APPLICATION FOR
COMMERCIAL GENERAL LIABILITY
AND
PROFESSIONAL LIABILITY
FOR CLINICAL TRIALS - PHARMACEUTICALS AND MEDICAL DEVICES

Submitted By: _____

Agency: _____

Address: _____

City: _____

State: _____

Zip: _____

Phone No.: _____

Quaker Special RIsk
12 Christopher Way, Suite 201
Eatontown, New Jersey 07724

Applicant's Instructions:

1. Answer all questions. If the answer to any question is NONE, please state NONE.
2. Please read carefully the statement at the end of this application.
3. Please attach additional sheets where further explanation or information is appropriate.

Please Type or Print

(You can complete this form on your computer, or you can print and fill it out by hand)

1. Applicant Proposed Effective Date: _____

A. Full name of all entities of the Applicant:

_____

_____

B. Mailing addresses: _____

Branch office address (es): _____

C. Web Address: _____

D. Contact name: _____ Title: _____

Telephone: _____ Email: _____

E. ☐ Corporation ☐ Partnership ☐ Proprietorship ☐ Other __ _____

F. Years in business under present name: _____

(1) Has Applicant ever engaged in this or similar biotech enterprises under a different name? ☐ Yes ☐ No

(2) If yes, please provide complete details:

_____

_____

_____

_____

_____

G. Current Insurance Coverage:

Carrier	Deductible/SIR	Limits	Retro Date

H. Has any insurer ever cancelled, restricted, or refused to renew your insurance? ☐ Yes ☐ No

If yes, please explain: _____

_____

2. Operations

A. Fully describe all operations of the Applicant:

_____

_____

_____

_____

B. For the Trial for which the applicant seeks coverage, please provide the following information:

Name of Trial: _____

_____

Purpose, or objective, of the Trial:_____

_____

Phase of testing: ☐ I ☐ II ☐ III ☐ IV ☐ OTHER (Please explain):

_____

_____

_____

Duration of Trial: _____

Number of subjects: Placebo _____ Non Placebo _____

Target subjects

Sex of subjects: ☐ M ☐F

Age group of subjects: ☐ 1 to 18 ☐ 19 to 40 ☐ 41 to 75 ☐ Other _____

Are subjects afflicted with ailment for which drug or device is being tested? ☐Yes ☐No

If not afflicted, are subjects healthy? ☐ Yes ☐No

Side effects of the product being tested: _____

_____

_____

Name and proposed indication/function of product being tested: _____

_____

_____

_____

Other approved indications/functions of product being tested: _____

_____

_____

Is this product or its components known or suspected to cause or contribute to any immune system reactions? ☐ Yes ☐ No

If yes, please describe: _____

_____

_____

Name of product manufacturer if other than applicant: _____

_____

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

If yes, please provide the following information:

Professional title: Description of services provided:

_____ _____

_____ _____

Is the clinical investigator an employee of your firm? ☐ Yes ☐ No

Is the clinical investigator an employee of the test site facility? ☐ Yes ☐ No

D. Test Sites: Check One: ⑨ Public ⑨ Privately -Owned

Facility & Location	Nonprofit Teaching Institute	Practice	Clinic/Lab	Other

(Please attach list if additional space needed.)

Will an Institute Review Board oversee the trials? ☐ Yes ☐ No

Are you (firm or individual) a member of this Board? ☐ Yes ☐ No

E. Are all participants required to sign an informed consent and exculpatory agreement? ☐ Yes ☐ No

F. Is this phase to be performed in accordance with an FDA approved protocol? ☐ Yes ☐ No

Will this phase and all previous related phases be performed in accordance with an FDA approved protocol? ☐Yes ☐ No

If no, please explain: _____

_____

_____

_____

3. Underwriting Experience

Provide a brief description of the results of any previous related Trials:

_____
_____
_____
_____
_____
_____

Fully describe any adverse results from previous related Trials, including animal studies and/or toxicity studies:

_____
_____
_____
_____
_____

List any claims related to above:

Claimant	DOL	Expense	Indemnity	Nature of Injury

Describe steps that have been taken to address these adverse results. To what extent will steps mitigate recurrence?

_____
_____
_____
_____
_____

Are you aware of any other incidents, conditions, or circumstances that may result in claims against you, or concerning this drug or device? ☐ Yes ☐ No

If yes, please explain:

_____
_____
_____

Please attach a copy of the following documents:

1. FDA Approved Protocol
2. Expiring Policy (if applicable)
3. Informed Consent Agreement
4. Contract between you and

- Clinical Trial Investigator if the investigator is not your employee or an employee of the test site facility
- Each Test Site Facility
- Product Manufacturer

FRAUD WARNING

Notice to Applicants of all states except New Jersey, New York, Pennsylvania, and Washington D.C.:
Any person who knowingly, and with the intent to defraud any insurance company or other person, files an application for insurance or statement of claim containing any material false information or conceals for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime and subjects the person to criminal and civil penalties and denial of insurance benefits.

Notice to New Jersey Applicants:
Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties.

Notice to New York Applicants:
Any person who knowingly and with the intent to defraud any insurance company or other person files an application for insurance or statement of claim containing any materially false information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime, and shall also be subject to a civil penalty not to exceed five thousand dollars and the stated value of the claim for each provision.

Notice to Pennsylvania Applicants:
Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance or a statement of claim containing any materially false information or conceals for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

Notice to Washington D.C. Applicants:
WARNING: It is a crime to provide false or misleading information to an insurer for the purpose of defrauding the insurer or any other person. Penalties include imprisonment and/or fines. In addition, an insurer may deny insurance benefits if false information materially related to a claim was provided by the applicant.

By signing this application I am attesting to the accuracy of information provided by the Applicant. If any responses in this application are found to be false or misleading and would alter the Company's decision to provide the insurance coverage applied for, it is agreed between the Company and the Applicant that the insurance policy will be rescinded.

I agree that this application shall be deemed to be attached to, and made part of the policy.

Signature of Applicant:*_____ Date:_____

Title:_____

(Owner, partner, officer)

By signing this, Applicant does not commit to purchase or the Company to issue the insurance.