



Clinical Trials Site Application

General and Medical Professional Liability Application

CLAIMS MADE FORM

I. Entity Name: _____

Type of Organization: Partnership Corporation Joint Venture Other: _____

Federal I.D. Number/EIN: _____ Website: _____

Mailing Address: _____

City: _____ County: _____ State: _____ Zip: _____

Phone: _____ Fax: _____

Principle office address (if different than mailing address): _____

City: _____ County: _____ State: _____ Zip: _____

Phone: _____ Fax: _____

Contact Person: _____ Title: _____

Phone: _____ Fax: _____ Email: _____

Please list all members (partners, major shareholders,) of the professional entity. Attach separate page if necessary:

Name _____ Title: _____ Date of Birth: _____

Home Address: _____ City: _____ County: _____

State: _____ Zip: _____ Social Security Number: _____

Name _____ Title: _____ Date of Birth: _____

Home Address: _____ City: _____ County: _____

State: _____ Zip: _____ Social Security Number: _____

II. I. Please describe the nature of your business/scope of medical services provided:

2. Length of time in business: _____ Length of time under current mgmt: _____

NOTE: If this is a new business, please answer the following questions based on projections, and provide any supporting documentation you may have (market research studies, business plan, etc.)

3. Volume of business (expressed in total # of consults/year, or # of images/slides read per year, etc.):
_____ Actual Projected (eg, if start-up)

Gross Annual Revenue: \$ _____ Actual Projected

4. Please describe the equipment entity uses for delivery of services, if applicable:

5. List hospitals or other medical entities with which your business has privileges or other ongoing relationships, contractual or otherwise. If applicable, please describe the nature of these relationships:

6. a. Are Physicians, Nurse Practitioners, and/or Physician Assistants employed by or work as independent contractors for the entity? Yes No

If YES to the above, please complete the following for each individual to be listed as named insureds for professional liability coverage. *Attach additional pages if needed*

Name/Professional Designation	# Hrs or Consults Worked Per week for Entity	List All Active Licenses Held (States with corresponding license #s)	Employee	Indep Contractor
	___ Hrs ___ Cons		<input type="radio"/>	<input type="radio"/>
	___ Hrs ___ Cons		<input type="radio"/>	<input type="radio"/>
	___ Hrs ___ Cons		<input type="radio"/>	<input type="radio"/>
	___ Hrs ___ Cons		<input type="radio"/>	<input type="radio"/>
	___ Hrs ___ Cons		<input type="radio"/>	<input type="radio"/>
	___ Hrs ___ Cons		<input type="radio"/>	<input type="radio"/>
	___ Hrs ___ Cons		<input type="radio"/>	<input type="radio"/>

- b. If a you are seeking "slot" policy (rather than each individual practitioner being listed as a named insured), please provider the following information:

1. Total number of practitioners to be covered under policy: _____
2. Total (combined) number of professional hours per week worked by all practitioners to be covered: _____

7. Do you employ any of the following health care providers? Yes No
If yes, indicate number of each:

- | | |
|-----------------------------------|-----------------------------------|
| ___ Nurse/RN | ___ X-ray Technician |
| ___ Nurse/LPN | ___ Medical Technician |
| ___ Nurse Anesthetist | ___ Laboratory Service Technician |
| ___ Ultrasound Technician | ___ Occupational Therapist |
| ___ Psychologist | ___ Respiratory Therapist |
| ___ Other (please specify): _____ | |

8. Please describe in detail the procedures used to credential physicians or otherwise check the qualifications of new employees or independent contractors.

Note: If credentialing service is used, please specify name and location of service:

9. Please list all entity accreditations, if applicable: _____
- _____

10. Do you anticipate any sale of assets, mergers, acquisitions, consolidation or change in operations or services within the next twelve (12) months? Yes No

If "Yes," please explain: _____

11. Do you anticipate a change in the scope of business and/or expansion of services within the next twelve months? Yes No

If "Yes," please explain: _____

12. CLINICAL TRIALS PRACTICE INFORMATION

- a. Do you ever act as a Principal Investigator? Yes No

- b. Have you ever been audited by the U.S. Food & Drug Administration (FDA)? Yes No

If yes, please indicate (continue/explain on separate sheet, if necessary):

Date: _____ Reason: For cause Volume/Data Integrity Random Other _____

Date: _____ Reason: For cause Volume/Data Integrity Random Other _____

Date: _____ Reason: For cause Volume/Data Integrity Random Other _____

As the result of any FDA audit or Form 483, have you ever been required to take corrective action, or been advised that a study you were working on did not meet data integrity requirements? If yes, please explain on separate sheet. ○ Yes ○ No

Please attach copy of any audit report or Form 483 issued to you as Principal Investigator by the FDA.

- c. Have you (or the clinic where you work) ever been audited by an Institutional Review Board (IRB)? ○ Yes ○ No
 If yes, please indicate: (continue on separate sheet, if necessary)

Audit Date	No Deficit Found	Warning Ltr No Action Req'd	Warning Ltr Action Req'd	Required to Stop Study	Decertified	Other (detail on separate sheet)
	○	○	○	○	○	○
	○	○	○	○	○	○
	○	○	○	○	○	○

- d. Have you ever been audited by a Sponsoring Drug Company? ○ Yes ○ No
- e. If yes, please state on separate sheet: date of any Company audit that required you to take corrective action, and the nature of that action or any company investigation or audit that resulted in you being suspended or terminated on a study.
- f. How many trials have you done in the last five years? _____
- g. What phases of testing do you expect to do during the policy year?
 Phase I Phase II Phase III Phase IV
 Other Research: _____
- h. Do you test medical devices? ○ Yes ○ No
- i. Do you conduct investigator-initiated studies? ○ Yes ○ No
- j. What indications were the drugs/devices of your studies intended to address?

- k. Please indicate companies who have sponsored your clinical trials:

<input type="checkbox"/> Abbott	<input type="checkbox"/> Bristol Meyers Squibb	<input type="checkbox"/> Johnson & Johnson	<input type="checkbox"/> Pfizer
<input type="checkbox"/> Amgen	<input type="checkbox"/> Cephalon	<input type="checkbox"/> McKesson	<input type="checkbox"/> Schering Plough
<input type="checkbox"/> AstraZeneca	<input type="checkbox"/> Forrest	<input type="checkbox"/> Merck	<input type="checkbox"/> Wyeth
<input type="checkbox"/> Aventis	<input type="checkbox"/> Jazz	<input type="checkbox"/> Novartis	<input type="checkbox"/>

- l. Please list any companies not named who have sponsored your clinical trials:

- m. Please list all current clinical trials below. Continue list on separate page if necessary.

Sponsor Company Name / Investigator Initiated	Purpose (eg. Diabetes, Depression, etc.)	Duration	# of Patients	Phase I, II, III or IV

III. I. Requested limits of insurance:

- \$500,000 per occurrence/\$1,000,000 annual aggregate
 \$1,000,000 per occurrence/\$3,000,000 annual aggregate
 Other: \$ _____ per occurrence/ \$ _____ annual aggregate

Requested Effective Date of Coverage: _____ Retroactive Date, if applicable: _____

2. Beginning with the most recent or current insurer, please list all current and prior liability insurers for this entity:

Name of Insurer	Coverage Type (Claims Made or Occurrence)	Policy Number	Policy Period

3. Have you ever had liability insurance declined, cancelled, issued with reduced limits or a deductible, issued with a special surcharge, or any other special terms, or has renewal been refused or not offered for this entity? Yes No

IV. Claims History

1. Has any claim or suit been brought against entity? Yes No
 If yes, please provide a loss run from each carrier for the past five (5) years

2. Do you have *knowledge* of any claims, potential claims, or suits in which this entity may become involved? Yes No
 If yes, please explain: _____

3. Are you aware of any *circumstances* which may result in a general liability claim or suit being made or brought against entity? Yes No
 If yes, please explain: _____

4. Has any claim or suit been made against entity that has not been reported to a prior insurer? Yes No

5. Has any physician or other healthcare provider employed by or independently contracted with entity applicant had any claim brought against them within the last five (5) years? Yes No

REQUESTED ATTACHMENTS:

(NOTE: You may submit your completed application without the following documents, however please be advised these documents may be needed to finalize the underwriting process.)

- a) Five (5) year loss runs for each physician to be listed as a *named insured*
- b) Copies of medical licenses for all physicians to be listed as *named insureds*
- c) Current liability policy if the coverage for which you are applying will be *replacement coverage*

By my signature below:

1) I warrant that the information provided in this application is true and complete and that no information which would influence the judgment or decision of the insurer to consider this application has been withheld.

2) I acknowledge that this application will be the basis of any insurance policy issued as a result of this application and will become part of the policy as if physically attached.

3) I acknowledge that if anything changes that makes the information contained in this application inaccurate or incomplete after the submission date but prior to the policy effective date, I have the duty to notify Campmed in writing of such occurrence, event or circumstance. I understand that after such notice, any outstanding quotation may be changed or withdrawn at the sole discretion of the insurer or their agent and that failure to provide this information can result in a denial of insurance coverage.

4) I authorize the release and exchange of current and future underwriting and claim information between any prior insurer(s) and Campmed Casualty & Indemnity Company, Inc. of Maryland and my broker, agent or peer review.

CAMPMED FRAUD STATEMENT

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 and denial of insurance benefits.

Please see the attached specific Fraud Warnings required by some states.

APPLICANT SIGNATURE: _____ DATE: _____

PRINT NAME: _____ TITLE: _____

PLEASE MAIL / FAX / EMAIL COMPLETED APPLICATION TO:

Campania
111 Berry Street SE, Vienna, VA 22180
Fax (703) 242-3815
msackie@thecampaniagroup.com

Thank you for choosing Campania for your insurance needs.

FRAUD WARNINGS

Notice to District of Columbia Applicants: 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.

Notice to Florida Applicants: Any person who knowingly and with intent to injure, defraud, or deceive any insurance company files a statement of claim or any application containing any false, incomplete or misleading information is guilty of a felony of the third degree.

Notice to Kentucky Applicants: 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 or concerning any fact material thereto commits a fraudulent insurance act, which is a crime.

Notice to Louisiana And West Virginia Applicants: Any person who knowing 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.

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

Notice to New Jersey Applicants: Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties.

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 materially false information or conceals, for the purpose of misleading, information or 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.

Notice to North Carolina Applicants: Any person who knowingly presents false information in an application for insurance is guilty of a felony and may be subject to fines and imprisonment.

Notice to Ohio Applicants: Any person who, with 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.

Notice to Pennsylvania Applicants: 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.

Notice to Tennessee and Virginia Applicants: 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.