Clinical Research Organizations & Clinical Trials Professional Liability

Insurance application form

US

The purpose of this application form is for us to find out more about you. You must provide us with all information which may be material to the cover you wish to purchase and which may influence our decision whether to insure you, what cover we offer you or the premium we charge you.

How to complete this form

The individual who completes this application form should be a senior member of staff at the company and should ensure that they have checked with other senior managers and colleagues responsible for arranging the insurance that the questions are answered accurately and as completely as possible. Once completed, please return this form to your insurance broker.

Section 1: Company Details

1.1 Please state the name and address of the principal company for whom this insurance is required. Cover is also provided for the subsidiaries of the principal company, but only if you include the data from all of these subsidiaries in your answers to all of the questions in this form.

a) Company name:

b) Is the name of the company different to its trading name? ☐ Yes ☐ No

If "yes", please state the trading name of the company:

Primary address (address, state, ZIP, country):

Website:

1.2 Date the business was established (MM/DD/YYYY):

1.3 Number of employees:

1.4 Please confirm if you are part of a corporate or other group structure where some parts of the group are not subject to this application for insurance: ☐ Yes ☐ No

If "yes", provide details:

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1.5 Please state your gross revenue in respect of the following years:

	Last policy year	Current policy year	New policy year
UK:	$	$	$
EUR:	$	$	$
USA:	$	$	$
Rest of World:	$	$	$

1.6 Please provide the wageroll split between the following categories:

	Employees	Subcontractor
Lab technicians:	$	$
Registered nurses/licensed practical nurses:	$	$
Principal investigators:	$	$
Clinical research associates:	$	$
Physicians and other healthcare/ medical practitioners:	$	$
Medical monitors:	$	$
Statistical management:	$	$
Legal counsel:	$	$
Quality/Regulatory compliance:	$	$
Medical writers:	$	$
Manual work	$	$
Administrative staff:	$	$
Other:	$	$

If "other", please provide full details:

1.7 Please provide details for the primary contact for this insurance policy:

Contact name:		Position:	
Email address:		Telephone number:	

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Section 2: Activities

2.1 Please check the box that best describes you:

- ☐ Independent Research Site
- ☐ Academic Medical Center
- ☐ Institutional Review Board
- ☐ Independent Review Board
- ☐ Decentralized Clinical Research Organisation
- ☐ Data Management Organisation
- ☐ Contract Research Organisation
- ☐ Clinical Research Staffing Organisation
- ☐ Site Management Organisation
- ☐ Other (please describe):

2.2 Do you provide research material/drug storage services to third parties? ☐ Yes ☐ No

2.3 Do you provide technology products and services? ☐ Yes ☐ No

a) If "yes", please describe the nature of your technology products and services:

b) If "yes", please state whether you provide hosting services to your clients: ☐ Yes ☐ No

2.4 Do you provide healthcare services to research subjects taking part in clinical trials? ☐ Yes ☐ No

If "yes", please confirm whether:

a) you will ensure that all employees and subcontractors providing healthcare services will be a suitably licensed physician or other licensed healthcare professional: ☐ Yes ☐ No

b) you will perform any planned or unplanned medical surgeries or lumbar puncture procedures on research subjects: ☐ Yes ☐ No

If "yes," please provide details:

2.5 Please state whether all personnel that come in contact with research subjects are subject to the following background checks:

a) Criminal and sexual offender registry checks: ☐ Yes ☐ No

b) verifying of professional credentials including certificates evidencing current licenses of all employees and independent contractors: ☐ Yes ☐ No

2.6 Do you provide overnight facilities for research subjects? ☐ Yes ☐ No

If "yes", please state:

a) the number of beds:

b) the proportion of beds stays occupied by minors over a 12 month period:

c) the proportion of beds stays occupied by women over a 12 month period:

2.7 Please provide the details below for your 3 largest contracts for the upcoming year:

Client:	Activity:	Contract length:	Contract Value:
			$
			$
			$

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2.8 Please state the proportion of active studies you are working on during the upcoming policy year below:

Phase I (%): Phase II (%): Phase III (%): Phase IV (%):

Other (Describe) [%]:

2.9 During the upcoming policy year will any of your work relate to the following products? ☐ Yes ☐ No

If "yes", please indicate below which products:

- ☐ Birth Control
- ☐ Reproductive drugs
- ☐ Ephedra, ephedrine, or pseudoephedrine
- ☐ Hormone replacement products
- ☐ Isotretinoin
- ☐ Implantable products
- ☐ Antidepressants, anti-anxiety, antipsychotic or mood stabilizing drugs
- ☐ Opioids
- ☐ Vaccines

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Section 3: Contract & Risk Management Information

3.1 Do you always enter into written contracts with your clients? ☐ Yes ☐ No

3.2 In your written contracts do you ever accept liability for consequential loss or financial damages greater than the value of the contract? ☐ Yes ☐ No

If "yes", please provide full details:

3.3 Do you require that contracts include indemnification from your client to you, including indemnification for product liability? ☐ Yes ☐ No

3.4 Do you employ subcontractors? ☐ Yes ☐ No

If "yes", please state whether:

a) they provide healthcare services on your behalf, in accordance with your answer to Q2.3: ☐ Yes ☐ No

b) they provide services other than healthcare services. What services do the subcontractors provide to you?

c) you sign reciprocal hold harmless agreements: ☐ Yes ☐ No

d) you ensure that subcontractors have their own professional indemnity and general liability insurance: ☐ Yes ☐ No

e) you check that their medical malpractice insurance extends to include their clinical trial work: ☐ Yes ☐ No

If you answered "yes" to d) and e) above, what is the limit of liability that subcontractors must purchase for:

Professional liability/ E&O insurance: $

General liability insurance: $

Section 4: Cyber Security Risk Management

4.1 Please describe the type, nature and volume of the data stored on, accessed or processed through your network, including a rough estimate of the total volume of unique individuals you hold data on:

4.2 Please describe your data back-up policy in detail, including the frequency of back-ups, the technology used, the types of back-ups, the storage method used (online or offline), how often you test the back-ups and how you protect your back-ups:

4.3 a) Please confirm whether multi-factor authentication (MFA) is always enabled for remote access to your network (include any remote desktop protocol (RDP) connections) and on all email accounts: ☐ Yes ☐ No

b) If "no", please explain in what circumstances MFA is not used and why:

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4.4 Please describe your data purging and retention policy:

4.5 Please confirm full details on this data, including the type and nature:

4.6 Please describe your approach towards protecting sensitive and confidential information (e.g. access controls, encryption, network segmentation etc.):

4.7 Please tick all the boxes below that relate to any cyber incident that you have experienced in the last three years (there is no need to highlight events that were successfully blocked by security measures):

☐ Cyber Crime ☐ Cyber Extortion ☐ Data Loss ☐ Denial of Service Attack

☐ Malware Infection ☐ Privacy Breach ☐ Ransomware

☐ Other (please specify)

If you ticked any of the boxes above, did the incident(s) have a direct financial impact upon your business of more than $10,000? ☐ Yes ☐ No

If "yes", please provide more information below, including details of the financial impact and measures taken to prevent the incident from ocurring again:

Section 5: Claims Experience

5.1 Please state whether you are aware of any incident:

a) which may result in a claim under any of the insurance for which you are applying to purchase in this application form: ☐ Yes ☐ No

b) which resulted in legal action being made against any of the companies to be insured within the last 5 years: ☐ Yes ☐ No

c) which resulted in any form of disciplinary action, statutory sanction or investigation for professional misconduct against you or your appointed investigators: ☐ Yes ☐ No

If yes to any of the above, please describe the incident, including the monetary amount of the potential claim or the monetary amount of any claim paid or reserved for payment by you or by an insurer. Please include all relevant dates, including a description of the status of any current claim which has been made but has not been settled or otherwise resolved.

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5.2 Please state whether any insurer has ever declined to insure you, imposed any special terms, cancelled or declined to renew your insurance:
☐ Yes ☐ No

If "yes", please provide full details:

Section 6: Additional Information

Please provide the following information when you send the application form to us.
· Directors or principals resumes if the company has been trading for less than 3 years; and
· The standard form of contract, end user license agreement or terms of use issued by the company.

Please provide this space below to provide us with any other relevant information:

Important notice

By signing this form you agree that the information provided is both accurate and complete and that you have made all reasonable attempts to ensure this is the case by asking the appropriate people within your business. CFC Underwriting will use this information solely for the purposes of providing insurance services and may share your data with third parties in order to do this. We may also use anonymized elements of your data for the analysis of industry trends and to provide benchmarking data. For full details on our privacy policy please visit *www.cfcunderwriting.com/privacy*

Contact Name: Position:

Signature: Date (MM/DD/YYYY):

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ALABAMA FRAUD WARNING: Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or who knowingly presents false information in an application for insurance is guilty of a crime and may be subject to restitution, fines or confinement in prison, or any combination thereof.

ARKANSAS FRAUD WARNING: Any person who knowingly presents a false or fraudulent claim for payment for 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.

CALIFORNIA FRAUD WARNING: For your protection California law requires the following to appear on this form. Any person who knowingly presents false or fraudulent information to obtain or amend insurance coverage or to make a claim for the payment of a loss is guilty of a crime and may be subject to fines and confinement in state prison.

COLORADO FRAUD WARNING: 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.

DISTRICT OF COLUMBIA FRAUD 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.

FLORIDA FRAUD WARNING: 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.

KANSAS FRAUD WARNING: Any person who, knowingly and with intent to defraud, presents, causes to be presented or prepares with knowledge or belief that it will be presented to or by an insurer, purported insurer, broker or any agent thereof, any written, electronic, electronic impulse, facsimile, magnetic, oral, or telephonic communication or statement as part of, or in support of, an application for the issuance of, or the rating of an insurance policy for personal or commercial insurance, or a claim for payment or other benefit pursuant to an insurance policy for commercial or personal insurance which such person knows to contain materially false information concerning any fact material thereto; or conceals, for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act.

KENTUCKY FRAUD WARNING: 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.

LOUISIANA FRAUD WARNING: 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.

MAINE FRAUD WARNING: 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.

MARYLAND FRAUD WARNING: Any person who knowingly or willfully presents a false or fraudulent claim for payment for a loss or benefit or who knowingly or willfully presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

NEVADA FRAUD WARNING: Any person who includes any materially false or materially misleading information on an application for an insurance policy may be guilty of a crime and subject to penalties that include imprisonment, fines and denial of insurance benefits.

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

NEW MEXICO FRAUD WARNING: 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.

NEW YORK FRAUD WARNING: 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 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.

OHIO FRAUD WARNING: Any person who, with the intent to defraud or knowing that he 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.

OKLAHOMA FRAUD 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.

OREGON FRAUD WARNING: Any person who, with an intent to knowingly defraud or knowingly facilitate a fraud against an insurer, submits an application or files a claim containing a false or deceptive statement or a material fact, may be guilty of insurance fraud.

PENNSYLVANIA FRAUD WARNING: 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.

PUERTO RICO FRAUD WARNING: 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 $5,000 and not more than $10,000, or a fixed term of imprisonment for 3 years, or both penalties. Should aggravating circumstances be present, the penalty thus established may be increased to a maximum of 5 years, if extenuating circumstances are present, it may be reduced to a minimum of 2 years.

RHODE ISLAND FRAUD WARNING: 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.

TENNESSEE FRAUD WARNING: 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.

VERMONT FRAUD WARNING: Any person who knowingly presents a false statement in an application for insurance may be guilty of a criminal offense and subject to penalties under state law.

VIRGINIA FRAUD WARNING: 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.

WASHINGTON FRAUD WARNING: 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.

WEST VIRGINIA FRAUD WARNING: 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.