

ADMIRAL INSURANCE COMPANY

1255 Caldwell Road

Cherry Hill, NJ 08034

Phone: 856-429-9200- Fax: 856-429-8611

Internet: <http://www.admiralins.com>APPLICATION FOR CLINICAL RESEARCH
ORGANIZATIONS & CLINICAL TRIALS FOR
PROFESSIONAL LIABILITY COVERAGE
(Claims Made Basis)**1. APPLICANT INFORMATION**

a. Applicant : _____

Address: _____
Street City/State Zip

b. Internet Address: _____

c. Name of Parent Company _____

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

e. _____ Corp _____ 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:

2. OPERATIONS

a. Please describe all operations to be Insured:

b. Fees & Receipts

Estimate for this year \$ _____ From _____ to _____	Number of test subjects: _____ Number under 18: _____
Estimate for last year \$ _____ From _____ to _____	Number of test subjects: _____ Number under 18: _____
Estimate for next year \$ _____ From _____ to _____	Number of test subjects: _____ Number under 18: _____

c. Percentage of foreign professional services and provide the names of countries involved: _____%

d. Please indicate the phases of testing for which you are seeking coverage: Phases _____
Please describe this phase: _____

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. Is the clinical investigator an employee of your firm? _____(yes) _____(no)

g. Is the clinical investigator an employee of the test site facility? _____(yes) _____(no)

h. 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.

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

3. TESTING INFORMATION

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

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

c. Will test subjects be required to signed an informed consent document? _____(yes) _____(no)

d. The anticipated trial period: From _____ to _____

e. How will the trial be conducted and by whom? Please attach a detailed explanation.

f. How will the trial be funded? _____

g. Where will the trial be performed? Please check the appropriate response.

() Facility & Location () Non-Profit Testing Institute () Institutional Review Board
() Clinical Research Center () Other (please describe)

Please attach a list if additional space is needed.

h. Will an Institutional Review Board oversee the trials? ____ (yes) ____ (no)
 Are you a member of this Board? ____ (yes) ____ (no)

i. 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 _____	_____	_____	_____

k. Are independent contractors required to carry their own insurance? ____ (yes) ____ (no)
 If yes, please attach a detailed explanation.

l. Do clients indemnify the insured except for acts of negligence? ____ (yes) ____ (no)

m. 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 & Sterioids	_____	_____
Vaccines	_____	_____
Injectables	_____	_____
Prescription Products	_____	_____
Over the Counter	_____	_____
Diet Aids	_____	_____
Vitamins	_____	_____
Food Supplement	_____	_____
Novel Drugs	_____	_____
Generic Off-Patient	_____	_____
Products, Other than Above	_____	_____
Instruments (x-diagnostic)	_____	_____
Cosmetics, Health & Beauty Aids	_____	_____
Surgical Equipment	_____	_____
Diagnostic Instruments & Equipment	_____	_____
Therapeutic Devices	_____	_____
Life Support	_____	_____
Pediatric Testing	_____	_____

4. APPLICANT HISTORY

a. Provide a brief description of the results of any previous related trials: _____

b. Fully describe any adverse results from previous related trials including animal studies and/or toxicity studies: _____

c. List any claims related information provided in 4(a) and 4(b) above:

<u>Claimant</u>	<u>Date of Loss</u>	<u>Expenses</u>	<u>Indemnity</u>	<u>Nature of Injury</u>
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

5. CLAIMS

(Attach a detailed explanation for any "Yes" answers)

	<u>YES</u>	<u>NO</u>
a. Are you aware of any incidents or circumstances which are likely to result in claims against you under the coverage sought herein?	_____	_____
b. Have you ever been inspected, surveyed, or audited by the Food & Drug Administration, the Center for Drug Evaluation and Research, or the Center for Biologics Evaluation and Research?	_____	_____
c. Have you ever been subject to any inquiry or investigation by any federal, state or local agency concerning your professional services?	_____	_____
d. Do you operate in compliance with the FDA's Good Clinical Practice Guidelines?	_____	_____
e. Have you ever been cited for any non-compliance of Good Clinical Practices or any federal state or local law, ordinance, directive or regulation?	_____	_____

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. Advertisements, brochures, descriptive, literature.
- b. Sample contract between you and the clinical trial investigator, if the investigator is not your employee or an employee of the test site facility.
- c. Informed consent document.
- d. Most recent Annual Report or audited financial statement
- e. Copy of letterhead or other business stationary.

NOTICE TO APPLICANT: The coverage applied for is SOLEY 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 understand and accept the notice stated above and that the information contained herein is true and this 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.

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