Policy Effective Date: _____

This is an application for a **CLAIMS MADE POLICY**. Should this application be accepted by the Company, coverage will apply to claims first made against the insured during the policy period. No coverage will apply for claims first made against the insured after the end of the policy period unless the extended reporting period applies. No coverage will apply for claims first made prior to the retroactive date shown in the declarations page of the policy. **The completion and submission of this application to the Company does not constitute a binder of insurance.** All questions must be answered.

If a question is not applicable, please answer "NA". If the answer to a question is none, state "None" or "0". If more space is required to answer a question completely, please provide a separate attachment and identify the question it responds to.

NOTE: If product liability coverage is not desired complete Questions 1-13, then proceed to question 33 for Contracted Professional Services

1. GENERAL INFORMATION:

A. Name of Applicant (legal name of the First Named Insured): _____

D.B.A. (Doing Business As): _____

Corporate Address: _____

City: _____ State: _____

Zip Code: _____ County: _____

Mailing Address: (if different) _____

Corporate Contact: _____ Title: _____ E-Mail Address: _____

Tel. Number: (_____) _____ Website: _____

Description of Operations**:** _____

Risk Control Contact**:** _____ Email Address: _____

B. Other Named Insured: Provide names (other than the First Named Insured) and descriptions of operations for all legal entities that are intended for coverage to apply. Describe the relationship between the first named insured and that entity below.

Entity Name	Description of Operations	% Owned	Date Acquired	Retroactive Date

2. First Named Insured is the following Type of Entity:

☐ Individual ☐ Partnership ☐ Corporation ☐ Joint Venture ☐ Other *(Describe)*

3. First Named Insured conducts the following Type of Operations:

☐ Research and Development ☐ Pharmaceuticals ☐ Medical Devices ☐ Professional Services
☐ Blood/Tissue ☐ Nutritional Supplements ☐ Distributor ☐ *Other Describe*

4. In what year did the applicant's operation begin?

5. Do you have a parent company? ☐ Yes ☐ No
If Yes, provide legal name of the Company:

6. Have you operated under another name? ☐ Yes ☐ No
   If Yes, please give full details:

7. Projected U.S. revenues for the current fiscal year? $

8. Projected foreign revenues for the current fiscal year? $

9. Total gross revenues for current fiscal year? $

10. Total gross revenues from previous fiscal year? $

    When does your fiscal year begin?

Please provide last audited financials for review with this Application.

11. LOSS HISTORY

* Total aggregate cost (losses from ground up including defense) for last five years.

Policy Period	Insurer	# of Claims	Total Incurred

**Attach previous carrier loss runs.*

Describe all incurred losses of $10,000 or more:

Any known occurrences, damages, suits, claims or circumstances not yet reported? ☐ Yes ☐ No
If yes, please submit details.

Have you ever had a batch or relation declared in any claim? ☐ Yes ☐ No
If yes, please submit details.

Have any of your products ever been the subject of a mass claim or tort? ☐ Yes ☐ No
If yes, please submit details.

12. COVERAGE HISTORY

Policy Period	Primary & Excess Limits	Retention	Carriers	Retro Date

If multiple retro dates are being requested please provide all details associated with the dates requested.

Has your insurance ever been canceled or non-renewed by a carrier? ☐ Yes ☐ No
if yes, please explain.

Do you have any discontinued operations or products? If yes, provide a detailed description to enable underwriting of the exposure within this coverage request or provide details if coverage was placed elsewhere. ☐ Yes ☐ No

Are any of your products and/or services excluded from current coverage? ☐ Yes ☐ No
if yes, please explain.

Type of Coverage you are applying for: (check one)

Primary Liability Insurance ☐ or
Excess Liability Insurance ☐ if Excess, provide full tower details and retroactive dates:

Coverage Parts Requested: Products Liability ☐ Professional Liability ☐ Cyber Liability ☐
Technology Professional Liability ☐ Medical Professional Liability ☐

Increase in Sub-limits: Mitigation Expense ☐ Class/Product Recall Expense ☐
Medical Expense (clinical trial participants ☐

What limit of liability are you applying for?

What is the retro-active date you are applying for?
If multiple retro dates are being requested please provide all details associated with the dates requested.

What Deductible or SIR are you requesting (occurrence/aggregate)? $ / $ ☐ Deductible ☐ SIR ☐ N

Will any of your products or services be insured with another carrier during the policy term requested? ☐ Yes ☐ No
if yes, please explain.

13. RISK MANAGEMENT – *please note that more details may be requested*

Loss Prevention/Control Program? ☐ Yes ☐ No
Written Quality Control Program? ☐ Yes ☐ No
Written Product Recall Plan? ☐ Yes ☐ No
Written Records Retention Program? ☐ Yes ☐ No
Do you have a business continuity plan in place? ☐ Yes ☐ No
Promotional materials, contracts, guarantees, & labeling jointly reviewed by each applicable discipline? ☐ Yes ☐ No
Other *(please explain)*

14. PRODUCT PROFILE. *If Product Liability coverage is not desired, proceed to question 32 for Contracted Professional Services. Provide a list of all products/services with annualized revenue and patient population expectations.*

Source/Potential Source of Revenues	%	Product Description
Medical Devices		
Diagnostics		
Proprietary Pharmaceuticals		
Generic Pharmaceuticals		
Contract Research		
Contract Manufacturing		
Distribution		
Medical Equipment Rentals/Leasing		
Medical Equipment Repair/Installation/Service		
Blood / Tissue		
Training		
Other *(please explain)*_____		

Note: You may be required to review plans and programs with CNA Risk Control.

15. PRODUCT BREAKDOWN - as a percent of total revenue

Pharmaceuticals

Description	%	Description	%
Vaccines		Imaging/Diagnostic Agents	
Hormones & Steroids		Nutripharmaceuticals	
Injectable/Oral Prescription		Vitamins/Food Supplements	
Topical Prescription		Diet Aids	
Drug Delivery		Other *(please explain)*	

Medical Devices

Description	%	Description	%
Cardiac		Therapy/rehab	
Anesthesia/respiratory		Dialysis	
Implants - Active		Infusion	
Implants - Non-Active		Non-Cardiac Catheters	
Lasers		Analytical Instruments	
Surgical Devices		Diagnostic Kits	
Dental Instruments		Durable Medical Equipment	
Monitoring		Hospital Products/Supplies	
Imaging Devices		Other *(please explain)*	

16. List new products expected to be introduced in this policy period:

17. Any distributed products manufactured outside U.S.? ☐ Yes ☐ No
If yes, provide details.

18. Any product components imported? ☐ Yes ☐ No
If yes, are they FDA approved? ☐ Yes ☐ No

19. Are any products manufactured sold under others' labels? ☐ Yes ☐ No
If yes, explain and provide contracts.

20. Are any products sold as components for other products? ☐ Yes ☐ No
If yes, explain and provide end-product details:

21. Do you require Certificates of Insurance from your suppliers? ☐ Yes ☐ No
What limits of liability do you require ?

22. Do you contract out product development, manufacturing, sales, or distribution? ☐ Yes ☐ No
If yes, please indicate activities contracted:

23. Do any of your product training/certification programs required FDA approval? ☐ Yes ☐ No

24. Are manufactured products Underwriting Laboratories listed or Canadian Standards Assn certified? ☐ Yes ☐ No

25. Do you use a facility for reliability/design validation? ☐ Yes ☐ No

26. Do any of your employees provide direct patient care? ☐ Yes ☐ No
If yes, do they carry their own individual medical malpractice insurance? ☐ Yes ☐ No

27. Do you operate an in-patient facility? ☐ Yes ☐ No

28. Do any of your employees participate on an Institution Review Board? ☐ Yes ☐ No

29. Do you or any of your employees have a financial interest in the products of your clients? ☐ Yes ☐ No
If yes, explain:

30. List largest clients for current year:

31. SPONSORED CLINICAL TRIALS

Product	# New Subjects Over Next Policy Period	Indications	Country

** Please attach FDA approved protocols & informed consent documents for active clinical trials.*

32. REGULATORY

To the best of your knowledge are you in compliance with FDA Regulations or foreign agency equivalent? ☐ Yes ☐ No

Any product recalls in the past year? ☐ Yes ☐ No
If yes, please submit details & recall status:

Within past 12 months, has there been any MDR's or AER's filed? ☐ Yes ☐ No
If yes, indicate the number of filings and the nature of each

Date & result of most recent FDA inspection.
(please submit a copy of Form 483 and your documented response)

Have any products or company practices been subject to an investigation by any government agency? ☐ Yes ☐ No
If yes, please explain:

Any clinical trials placed on a clinical hold? ☐ Yes ☐ No
If yes, provide details:

Do you audit Clinical Investigator performance? ☐ Yes ☐ No

Any warning letters issued against you in the last 3 years? ☐ Yes ☐ No
If yes, please explain:

33. CONTRACTED PROFESSIONAL SERVICES. *If none, please proceed to question 39.*

Policy Period	Primary & Excess Limits for Prof Svs/E&O	Carriers. Prof	Retro Date for Prof Svs/E&O

34. Please describe in detail the professional services performed by the Applicant.

35. Indicate the approximate percentage derived from each of the professional services listed in the question above

%

%

%

36. CONTRACT ANALYSIS: *Please confirm that the applicant's service agreements contain the following provisions. If they do not, please explain why not. Please provide contract template for contract with sponsor and contract with investigator*

Does an attorney review all contracts or agreements including changes prior to use?	☐ Yes ☐ No
All duties and responsibilities of each party	☐ Yes ☐ No
Arbitration Clause	☐ Yes ☐ No
Choice of Law or Jurisdiction	☐ Yes ☐ No
Force Majeure (extends to any and all events outside applicant's control)	☐ Yes ☐ No
Guarantees	☐ Yes ☐ No
Hold Harmless Agreements/Indemnification	☐ Yes ☐ No
Limitation Of Consequential Damages	☐ Yes ☐ No
Limitation Of Liabilities	☐ Yes ☐ No
Warranty Disclaimers	☐ Yes ☐ No
Does applicant use a written contract or agreement with all clients? *If yes, please provide a copy of your standard agreement/template.*	☐ Yes ☐ No

37. PROFESSIONAL SERVICES

Do any of applicant's employees or sub-contractors provide direct patient care? *If yes, please explain:*	☐ Yes ☐ No
If there are employees or sub-contractors providing direct patient care, do they carry their own individual medical professional liability insurance?	☐ Yes ☐ No
Does the applicant operate an inpatient facility?	☐ Yes ☐ No
Do any of applicant's employees participate on an institutional review board?	☐ Yes ☐ No
Are any contracts past due or has a client stopped paying or asked for a refund in the last 3 years? *if yes, provide details*	☐ Yes ☐ No

What is the average length of time of applicant's contracts?

Identify your three largest contracts.

38. REGULATORY

Are you consistently in compliance with FDA or foreign agency equivalent Good Clinical Practices? ☐ Yes ☐ No

Are adverse event trends and significant adverse events reported to the IRB and the FDA? ☐ Yes ☐ No

What is the date and outcome of the most recent FDA inspection?
(Please submit a copy of Form 483 and your documented response).

What is the date and outcome of the most recent inspection report from the Office for Human Research Protections for federally funded research?

Have any company practices been subject to an investigation by a government agency? ☐ Yes ☐ No
If yes, please explain:

Have any clinical trials been discontinued or suspended due to safety reasons? ☐ Yes ☐ No
If yes, provide details:

Have any warning letters issued against you in the last 3 years? ☐ Yes ☐ No
If yes, please explain:

39. BIO-SAFETY HAZARD. Are any facilities are designated as Bio-Safety Hazard III or IV? ☐ Yes ☐ No

If yes, describe facility and provide details.

****

Please include the following with this application:

- Standard/master service contracts & indemnification agreements
- If a private company, provide most recent Annual Report/Audited Financial Statement
- Clinical trial protocols, informed consent documents and investigator agreements
- Most recent accreditation/regulatory agency survey reports
- Contract template for contract with sponsor
- Senior staff members' curriculum vitae
- Quality improvement, risk management, and patient safety plans/programs
- Adverse event and significant adverse event reporting policy and procedure
- Marketing or advertising brochures or descriptive materials provided to clients or potential research subjects
- Procedures for Label Change

FRAUD NOTICE – WHERE APPLICABLE UNDER THE LAW OF YOUR STATE

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 or incomplete information, or conceals for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime AND MAY BE SUBJECT TO CIVIL FINES AND CRIMINAL PENALTIES (for New York residents only: and shall also be subject to a civil penalty not to exceed five thousand dollars and the stated value of the claim for each such violation.) (For Pennsylvania Residents only: Any person who knowingly and with intent to injure or defraud any insurer files an application or claim containing any false, incomplete or misleading information shall, upon conviction, be subject to imprisonment for up to seven years and payment of a fine of up to $15,000.) (For Tennessee Residents only: Penalties include imprisonment, fines and denial of insurance benefits.)

Applicable in Colorado

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 California

For your protection California law requires the following to appear on this form: Any person who knowingly presents a false or fraudulent claim for the payment of a loss is guilty of a crime and may be subject to fines and confinement in state prison.

Completing and signing this application does not bind coverage. Coverage will not be bound, nor will a policy be issued until the applicant signifies acceptance of the Company's premium quotation.

AUTHORIZATION

I have answered the questions in the Application to the best of my ability and declare that, to the best of my knowledge, the statements set forth herein are true and correct. My signing of the Application does not bind the Insurance Company to complete the insurance, but it is agreed that this Application shall be the basis of the contract should a policy be issued.

A signature from the Applicant can be obtained electronically or "wet" prior to quote or binding.

If the applicant decides to submit their signature electronically the Applicant must check the "I Accept" button below. By doing so the Applicant hereby consents and agrees that their use of a key pad, mouse or other device to check the "I Agree" button constitutes their "signature", acceptance and agreement as if actually signed by the Applicant in writing and has the same force and effect as a signature affixed by hand. Further, the Applicant agrees the lack of a certification authority or other third party verification will not in any way affect the validity or enforceability of their signature or any resulting contract. After checking the "I Accept" button the Applicant must type in the name of the person completing this application, their title and date.

If the Applicant decides to submit a "wet" signature please have the Applicant sign, add their title and date the application prior to quoting or binding.

ELECTRONIC SIGNATURE

☐ Accept Name_____ Title _____ Date _____
(Person completing this application)

WET SIGNATURE

Signature in full **Date**

Name - please print

If not signing electronically, provide signature by a principal of the business- Original signature is needed prior to binding. You may either fax or email the original signature page directly to your underwriter.

Is your agency ☐ **Retail** ☐ **Wholesale**

Agency/Broker Name: _____ Address: _____

City: _____ State: _____ Zip Code: _____

Person Submitting Application: _____ Telephone Number: _____ E-mail: _____

This product will be underwritten in one of the CNA property/casualty companies. CNA is a registered service mark and trade name of CNA Financial Corporation.

Disclaimer: E-mail and on-line forms are not secure against interception and senders do not have a reasonable expectation of privacy. If you are concerned about transmitting this information electronically, please contact us for an alternative method to provide the necessary information.