

APPLICATION FOR CLINICAL RESEARCH ORGANIZATIONS & CLINICAL TRIALS FOR PROFESSIONAL LIABLITY COVERAGE (CLAIMS MADE BASIS)

	Name of A	Applicant:				
		(Includ	e all dba's and sub	sidiaries s	eeking coverage under the	policy for which you are applyin
	Address: _					
		Street			City/State	Zip
2.	Internet A	Address:				
3.	Corp	Partnership	Joint Venture	LLC	Other	
ŀ.	Date Estal	blished	(mm/dc	l/yy)		
5.	Indepe Institut Site Ma	ndent Research S tional Review Boa anagement Organ	iite	Academ Contrac Indeper	st describes the Applicant: nic Medical Center t Research Organization ndent Review Board	
	Phase Phase Phase Other	I II III				nment sponsored research, etc.
	Pharma Biologic Medica	aceuticals		v if the cli	nical trials engaged in by th	e Applicant are for:
5.		olicant ever engag		ar enterpri	ses under a different name	? Yes No
7.		providing service se advise which co		cts outsid	e of the United States?	/es No

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8.	Please list all current trials including the type of drug or device, the Phase and the trial state include trials that haven't started yet, but will start within the next 12 months. Please use necessary.			
9.	Fully describe any adverse results from previous related trials including animal studies and	l/or toxi	city 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? If yes, please provide details.	∕es N	No	
13.	Please provide the name of the device/pharmaceutical manufacturers for which you are	conduct	ing 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 b. Services directly to a sponsor c. Manage Trials d. Evaluate and monitor reports and prepare materials to be submitted to the FDA e. Develop trial protocol and consent forms f. Direct patient contact services (dosing patients with study drug, drawing blood, etc.) g. Manage multiple sites (data management only) h. Product development i. Provide central laboratory services j. Subcontract central laboratory services k. Employ/contract staffing	Yes	No	
	I. Recruitment of Study Participants m. Regulatory compliance consulting n. Quality Review (for other organizations) o. Other:	Yes Yes Yes	No No No	

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	If yes, please provide complete details in	icluding whether o	r not you ar	e insured elsewh	ere for this exposure.
21.	Fees & Receipts				
	Estimate for the next 12 months \$	(Domestic)	Number o	of test subjects:	Number under 18 yo
	\$	(Foreign)			
	Last 12 months \$	(Domestic)	Number o	of test subjects:	Number under 18 yo
	\$	(Foreign)			
22.	Please indicate the number of employed	d professionals or i	•	contractors. (If Contractor Independent)	none, state none)
	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 If no, please attach a detailed explanation		n insuranceí	? Yes No	
24.	Is the clinical investigator an employee o	of your firm? Ye	es No		
25.	Is the clinical investigator an employee o	of the test site facili	ty? Yes	No	

No

No

19. Do all of the manufacturers cover you for your liability associated with their products other than for your alleged breaches

17. Will an Institutional Review Board oversee the trials? Yes

No

20. Will you or your employees provide any health care services in conjunction with this trial? Yes

18. Are you a member of the Board? Yes

Yes

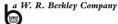
of protocol?

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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?
	Carrier Limits Deductible/SIR Premium Policy Term
20	Device a constant of the Device of Device of the U.S. A. V. A. A. A. V. A.
۷۵.	Do you currently carry GL and Products Liability? Yes No.

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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 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 and this application will be made a pert of the policy. 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	Current Date:
Representative:	
Title	
If you prefer not to return Application with an electron	onic signature, please print and sign below.
Signature of Applicant of Authorized Representative	Current Date:

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 enployee of the test site facility.
- c. Informed consent document

Please provide any additional details in the space provided:

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