



P.O. Box 650 • 57 Parker Rd. • Barre, VT 05641 • 800-548-4301 • www.neee.com

LIFE SCIENCES CLINICAL TRIALS SUPPLEMENTAL APPLICATION

COMPLETE IN ADDITION TO THE KINSALE PHARMACEUTICALS OR MEDICAL DEVICES SUPPLEMENTAL APPLICATION.

ATTACH ADDITIONAL SHEETS AS NECESSARY.

ANSWER ALL QUESTIONS. If not applicable, indicate N/A.

GENERAL INFORMATION

1)

Named Insured:			
Additional Named Insureds:			
Brokerage/Broker:		Agency/Agent:	
Renewal?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Policy Number:	
Effective Date:			
Website:			

2)

Current/Most Recent Professional Liability Carrier Information:

Carrier:			
Limit of Insurance:			
Deductible:		Premium:	
Policy Term Dates:			
Offering renewal?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Claims made?	Yes <input type="checkbox"/> No <input type="checkbox"/> Retroactive date:

Please attach copies of the following:

- a) Currently valued Professional Liability five year loss runs, including claim detail for all losses open or exceeding \$15,000
- b) Copy of your current Professional Liability insurance Declarations Page (claims made policies must reflect the retroactive date and limits for retro continuity)
- c) A copy of your Informed Consent documents
- d) A copy of all contracts between you and any Principal Investigators or trial sponsors
- e) A copy of all marketing materials, brochures, description of operations, etc. if a website is not available
- f) A copy of your current financial statement
- g) A detailed description of all healthcare services provided by your employees

3)

What are your operations? _____

4)

Your enterprise is:

For Profit

Not for Profit

Other: _____

- 5) Who is your inspection contact? _____
 a. What is their phone number? _____
 b. What is their email address? _____
- 6) Are you owned by, associated with, or controlled by another entity? Yes No
 a. If yes, which? _____
- 7) Are you accredited by any industry body or regulatory authority? Yes No
 a. If yes, which one(s)? _____
- 8) Are you a member of any industry trade organizations? Yes No
 a. If yes, which one(s)? _____
- 9) Please complete the following for your revenues and participants:

	Revenues	Participants
Next 12 Months		
Previous 12 Months		
Two Years Prior		
Three Years Prior		
Four Years Prior		

OPERATIONS

- 10) Do you operate an in-patient facility? Yes No
 a. If yes, how many beds? _____
- 11) Do you ever act as both the trial sponsor and clinical investigator? Yes No
- 12) Do you recruit or enroll your own study participants? Yes No
- 13) Are all participants required to sign an Informed Consent document? Yes No
- 14) Do you enroll minors in your trials? Yes No
- 15) Do you sign a written contract with all trial sponsors? Yes No
- 16) Do you require a Certificate of Insurance providing proof of product liability coverage from each trial sponsor? Yes No
 a. If yes, what limits? _____
- 17) Are all of your clinical trials approved by and subject to oversight under an Institutional Review Board? Yes No
- 18) Do your investigators conduct trials in accordance with FDA approved protocols? Yes No
- 19) Do you comply with FDA Good Clinical Practice guidelines (GCPs)? Yes No
 a. Do you have written procedures in place to ensure compliance with GCPs? Yes No
 b. Have you ever been found not in compliance of GCPs by any regulatory authority? Yes No
 c. Do you require that all staff complete a formal training program on all policies and procedures including GCPs? Yes No

- 20) Do you require all subcontractors providing services in connection with your trial to carry their own professional liability insurance coverage? Yes No
- a. If yes, what limits? _____

CLINICAL TRIAL INFORMATION

- 21) For each of the below tables, please provide your percentage breakdowns:

Trial Phase	Percentage
Phase I	%
Phase II	%
Phase III	%
Phase IV	%
Other: _____	%

Services Provided For	Percentage
CRO	%
Manufacturer	%
Academic Medical Facility	%
Research Organization	%
Other: _____	%

Product or Procedure	Percentage
Pharmaceuticals	%
Biologics	%
Medical Devices	%
Investigational Procedure	%
Other: _____	%

Trials	Percentage
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	%
Over-The-Counter	%
Prescription Drugs	%
Psychiatric Drugs	%
Surgical Equipment	%
Vaccines	%
Other: _____	%
Other: _____	%

22) Please list all active clinical trials. Duplicate the following page as needed:

Name	Number of Subjects	Phase	Location	Length
Description:				

Name	Number of Subjects	Phase	Location	Length
Description:				

Name	Number of Subjects	Phase	Location	Length
Description:				

Name	Number of Subjects	Phase	Location	Length
Description:				

STAFF INFORMATION

23) Please complete the following for your staff:

	Employees		Independent Contractors	
	Full-Time	Part-Time	Full-Time	Part-Time
Principal Investigator				
Physician				
RN/LPN				
Research Associates				
Research Monitors				
Regulatory Compliance				
Data Management				
Other: _____				
TOTAL:				

24) Please list each Principal Investigator and Sub-Investigator:

Name	State License Number	Average hours/week	Individual Insurer and Limits

- a. Do you require all Principal Investigators and Sub-Investigators to carry their own professional liability insurance? Yes No
- b. If yes to a., what limits do you require? _____
- c. If no to a., are you requesting coverage for these investigators under this policy application? Yes No
- d. If yes to c., what limits are you seeking? _____

25) Which of the following procedures do you use for hiring/screening professionals and paraprofessionals who provide services in your operations? Check all that apply:

- Check of educational background
- Check of previous employers – In writing
- Criminal background check – State
- Drug screening
- Abuse screening
- Verification of license validity, suspensions, revocations, citations, or pending disciplinary actions
- Verification of any pending disciplinary actions by current or previous employers
- Verification of Professional Liability or other workplace related claims history against the applicant
- Other: _____
- Check of residency program
- Check of previous employers – By telephone
- Criminal background check – Federal
- Alcohol screening
- Reference verification

COVERAGE AND LOSS HISTORY

- 26) Has any regulatory authority taken any action against you or any of your employees? Yes No
If yes, please attach an explanation and copies of all citations.
- 27) Have you or any of your employees ever had any professional license or license to prescribe and or dispense narcotic ever been limited, suspended, revoked, denied, or investigated by any licensing board or regulatory agency? Yes No
If yes, please attach an explanation.
- 28) How many adverse events have been reported to you, the FDA or any other regulatory authority concerning your clinical trials in the last five years? **Please attach an explanation for each adverse event.** _____
- 29) During the past five years, has any insurer ever canceled or non-renewed similar insurance to any applicant or has your insurance been canceled for nonpayment of premium by any insurance or finance company. Yes No
If yes, please attach an explanation.
- 30) Has any lawsuit ever been filed, or any claim otherwise been made against you or or any other person proposed for this insurance, including any partnership or joint venture of which you have been a member or your company's predecessors in business, or against any person, company or entities on whose behalf your company has performed operations or assumed liability? Yes No
If yes, please attach an explanation.
- 31) Is your company aware of any occurrences, facts, circumstances, incidents, situations, act, error, omission or records request from an attorney which may result in a claim or suit? Yes No
If yes, please attach an explanation.

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: _____