

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

	(Include all dba's and subsidiaries seeking coverage under the policy for which you are applying.)				
	Address:				
	Street	City/State	Zip		
2.	Internet Address:				
	Corp Partnership Joint Ventu	ure LLC Other			
	Date Established(mm	n/dd/yy)			
	Select the button next to the description but Independent Research Site Institutional Review Board Site Management Organization Other (Please describe in the space pro	Academic Medical Center Contract Research Organization Independent Review Board			
	Please indicate for which phases of resear Phase I Phase II Phase III Phase IV Other (i.e. pre-clinical, non-biomedical "other" please describe:	rch coverage is being sought: Il research, social sciences research, governme	nt sponsored research, etc.)		
	Please select the corresponding button be Pharmaceuticals Biologics Medical Devices Other (please describe)	pelow if the clinical trials engaged in by the App	olicant are for:		
		imilar enterprises under a different name?	Yes No		

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8.	Please list all current trials including the type of drug or device, the Phase and the trial sta 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	I/or toxicit	y 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.	Yes No	0	
13.	Please provide the name of the device/pharmaceutical manufacturers for which you are	conductin	g these tria	als.
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	
	I. Recruitment of Study Participants	Yes	No	
	m. Regulatory compliance consulting n. Quality Review (for other organizations)	Yes Yes	No No	
	o. Other:	165	INU	

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20.	Will you or your employees provide any If yes, please provide complete details in				
21.	Fees & Receipts				
	Estimate for the next 12 months \$	(Domestic)	Number of test s	subjects:	Number under 18 yo:
	\$	(Foreign)			
	Last 12 months \$  \$		Number of test s	subjects:	Number under 18 yo
22.	Please indicate the number of employed	d professionals or Employees	Cont	actors. (If ractor endent)	none, state none)
			/III a C p		<u>Total</u>
	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				Total
23.	Lab Tech. Clinical Investigator Clinical Research Assoc. Physician Medical Monitor Engineer Statistical Management Data Entry Legal Counsel Quality/Regulatory Compliance Medical Writing Administrative	d to carry their ow		es No	
	Lab Tech. Clinical Investigator Clinical Research Assoc. Physician Medical Monitor Engineer Statistical Management Data Entry Legal Counsel Quality/Regulatory Compliance Medical Writing Administrative Other Are all independent contractors required	d to carry their ow			

No

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

No

17. Will an Institutional Review Board oversee the trials?

No

18. Are you a member of the Board?

Yes

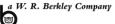
of protocol?

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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
28.	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 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 s	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:

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