



## BIOMEDICAL AND LIFE SCIENCE APPLICATION CONTRACT RESEARCH ORGANIZATIONS

PLEASE ANSWER ALL QUESTIONS – IF AN ANSWER TO A QUESTION IS NONE, STATE "None" or "0"  
IF THEY DO NOT APPLY, INDICATE "N/A" - IF SPACE IS INSUFFICIENT PLEASE USE SEPARATE SHEETS

### GENERAL INFORMATION

1. **Named Insured** (as it should appear on the policy):

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2. **Mailing Address:**

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3. **Location Address** (if different than mailing address above):

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4. **Website Address:** \_\_\_\_\_

### COMPANY INFORMATION

1. Year established: \_\_\_\_\_

2. Have you acquired any companies within the last 5 years?  Yes  No  
If Yes, please provide details:

3. Please list all subsidiary companies for whom cover is required. (Cover will not be provided for subsidiaries unless listed and agreed upon by us)

4. Are you a subsidiary of another company?  Yes  No  
 If Yes, please provide details:

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5. Have you every operated under another name?  Yes  No  
 If Yes, please provide details:

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6. Describe your business activities:

7. Please provide a breakdown of your gross revenue by country (DOLLAR AMOUNT):

Country	Previous 12 months	Anticipated for the next 12 months
Canada		
United States		
Other; please list:		

**PROFESSIONAL SERVICES INFORMATION**

Service	% of Total Revenue	Service	% of Total Revenue
Bioequivalency/Bioavailability Testing		Pharmacodynamics	
Biostatistics		Pharmacokinetics	
Clinical Investigations		Preclinical Testing	
Clinical Participant Recruitment		Protocol Design	
Clinical Staff Recruitment/Training		Publications	
Contract Manufacturing		Regulatory Consulting	
Contract Research		Sales & Marketing	
Database Management		Site Management	
Lab Services		Software Design	
Marketing		Other; please describe	

2. Do you plan to introduce any new services within the next 12 months?  Yes  No  
If yes, please provide details:

3. Please answer the following questions if your company conducts clinical investigations:

- a) Are all of your clinical trials approved by the appropriate regulatory authorities?  Yes  No
- b) Do you conduct Planned Emergency Use Trials?  Yes  No
- c) Do you conduct trials that involve a research subject who is:
- 1) Pregnant at the time of or during the course of the clinical trial or pre-trial assessment  Yes  No
  - 2) Under the age of 18 years at the time of the clinical trial or pre-trial assessment  Yes  No
  - 3) Incapable of giving their legal consent to participate in the clinical trial  Yes  No
  - 4) A prisoner  Yes  No
  - 5) An employee of yours or of the investigator  Yes  No

If Yes to any of the above, please provide a copy of the relevant protocol and patient information sheet/informed consent.

d) What Trial Phases does your company conduct?

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e) Does your company conduct your own clinical trials?  Yes  No

f) Does your company recruit their own subjects?  Yes  No  
If No, please provide the source:

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g) Are all participants required to sign an informed consent form?  Yes  No

h) Do you require all informed consent documents be readable at a Grade 8 level or below?  Yes  No

i) Do your company employees provide medical advice or services?  Yes  No  
If Yes:

1) Please describe the type of medical advice or service: \_\_\_\_\_

2) What are their qualifications? \_\_\_\_\_

3) Do they carry their own medical mal practice insurance?  Yes  No

j) Do you operate an in-patient facility?  Yes  No

k) Have you discontinued any clinical trial over concerns about the potential health risks to trial subjects?  Yes  No  
If Yes, please provide details:  
\_\_\_\_\_

l) Have any of your clinical trials been suspended or cancelled by Health Canada or equivalent local authority?  Yes  No  
If Yes, please provide details:  
\_\_\_\_\_

4. Please list your 3 largest customers:

Customer	Size of Contract	Length of Contract	Type of Product/Service

**REGULATORY AND COMPLIANCE INFORMATION**

1. To the best of your knowledge are you currently in compliance with all applicable government regulations?  Yes  No  
If No, please explain:  
\_\_\_\_\_

2. Have any ever been in breach of any regulations?  Yes  No  
If Yes, please explain:

**RISK MANAGEMENT INFORMATION**

1. Do you use a standard written contract?  Yes  No  
Do you ever deviate from the standard contract?  Yes  No  
If Yes, indicate percentage: \_\_\_\_\_
2. Does your standard contract include:
- a) Statement of Work and Specifications  Yes  No
  - b) Limitation of Liabilities  Yes  No
  - c) Limitation for Consequential Damages  Yes  No
  - d) Force Majeure  Yes  No
  - e) Disclaimer of Warranties  Yes  No
  - f) Exclusive Remedies  Yes  No
  - g) Dispute Resolution  Yes  No
  - h) Venue or Governing Law  Yes  No
3. Are all contracts reviewed by legal counsel?  Yes  No
4. Do you have a formal quality control program in place?  Yes  No  
If Yes, when was it last updated?  
\_\_\_\_\_
5. Do you have a formal recall plan in place?  Yes  No  
If Yes, when was it last updated?  
\_\_\_\_\_
6. Do you have a system for documenting incident reports or complaints?  Yes  No  
If Yes:
- a) Who is responsible for recording and handling complaints?  
\_\_\_\_\_
  - b) How long are records retained? \_\_\_\_\_
7. Do you maintain samples of your products?  Yes  No  
If Yes, how long are they retained? \_\_\_\_\_
8. Do you require certificates of insurance from all suppliers and sub-contractors?  Yes  No

**PREMISES INFORMATION**

1. Do you store any hazardous substances on your premises?  Yes  No
- a) If Yes, are you in compliance with all applicable laws regarding hazardous materials handling and disposal?  Yes  No
- b) Have you ever had a biohazard release?  Yes  No
2. Do you have any live viruses on your premises?  Yes  No  
If Yes:
- a) Identify the viruses: \_\_\_\_\_
- b) How are they contained? \_\_\_\_\_
3. Do you have any laboratory animals on your premises?  Yes  No  
If Yes:
- a) Identify type of animal(s): \_\_\_\_\_
- b) Number of animals: \_\_\_\_\_
- c) Their intended purpose: \_\_\_\_\_

**COVERAGE REQUIREMENTS**

What type of coverage and limit of liability are you seeking?

<u>Type of Coverage</u>	<u>Limit of Liability</u>
General Liability:	_____
Products Liability:	_____
Errors & Omissions Liability:	_____
Other, please specify: _____	_____

**LOSS INFORMATION**

1. Has your Company ever had a written demand or civil proceeding for damages made against them?  Yes  No  
If Yes, please provide the following details on a separate sheet:
- Date of claim
  - Claimant's name
  - Nature of claim
  - Amount of indemnity payment and amount of defense costs
  - Final dispositions or current status of claim
2. Are you aware of any circumstances that might give risk to a claim?  Yes  No  
If Yes, please provide details:

**INSURANCE HISTORY**

1. Is your Company currently insured?  Yes  No  
 If Yes, please complete the table below for the past 3 years:

Insurance Company	Policy Period	Limit of Liability	Deductible	Retroactive Date	Coverage Type	Premium

2. Has any insurance company ever:
- a) Declined you application for insurance?  Yes  No
  - b) Refused to renew any insurance policy?  Yes  No
  - c) Cancelled any insurance policy?  Yes  No

Please include the following with the application:

- Brochures, descriptive literature
- Sample Service Contracts & Indemnification Agreements
- Senior staff curriculum vitae

The completion and submission of this application to the Company does not constitute a promise to provide coverage or a binder of insurance.

**THE UNDERSIGNED HEREBY ACKNOWLEDGES THE TRUTH OF THE STATEMENTS CONTAINED HEREIN.**

**IF THE INFORMATION PROVIDED IN THIS APPLICATION SHOULD CHANGE BETWEEN THE DATE OF THE APPLICATION AND THE EFFECTIVE DATE OF THE POLICY, THE UNDERSIGNED WARRANTS THAT THEY WILL IMMEDIATELY REPORT SUCH CHANGES TO THE INSURER.**

**THE COMPLETION AND SIGNING OF THIS APPLICATION DOES NOT CONSTITUTE A PROMISE TO PROVIDE COVERAGE. HOWEVER, IF A POLICY IS ISSUED, THIS APPLICATION SHALL SERVE AS THE BASIS OF SUCH CONTRACT AND WILL BE ATTACHED TO, AND FORM PART OF THE POLICY.**

I AUTHORIZE YOU TO COLLECT, USE AND DISCLOSE PERSONAL INFORMATION AS PERMITTED BY LAW, IN CONNECTION WITH YOUR COMMERCIAL INSURANCE POLICY OR A RENEWAL, EXTENSION OR VARIATION THEREOF, FOR THE PURPOSES NECESSARY TO ASSESS THE RISK, INVESTIGATE AND SETTLE CLAIMS, AND DETECT AND PREVENT FRAUD, SUCH AS CREDIT INFORMATION, AND CLAIMS HISTORY.

**For purposes of the Insurance Companies Act (Canada), this document was issued in the course of Lloyd's Underwriters' insurance business in Canada.**

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Signature of Applicant (authorized representative)

Date

SUBMITTED BY: \_\_\_\_\_

EMAIL: \_\_\_\_\_

**For contact information visit:**

**[www.a Uf\\_Y`\]bhYfbUj\]cbU'W](http://www.a Uf_Y`]bhYfbUj]cbU'W)**