

Clinical Research Liability Insurance

New Business Application



Instructions:

- Answer ALL questions completely, leaving No blanks. If any questions, or part thereof, do not apply, print “N/A” in the appropriate space. Any spaces left blank will be interpreted to not apply.
- If additional space is needed, please use a separate sheet and reference the applicable question number.
- This application must be completed, dated and signed by a Principal or Officer of your firm. Underwriters will rely on all statements made in this application.

Supplemental Information:

- Supplemental application, if available.
- List of active clinical trials scheduled for upcoming policy term (include product name/ protocol number, trial phase, number of participants etc.)
- Current insurance company loss reports for the past five (5) years. Specify date, description and amount outstanding/current reserve for each claim.
- Most current annual financial statements (audited or compiled), or IRS Form 990 if non-profit.
- Expiring DEC page

Today’s Date: _____

Quote by: _____

SECTION 1. PRODUCER INFORMATION	
1. Agency Name: _____	2. Contact Person: _____
3. Mailing Address: _____	4. Phone Number: _____
5. Email Address: _____	6. Agent/Broker License #: _____

SECTION 2. APPLICANT INFORMATION	
1. First Named Insured (Applicant Entity Name): _____	2. DBA Name (if Applicable): _____
3. Mailing Address _____	4. Country in which services are provided: _____
5. Date Business First Established: _____	6. Employer Federal Tax ID Number: _____
7. Phone Number: _____	8. Fax Number: _____
9. Website: _____	10. Risk Manager Contact & Email Address: _____

11. Type of Entity:

- | | | |
|--|---|---|
| <input type="checkbox"/> Corporation | <input type="checkbox"/> Joint Venture | <input type="checkbox"/> Non-profit |
| <input type="checkbox"/> Partnership, LLC | <input type="checkbox"/> Professional Association | <input type="checkbox"/> Proprietorship |
| <input type="checkbox"/> Other (specify) _____ | | |

12. You are:

- | | | |
|---|---|---|
| <input type="checkbox"/> Contract Research Organization | <input type="checkbox"/> Data Safety Monitoring Board | <input type="checkbox"/> Independent Research Site |
| <input type="checkbox"/> Institutional Review Board | <input type="checkbox"/> Research Institute –NFP | <input type="checkbox"/> Site Management Organization |
| <input type="checkbox"/> Trial Sponsor | <input type="checkbox"/> Other (specify) _____ | |

**Please complete the supplemental questionnaire regarding your operations to be considered for favorable pricing, terms and conditions*

Clinical Research Liability Insurance New Business Application



13. Do you participate in pediatric studies? Yes No
14. Do you provide services or have operation at more than one location?
If Yes, please list: ___ Yes No
15. Has your research related operations or services changed in any material way in the past 5 years?
If Yes, please explain: ___ Yes No
16. What % of your current business is related to the following areas?
Interventional Trials: ___% Observational Trials: ___%
17. Additional Insureds:
Please provide a list of all entities to be named as an Additional Insured(s) with complete names and insurable interest:
- | Name | Insurable Interest |
|-------|--------------------|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

SECTION 3. FINANCIAL & STAFFING INFORMATION

1. If you are a not-for-profit organization, please complete the following with the understanding that revenue is defined as “all sources of income/funding,” i.e. donations, grants etc.
*If you do not generate revenue, complete the following by showing annual expenditures in lieu of revenues.

	3 Years Prior	2 Years Prior	1 Year Prior	Current or Expiring Year	Projected for Policy Period
Gross Revenue:	\$_____	\$____	\$____	\$____	\$____
Pass Through Revenues					
Net Income or Loss					

2. If applicable, please provide the projected revenues for the next 12 months in USD: n/a
United States \$___ Canada \$___ UK/Ireland/Australia \$___ Rest of World \$___

1. Have you had any clients that represent 20% or more of your total annual revenues in the past 3 years? If Yes, please list: ___ Yes No

2. Description of employees or contracted personnel:

	Number of Employees (FTE's) (Hours)	Number of IC's (FTE's) (Hours)	Carry Their Own Insurance
Principal Investigator			<input type="checkbox"/> Yes <input type="checkbox"/> No
Sub Investigator			<input type="checkbox"/> Yes <input type="checkbox"/> No
Clinical Research Associates			<input type="checkbox"/> Yes <input type="checkbox"/> No
Clinical Research Coordinators			<input type="checkbox"/> Yes <input type="checkbox"/> No
Other			<input type="checkbox"/> Yes <input type="checkbox"/> No

Clinical Research Liability Insurance New Business Application



3. Do your PIs, CRC's or CRAs have less than 5 years of clinical research experience? Yes No
If Yes, please list: ____
PIs: ____% CRCs: ____% CRAs: ____%

SECTION 4. ACCREDITATION & REGULATORY INFORMATION

1. Are you currently accredited by an industry body or regulatory entity? Yes No
If Yes, please list: ____
2. Has there ever been any governmental or regulatory investigation or proceeding against or involving the activities of the Applicant or any proposed insured, or has the Applicant or any proposed insured been sanctioned by or entered into a settlement agreement with any governmental or regulatory agency, involving services for which coverage is being sought? (Include currently pending investigations or proceedings.) Yes No
Regulatory actions under this question include Black Box event, 483 observations and any suspension of a trial for safety reasons.
If Yes, please explain: _____
3. Are you in compliance with all State, Federal and local laws? Yes No
If No, please explain: ____

SECTION 5. DATA COLLECTION & MANAGEMENT

1. Do you provide data management services? Yes No
If No, skip to Question 4.
If Yes,
 - Does it include transcribing/ maintaining case report forms, patient recruitment records, etc.? Yes No
 - Do you aggregate subject data in its networks? Yes No
 - Do you evaluate/monitor reports and prepare materials to be submitted to the FDA? Yes No
 - Are all electronic records backed up? Yes No
 - Are the backups stored off site? Yes No
2. Do you keep hard copy records (case report forms, patient recruitment records, etc.)? Yes No
3. Do you outsource data management services? Yes No
If Yes, is there a contract in place whereby the independent contractor agrees to indemnify you? Yes No
4. Are you compliant with HIPAA regulations? Yes No
- Yes No



Clinical Research Liability Insurance New Business Application

SECTION 6. CONTRACTS

1. Do you enter into written contracts to provide/ receive Yes No

2. Do you enter into written contracts with parties other than trial sponsors and/or research sites? Yes No
 If Yes, do you agree, pursuant to such contracts, to indemnify and hold harmless such third parties? Yes No

3. Does the Applicant require a written contract with any subcontractors providing services to Applicant related to research activities? Yes No

4. Does an attorney review all of Applicant's contracts or agreements including any subsequent changes thereto, prior to entering into such contract or agreement? Yes No

5. Do you require that contracts to include:
 - Duties and responsibilities of each party are clearly defined. Yes No
 - Arbitration Clause Yes No
 - Choice of law or jurisdiction Yes No
 - Force Majeure Yes No
 - Limitation of consequential damages Yes No
 - Limitation of Liability Yes No
 - Warranty Disclaimers Yes No

SECTION 7. PREVIOUS INSURANCE

1. Clinical Research Liability Insurance Coverage Information. Provide the following information for each of the last 3 years starting with the current or expiring year.

Company	Policy Period	Limits of Liability Each claim/Aggregate	Retention/Deductible Each claim/aggregate	Premium	CM/Occ.
_____	_____	\$_____/ \$_____	\$___/ \$___	\$_____	<input type="checkbox"/> CM Retro Date: _____
___	___	\$___/ \$___	\$___/ \$___	\$___	<input type="checkbox"/> CM Retro Date: ___
___	___	\$___/ \$___	\$___/ \$___	\$___	<input type="checkbox"/> CM Retro Date: ___

Yes No

2. Have you been continuously insured under a claims made professional liability policy since the retro date mentioned above?

3. Have you ever had professional liability insurance canceled or Non-renewed? Yes No

Clinical Research Liability Insurance New Business Application



SECTION 8. CLAIMS & INCIDENT REPORTING INFORMATION

1. Are you aware of any events which may result in any claim or suit being made? Yes No
2. If this application is for new Claims-Made coverage including prior acts, will all current Primary and Excess Claims-Made policies accept claims for (a) a written Notice, demand or service of suit against any Applicant, and (b) specific circumstances reasonably likely to give rise to a written Notice, demand or service of suit against any Applicant? Yes No
If Yes, do you have a process to identify claims and specific circumstances regarding loss events reasonably likely to give rise to a written Notice, demand or service of suit, for purposes of timely reporting to the Applicants' Claims-Made insurers before expiration? Yes No

SECTION 9. FRAUD STATEMENTS

GENERAL STATEMENT

Any person who knowingly and with intent to defraud any insurance company or another 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 subjects the person to criminal and [NY: substantial] civil penalties. (Not applicable in CO, DC, FL, HI, MA, NE, OH, OK, OR, VT or WA; in LA, ME, TN and VA, insurance benefits may also be denied).

APPLICABLE IN COLORADO

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 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 THE DISTRICT OF COLUMBIA

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.

APPLICABLE IN FLORIDA

Any person who knowingly, and with intent to injure, defraud, or deceive any insurer files a statement of claim or an application containing any false, incomplete or misleading information is guilty of a felony of the third degree.

APPLICABLE IN HAWAII

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.

APPLICABLE IN MASSACHUSETTS, NEBRASKA, OREGON AND VERMONT

Any person who knowingly and with intent to defraud any insurance company or another 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, may be committing a fraudulent insurance act, which may be a crime and may subject the person to criminal and civil penalties.

APPLICABLE IN OHIO

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.

APPLICABLE IN OKLAHOMA

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

APPLICABLE IN WASHINGTON

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.

Clinical Research Liability Insurance New Business Application



BY SIGNING THIS APPLICATION, THE APPLICANT WARRANTS TO THE COMPANY THAT ALL STATEMENTS MADE IN THIS APPLICATION ABOUT THE APPLICANT AND ITS OPERATIONS ARE TRUE AND COMPLETE, AND THAT NO MATERIAL FACTS HAVE BEEN MISSTATED IN THIS APPLICATION OR CONCEALED. COMPLETION OF THIS FORM DOES NOT BIND COVERAGE. THE APPLICANT'S ACCEPTANCE OF THE COMPANY'S QUOTATION IS REQUIRED BEFORE THE APPLICANT MAY BE BOUND AND A POLICY ISSUED.

This application does Not bind YOU or US to complete the insurance, but it is agreed that the information contained herein shall be the basis of the contract should a policy be issued.

Applicant's Name: _____
(Please Type or Print Name)

Applicant's Title: _____
(Please Type or Print Title)

Applicant's Signature: _____ Date: _____
(Must be signed by an active Owner, Partner or Executive Officer.)

Producer's Name: _____
(Please Type or Print Name)

Producer's Signature: _____ Date: _____