R&D

INSURANCE FOR RESEARCH & DEVELOPMENT COMPANIES

APPLICATION FORM

INTRODUCTION

The purpose of this application form is for us to find out who you are and to obtain information relevant to the cover provided by the BioSurance™ R&D policy. Completion of this application form does not oblige either party to enter into a contract of insurance.

Insurance is a contract of utmost good faith. This means that the information you provide in this application form must be complete, accurate and not misleading. It also means that you must tell us about all facts and matters which may be relevant to our consideration of your application for insurance. Any failure by you in this regard may entitle us to treat this insurance as if it never existed. If a contract of insurance is agreed between you and us this application form will form the basis of the contract.

Important: Some of the cover provided by this policy is on a claims made basis. This means that a claim must be first made against the Insured and notified to us during the period of the policy to be covered and a claim wil not be covered if it arises out of any actual or alleged wrongful act occurring before the Retroactive Date.

HOW TO COMPLETE THIS FORM

Whoever fills out the form must be a principal, partner or director of the applicant firm and should make all the necessary enquiries of their fellow partners, directors and employees to enable all the questions to be answered.

If you require any extra space to complete the answers to questions contained within this application form please continue your response in the Additional Information section at the back of the form. Once you have completed the form please return directly to your insurance agent.

SECTION 1: COMPANY DETAILS

1.1 Please provide the following details:

Insured company:

Contact name:

Address:

Postal code:

Telephone: Email address:

Fax: Website:

1.2 Please state when your company was established: DD / MM / YY

1.3 Please briefly describe below the nature of your business activities:

If you have a brochure, or company literature, please attach to this form

1.4 Please outline below your business development plans for the next 12 months, including the number of products under development and the stage of development for each:

If you have a copy of an up to date business plan, please attach to this form

1.5 Please state the number of employees:

SECTION 2: PREMISES DETAILS

2.1 Please provide below details of your premises:

PREMISES 1

Address:

Postal code:

Details of usage (e.g. labs, storage, offices etc.):

PREMISES 2

Address:

Postal code:

Details of usage:

Please continue on a separate sheet if more than two premises are to be insured

2.2 Please provide details of the premises of your supply chain partners that carry out significant work on your behalf, including those where you require cover for damage to your property and those where you have a significant reliance on them for your business activities:

Name and Address	Details of Usage

2.3 Are all of the premises:

a) Constructed with external walls of brick, stone or concrete and roofed with slate, tiles, concrete, metal, asbestos or any other non-combustible material? ☐ Yes ☐ No

b) Free from cracks or other signs of damage that may be due to subsidence, landslip or heave and have not previously suffered damage by any of these causes? ☐ Yes ☐ No

c) In an area free from flooding and not near the vicinity of any rivers, streams or tidal waters? ☐ Yes ☐ No

d) In a good state of repair? ☐ Yes ☐ No

e) Self contained with a lockable entrance door? ☐ Yes ☐ No

f) Protected by fire and intruder alarms that are subject to an annual maintenance contract? ☐ Yes ☐ No

NOTE: We may refuse to pay a claim if all of the devices for the protection of your premises (including locks and alarms) are not put into full and effective operation whenever the premises are closed for business or left unattended.

g) Heated by a conventional electric, gas, oil or solid fuel heating system? ☐ Yes ☐ No

h) Fitted with electrical installations which are inspected at least every 5 years by a qualified electrician and any defect remedied? ☐ Yes ☐ No

i) Lifts, boilers, steam and pressure vessels inspected and approved to comply with all of the statutory requirements? ☐ Yes ☐ No

NOTE: Assuming you have answered yes to questions h) and i) above, it is important to keep records of all relevant inspections as we may ask for evidence for these before paying a claim.

If you have answered no to any of the above questions, please provide further details:

2.4 If any of the premises listed in 2.1 and 2.2 contain composite or sandwich panels, please provide details:

Address	Are panels exterior or interior?	Type of Panel (Make, model, core material)	Are products LPS1181: 2003 or FMRC4880 (1994) approved?

SECTION 3: ACTIVITIES

3.1 Do you directly work with, or store, radioactive or biohazardous materials at your premises? ☐ Yes ☐ No

If yes, please provide further details below including types of materials, quantities used and how you manage the process of using, storing and disposal:

3.2 Is your stock sensitive to changes in environmental conditions? ☐ Yes ☐ No

If yes, please answer the following:

a) What proportion of stock is temperature sensitive? ____ %

b) Is all stock stored in fridges / freezers which are less than 3 years old, or subject to maintenance agreements? ☐ Yes ☐ No

c) Is electricity delivered by underground cables, with no overhead power lines in the immediate vicinity? ☐ Yes ☐ No

d) Do all fridges / freezers have back up power generators? ☐ Yes ☐ No

If yes, how many hours back up is provided? ____ Hours

e) Do you have an alarm system that activates if the temperature falls outside the prescribed range? ☐ Yes ☐ No

f) Is the alarm system monitored by a third party central station? ☐ Yes ☐ No

g) Is stock duplicated in more than one freezer on the same site? ☐ Yes ☐ No

h) Is stock duplicated in more than one freezer at different sites? ☐ Yes ☐ No

i) Do you have a formal Business Continuity Plan for a power outage or failure in storage arrangements? ☐ Yes ☐ No

3.3 Are specialist couriers utilized for stock transport? ☐ Yes ☐ No

If no, please provide details of the arrangements:

3.4 Please state stock consignment values:

	Annual Value	Maximum Value of one Consignment
Canada:		
Outside Canada, but within North America:		
Elsewhere in the world:		

3.5 Will you transport stock to areas where the government currently advises against travel? ☐ Yes ☐ No

If yes, please provide details below:

3.6 Are you involved with R&D of your own products? ☐ Yes ☐ No

If no, please go to question 3.10

3.7 Please state your annual gross expenditure:

3.8 Please state what proportion of your annual gross expenditure is attributable to:

Fixed internal cost (including payroll):	%
Variable internal cost (such as lab consumables):	%
Contractually committed payments for services to third parties:	%
Third party contracts with full 'force majeure' provisions to your benefit:	%

3.9 Please provide details of your contingency plans to continue R&D activities, if damage at the premises listed in 2.2 means your supply chain partners are unable to fulfil contractual commitments:

Supplier Name	Nature of Reliance	Contingency Plans

3.10 Do you receive income from products or services provided to third parties? ☐ Yes ☐ No

If no, please go to section 4

If yes, please state the income received in the box below (in CAD):

Location of Client	Last Complete Financial Year		Current Financial Year (estimate)	
	Products	Services	Products	Services
Canada:				
USA:				
Elsewhere in the world:				
Total:				

3.11 Please give details of the 3 largest contracts that you have carried out in the last 3 years:

Client Name	Client Business	Nature of Work Undertaken for this Contract	Your Annual Income from this Contract	Start Date	Completion Date
				MM / YY	MM / YY
				MM / YY	MM / YY
				MM / YY	MM / YY
				MM / YY	MM / YY
				MM / YY	MM / YY
				MM / YY	MM / YY

3.12 What approximate percentage of your income, in your current financial year, will be paid to sub-contractors? ☐ %

3.13 Will sub-contractors carry the following insurance:

a) Products liability for CMOs? ☐ Yes ☐ No

b) Errors and omissions for CROs, contract research service providers and other consultants? ☐ Yes ☐ No

c) Medical Malpractice (or equivalent government liability) for clinical investigators conducting your clinical trials? ☐ Yes ☐ No

3.14 Will your products be marketed for human consumption in the next 12 months? ☐ Yes ☐ No

If no, please go to section 4

If yes, please attach literature for each of these products, including brochures, technical literature, sale conditions

3.15 Please state the percentage of your income generated by sales of these products, including component parts: ☐ %

3.16 Are these products:

a) Vaccines? ☐ Yes ☐ No

b) Gene therapy? ☐ Yes ☐ No

c) Cell therapy? ☐ Yes ☐ No

d) Acutane, amenorone forte, bupropion, canthaxanthin, cisapride, danthron, debendox, DEHP, dexfenfluramine, diazepines, dicyclomine, diethylstilbestrol (DES), dioxins, ephedrine, fenfluramine, fibrates, germanium, halogenated 8, hydroxy quinolines, hydroquinone, isotretinoin, lotronex, l-tryptophan, methylphenidate, nefazodone, oxazepines, paxil, pertussis vaccine, phenfluramine, phentermine, phenylpropanolamine (PPA), piper methysticum, primodos, prozac, remoxipride, retinoids, risperidone, serzone, silicone gel used as part of an injection or as part of an implantable device, statins, swine-flu vaccine, thalidomide, thiazepines, thimerosol or thimersal, tretinoin, troglitazone, tryptophan? ☐ Yes ☐ No

e) Implantable medical devices? ☐ Yes ☐ No

f) Skin whitening products? ☐ Yes ☐ No

g) Birth control products or devices? ☐ Yes ☐ No

If yes to any of the above, please provide details:

3.17 Could the failure of these products or services result in:

a) Loss of life or injury to a person? ☐ Yes ☐ No

b) Damage or destruction to physical property? ☐ Yes ☐ No

c) Significant third party financial loss? ☐ Yes ☐ No

If yes to any of the above, please provide details:

3.18 Is the delivery of these products and services time critical to the third parties using them (such as a clinical trial)? ☐ Yes ☐ No

If yes, please provide details:

SECTION 4: CONTRACT MANAGEMENT

4.1 Is all work carried out (by you, or for you) under a written contract? ☐ Yes ☐ No

4.2 Are all contracts reviewed by independent, qualified legal advisers? ☐ Yes ☐ No

If no, please outline the procedures used for developing and reviewing contracts:

4.3 Are rights of recourse retained against CMOs, CROs, clinical investigators and all other supply chain partners? ☐ Yes ☐ No

If no, please explain why:

4.4 In your written contracts do you ever accept liability for consequential loss or financial damages greater than the value of the contract? ☐ Yes ☐ No

If yes, please provide details:

4.5 Do your written contracts ever contain 'Hold Harmless' or 'Indemnification' clauses in which you accept liability for loss of life, injury, property damage, or financial losses in circumstances other than where they are caused by your negligence? ☐ Yes ☐ No

If yes, please provide details:

4.6 In your written contracts, do you ever provide guarantees of products or services? ☐ Yes ☐ No

If yes, please provide details:

SECTION 5: CLINICAL TRIALS

Only complete this section if you require cover for Clinical Trials

In respect of each of the clinical trials listed below, please attach the following (in English):
a) Trial Protocol
b) Patient Information
c) Patient Informed Consent form
d) A list of the Clinical Investigator sites

5.1 Please provide below details of completed trials for which cover is required:

Protocol Number and Description	Date Treatment Completed	Number of Subjects	Country
	DD / MM / YY		
	DD / MM / YY		
	DD / MM / YY		
	DD / MM / YY		

5.2 Please provide below the details of ongoing trials, or trials that are expected to commence in the next 12 months, for which primary cover is required:

Protocol Number and Description	Start Date	Expected End Date	Number of Subjects	Country
	DD / MM / YY	DD / MM / YY		
	DD / MM / YY	DD / MM / YY		
	DD / MM / YY	DD / MM / YY		
	DD / MM / YY	DD / MM / YY		

5.3 Please provide below the details of ongoing trials, or trials expected to commence in the next 12 months, for which a separate primary insurance policy will be in place and therefore excess cover only is required:

Protocol Number and Description	Start Date	Expected End Date	Number of Subjects	Country	Insurer and Policy Number for Underlying Policy
	DD / MM / YY	DD / MM / YY			
	DD / MM / YY	DD / MM / YY			
	DD / MM / YY	DD / MM / YY			
	DD / MM / YY	DD / MM / YY			

5.4 Are you the sponsor in respect of each of the clinical trials listed above? ☐ Yes ☐ No

If no, please state the nature of your interest:

5.5 Are any of the clinical trials listed above testing products that are 'First in Man'? ☐ Yes ☐ No

If yes, please provide details:

5.6 In respect of the clinical trials listed above, will any of the following be tested:

a) Vaccines? ☐ Yes ☐ No

b) Gene therapy? ☐ Yes ☐ No

c) Cell therapy? ☐ Yes ☐ No

d) Acutane, amenorone forte, bupropion, canthaxanthin, cisapride, danthron, debendox, DEHP, dexfenfluramine, diazepines, dicyclomine, diethylstilbestrol (DES), dioxins, ephedrine, fenfluramine, fibrates, germanium, halogenated 8, hydroxy quinolines, hydroquinone, isotretinoin, lotronex, l-tryptophan, methylphenidate, nefazodone, oxazepines, paxil, pertussis vaccine, phenfluramine, phentermine, phenylpropanolamine (PPA), piper methysticum, primodos, prozac, remoxipride, retinoids, risperidone, serzone, silicone gel used as part of an injection or as part of an implantable device, statins, swine-flu vaccine, thalidomide, thiazepines, thimerosol or thimersal, tretinoin, troglitazone, tryptophan? ☐ Yes ☐ No

e) Implantable medical devices? ☐ Yes ☐ No

f) Skin whitening products? ☐ Yes ☐ No

g) Birth control products or devices? ☐ Yes ☐ No

If yes to any of the above, please provide details:

5.7 In respect of any of the clinical trials listed in questions 5.1 to 5.3, are / were more than 25% of the research subjects under 16 years? ☐ Yes ☐ No

If yes, please provide details:

5.8 In respect of any of the clinical trials listed in questions 5.1 to 5.3, are / were more than 25% of the research subjects women of child bearing age? ☐ Yes ☐ No

If yes, please provide details:

5.9 Are all clinical trials conducted in accordance with all relevant local laws and regulations? ☐ Yes ☐ No

If no, please explain why:

5.10 In respect of all completed and ongoing trials, have you:

a) Made all necessary filings? ☐ Yes ☐ No

b) Received all required authorisations? ☐ Yes ☐ No

c) Had the protocol approved by an independent Ethics Committee? ☐ Yes ☐ No

If no to any of the above, please explain why:

5.11 Do you ever act as both trial sponsor and clinical investigator? ☐ Yes ☐ No

If yes, please provide details:

5.12 Have you stopped or suspended any clinical trials for safety reasons? ☐ Yes ☐ No

If yes, please provide details:

5.13 Have any research subjects suffered death, injury, disease or illness (whether physical or mental) as a result of participation in a clinical trial sponsored by you, in the past 5 years? ☐ Yes ☐ No

If yes, please provide details:

SECTION 6: COVER LIMITS AND SUMS INSURED

6.1 Would you like cover for damage to your property? ☐ Yes ☐ No

If no, please go to question 6.7

If yes, please attach information regarding the value of the following property, including estimated maximum values at risk at any one time where applicable, at the premises listed in question 2.1 and 2.2:

a) Buildings
b) Tenants improvements, fixtures & fittings
c) Laboratory equipment
d) Fixed electronic equipment
e) Portable electronic equipment
f) Lab consumables and R&D Stock (including the cost of materials and other re-creation costs)
g) Third party stock in your custody and control
h) Research animals (showing the total value and the estimated maximum value of a single animal)
i) Any other property not listed above

6.2 Would you like the policy to cover any of the following:

a) Spoilage of perishable stock?	☐ Yes	☐ No
b) Pollution or contamination?	☐ Yes	☐ No
c) Machinery breakdown?	☐ Yes	☐ No
d) Property in transit?	☐ Yes	☐ No
e) Terrorism?	☐ Yes	☐ No
f) Ideologically motivated attack (that is not declared an act of terrorism by the goverment)?	☐ Yes	☐ No
g) Earthquake?	☐ Yes	☐ No
h) Flood?	☐ Yes	☐ No

6.3 Would you like business interruption cover? ☐ Yes ☐ No

If yes, please state the 'First Loss' sum insured required:

6.4 Please state the sublimits required for business interruption following damage at the premises of your supply chain partners listed in question 2.2:

Supply Chain Partner Name	Business Interruption Sublimit

6.5 Please state the Indemnity Period required (6 - 24 months): Months

6.6 Would you like cover for Commercial General Liability? ☐ Yes ☐ No

If yes, please state the Limit of Liability required:

6.7 Would you like cover for Products and Services Liability? ☐ Yes ☐ No

If yes, please state the Limit of Liability required:

SECTION 7: CLAIMS EXPERIENCE AND INSURANCE HISTORY

7.1 Please provide details of your current insurance:

Type	Expiry Date	Retroactive Date	Insurer
Property and Business Interruption:	DD / MM / YY	Not applicable	
Commercial General Liability:	DD / MM / YY	Not applicable	
Products Liability:	DD / MM / YY	DD / MM / YY	
Errors and Omissions:	DD / MM / YY	DD / MM / YY	
Clinical Trials:	DD / MM / YY	DD / MM / YY	

7.2 Regarding all of the types of insurance to which this application form relates, AFTER ENQUIRY:

a) are you aware of any loss or damage, whether insured or not, that has occurred to any of the Companies to be insured (or to any existing or previous business of the partners or directors of any of the Companies to be insured) within the last 5 (five) years, or
b) are you aware of any circumstances which may give rise to a claim against any of the Companies to be insured or any partners or directors thereof, or
c) have any claims or cease and desist orders been made against any of the Companies to be insured, or partners or directors thereof, or
d) have any partners or directors of the Companies to be insured been found guilty of any criminal, dishonest or fraudulent activity or been investigated by any regulatory body?

With reference to questions a, b, c and d above: ☐ Yes ☐ No

If the answer to the above is yes, then please attach full details including an explanation of the background of events, the maximum amount involved / claimed, the status of the claim(s) or circumstance(s) and any reserve(s) or payment(s) made by you and / or by Insurers, and the dates of all developments and payments.

SECTION 8: DECLARATION

- I / we declare that after proper enquiry the statements and particulars given above are true and that I /we have not mis-stated or suppressed any material fact.
- I / we agree that this Application Form, together with any other material information supplied by me / us shall form the basis of any contract of insurance effected thereon.
- I / we undertake to inform Underwriters of any material alteration to these facts occurring before the completion of the contract.

Signed: _____ Full Name: _____

Position held at Insured: _____ Date: DD / MM / YY

ADDITIONAL INFORMATION: