

**APPLICATION FOR CLINICAL TRIALS**

Instructions to the Applicant – please complete this application in ink and answer all questions completely. Attach extra sheets as necessary should you run out of space provided. An incomplete or illegible application cannot be processed. Completion of this application neither binds coverage nor guarantees that a policy will be issued.

Provide a fully completed application, signed and dated by the owner, partner, or officer not earlier than 45 days before the proposed effective date of coverage.

If a question is not applicable, then state "N/A".

The following information must be submitted with the completed application:

- Copy of your current professional liability insurance Declarations Page (claims made policies must reflect the retroactive date)
- Copy of your Informed Consent documents
- Copy of all contracts between you and any Principal Investigators or trial sponsors
- Copy of your advertisements
- Copy of your current Financial Statement
- 5-year company loss runs, valued within the last 60 days

**GENERAL INFORMATION**

Applicant Name: \_\_\_\_\_

List of Any Previous Names or Organizations: \_\_\_\_\_

Date Established: \_\_\_\_\_ Website: \_\_\_\_\_

Mailing Address: \_\_\_\_\_

Additional Locations: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Applicant is: Corporation  Partnership  Joint Venture  Not For Profit   
Limited Liability Company  Individual  Other

Audit Contact: \_\_\_\_\_ Phone Number: \_\_\_\_\_



Description of Operations: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Revenues and Anticipated Number of Participants

	Revenues	Participants
Upcoming Year	_____	_____
Current Year	_____	_____
First Prior Year	_____	_____
Second Prior Year	_____	_____
Third Prior Year	_____	_____

**STAFFING**

1. Please indicate the number of employed professionals or independent contractors

Staff:	Full Time	Part Time	Contracted
Principal Investigator			
Physician			
RN/LPN			
Research Associates			
Research Monitors			
Regulatory Compliance			
Data Management			
Other (specify)			

Check the hiring procedures that apply or are performed:

- Criminal Background Checks
- Drug, alcohol and sexual abuse screening or testing
- Verification of certification or professional licensing
- Reference Checks
- Questioning of employees in their previous involvement as defendants in professional malpractice litigation.



2. Please list each Principal Investigator and Sub Investigator

NAME	STATE LICENSE	AVERAGE HOURS WORKED PER WEEK FOR THE APPLICANT	INDIVIDUAL INSURER & LIMITS

3. Do you require all of your Principal Investigators and Sub Investigators to carry their own professional liability limits? Yes  No
- i. If yes, what are the minimum limits required? \_\_\_\_\_
- ii. If no, are you requesting coverage for them under this policy? Yes  No
- iii. If yes, what are the minimum limits required? \_\_\_\_\_
- iv. If no, are you requesting coverage for them under this policy? Yes  No

**OPERATIONS**

1. Do you manufacture or distribute any products? Yes  No
2. Do you sign a written contract with all trial sponsors? Yes  No
3. Do you require a Certificate of Insurance providing proof of product liability coverage from each trial sponsor? Yes  No
- If yes, what are the minimum limits required? \_\_\_\_\_
4. Do you require all subcontractors providing services in connection with your trial to carry their own professional liability insurance coverage? Yes  No
- If yes, what are the minimum limits required? \_\_\_\_\_
5. Do you ever act as both the trial sponsor and clinical Investigator? Yes  No
6. Do you recruit or enroll your own study participants? Yes  No
7. Are participants required to sign an informed consent document? Yes  No
8. Do you enroll minors in your trials? Yes  No



9. Are all of your clinical trials approved and subject to oversight by an Institutional Review Board? Yes  No

10. Do your investigators conduct trials in accordance with FDA approved protocols? Yes  No

11. Please describe all health care services your employees provide (attach a separate sheet if necessary):

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

If yes, how many beds? \_\_\_\_\_

13. Do you comply with the FDA Good Clinical Practice Guidelines? Yes  No

i. Do you have written procedures in place to insure compliance with GCP's? Yes  No

ii. Have you ever been found not in compliance of GCP's by any regulatory authority? Yes  No

iii. Do you require that all personnel complete a formal training program on all policies and procedures including GCP's? Yes  No

14. Are you accredited by any industry body or regulatory authority? If yes, please list. Yes  No

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15. Are you a member of any industry trade organization? If yes, please list. Yes  No

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## CLINICAL TRIALS

1. Please indicate the percentage for the following:

i. Trial Phase:

Phase I -	_____
Phase II -	_____
Phase III -	_____
Phase IV -	_____
Other (describe) -	_____

\_\_\_\_\_

ii. Services provided for:

CRO -	_____
Manufacturer-	_____
Academic Medical Facility -	_____
Research Organization -	_____
Other (describe) -	_____

\_\_\_\_\_

iii. Product or Procedure:

Pharmaceuticals -	_____
Biologics -	_____
Medical Devices -	_____
Investigational Procedure -	_____
Other (describe) -	_____

\_\_\_\_\_



- iv. Trials:
  - Class III Medical Devices - \_\_\_\_\_
  - Controlled Substances - \_\_\_\_\_
  - Cosmetics - \_\_\_\_\_
  - Diagnostic Instruments - \_\_\_\_\_
  - Diet Aides - \_\_\_\_\_
  - Dietary Supplements - \_\_\_\_\_
  - Food - \_\_\_\_\_
  - Hormones or Steroids - \_\_\_\_\_
  - Implantable Devices - \_\_\_\_\_
  - In-patient - \_\_\_\_\_
  - Investigational Devices - \_\_\_\_\_
  - Investigational New Drugs - \_\_\_\_\_
  - Off-label Use - \_\_\_\_\_
  - OTC - \_\_\_\_\_
  - Prescription Drugs - \_\_\_\_\_
  - Psychiatric Drugs - \_\_\_\_\_
  - Surgical Equipment - \_\_\_\_\_
  - Vaccines - \_\_\_\_\_
  - Other (describe) - \_\_\_\_\_

2. Please list all active clinical trials. Please attach a separate sheet if additional space is needed.

Name	# of Subjects	Phase	Location	Length
Description				
Name	# of Subjects	Phase	Location	Length
Description				
Name	# of Subjects	Phase	Location	Length
Description				
Name	# of Subjects	Phase	Location	Length
Description				
Name	# of Subjects	Phase	Location	Length
Description				
Name	# of Subjects	Phase	Location	Length
Description				



## LOSS HISTORY

1. How many adverse events have been reported to you, the FDA and/or any other regulatory authority concerning your clinical trials in the last 5 years? Please provide details. \_\_\_\_\_

2. Has any claim been made against any person or organization proposed for this insurance during the last five (5) years? Yes  No

If yes, please provide five (5) year loss history for all claims, including any predecessor. Attach a description of any loss greater than \$10,000.

Year	No. of Claims	Total Amounts Paid	Amounts Reserved	Total Incurred	Date of Loss Info.

3. Is any person or organization proposed for this insurance aware of any fact, incident, circumstance, situation, condition, defect or suspected defect which may result in a claim, such that would fall under the proposed insurance? Yes  No

If yes, please provide details. \_\_\_\_\_

## INSURANCE INFORMATION

1. Has any insurer declined, canceled, or nonrenewed any General Liability, Professional Liability or similar insurance on behalf of any person or organization proposed for this insurance? Yes  No

If yes, please provide details. \_\_\_\_\_

2. Provide the following insurance information for the prior five (5) years:

Year	Limits of Liability	Deductible/SIR	Premium	Effective Dates	Retroactive Date

3. Indicate the limits of liability and deductible requested:

i. General Liability Limits - \$ \_\_\_\_\_ / \$ \_\_\_\_\_ Deductible - \$ \_\_\_\_\_

ii. Professional Liability Limits - \$ \_\_\_\_\_ / \$ \_\_\_\_\_ Deductible - \$ \_\_\_\_\_



## FRAUD WARNING

**NOTICE TO ALABAMA, ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, CONNECTICUT, DELAWARE, GEORGIA, IDAHO, ILLINOIS, INDIANA, IOWA, KANSAS, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NEVADA, NEW HAMPSHIRE, NORTH CAROLINA, NORTH DAKOTA, OREGON, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TEXAS, UTAH, VERMONT, WASHINGTON, WEST VIRGINIA, WISCONSIN, AND WYOMING APPLICANTS:** In some 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, for the purpose of misleading, conceals information concerning any fact material thereto, may commit a fraudulent insurance act which is a crime in many states.

**NOTICE TO COLORADO APPLICANTS:** 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 policy holder or claimant for the purpose of defrauding or attempting to defraud the policyholder or claiming with regard to a settlement or award payable for insurance proceeds shall be reported to the Colorado Division of Insurance within the Department of Regulatory Agencies.

**NOTICE TO DISTRICT OF COLUMBIA APPLICANTS: WARNING:** It is a crime to provide false or misleading information to an insurer for the purpose of defrauding the insurer or any other person. Penalties include imprisonment and/or fines. In addition, an insurer may deny insurance benefits if false information materially related to a claim was provided by the applicant.

**NOTICE TO FLORIDA APPLICANTS:** Any person who knowingly and with intent to injure, defraud or deceive any insurance company files a statement of claim containing any false, incomplete or misleading information is guilty of a felony of the third degree.

**NOTICE TO HAWAII APPLICANTS:** For your protection, Hawaii law requires you to be informed that presenting a fraudulent claim for payment of a loss or benefit is a crime punishable by fines or imprisonment, or both.

**NOTICE TO KENTUCKY APPLICANTS:** Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance 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.

**NOTICE TO LOUISIANA APPLICANTS:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

**NOTICE TO MAINE APPLICANTS:** 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, or denial of insurance benefits.

**NOTICE TO NEW JERSEY APPLICANTS:** Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties.

**NOTICE TO NEW MEXICO APPLICANTS:** Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to civil fines and criminal penalties.

**NOTICE TO NEW YORK APPLICANTS:** Any person who knowingly and with intent to defraud an 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 shall also be subject to a civil penalty not to exceed \$5,000 and the stated value of the claim for each such violation.

**NOTICE TO OHIO APPLICANTS:** Any person who, with intent to defraud or knowing that he/she is facilitating a fraud against an insurer, submits an application or files a claim containing a false or deceptive statement is guilty of insurance fraud.

**NOTICE TO OKLAHOMA APPLICANTS: WARNING:** Any person who knowingly, and with intent to injure, defraud or deceive any insurer, makes a any claim for the proceeds of an insurance policy containing any false, incomplete or misleading information is guilty of a felony.



**NOTICE TO PENNSYLVANIA APPLICANTS:** Any person who knowingly and with intent to defraud any insurance company, or other person, files an application for insurance or statement of a 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 the person to criminal and civil penalties.

**NOTICE TO TENNESSEE APPLICANTS:** It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits.

**NOTICE TO VIRGINIA APPLICANTS:** It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits.

**The Applicant acknowledges that the answers provided herein are based on a reasonable inquiry and/or investigation. The Applicant warrants that the above statements and particulars together with any attached or appended documents are true and complete and do not misrepresent, misstate or omit any material facts.**

**The Applicant agrees to notify us of any material changes in the answers to the questions on this questionnaire which may arise prior to the effective date of any policy issued pursuant to this questionnaire and the Applicant understands that any outstanding quotations may be modified or withdrawn based upon such changes at our sole discretion.**

**Completion of this form does not bind coverage. Applicant's acceptance of the company's quotation is required prior to binding coverage and policy issuance.**

**All written statements and materials furnished to the company in conjunction with this application are hereby incorporated by reference into this application and made a part of this application.**

Applicant: \_\_\_\_\_ Title: \_\_\_\_\_

FEIN #: \_\_\_\_\_

Applicant's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Agent / Broker Name: \_\_\_\_\_

