

Small Business – Life Sciences

Contract Research Organization Application

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 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, answer N/A. If the answer to the 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.

Applicant Information

Applicant's Legal Name
Applicant's Location Address
Address Line 2
City, State, ZIP Code
If mailing address is not the same as the location address, enter the mailing address below.
Applicant's Mailing Address
Address Line 2
City, State, ZIP Code
Contact Phone Number
Email Address
Website Address
Legal Entity Type
Years in Business
Description of Operations

 Acquisition Company Name
 Acquisition Date

If any acquisitions/mergers have occurred in the last 5 years, list below.

Current Policy Information

Effective Date	_ Expiration Date
Retroactive Date	
If coverage with a prior carrier exists, list below.	
Prior Carrier	
Effective Date	
Expiration Date	
Limit Type	
Each Claim Limit	
Each Claim Deductible	
Each Claim SIR	
Aggregate Limit	
Aggregate Deductible	
Aggregate SIR	
Retroactive Date	

List any paid, reserved or pending claim activity not yet reported to current carrier.

Date of Claim	Type/Description of Claim	Estimated Amount of Claim	Carrier

If the applicant has additional entities to be included as "Named Insureds," schedule below.

Additional Entity to be Included as Named Insured	Street Address, City, State, ZIP Code	Description of Operations	% of Ownership	Retroactive Date

Coverage Underwriting/Eligibility Questions

Does the applicant's research include any of the following?

Breast, Buttocks, Facial and/or	Gene and/or Stem Therapy	Pediatrics
Pectoral Implants	Live Virus Vaccine Studies	Pregnant Women
Blood and/or Blood Products	Minor Enrollees	Prisoners
Clinical Trials Where No-Fault Coverage Exists	Nursing Mothers	None of the Above
Contraceptive Devices or Medications	Obesity and/or Weight Loss Drugs	

Does the applicant require the use of a Master Service Agreement (MSA) or contract/purchase orders for engagements with current and any future business partners?

Complete only if requesting Professional Liability.

Contract Analysis - Identify provisions in the applicant's service agreements.

Check all that apply.

All Duties and Responsibilities of	Choice of Law or Jurisdiction	Limitation of Consequential Damages
Each Party	Force Majeure (Extends to Any and All	Limitation of Liabilities
Arbitration Clause	Events Outside Applicant's Control)	Warranty Disclaimers
Attorney Review of all Contracts and Agreements Including Changes Prior	Guarantees	
to Use	Hold Harmless Agreements/ Indemnifications	

Revenue

Projected Domestic Revenue _____

Projected Foreign Revenue _____

Yes

No

Policy Underwriting Questions

Professional Services

Does the applicant have payment dispute and claim handling procedures in place?	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
In the last 3 years, do any contracts:		
Have past due payments owed?		
Have clients who have stopped paying?		
Have clients who have asked for a refund?	Yes	No
<u>If yes, provide details.</u>		

Provide the following information regarding your five (5) largest clients (determined as a percentage of the total gross revenue for the past fiscal year).

Client	Size of Contract	Length of Contract	Description of Services

Regulatory

Are you consistently in compliance with FDA or foreign agency equivalent Good Clinical Practices?	Yes	Νο	N/A
Has the applicant reported any adverse event(s) or significant adverse event(s) to the Institutional Review Board (IRB) or the Federal Drug Administration (FDA)?	Yes	No	N/A
Has the applicant had an FDA inspection in the last 3 year?	Yes	No	N/A

Explain any findings

Has the applicant had an inspection from the Office for Human Research Protections for federally funded research in the last 3 years?	Yes	No	N/A
Explain any findings.			
Have any company practices been subject to an investigation by a government agency?	Yes	No	N/A
Explain any findings.			
Have any of the applicant's clinical trials been discontinued or suspended due to safety reasons?	Yes	No	N/A
<u>If yes, explain</u> .			

Risk Management

Does the applicant have a designated risk manager?	Yes	No
Is there a written and implemented loss prevention/control program?	Yes	No
Is there a written and implemented quality management/regulatory affairs program?	Yes	No
Does the applicant have formalized client complaint resolution policy and procedures?	Yes	No
Is there a written and implemented records retention program?	Yes	No
Are patient recruitment materials reviewed by risk management and legal counsel?	Yes	No
If no, to what extent do you grant authority to individual entities or employees?		

Does the applicant have a process for auditing any of your service providers to ensure they areadhering to contract/protocol or agreements? (i.e. investigators)YesYesNo

Professional Service(s) Schedule

Describe all professional services planned for the next 12 months. Complete if your risk provides any professional services.

Professional Service Description	% of Total Revenue Derived from Professional Service

General Policy Coverage

Select Coverage(s) Needed

Products Liability Professional Liability

Products Liability Limits

Each Claim Limit	\$1,000,000 \$8,000,000	\$2,000,000 \$9,000,000	\$3,000,000 \$10,000,000	\$4,000,000	\$5,000,000	\$6,000,000	\$7,000,000				
Each Claim Deduct	t ible \$5,000	\$10,000	\$15,000 \$2	5,000 \$50,0	000 \$75,000	\$100,000					
Aggregate Limit	\$1,000,000 \$8,000,000	\$2,000,000 \$9,000,000	\$3,000,000 \$10,000,000	\$4,000,000	\$5,000,000	\$6,000,000	\$7,000,000				
Aggregate Deduct	t ible Unlimit \$100,0		gate) \$5,000 0 \$500,000	\$10,000 Other		\$25,000 \$50,	000 \$75,000				
Products Liability Retroactive Date											
Medical Expenses											
Each Person Limit \$1,000 \$5,000 \$10,000 \$25,000											
Aggregate Limit	\$5,000 \$10	0,000 \$25,00	00								
Product Recall/Withdrawal (Class 1 Product Recall only – \$25,000 limit automatically included)											
Optional Sublimit Excluded \$50,000 \$100,000 \$250,000											
Coinsurance (%)	10% 20%										
Aggregate Deductible \$10,000 \$15,000 \$25,000 \$50,000 \$100,000 \$150,000											

Terrorism

Terrorism Coverage (Select if coverage is desired)

If Terrorism is rejected, TRIA Rejection form must be completed at end of application.

Professional Liability

Each Claim Limit	\$1,000,000	\$2,000,000	\$3,000,000	\$4,000,000	\$5,000,000	\$6,000,000					
	\$7,000,000	\$8,000,000	\$9,000,000	\$10,000,000	C						
Each Claim Deduct	:ible \$5,000	\$10,000	\$15,000 \$2	\$5,000 \$50	,000 \$75,00	00 \$100,000					
Aggregate Limit	\$1,000,000 \$7,000,000	\$2,000,000 \$8,000,000	\$3,000,000 \$9,000,000	\$4,000,000 \$10,000,000	\$5,000,000	\$6,000,000					
Aggregate Deduct	i ble Unlim \$75,00	ited (No Aggre	gate) \$5,000 \$250,000	\$10,000 \$500,000	\$15,000 Other	\$25,000 \$50,000					
Professional Liability Retroactive Date											

Mitigation Expenses – Applies to both Products and Professional coverage if purchased together or separately (\$250,000 limit automatically included)

Optional Sublimit Excluded \$500,000 \$750,000 \$1,000,000

Coinsurance (%) 20% (only option)

The undersigned **authorized officer of the applicant** knows of no other relevant facts which might affect the Company's judgment when considering this renewal application and warrants that the statements herein are true, and it is agreed that this renewal application shall be the basis of the renewal contract and shall be deemed incorporated therein should the Company evidence its acceptance of this renewal application by issuance of a renewal policy. It is agreed that this renewal application shall be deemed to be attached to and made part of the renewal policy, if issued, as if physically attached to the renewal policy.

Signature

Title

Print Name

Terrorism Rejection OFFER OF REJECTION OF CERTIFIED ACTS OF TERRORISM COVERAGE

INSTRUCTIONS TO INSURED

Solely with respect to any coverages other than a crime, auto, professional liability coverage or any other coverage exempt from the Terrorism Risk Insurance Act, as extended and reauthorized ("Act"), you are hereby notified that under the Act you have a right to purchase insurance coverage of losses arising out of acts of terrorism, as defined in Section 102(1) of the Act, and in accordance with the provisions of such Act and subject to all applicable policy provisions. The Act established a federal program within the Department of the Treasury, under which the federal government shares, with the insurance industry, the risk of loss from future terrorist attacks. This Act applies when the Secretary of the Treasury certifies that an event meets the definition of an act of terrorism, which is an act committed by an individual or individuals to coerce the government or population of the United States, that results in aggregate losses of \$5 million or more. The 2007 re-authorization no longer requires the act of terrorism to be committed by or on behalf of a foreign interest and certified acts of terrorism now encompass, for example, a terrorist act committed against the United States government by a United States citizen when the act is determined by the federal government to be "a certified act of terrorism. "You may choose to exclude Certified Acts of Terrorism, as described above. This Rejection of Certified Acts of Terrorism Coverage Form is valid only if fully completed and returned to us. For each Coverage Part rejected, the corresponding "Reject" area must be checked, and the "Policy Number" and "Policy Period" must be indicated. In addition, the SIGNATURE BLOCK (below) must be completed in its entirety. The applicable policy will then be endorsed to exclude terrorism, and the premium recalculated. Solely with respect to Property Policies, the states of CA, CT, GA, HI, IA, IL, MA, ME, MO, NC, NJ, NY, OR, RI, WA, WI, and WV have Standard Fire Policy (SFP) statutes that are applicable to your Property and, in CA, ME, MO, OR and WI, to your Inland Marine coverages. In these states, coverage is required to be provided for fire damage that results or follows from any cause of loss, even those that are otherwise excluded. As a result, although certified acts of terrorism are excluded from your policy, we are statutorily required to insure against fire damage that might result from otherwise excluded acts of terrorism. In addition, certain states may not allow coverage for certified acts of terrorism to be rejected for any coverage part. Terrorism coverage can not be rejected for Workers' Compensation in any state. If the circumstances in the above paragraph apply, the United States Government, Department of the Treasury, will pay a share of terrorism losses insured under the federal program. The federal share equals 85% of that portion of the amount of such insured losses that exceeds the applicable insurer retention. However, if aggregate insured losses attributable to terrorist acts certified under the Act exceed \$100 billion in a Program Year (January 1 through December 31), the Treasury shall not make any payment for any portion of the amount of such losses that exceeds \$100 billion. Further, this coverage is subject to a limit on our liability, pursuant to the federal law where if aggregate insured losses attributable to terrorist acts certified under the Act exceed \$100 billion in a Program Year (January 1 through December 31) and we have met our insurer deductible under the Act, we shall not be liable for the payment of any portion of the amount of such losses that exceeds \$100 billion, and in such case insured losses up to that amount are subject to pro rata allocation in accordance with procedures established by the Secretary of the Treasury.

REJECTION OF TERRORISM STATEMENT

I hereby agree to the rejection of terrorism coverage. I understand that a rejection of terrorism coverage means the exclusion of foreign and domestic acts of terrorism that are determined by the Department of Treasury to be Certified Acts of Terrorism as defined in the Terrorism Risk Insurance Act. I also recognize by waiving this coverage, if I so choose to add terrorism coverage on at a later date within this policy term, coverage will not be available if the alert level has been raised above "orange". I hereby agree that I am abiding by the rules and terms of my mortgagee, loss payee or additional insured as interest may appear, and have notified them of my intent to reject coverage

SIGNATURE BLOCK

Ву ___

Authorized Representative's Signature

Authorized Representative's Title

Date

Named Insured

Fraud Warnings

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 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 DC residents only

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 applicant.

For FL residents only

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.

For LA residents only

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.

For ME residents only

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 a denial of insurance benefits.

For NY residents only

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 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 OK residents only

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.

For PA residents only

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 conceals for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

For PR residents only

Any person who knowingly and with the intention of defrauding presents false information in an insurance application, or presents, helps, or causes the presentation of a fraudulent claim for the payment of a loss or any other benefit, or presents more than one claim for the same damage or loss, shall incur a felony and, upon conviction, shall be sanctioned for each violation by a fine of not less than five thousand dollars (\$5,000) and not more than ten thousand dollars (\$10,000), or a fixed term of imprisonment for three (3) years, or both penalties. Should aggravating circumstances [be] present, the penalty thus established may be increased to a maximum of five (5) years, if extenuating circumstances are present, it may be reduced to a minimum of two (2) years.'

For TN residents only

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. Penalties include imprisonment, fines and denial of insurance benefits.

For VT residents only

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 may be a crime and may be subject to civil fines and criminal penalties.

For WA residents only

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. Penalties include imprisonment, fines and denial of insurance benefits.

"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." 48.135.080. Required statement on all insurance applications and claim forms

No later than six months after July 1, 2006, or when the insurer has used all its existing paper application and claim forms which were in its possession on July 1, 2006, whichever is later, all applications for insurance, and all claim forms regardless of the form of transmission provided and required by an insurer or required by law as condition of payment of a claim, must contain a statement, permanently affixed to the application or claim form, that clearly states in substance the following:

"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."

One or more of the CNA companies provide the products and/or services described. The information is intended to present a general overview for illustrative purposes only. It is not intended to constitute a binding contract. Please remember that only the relevant insurance policy can provide the actual terms, coverages, amounts, conditions and exclusions for an insured. All products and services may not be available in all states and may be subject to change without notice. "CNA" is a registered trademark of CNA Financial Corporation Subsidiaries use the "CNA" service mark in connection with insurance underwriting and claims activities. Copyright © 2023 CNA. All rights reserved.

