Admiral INSURANCE GROUP | a Berkley Company

CLINICAL RESEARCH ORGANIZATIONS & CLINICAL TRIALS PROFESSIONAL LIABILITY APPLICATION and GENERAL LIABILITY APPLICATION

(CLAIMS MADE AND REPORTED COVERAGE)

SECTION I – GENERAL INFORMATION

1) Name of Applicant:

(Include all DBA's and subsidiaries seeking coverage under the policy for which you are applying)

2) Applicant's address:

3) Website:

4) ☐ Corporation ☐ Partnership ☐ Joint Venture ☐ LLC ☐ Other:

5) Date Established:

6) FEIN:

SECTION II – FACILITY OPERATIONS

7) Select the description below that best describes the applicant:

- ☐ Independent Research Site
- ☐ Academic Medical Center Contract
- ☐ Institutional Review Board
- ☐ Research Organization
- ☐ Site Management Organization
- ☐ Independent Review Board
- ☐ Other (Describe):

Indicate for which phases of research coverage is being sought:

- ☐ Phase I
- ☐ Phase II
- ☐ Phase III
- ☐ Phase IV
- ☐ Other (i.e. pre-clinical, non-biomedical research, social sciences research, government sponsored research, etc.)
  If Other, provide details:

Select the corresponding button below if the clinical trials engaged in by the Applicant are for:

- ☐ Pharmaceuticals
- ☐ Biologics
- ☐ Medical Devices
- ☐ Other (Describe):

8) Has the applicant ever engaged in this or similar enterprises under a different name? ◯ Yes ◯ No
If Yes, provide details:

9) Will you be providing services or testing products outside of the United States? ◯ Yes ◯ No
If Yes, advise which countries:

10) Fees & Receipts

Estimate for the next 12 months		**Number of Test Subjects**	**Number under 18 years old**
$	Domestic		
$	Foreign		
Last 12 months		**Number of Test Subjects**	**Number under 18 years old**
$	Domestic		
$	Foreign		

11) List all current trials. Include trials for the past 12 months and upcoming 12 months (including those that have not started yet but will start in the next 12 months).

Clinical Trial Name and Description	Product Type	Projected Test Participants	Phase	Trial Duration	Start Date	Expected End Date

12) Describe in detail all your professional services and indicate the percentage of gross receipts/revenues derived from each activity:

Description of Professional Services	**Percentage of Revenue**
	%
	%
	%
	%

13) Fully describe any adverse results from previous related trials including animal studies and/or toxicity studies:

14) Provide a detailed explanation of how test subjects will be recruited:

15) Will all test subjects be required to sign an informed consent document? ◯ Yes ◯ No

16) Provide the name of the device/pharmaceutical manufacturers for which you are conducting these trials:

17) How will the trials be funded?

18) Where will the trials be performed? Check the appropriate response.

☐ Your Facility ☐ Non-Profit Testing Institute ☐ Hospital ☐ Clinical Research Center

☐ Other (Describe):

19) Does the Applicant provide:

a. Services to entities other than a sponsor ◯ Yes ◯ No

b. Services directly to a sponsor ◯ Yes ◯ No

c. Manage trials ◯ Yes ◯ No

d. Evaluate and monitor reports and prepare materials to be submitted to the FDA ◯ Yes ◯ No

e. Develop trial protocol and consent forms ◯ Yes ◯ No

f. Direct patient contact services (dosing patients with study drug, drawing blood, etc.) ◯ Yes ◯ No

g. Manage multiple sites (data management only) ◯ Yes ◯ No

h. Product development ◯ Yes ◯ No

i. Provide central laboratory services ◯ Yes ◯ No

j. Subcontract central laboratory services ◯ Yes ◯ No

k. Employ/contract staffing ◯ Yes ◯ No

l. Recruitment of study participants ◯ Yes ◯ No

m. Regulatory compliance consulting ◯ Yes ◯ No

n. Quality review (for other organizations) ◯ Yes ◯ No

o. Other: ◯ Yes ◯ No

20) Will an Institutional Review Board oversee the trials? ◯ Yes ◯ No

21) Are you a member of the Board? ◯ Yes ◯ No

22) Do all of the manufacturers cover you for your liability associated with their products other than for your alleged breaches of protocol? ◯ Yes ◯ No

23) Will you or your employees provide any health care services in conjunction with this trial? ◯ Yes ◯ No

a. If Yes, are those health care services insured elsewhere? Provide proof of coverage. ◯ Yes ◯ No

b. If Yes, provide details on the type of healthcare services performed:

SECTION III – STAFF

24) Indicate the number of employed professionals or independent contractors (if none, state none):

	Employees	Contractor (Independent)	Total
RN/LPN			
Lab Technician			
Clinical Investigator			
Clinical Research Associate			
Physician			
Medical Monitor			
Engineer			
Statistical Management			
Data Entry			
Legal Counsel			
Quality/Regulatory Compliance			
Medical Writing Administrative			
Other:			

25) Are all independent contractors required to carry their own insurance? ◯ Yes ◯ No
If No, attach a detailed explanation.

26) Is the clinical investigator an employee of your firm? ◯ Yes ◯ No

27) Is the clinical investigator an employee of the test site facility? ◯ Yes ◯ No

SECTION IV – NETWORK SECURITY AND DATA PRIVACY PROCEDURES

28) Do you currently purchase a standalone cyber policy? ◯ Yes ◯ No
If Yes, please provide the following information:

Carrier	Limit	Deductible	Premium	Policy Term	Retro Date

29) Do you employ the following tools to protect private sensitive data?

a. Anti-Virus and Firewalls ◯ Yes ◯ No

b. Encryption ◯ Yes ◯ No

c. Formal Password Management Procedures ◯ Yes ◯ No

30) Are you compliant with the Health Information Portability and Accountability Act (HIPAA) and Health Information Technology for Economic Critical Health Act (HITECH)? ◯ Yes ◯ No

31) Have you ever experienced a security breach, data loss or denial of service attack? ◯ Yes ◯ No
If Yes, complete a Supplemental Claim Information Form for each and every claim.

SECTION V – RISK MANAGEMENT AND CLAIMS HISTORY

(*Attach a detailed explanation for any yes answers)

32) 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

33) Have you ever been subject to any inquiry or investigation by any federal, state or local agency concerning your professional services? ◯ Yes ◯ No

34) Do you operate in compliance with the FDA's Good Clinical Practice Guidelines? ◯ Yes ◯ No

35) 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

36) Are you aware of any incidents related to your clinical trials for which a claim could be made against you? ◯ Yes ◯ No

37) Have you ever had a claim as respects to your professional liability? ◯ Yes ◯ No
If Yes, complete the Supplemental Claim Information Form for each and every claim.

32) Do you currently carry Professional Liability? ◯ Yes ◯ No

Provide details below for the last five years of coverage.

Carrier	Limit	Deductible	Premium	Policy Term	Retro Date

33) Do you currently carry GL and Products Liability? ◯ Yes ◯ No

34) Are you interested in a quote for General Liability? ◯ Yes ◯ No
If Yes, complete the General Liability Supplemental Application below.

GENERAL LIABILITY SUPPLEMENTAL APPLICATION

SECTION I – YOUR LOCATIONS

IF YOU HAVE MORE THAN FIVE (5) LOCATIONS, PROVIDE A SPREADSHEET WITH THE INFORMATION BELOW FOR EACH LOCATION.

1)

Loc #	Facility Name	Address	Description / Use	Square Footage
1				
2				
3				
4				
5				

	Location 1	Location 2	Location 3	Location 4	Location 5
Own or Lease	◯ Own ◯ Lease	◯ Own ◯ Lease	◯ Own ◯ Lease	◯ Own ◯ Lease	◯ Own ◯ Lease
% occupied by applicant	%	%	%	%	%
Are there other occupants?	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No
# of beds / units (if applicable)					

SECTION II – MAINTENANCE

2) Does the Applicant have a full-time maintenance staff? ◯ Yes ◯ No

Confirm the type of maintenance, service and repair performed by the Applicant (Direct) or subcontracted (Subbed) by completing the table below.
NOTE: Direct is a percentage of total direct payroll and Subbed is a percentage of total subcontractor cost.

Type	Direct	Subbed
Snow & Ice Removal	%	%
Janitorial/Cleaning Services	%	%
General Maintenance & Repairs	%	%
Landscaping	%	%
Other:	%	%

3) Does the Applicant have written procedures for routine inspections of the premises to identify and address potential liability hazards? ◯ Yes ◯ No

If Yes, are records of the completed inspections and repairs retained for at least five years? ◯ Yes ◯ No

4) Are there any construction projects planned for the upcoming policy term? ◯ Yes ◯ No

If Yes, provide full details of project, location, total costs, payroll and sub costs:

a. Will the construction be subbed out? ◯ Yes ◯ No

b. Are signs clearly posted to warn the third party of construction and/or during routine Maintenance? ◯ Yes ◯ No

SECTION III – FIRE-LIFE SAFETY INFORMATION

5) Are all of your locations equipped with:

a. Complete sprinkler system? ◯ Yes ◯ No

b. At least two clearly marked exits on each floor? ◯ Yes ◯ No

c. Smoke detectors? ◯ Yes ◯ No

d. Emergency electrical system? ◯ Yes ◯ No

e. Heat sensors? ◯ Yes ◯ No

f. Fire escape(s)? ◯ Yes ◯ No

g. Posted emergency evacuation procedures? ◯ Yes ◯ No

h. Properly maintained fire extinguishers? ◯ Yes ◯ No

Attach a separate sheet detailing any No answers.

SECTION IV – OTHER PREMISES EXPOSURES

6) Are any of the following provided:

a. Sale of any food or drinks? ◯ Yes ◯ No

b. Recreational facilities? ◯ Yes ◯ No

c. Gym or exercise equipment available to members or the public? ◯ Yes ◯ No

d. Swimming pool on any premises? ◯ Yes ◯ No

e. Daycare or childcare services? ◯ Yes ◯ No

f. Sponsor any sporting or social events? ◯Yes ◯No

g. Hold any fundraising events? ◯Yes ◯No

h. Provide alcohol with any of your events or services? ◯Yes ◯No

i. Participation in trade shows, exhibits or conventions? ◯Yes ◯No

j. Any plans for new construction or renovations during the next twelve (12) months? ◯Yes ◯No

Attach a separate sheet detailing any Yes answers.

SECTION V – PRODUCTS AND EQUIPMENT SOLD OR LEASED

7) Do you loan, lease or rent equipment to others? ◯Yes ◯No

a. Annual gross revenue **for equipment rental**? $

b. With or without operator (technician)? ◯With ◯Without
Provide details:

c. Who is responsible for equipment maintenance?

8) Do you sell durable medical equipment? ◯Yes ◯No
If Yes, complete the following table for Medical Equipment Suppliers Revenue:

	Annual Sales	Annual Lease/Rental
Category I: Expendable Items (i.e. adhesive tape, bandages, hypodermic needles)	$	$
Category II: Non-Expendable Items (i.e. hospital beds, bathroom safety bars, canes, walkers, wheelchairs, crutches, IV stands, etc.)	$	$
Category III: Diagnostic or Treatment Devices (i.e. oxygen, IV pumps, blood pressure gauges, transmitting devices)	$	$
Category IV: Life Sustaining or Critical Life Monitoring Equipment or Devices (i.e. dialysis machines, heart/lung machines, ventilators, etc.)	$	$

SECTION VI – ADVERTISING

9) Do you obtain proper consents and utilize contractual agreements prior to using the image/oral/written publication of any person/celebrity? ◯N/A ◯Yes ◯No

10) Are you making any structure/function claims for your products on labels, websites or other marketing materials? ◯Yes ◯No

Do you maintain documentation that substantiates each claim you make? ◯Yes ◯No
If Yes, explain the documentation and length of time records are retained:

SECTION VII – ADDITIONAL INSUREDS

11) List all parties that should be considered for Additional Insured status under the General Liability.
Include a copy of the contract for each entity and a certificate of insurance evidencing GL coverage in place.

Name and Address	Relationship to Applicant

SECTION VIII – PRODUCTS & COMPLETED OPERATIONS

Attach a separate sheet detailing any Yes answers, along with a list of products sold.

If product labels cannot be found on your website, include copies with this application.

12) Do you sell any products? ◯Yes ◯No
If No, skip to question 29.

If Yes, answer the following questions and include product brochures.

Describe the types of products you sell:

13) Total gross revenue **from product sales**:

a. Last twelve (12) months: $

b. Next twelve (12) months: $

14) Any herbal supplements, homeopathic remedies, and/or nutraceuticals? ◯Yes ◯No

15) Do any of your products include:

a. Caffeine exceeding 300 mg per servicing (all sources)? ◯Yes ◯No

b. Cannabidiol (CBD) hemp products? ◯Yes ◯No

c. Class I & Class II Medical Products / Devices? ◯Yes ◯No

16) Do you mix or compound any ingredients? ◯Yes ◯No

17) Is a prescription required for any of the products you sell? ◯Yes ◯No

18) Are products of others sold or re-packaged under your label? ◯Yes ◯No

19) Do all of your labels include a disclaimer that the FDA has not evaluated the claims on your labels and that your products are not intended to diagnose, treat, cure or prevent any diseases? ◯Yes ◯No

20) Do you obtain Certificates of Insurance from all suppliers evidencing Product Liability Insurance? ◯Yes ◯No

21) Are foreign products sold, distributed, or used as components? ◯Yes ◯No

22) Have any of your products been recalled, discontinued or changed? ◯Yes ◯No

23) Do you offer training or instruction to the user of your products? ◯Yes ◯No

24) Do you offer guarantees, warranties or Hold Harmless agreements with your products? ◯Yes ◯No

25) Do you install, service of demonstrate products? ◯Yes ◯No

26) Is research and development conducted or new products? ◯Yes ◯No

27) Are any new products planned in the next year? ◯Yes ◯No
If Yes, provide explanation:

28) Are you a manufacturer, wholesaler or importer of products to others? ◯Yes ◯No

If Yes, answer the following questions and attach a separate sheet detailing any No answers, along with copies of product labels (if not available on website).

a. Are all warning labels and instructions for use reviewed by outside legal counsel? ◯Yes ◯No

b. Has legal counsel reviewed your labeling and confirmed it is in compliance with regulations established by the FDA and FTC? ◯Yes ◯No

c. Have you conducted or are you planning to conduct human clinical trials to substantiate your product claims? ◯Yes ◯No

SECTION IX – PRIOR GENERAL LIABILITY COVERAGE HISTORY

29) List prior General Liability insurance carried for each of the past five (5) years. If NONE, check this box ☐

Insurance Company	Limits of Liability	Deductible	Premium	Expiration Mo/Day/Yr	Was this a Claims Made Policy Form?	Retro Date
					◯Yes ◯No	
					◯Yes ◯No	
					◯Yes ◯No	
					◯Yes ◯No	
					◯Yes ◯No	

SECTION X – CLAIMS

PROVIDE 5 YEARS OF CURRENTLY VALUED LOSS RUNS.

30) Has any General Liability claim or suit been brought against you and/or any of your employees? ◯Yes ◯No
If Yes, complete a Supplemental Claim Information Form for each and every claim or suit.

31) Are any persons or entities proposed for this insurance aware of any fact, circumstance, or situation which may result in a GL claim, and has not been reported to your current GL insurance carrier? ◯None to Report ◯Yes ◯No
If Yes, provide details:

32) Are you aware of any incident, condition, circumstance, defect or suspected defect in any product, which may result in a claim or claims against you that are not listed above? ◯None to Report ◯Yes ◯No
If Yes, provide details:

Please attach the following information:

- Advertisements, brochures, descriptive literature
- Sample contract between you and the clinical trial investigator, if the investigator is not your employee or employee of the test site facility
- Informed consent document

Fraud Notices

Applicable in AL, AR, DC, LA, MD, NM, RI and WV: Any person who knowingly (or willfully)* presents a false or fraudulent claim for payment of a loss or benefit or knowingly (or willfully)* presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison. *Applies in MD only.

Applicable in CO: It is unlawful to knowingly provide false, incomplete, or misleading facts or information to an insurance company for the purpose of defrauding or attempting to defraud the company. Penalties may include imprisonment, fines, denial of insurance and civil damages. Any insurance company or agent of an insurance company who knowingly provides false, incomplete or misleading facts or information to a policyholder or claimant for the purpose of defrauding or attempting to defraud the policyholder or claimant with regard to a settlement or award payable from insurance proceeds shall be reported to the Colorado Division of Insurance within the Department of Regulatory Agencies.

Applicable in FL and OK: Any person who knowingly and with intent to injure, defraud or deceive any insurer files a statement of claim or an application containing any false, incomplete, or misleading information is guilty of a felony (of the third degree)*. * Applies in FL only.

Applicable in KS: Any person who knowingly and with intent to defraud, presents, causes to be presented, or prepares with knowledge or belief that it will be presented, to or by an insurer, purported insurer, broker or any agent thereof, any written statement as part of, or in support of, an application for the issuance of, or the rating of an insurance policy for personal or commercial insurance, or a claim for payment or other benefit pursuant to an insurance policy for commercial or personal insurance which such person knows to contain materially false information concerning any fact material thereto; or conceals, for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act.

Applicable in KY, NY, OH and PA: Any person who knowingly and with 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 subjects such person to criminal and civil penalties (not to exceed five thousand dollars and the stated value of the claim for each such violation)*. *Applies in NY only.

Applicable in ME, TN, VA, and WA: It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties (may)* include imprisonment, fines and denial of insurance benefits. *Applies in ME only.

Applicable in NJ: Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties.

Applicable in OR: Any person who knowingly and with intent to defraud or solicit another to defraud the insurer by submitting an application containing a false statement as to any material fact may be violating state law.

Applicable in PR: Any person who knowingly and with the intention of defrauding presents false information in an insurance application, or presents, helps, or causes the presentation of a fraudulent claim for the payment of a loss or any other benefit, or presents more than one claim for the same damage or loss, shall incur a felony and, upon conviction, shall be sanctioned for each violation by a fine of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), or a fixed term of imprisonment for three (3) years, or both penalties. Should aggravating circumstances [be] present, the penalty thus established may be increased to a maximum of five (5) years, if extenuating circumstances are present, it may be reduced to a minimum of two (2) years.

Applicable in all other States: Any person who knowingly and with 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 material fact, commits a fraudulent insurance act, which is a crime and may also be subject to civil penalty.

Other State Notices

Applicable in RI: THIS INSURANCE CONTRACT HAS BEEN PLACED WITH AN INSURER NOT LICENSED TO DO BUSINESS IN THE STATE OF RHODE ISLAND BUT APPROVED AS A SURPLUS LINES INSURER. THE INSURER IS NOT A MEMBER OF THE RHODE ISLAND INSURERS INSOLVENCY FUND. SHOULD THE INSURER BECOME INSOLVENT, THE PROTECTION AND BENEFITS OF THE RHODE ISLAND INSURERS INSOLVENCY FUND ARE NOT AVAILABLE.

I/We understand that this is an application for insurance only and that the completion and submission of this Application does not bind the Company to sell nor the applicant to purchase this insurance. I/We hereby declare that the above statements and particulars are true and I/we agree that this Application shall be the basis for any contract of insurance issued by the Company in response to it.

Electronic Signature of Applicant or Authorized Representative:

Title: Date:

If you prefer not to return the questionnaire with an electronic signature, please print and sign.