Admiral INSURANCE GROUP | a Berkley Company

CLINICAL RESEARCH ORGANIZATIONS & CLINICAL TRIALS PROFESSIONAL LIABILITY APPLICATION

(CLAIMS MADE AND REPORTED COVERAGE)

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) 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):

Please 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:

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

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

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

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

9) Please list all current trials including the type of drug or device, the Phase and the trial start/end dates. Please include trials that haven't started yet, but will start within the next 12 months. Use a separate attachment if necessary.

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

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

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

13) Are you aware of any other approved usages of the devices or drugs you are testing? ◯ Yes ◯ No
If yes, provide details.

14) Please provide the name of the device/pharmaceutical manufacturers for which you are conducting these trials.

15) How will the trials be funded?

16) Where will the trials be performed? Please check the appropriate response.

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

☐ Other (Describe):

17) 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

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

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

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

21) Will you or your employees provide any health care services in conjunction with this trial? ◯ Yes ◯ No
If yes, provide complete details including whether or not you are insured elsewhere for this exposure.

22) 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		

23) Please 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:			

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

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

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

27) CLAIMS AND DISCIPLINARY HISTORY

(*Attach a detailed explanation for any yes answers)

a. 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

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

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

d. 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

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

f. 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.

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

If yes, what is the retroactive date on your current policy?

Please provide details below for the last five years of coverage.

Carrier	Limit	Deductible	Premium	Policy Term	Retro Date

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

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

RESET SAVE PRINT EMAIL

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.

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.