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:

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:	

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:
			$
			$
			$

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

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:

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.

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):