Admiral INSURANCE GROUP
a Berkley Company

# APPLICATION FOR CLINICAL RESEARCH ORGANIZATIONS & CLINICAL TRIALS FOR PROFESSIONAL LIABILITY COVERAGE

## (CLAIMS MADE COVERAGE)

1. Name of Applicant: _____
(Include all dba's and subsidiaries seeking coverage under the policy for which you are applying.)

Address: _____ _____ _____
Street City/State Zip

2. Internet Address: _____

3. ○ Corp ○ Partnership ○ Joint Venture ○ LLC ○ Other _____

4. Date Established _____ (mm/dd/yy)

5. Select the button next to 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 (Please describe in the space provided):

   _____

   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" please describe:

     _____

   Please select the corresponding button below if the clinical trials engaged in by the Applicant are for:
   - ○ Pharmaceuticals
   - ○ Biologics
   - ○ Medical Devices
   - ○ Other (please describe) _____

6. Has the applicant ever engaged in this or similar enterprises under a different name? ○ Yes ○ No
   If yes, please explain:

   _____

7. Will you be providing services or testing products outside of the United States? ○ Yes ○ No
   If yes, please advise which countries:

   _____

8. 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. Please use an attachment if necessary.

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

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

11. Will all test subjects be required to sign an informed consent document? ○ Yes ○ No

12. Are you aware of any other approved usages of the devices or drugs you are testing? ○ Yes ○ No
If yes, please provide details.

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

14. How will the trials be funded?

15. Where will the trials be performed? Please check the appropriate response.
○ Your Facility ○ Non-Profit Testing Institute ○ Hospital
○ Clinical Research Center ○ Other (please describe)

16. Select the button next to the services provided by the Applicant.

| | |
|---|---|
| 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: | |

17. Will an Institutional Review Board oversee the trials? Yes No

18. Are you a member of the Board? Yes No

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

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

21. Fees & Receipts

| | | |
|---|---|---|
| Estimate for the next 12 months<br>$ (Domestic)<br>$ (Foreign) | Number of test subjects: | Number under 18 yo: |
| Last 12 months<br>$ (Domestic)<br>$ (Foreign) | Number of test subjects: | Number under 18 yo: |

22. Please indicate the number of employed professionals or independent contractors. (If none, state none)

| | Employees | Contractor (Independent) | Total |
|---|---|---|---|
| RN/LPN | | | |
| Lab Tech. | | | |
| Clinical Investigator | | | |
| Clinical Research Assoc. | | | |
| Physician | | | |
| Medical Monitor | | | |
| Engineer | | | |
| Statistical Management | | | |
| Data Entry | | | |
| Legal Counsel | | | |
| Quality/Regulatory Compliance | | | |
| Medical Writing Administrative | | | |
| Other | | | |

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

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

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

26. 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 of 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, please complete the Supplemental Claim Form with your submission of this application. Form Link

27. 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 | Limits | Deductible/SIR | Premium | Policy Term |
|---|---|---|---|---|
| | | | | |

28. Do you currently carry GL and Products Liability? ○ Yes ○ No

☐ The applicant declares that the above statements and representations are true and correct and that no facts have been suppressed or misstated. The completion of this application does not bind the Company to sell nor the applicant to purchase this insurance, but any subsequent contract issued will be in full reliance upon the statement and representations made in this application. The applicant understands that any subsequent contract issued by the Company will be issued on a claims made form.

Electronic Signature of Applicant of Authorized Representative:

Current Date:

Title:

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

Signature of Applicant of Authorized Representative:

Current Date:

Title:

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 employee of the test site facility.
c. Informed consent document

Please provide any additional details in the space provided:

RESET SAVE AS PRINT EMAIL