

ADMIRAL INSURANCE COMPANY

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APPLICATION FOR CLINICAL RESEARCH
ORGANIZATIONS & CLINICAL TRIALS FOR
PROFESSIONAL LIABILITY COVERAGE
(Claims Made Basis)

1. APPLICANT INFORMATION

a. Applicant: _____

Address: _____

b. Internet address: _____

c. Name of Parent Company: _____

d. Does the Parent Company afford professional coverage to you? _____

e. _____ Corporation _____ Partnership _____ Joint Venture _____ LLC _____ Other

f. Date Established _____ (mm/dd/yy)

g. Has the applicant ever engaged in this or similar enterprises under a different name? Explain. _____

h. Please identify the countries outside of the U.S. where your products will be tested: _____

i. Do you manufacture or sell any products? ____ Yes ____ No. If yes, please attach a detailed description of current products and any future products being researched.

2. OPERATIONS

a. Please describe all operations to be Insured: _____

b. Fees & Receipts

Estimate for this year \$ _____

Number of test subjects: _____

Number under 18: _____

From _____ To _____

Estimate for last year \$ _____

Number of test subjects: _____

Number under 18: _____

From _____ To _____

Estimate for next year \$ _____

Number of test subjects: _____

Number under 18: _____

From _____ To _____

c. Percentage of foreign professional services _____. Provide the names of countries involved. _____

d. Phase of testing for which applicant seeks coverage:

	Revenues	# Test Subjects	Length of Trial
PHASE I:	_____	_____	_____
PHASE II:	_____	_____	_____
PHASE III:	_____	_____	_____
PHASE IV:	_____	_____	_____
OTHER:	_____	_____	_____

Please use another sheet of paper if all information cannot be captured above.

e. Will you or your employees provide any health care services in conjunction with this trial? ___ Yes ___ No.

Professional Title: _____

Description of services provided: _____

f. Does your firm: ___ Actually perform clinical trials.
___ Monitors the clinical investigator.
___ Monitors the clinical investigator and performs trials.

g. Is the clinical investigator an employee of your firm? ___ Yes ___ No

h. Is the clinical investigator an employee of the test site facility? ___ Yes ___ No

i. Please provide the name and the proposed use or function of the product being tested. _____

Are you aware of any other approved uses or functions of the product being tested? ___ Yes ___ No. If yes, please attach a detailed explanation.

Do you have any knowledge that this product or any of its components might cause or contribute to any Immune system reactions? ___ Yes ___ No. If yes, please attach a detailed explanation.

j. Please provide the name of the product manufacturer (if other than yourself) _____

k. Do you perform any environmental testing or consulting? ___ Yes ___ No

3. TESTING INFORMATION

a. Please indicate the anticipated number of test subjects over the next 12 months: _____

b. Are all trials performed in accordance with FDA approved protocols? ___ Yes ___ No. If no, please explain.

c. How will test subjects be recruited? Please provide a detailed explanation. _____

- d. Will test subjects be required to sign an informed consent document? ___ Yes ___ No
- e. The anticipated trial period: From _____ To _____
- f. How will the trial be conducted and by whom? Please attach a detailed explanation.
- g. How will the trial be funded? _____
- h. Where will the trial be performed? Please check the appropriate response.
 Facility & Location Non-Profit Testing Institute Institutional Review Board
 Clinical Research Center Other (describe) _____
 Please attach a list if additional space is needed.
- i. Are there any clinical trials performed that require overnight stays? ___ Yes ___ No.
 If yes, please answer the following:
 Number of beds at the facilities: _____
 % of clinical trials with this exposure: _____
 What type of trials are conducted for the overnight stays? _____
- j. Will an institutional Review Board oversee the trials? ___ Yes ___ No
 Are you a member of this Board? ___ Yes ___ No
- k. Please indicate the number of employed professionals or independent contractors. (If none, state none)

	<u>Employees</u>	<u>Contractor (Independent)</u>	<u>Total</u>
RN/LPN	_____	_____	_____
Lab Tech.	_____	_____	_____
Clinical Investigator	_____	_____	_____
Clinical Research Assoc.	_____	_____	_____
Physician	_____	_____	_____
Medical Monitor	_____	_____	_____
Engineer	_____	_____	_____
Biostatistician	_____	_____	_____
Data Entry	_____	_____	_____
Legal Counsel	_____	_____	_____
Other _____	_____	_____	_____

- l. Are independent contractors required to carry their own insurance? ___ Yes ___ No If yes, please attach a detailed explanation.
- m. Do clients indemnify the insured except for acts of negligence? ___ Yes ___ No
- n. Please indicate testing performed on specific products over the last 12 months and anticipated testing to be performed over the next 12 months:

<u>Product</u>	<u>Last 12 Months</u>	<u>Next 12 Months</u>
Hormones & Steroids	_____	_____
Vaccines	_____	_____
Injectables	_____	_____
Prescription products	_____	_____
Over the Counter	_____	_____
Diet Aids	_____	_____
Vitamins	_____	_____
Food Supplement	_____	_____
Novel Drugs	_____	_____

6. COVERAGE

- a. Limits of liability desired: \$ _____
- b. Deductible desired: \$ _____
- c. Present coverage

<u>Prof/GL Carrier</u>	<u>Limits</u>	<u>Deductible/SIR</u>	<u>Claims Made?</u>		<u>Premium</u>
			<u>Yes</u>	<u>No</u>	

d. Retroactive date (if applicable) _____

7. ADDITIONAL INFORMATION

Please provide the following information with this application:

- a. List of trials engaged in or projected in the next 12 months. Must include the following:
 - 1. Name of product
 - 2. Summary of its intended purpose
 - 3. Manufacturer
 - 4. Length of trial
 - 5. Number of participants of trial.
- b. Advertisements, brochures, descriptive, literature.
- c. Sample of Informed Consent Agreement
- d. Sample of contract between you and the clinical trial investigator, if the investigator is not your employee or an employee of the test site facility.
- e. Copy of Contract with pharmaceutical and/or research firms.
- f. Resumes/CV's of investigators.
- g. Most recent Annual Report or audited financial statement.
- h. Copy of letterhead or other business stationary.

NOTICE TO APPLICANT: The coverage applied for is SOLELY AS STATED IN THE POLICY, which provides coverage on a "CLAIMS MADE" basis for ONLY THOSE CLAIMS THAT ARE FIRST MADE AGAINST THE INSURED DURING THE POLICY PERIOD unless the extended reporting period option is exercised in accordance with the terms of the policy.

WARRANTY: I/We warrant to the Insurer, that I/We understand and accept the notice stated above and that the information contained herein is true and that it shall be the basis of the policy of insurance and deemed incorporated therein, should the insurer evidence its acceptance of this application by issuance of a policy. I/We authorize the release of claim information from any prior insurer to Admiral Insurance Company.

Name of Applicant

Title (officer, partner, etc.)

Signature of Applicant

Date

SIGNING this application does not bind the Applicant or the Insurer or the Underwriting Manager to complete the insurance, but one copy of this application will be attached to the policy , if issued.