Clinical research services
Application form

Applicant information

1. Entity name (you)
2. Principal business address
3. Telephone number
4. Website
5. Date established
6. Applicant's practice is a:

solo practitioner (unincorporated) ☐ solo practitioner (incorporated) ☐

corporation (for-profit) ☐ corporation (non-profit) ☐

individual, employee of: partnership ☐

(provide name of employer) ☐

7. Please provide a detailed description of operations:

8. Please state sources and amounts of total revenue:

	in last 12 months	for next 12 months
Fee for services	$	$
Government funding	$	$
Other – specify:	$	$

9. Please indicate the total number of:
   a. individual subjects monitored in the **last** 12 months:
   b. individual subjects monitored for the **next** 12 months:
   c. anticipated trials in the **next** 12 months:

Operations/services

10. Are your services limited to data analysis or consulting? (ie. not subject monitoring/exams or patient recruiting) Yes ☐ No ☐
11. Which trial phases are you involved in?

Phase I ☐ Phase II ☐

Phase III ☐ Phase IV ☐

12. What percentage of subjects monitored are minors? %
13. How are test subjects recruited?

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14. Are any of your subjects also patients of any physician employed or contracted by you? Yes ☐ No ☐

15. Please indicate the types of trials you currently are or will be involved in over the next 12 months:

a.	cosmetic/dermatology	☐	i.	laser treatment	☐
b.	cardiovascular	☐	j.	immunology	☐
c.	pulmonary	☐	k.	metabolic	☐
d.	obstetric	☐	l.	oncology	☐
e.	gynecologic	☐	m.	neurology	☐
f.	herbal/holistic	☐	n.	endocrinology	☐
g.	bariatric	☐	o.	physiology	☐
h.	surgical	☐	p.	other (describe below)	☐

16. Please indicate the product types for all current and future trials to be performed in the next 12 months:

a.	oral prescription	☐	e.	diagnostic equipment	☐
b.	supplement/vitamin	☐	f.	prosthetic	☐
c.	injectable	☐	g.	over the counter	☐
d.	medical device	☐	h.	other (describe below)	☐

17. Please describe any adverse results from previous studies that you were involved in:

18. Have you ever been involved in a trial for a product, drug or device that was later recalled or issued a black box warning? Yes ☐ No ☐

If Yes, please explain:

19. Do you:

a. act as a trial sponsor? Yes ☐ No ☐

b. consult on trial design or administration? Yes ☐ No ☐

c. design, develop or manufacture any products, drugs or devices? Yes ☐ No ☐

d. perform any environmental testing or consulting? Yes ☐ No ☐

e. own or operate any business other than that described in question 7 above? Yes ☐ No ☐

f. own, operate, or administer any inpatient or residential facility? Yes ☐ No ☐

If Yes to any of the above, please describe below:

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20. Are you required to include any non-owned entity as an additional insured on the coverage you are seeking under this policy? Yes ☐ No ☐

If Yes, please explain:

21. If any revenue is derived outside of the US or it's territories, please provide a list of all countries where work is performed and the percentage of revenue derived from each:

Country	Including a physical location?	Percentage
	Yes ☐ No ☐	%
	Yes ☐ No ☐	%
	Yes ☐ No ☐	%
	Yes ☐ No ☐	%

Staff details

22. Please indicate the number of employed and contracted staff:

Profession	**Employed**	**Contracted**
Clinical investigator		
Clinical research associate (CRA)		
Data entry		
Imaging technician		
Lab tech		
Medical assistant		
Medical monitor		
Nurse		
Physician		
Other – specify:		

a. Are all of the above registered or licensed in accordance with all applicable state laws? Yes ☐ No ☐

If No, please attach an explanation.

b. Do you require contracted staff to carry their own professional liability insurance? Yes ☐ No ☐

c. Do you maintain certificates of insurance to confirm such coverage? Yes ☐ No ☐

d. Has the applicant or have any of the above employees/contractors:

i. ever been the subject of disciplinary or investigative proceedings or reprimand by a governmental or administrative agency, hospital or professional association? Yes ☐ No ☐

ii. ever been convicted for an act committed in violation of any law or ordinance other than traffic offenses? Yes ☐ No ☐

iii. ever been treated for alcoholism or drug addiction? Yes ☐ No ☐

iv. ever had any state professional license or license to prescribe or dispense narcotics refused, suspended, revoked, renewal refused or accepted only on special terms or ever voluntarily surrendered same? Yes ☐ No ☐

If Yes to any of the above, please attach an explanation.

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23. Do any physicians perform direct patient care services on behalf of the applicant? Yes ☐ No ☐

24. Do all physicians performing direct patient care services maintain separate medical malpractice coverage extending to these services? Yes ☐ No ☐

If No, please submit a physician supplemental application and C.V. for each physician to be included for coverage.

Risk management

25. Are all studies performed in accordance with an FDA approved protocol? Yes ☐ No ☐

26. Are all test subjects required to sign an informed consent document? Yes ☐ No ☐

27. Will an institutional review board oversee any of your trials? Yes ☐ No ☐

28. Have you implemented procedures to ensure HIPAA compliance? Yes ☐ No ☐

29. Do you advertise your services or solicit business electronically or through telecommunications? Yes ☐ No ☐

If Yes, please describe your advertising activities:

Insurance and claims history

30. Has any similar insurance ever been declined or cancelled? Yes ☐ No ☐

If Yes, please explain in the comments section.

31. Does any person to be insured have knowledge or information of any act, error, or omission which might reasonably be expected to give rise to a claim? Yes ☐ No ☐

If Yes, please attach complete details including a description of the incident(s).

32. After inquiry have any claims been made against any proposed insured(s) during the past five (5) years? Yes ☐ No ☐

If Yes, please complete a supplemental claim form for each claim.

How many claims have been made in the last five (5) years?

33. a. List prior professional liability insurers for the past five years (if none, please tick box). ☐

Insurer	Dates covered from-to (mm/dd/yy)	Limits of liability per claim/ aggregate	Deductible	Premium	Coverage type: occurrence or claims-made

b. If the current/expiring policy is on a claims-made form, what is the retroactive date?

34. a. Is the applicant currently insured under a commercial general liability policy including products and completed operations coverage? Yes ☐ No ☐

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Insurer	Dates covered from-to (mm/dd/yy)	Limits of liability per claim/ aggregate	Deductible	Premium	Coverage type: occurrence or claims-made

b. If the current/expiring policy is on a claims-made form, what is the retroactive date?

Comments section

It is understood and agreed that with respect to questions 31 and 32, that if such knowledge or information exists any claim or action arising there from is excluded from this proposed coverage.

Notice to New York applicants: any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance containing any false information, or conceals for the purpose of misleading, information concerning any material thereto, commits a fraudulent insurance act, which is a crime.

The applicant hereby acknowledges that he/she/it is aware that the limit of liability shall be reduced, and may be completely exhausted, by the costs of legal defense and, in such event, the Insurer shall not be liable for the costs of legal defense or for the amount of any judgment or settlement to the extent that such exceeds the limit of liability.

The applicant further acknowledges that he/she/it is aware that legal defense costs that are incurred shall be applied against the deductible amount.

I DECLARE that, after inquiry, the above statements and particulars are true and I have not suppressed or misstated any material fact and that I agree that this application shall be the basis of the contract with the underwriters.

Name of applicant

Signature of person authorized to execute on behalf of the applicant:

Name/title of person authorized to execute on behalf of the applicant:

Date

This application form duly completed, together with any supplementary information, must be signed in ink or by electronic signature by the person indicated. Signing of this form does not bind the applicant or the underwriters to complete this insurance.

A copy of this application should be retained for your records.