



Small Business – Life Sciences

# Contract Research Organization Application

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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 \_\_\_\_\_

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

Acquisition Company Name	Acquisition Date

### 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 Pectoral Implants | Gene and/or Stem Therapy         | Pediatrics        |
| Blood and/or Blood Products                       | Live Virus Vaccine Studies       | Pregnant Women    |
| Clinical Trials Where No-Fault Coverage Exists    | Minor Enrollees                  | Prisoners         |
| Contraceptive Devices or Medications              | Nursing Mothers                  | None of the Above |
|   | 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? Yes      No

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

### Revenue

Projected Domestic Revenue \_\_\_\_\_

Projected Foreign Revenue \_\_\_\_\_

## 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? Yes    No
  - Have clients who have stopped paying?
  - Have clients who have asked for a refund? Yes    No
- If yes, provide details.

**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    No    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
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Explain any findings.

Have any company practices been subject to an investigation by a government agency?	Yes	No	N/A
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Explain any findings.

Have any of the applicant's clinical trials been discontinued or suspended due to safety reasons?	Yes	No	N/A
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If yes, explain.

## Risk Management

Does the applicant have a designated risk manager?	Yes	No
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Is there a written and implemented loss prevention/control program?	Yes	No
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Is there a written and implemented quality management/regulatory affairs program?	Yes	No
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Does the applicant have formalized client complaint resolution policy and procedures?	Yes	No
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Is there a written and implemented records retention program?	Yes	No
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Are patient recruitment materials reviewed by risk management and legal counsel?	Yes	No
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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 are adhering to contract/protocol or agreements? (i.e. investigators)	Yes	No
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### 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    \$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

Each Claim Deductible    \$5,000    \$10,000    \$15,000    \$25,000    \$50,000    \$75,000    \$100,000

Aggregate 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

Aggregate Deductible    Unlimited (No Aggregate)    \$5,000    \$10,000    \$15,000    \$25,000    \$50,000    \$75,000  
                                  \$100,000    \$250,000    \$500,000    Other \_\_\_\_\_

Products Liability Retroactive Date \_\_\_\_\_

#### Medical Expenses

Each Person Limit    \$1,000    \$5,000    \$10,000    \$25,000

Aggregate Limit    \$5,000    \$10,000    \$25,000

#### 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







## 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.”