product for another organisation's clinical study/trial the past twelve (12) months? ☐ Yes ☐ No ☐ N/A

Do You have operations in/exports to the United States? ☐ Yes ☐ No

If 'yes', are such products approved by the U.S. Food and Drug Administration (FDA)? ☐ Yes ☐ No

Supply the dates of the most recent TGA or similar authority inspection:

Have any products or company practices been subject to an investigation by any government agency? ☐ Yes ☐ No

If 'yes', please explain

Are any product components imported? ☐ Yes ☐ No

If yes, are they TGA approved? ☐ Yes ☐ No

Do any of Your products training/certification programs require the approval of the TGA or any other similar national organisation? ☐ Yes ☐ No

Are manufactured products UL listed and/or CSA certified? ☐ Yes ☐ No

Are the manufactured products listed or certified by any national organisation? ☐ Yes ☐ No

Do You use another organisation for reliability/design validation? ☐ Yes ☐ No

Do You require certificates of insurance from suppliers? ☐ Yes ☐ No

If yes, indicate limits required:

Have You had any product recalls in the past year? ☐ Yes ☐ No

If 'yes', please provide details and current recall status

Within the past twelve months, have You filed any medical device reports? ☐ Yes ☐ No

If 'yes', indicate the number of filings and the nature of each filing

Have any clinical trials been placed on hold? ☐ Yes ☐ No

If 'yes', provide details

Do You audit clinical investigator performance? ☐ Yes ☐ No

Have You received any warning letters during the last three (3) years? ☐ Yes ☐ No

If 'yes', please explain

Is there a written and implemented loss prevention/control programme? ☐ Yes ☐ No

If 'yes', please note the name and title of the individual responsible for the programme

Is there a written and implemented quality control programme? ☐ Yes ☐ No

Is there a written and implemented product recall plan? ☐ Yes ☐ No

Are promotional materials, contracts, guarantees, and labelling reviewed by risk management and legal counsel? ☐ Yes ☐ No

Cyber

Do You require incidental cyber insurance? (Full cyber coverage may be considered on a standalone basis as a separate policy if the incidental cover is insufficient for Your needs)	Yes	No
Do You have controls in place ensuring timely removal of system access when an employee leaves the organisation, or when access is no longer required for business purposes?	Yes	No
Do You perform backups of data, applications and system configurations at least weekly?	Yes	No
If the backups are physically stored off-site, are they are encrypted?	Yes	No
Do You know what sensitive or private information is in Your custody, where it is stored and how to contact individuals in the event of a breach?	Yes	No
Do You have and follow a data retention and destruction policy?	Yes	No
Do You have the following security standards in place:		
• regularly updated firewalls and anti-virus systems?	Yes	No
• security patches for Your system are implemented as soon as practical?	Yes	No
If remote access is allowed to Your corporate network, do You limit to 2FA (e.g. some combination of VPN or Access Token, and password/account login) only?	Yes	No
Do You encrypt sensitive data that is physically removed from Your premises by mobile device (e.g. laptop/USB/ mobile phones)?	Yes	No
Are You aware of a matter that is reasonably likely to give rise to any loss or claim, or have You suffered any loss or has any claim being made against You in the last 5 years?	Yes	No
Have You been subject to any government action, investigation or subpoena regarding any alleged violation of any privacy/data security law or regulation?	Yes	No

Insurance and Loss History

Loss History

(Provide total aggregate losses from ground up, including related claim defence expenses, for the last five (5) years and attach previous insurer loss history.)

Policy Period	Insurer	No. of Claims	Total Incurred

Have any known occurrence(s) not yet been reported? ☐ Yes ☐ No

If 'yes', please submit details

Coverage History

Policy Period	Primary and Excess Limits	Insurer(s)	Retroactive Date

Has any insurer ever cancelled or non-renewed any of Your insurance coverages? ☐ Yes ☐ No

If 'yes', please explain

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Declaration

This Declaration must be signed by the intending insured as the Proposer(s). If the intending insured is a Company, Partnership or other business venture or involves more than one person or entity, then the person signing this declaration must be authorised to sign on behalf of all persons / entities identified as the intending insured(s).

Before completing this document, I/We have read and understood the information herein, including the Important Information.

I/We agree that this Proposal Form together with any other information supplied by me/us shall form the basis of any Contract of Insurance effected.

I/We undertake to inform the insurer of any material alteration to this information occurring before the proposed insurance commences.

I/We declare that the statements and particulars contained in this Technology Insurance Proposal Form are true and complete and that I/we have not misstated or suppressed any material facts.

I/We understand that the insurer is relying on information supplied herein to decide whether or not to accept or reject this risk and that no material information has been knowingly withheld.

I/We acknowledge that by submitting this completed Proposal Form (with any other information) I/We consent that the insurer may use and disclose my/our personal information in accordance with the "Privacy Statement" at the beginning of this Proposal. This consent remains valid until I/We alter or revoke it by written notice.

I/We also undertake to advise any changes to my/our personal information.

I/We authorise SURA Technology Risks or its agent to give to and obtain from other insurers, insurance reference bureaus and credit reporting agencies any information relating to the insured's credit or insurance history as well as insurance claims information obtained during the course of this contract.

Name of firm

Signature

(This Proposal is to be signed by a Principal, Partner or Director of the Proposed Insured)

Title of signatory

Full name

Date

/ /