



## CONTRACT RESEARCH ORGANIZATION ERRORS AND OMISSIONS INSURANCE

### APPLICATION

THIS APPLICATION IS FOR A CLAIMS MADE POLICY

**PLEASE ENSURE THAT THE FOLLOWING ARE PROVIDED WITH THE APPLICATION**

- Curriculum vitae of key personnel
- Company promotional literature
- Copies of sample contracts with clients

#### 1. GENERAL INFORMATION

1. Name of Organization or Legal Entity (Company) including any subsidiaries :

\_\_\_\_\_ (please show complete name as you wish it to appear on the policy)

2. Address (Not P.O. Box):

Website: \_\_\_\_\_

3. Location of research facilities:

4. Prior Company names:

5. Parent Company:

6. Coverage requested: Limit of Liability: \$ \_\_\_\_\_ Annual Aggregate: \$ \_\_\_\_\_ Deductible: \$ \_\_\_\_\_

#### 2. COMPANY INFORMATION

7. Years in business: \_\_\_\_\_

8. Company structure:  Individually owned  Corporation  Partnership  Other \_\_\_\_\_

9. Fully describe your Company's operations:

1) Gross Revenues for your last twelve (12) months or your last fiscal year (\$CDN):

CANADA \$ \_\_\_\_\_ U.S. \$ \_\_\_\_\_ OTHER (please list countries): \_\_\_\_\_ \$ \_\_\_\_\_  
\_\_\_\_\_ \$ \_\_\_\_\_  
\_\_\_\_\_ \$ \_\_\_\_\_

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2) Estimated Gross Revenues for your next twelve (12) months or your next fiscal year (\$CDN):

CANADA \$ \_\_\_\_\_ U.S. \$ \_\_\_\_\_ OTHER (please list countries) \_\_\_\_\_ \$ \_\_\_\_\_  
 \_\_\_\_\_ \$ \_\_\_\_\_  
 \_\_\_\_\_ \$ \_\_\_\_\_

**3. RESEARCH AND CLINICAL TRIALS INFORMATION**

10. Your Company was engaged in the following activities during the last twelve (12) months:

ACTIVITIES	GROSS RECEIPTS		
	CANADIAN	U.S.	OTHER
Phase I Testing			
Phase II Testing			
Phase III Testing			
Phase IV Testing			
<b>Other</b> (please explain):			
1)			
2)			
3)			
4)			
5)			
6)			
Totals (must equal figures in Section 2. C)1) above):			

11. Your Company anticipates being engaged in the following activities in the next twelve (12) months:

ACTIVITIES	GROSS RECEIPTS		
	CANADIAN	U.S.	OTHER
Phase I Testing			
Phase II Testing			
Phase III Testing			
Phase IV Testing			
<b>Other</b> (please explain):			
1)			
2)			
3)			
4)			
5)			
6)			
Totals(must equal figures in Section 2. C) 2) above):			

12. List your Company's five (5) largest clients and provide the following details:

CLIENT	RESEARCH	LENGTH OF CONTRACT	DATE BEGAN

13. Does your Company conduct its own clinical trials?  YES  NO  
 Does your Company have direct patient contact?  YES  NO  
 Does your Company find its own subjects?  YES  NO

If subjects are provided by an outside source, what is the source? \_\_\_\_\_

14. Do hospitals or doctors conduct any part of your Company's clinical trials at their premises?  YES  NO  
 Are all participants required to sign an informed consent and exculpatory agreement?  YES  NO  
 If NO, please explain why not?  
 \_\_\_\_\_  
 \_\_\_\_\_

15. Does your Company contract with anyone else to conduct clinical trials on its behalf?  YES  NO  
 If YES, who and for what services?  
 \_\_\_\_\_  
 \_\_\_\_\_

16. Do your Company's employees give medical advice in conjunction with a clinical trial?  YES  NO  
 Do they advise physicians?  YES  NO  
 What qualifications does the Company's employees have who are engaged in this activity?  
 \_\_\_\_\_  
 \_\_\_\_\_

17. Do any of your Company's employees provide direct medical services to patients during clinical trials, including the drawing of blood samples?  YES  NO  
 If YES, please advise the type of professional and describe services provided:  
 \_\_\_\_\_  
 \_\_\_\_\_

18. Does your Company keep laboratory animals on the premises?  YES  NO  
 If YES, please indicate the type of animals, the quantity and their purpose.

ANIMAL	QUANTITY	PURPOSE

19. What materials or products handled by your employees are poisonous either by themselves or in combination with other material?  
 If none, state none.  
 \_\_\_\_\_  
 \_\_\_\_\_

20. Does your Company have live viruses on its premises?  YES  NO  
 If YES, list viruses and how are they contained?  
 \_\_\_\_\_  
 \_\_\_\_\_

21. Does your Company have a license or governmental authority to keep live viruses?  YES  NO  
 If YES, please confirm license number and/or advise who the approving authority is.  
 \_\_\_\_\_  
 \_\_\_\_\_

**4. QUALITY CONTROL**

22. Describe your Company's isolation, containment and environmental controls: \_\_\_\_\_

23. Are written control procedures prepared for each type of experiment and followed in each experiment?  YES  NO  
 If NO, please explain why not:  
 \_\_\_\_\_  
 \_\_\_\_\_

24. Do researchers and technicians specialize in the research and experiments they are conducting?  YES  NO  
 If NO, please explain:  
 \_\_\_\_\_  
 \_\_\_\_\_

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- 25. Are all researchers and technicians trained in the biology of the organisms studied and aseptic techniques?  YES  NO  
If NO, please explain:  
\_\_\_\_\_  
\_\_\_\_\_
  
- 26. Are all employees aware of emergency procedures for accidental biological contamination?  YES  NO  
Does your Company conduct safety drills?  YES  NO  
If YES, how often? \_\_\_\_\_  
Does your Company have a medical surveillance program in place for its employees?  YES  NO
  
- 27. Are government regulations complied with when hazardous biological materials are shipped, stored or received?  YES  NO  
If NO, please explain:  
\_\_\_\_\_  
\_\_\_\_\_
  
- 28. Has an institutional biohazard committee been established?  YES  NO  
If YES, how often do they meet? \_\_\_\_\_
  
- 29. Does your Company comply with all applicable government regulations?  YES  NO  
If NO, please explain:  
\_\_\_\_\_  
\_\_\_\_\_
  
- 30. Has your Company ever been in breach of any regulations?  YES  NO  
If NO, please explain:  
\_\_\_\_\_  
\_\_\_\_\_
  
- 31. Does your Company keep record of incident reports or complaints?  YES  NO  
If YES, who is responsible for these matters? \_\_\_\_\_  
If NO, why? \_\_\_\_\_

**5. PREVIOUS INSURANCE / CLAIM INFORMATION**

- 32. During the last five (5) years, has your Company carried Errors and Omissions/Products insurance?  YES  NO  
If YES, please complete the following for all previous policies:

INSURER	TERM	LIMIT	DEDUCTIBLE	PREMIUM

- 33. When was the first date on which your Company purchased continuous claims made coverage? \_\_\_\_\_
  
- 34. Has your Company ever been declined, non-renewed or cancelled by any insurer for Errors and Omissions insurance?  YES  NO  
If YES, please explain:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
  
- 35. Has your Company ever had a claim(s) made against it?  YES  NO  
If YES, please provide full details of the following on a separate sheet for each claim:  

1) Date of claim/loss	2) Claimant's name	3) Nature of claim
4) Amount of indemnity payment and amount of defense costs		5) Current status of claim (i.e. Closed, Open)

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36. Is your Company aware of any incident or circumstance which may reasonably result in a claim?  YES  NO

If YES, please describe in detail for each incident:

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Without limitation of any other remedy available to the Insurer, it is hereby agreed that if there be knowledge of any such fact, circumstance or situation, any claim or action subsequently emanating therefrom is excluded from coverage under the proposed insurance.

**6. NOTICE CONCERNING PERSONAL INFORMATION**

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By purchasing insurance from Beazley Canada Limited, a customer provides Beazley with his or her consent to the collection, use and disclosure of personal information, including that previously collected, for the following purposes:

- the communication with underwriters;
- the underwriting of policies;
- the evaluation of claims;
- the detection and prevention of fraud;
- the analysis of business results;
- purposes required or authorized by law.

For the purposes identified above, personal information may be disclosed to Beazley's related or affiliated companies and service providers.

Further information about Beazley's personal information protection policy may be obtained by contacting their privacy officer at 416-601-2155.

**7. WARRANTY STATEMENT**

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The undersigned warrants that to the best of his or her knowledge, the statements set forth in this Application are true. The undersigned also warrants that they have not suppressed or misstated any material facts.

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 he or she will immediately report such changes to the Insurer.

Signing of this Application does not bind the undersigned to purchase this insurance, nor does it bind the Insurer to complete this insurance. However, should the Insurer bind and issue a policy, this Application shall serve as the basis of such contract and will be attached to and form part of the policy.

SIGNED: \_\_\_\_\_  
(Authorized Representative)

DATE: \_\_\_\_\_

NAME (Please Print): \_\_\_\_\_

TITLE/POSITION: \_\_\_\_\_