



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, county, postcode, country):

Website:

- 1.2 Date the business was established (DD/MM/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:



Clinical Research Organisations & Clinical Trials Professional Liability

Insurance application form

UK

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:	£	£	£
Canada:	£	£	£
Rest of World:	£	£	£

1.6 Please provide the payroll 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:	£	£
Janitorial and engineering	£	£
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	Data Management Organisation
Academic Medical Center	Contract Research Organisation
Institutional Review Board	Clinical Research Staffing Organisation
Independent Review Board	Site Management Organisation
Decentralized Clinical Research 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:
			£
			£
			£



Clinical Research Organisations & Clinical Trials Professional Liability

Insurance application form

UK

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

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 occurring 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 (DD/MM/YYYY):