☐ **Deerfield Insurance Company**
☐ **Evanston Insurance Company**
☐ **Essex Insurance Company**
☐ **Markel American Insurance Company**
☐ **Markel Insurance Company**
☐ **Associated International Insurance Company**

APPLICATION FOR CLINICAL RESEARCH ORGANIZATIONS & CLINICAL TRIALS FOR PROFESSIONAL AND GENERAL LIABILITY INCLUDING PRODUCTS LIABILITY INSURANCE

(Claims Made Basis)

APPLICANT'S INSTRUCTIONS:

1. Answer all questions. If the answer requires detail, please attach a separate sheet.
2. Application must be signed and dated by owner, partner or officer.
3. Please do not complete application earlier than 45 days before proposed effective date of coverage.
4. PLEASE READ CAREFULLY THE STATEMENTS AT THE END OF THIS APPLICATION.

(PLEASE TYPE OR PRINT IN INK)

1. APPLICANT INFORMATION

a. Full name of Applicant: _____

b. Principal business premise address: _____
(Street) (County)

_____
(City) (State) (Zip)

c. Number of Employees: Full time _____ Part time _____ Seasonal _____ Total _____

d. Additional office locations: _____

e. Name of parent company: _____

f. Please describe all operations to be insured: _____

_____

g. Phone: ( ) _____

h. ☐ Corporation ☐ Partnership ☐ Joint Venture ☐ Sole Proprietor ☐ Other

i. Date Established: _____

2. APPLICANT OPERATIONS

a. Fees and Receipts

Estimate for Current Year	Estimate for Next Fiscal Year
Date: From _____to_____	Dates: From _____to_____

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

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

d. Please indicate the phase of testing for which you are seeking coverage: Phase

(i) Please describe this phase: _____

_____

(ii) Will this phase be performed in accordance with an FDA approved protocol?..... ☐ Yes ☐ No
If No, please explain. _____

(iii) Please indicate IND number: _____

(iv) Will this phase and have all previous related phases been performed in accordance with an FDA approved protocol? ..... ☐ Yes ☐ No
If No, please explain. _____

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

If Yes: 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. (i) Please provide the name and the proposed use or function of the product being tested.

_____

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

(iii) 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): _____

j. Is the Applicant a "Covered Entity" under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule? ..... ☐ Yes ☐ No

If Yes,

(i) Has the Applicant implemented procedures to comply with the HIPAA Privacy Rule? ..... ☐ Yes ☐ No

(ii) Provide the name and title of the Applicant's Privacy Officer. _____

Our Business Associate Agreement is available at www.markelcorp.com. This is the only Business Associate Agreement we will recognize.

3. TESTING INFORMATION

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

b. Please give the sex and age of the test subjects: _____

_____

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

☐ Clinical Research Center ☐ Other (please describe) _____

(Please attach a list if additional space is needed.)

i. (i) Will an Institutional Review Board oversee the trials? ..... ☐ Yes ☐ No

(ii) Are you a member of this Board? ..... ☐ Yes ☐ No

j. Please indicate the number of employed professionals or independent contractors. (IF NONE, STATE NONE.)

	Employee	Contractor Independent	Total
(i) RN/LPN	_____	_____	_____
(ii) Lab Tech.	_____	_____	_____
(iii) Clinical Investigator	_____	_____	_____
(iv) Clinical Research Assoc.	_____	_____	_____

	Employee	Contractor Independent	Total
(v) Physician	_____	_____	_____
(vi) Medical Monitor	_____	_____	_____
(vii) Engineer	_____	_____	_____
(viii) Biostatistician	_____	_____	_____
(ix) Data Entry	_____	_____	_____
(x) Legal Counsel	_____	_____	_____
(xi) Other_____	_____	_____	_____
_____	_____	_____	_____

k. Do you perform any environmental testing or consulting?..... ☐ Yes ☐ No
If Yes, please attach a detailed explanation.

l. Please indicate testing performed on specified products over the last 12 months and anticipated testing to be performed over the next 12 months:

	Last 12 Months	Next 12 Months
(i) Hormones & Steroids	_____	_____
(ii) Vaccines	_____	_____
(iii) Injectables	_____	_____
(iv) Prescription Products	_____	_____
(v) Over the Counter	_____	_____
(vi) Diet Aids	_____	_____
(vii) Vitamins	_____	_____
(viii) Food Supplements	_____	_____
(ix) Novel Drugs	_____	_____
(x) Generic Off-Patient	_____	_____
(xi) Products, Other than Above	_____	_____
(xii) Instruments (x-diagnostic)	_____	_____
(xiii) Cosmetics, Health & Beauty Aids	_____	_____
(xiv) Surgical Equipment	_____	_____
(xv) Diagnostic Instruments & Equipment	_____	_____
(xvi) Therapeutic Devices	_____	_____
(xvii) Life Support	_____	_____
(xviii) Other	_____	_____

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:

Claimant	Date of Loss	Expense	Indemnity	Nature of Injury

5. CLAIMS

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

a. Are you aware of any incidents or circumstances which are likely to result in claims against you under the coverage sought herein? ☐ Yes ☐ No

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? ☐ Yes ☐ No

c. Have you ever been subject to any inquiry or investigation by any federal, state or local agency concerning your professional services? ☐ Yes ☐ No

d. Do you operate in compliance with the FDA's Good Clinical Practice Guidelines? ☐ Yes ☐ No

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? ☐ Yes ☐ No

6. COVERAGE

a. Limits of liability desired: $_____

b. Amount of deductible desired: $_____

c. Present coverage

Carrier	Prof	GL	Deductible/SIR	Limits	Claims Made? Yes	No

If Yes, please provide an explanation.

d. Retroactive date (if applicable) _____

7. ADDITIONAL INFORMATION

Please provide the following information with this application:

(i) Advertisements, brochures, descriptive literature.

(ii) Sample contract between you and the clinical trial investigator, if the investigator is not your employee or an employee of the test site facility.

(iii) Informed consent document.

(iv) Most recent Annual Report or audited financial statement

(v) 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 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 the underwriting manager, Company and/or affiliates thereof.**

_____ _____

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.