



MEDICAL TECHNOLOGY PRODUCT DEPARTMENT

Application for

PRODUCTS LIABILITY COVERAGE
CLINICAL TRIALS / MEDICAL DEVICES

This is an application for CLAIMS MADE POLICY. Should this application be accepted by Steadfast Insurance Co., coverage will apply to claims first made against the insured during the policy period. No coverage will apply for claims first made against the insured after the end of the policy period unless the extended discovery period applies. No coverage will apply for claims first made prior to the retroactive date shown in the declarations page of the policy.

THE COMPLETION OF AND SUBMISSION TO STEADFAST INSURANCE CO.
OF THIS APPLICATION DOES NOT CONSTITUTE A BINDER OF INSURANCE

All questions must be answered completely. If a question is not applicable, please answer "NA". If the answer to a question is none, state "None" or "O". If more space is required to completely answer a question, please attach a separate sheet of paper and identify the question it responds to. PLEASE LEAVE NO SPACES BLANK.

ZURICH US
200 WEST ADAMS STREET, SUITE 1800, CHICAGO, ILLINOIS, 60606 (312) 419-3883

ZURICH INSURANCE COMPANY, AMERICAN GUARANTEE AND LIABILITY INSURANCE COMPANY,
ZURICH AMERICAN INSURANCE COMPANY OF ILLINOIS, AMERICAN ZURICH INSURANCE COMPANY,
ZURICH AMERICAN LLOYDS



PLEASE TYPE OR PRINT

1. APPLICANT

1. Proposed Named Insured _____

2. Mailing Address _____

Web site: _____

Insurance Contact _____

Telephone number _____

E-mail address _____

3. Parent Company _____

4. Does any of the insurance purchased by the above Parent Company afford any coverage to you: _____

5. Years in business under present name: _____

6. Have you operated under another name in the past? _____

If yes, please give full details:

7. Is your company an:

Individual

Corporation

Joint Venture

If a partnership, please advise who the partnership

Partnership

is with: _____

8. Location of all Research facilities: _____

9. Location of all Production facilities: _____



10. Location of all Distribution facilities: _____

11. Present Coverage:

Carrier: _____

Deductible/SIR: _____

Limits: _____

Retro Date: _____

Has any carrier ever canceled, restricted or refused to renew your liability insurance? Yes No

If yes, please explain: _____

II. OPERATIONS

1. Fully describe all operations of your company:

2. Does your company have any current products on the market or new products approved by the FDA? If yes, please explain:

3. Products Under Development or in Clinical Trials:
This Project is: Planned _____ Current _____ Completed _____

4. Nature of Study and Name of Product:

5. Description of device:



6. Is the proposed device:

- *a diagnostic device
- *veterinary use device
- *therapeutic device
- *life support device
- *software controlled or operated
- *classified as a “significant risk device”
- *patient monitoring device
- *use with laboratory animals only
- *radiological device
- *surgical device
- *implant

7. Will the proposed clinical trial investigation involve:

- *an invasive procedure
- *an invasive sampling procedure with a significant risk to the patient subject
- *introduction of energy into the patient subject

If yes, please explain: _____

8. Please check the current stage completed on this project:

- _____ Investigational New Drug Application Filed
(Please provide IND #)
- _____ Clinical Testing: Phase I _____ Phase II _____ Phase III _____
- _____ New Drug Application Filed

9. Is this project under a research and development contract or internal? _____

If under contract, for whom, and specify the remuneration basis (e.g. benchmarks, royalties, from product sales, etc...)

If under contract, please indicate anticipated receipts this year:

10. Does the sponsor or any member of the trial research team have any financial ties or own stock in your company or a company controlled by you? Yes No

If yes, please elaborate:

11. Do you intend to manufacture and sell the product yourself or license your process to others? _____



If the process is to be licensed to others, will any physical substance(s) be transferred to your client (e.g. microbes for industrial scale-up), or will your client be provided a report and description of the implementation procedure for this process? _____

If the former, please explain: _____

12. Please complete the following as it relates to your planned or current Human Clinical Trial:

a. Who will manufacture the product undergoing investigation?
Do any Hold Harmless Agreements exist?

b. Has the product been in use for other indications?
If yes, what are the other indications?

c. What is the number, sex and age of the test subjects?

d. What is exclusionary criteria for test subjects?

e. What is the length of the trials?

f. Where will the trials be conducted?

g. Who will be conducting the trials?
(Please attach a copy of Curriculum Vitae)

h. Who is funding the trials?



III. UNDERWRITING EXPERIENCE

1. Provide a brief description of the results of any previous related trials:

2. Fully describe any expected adverse results based on previous related trials including animal studies and/or toxicity studies:

3. List any claims related to above:

Claimant	DOL	Expense	Indemnity	Nature of Injury	
_____	_____	_____	_____	_____	—
_____	_____	_____	_____	_____	
_____	_____	_____	_____	_____	
_____	_____	_____	_____	_____	

4. Describe steps that have been taken to address these adverse results. To what extent will steps mitigate reoccurrence?

5. Are you aware of any other incidents, conditions or circumstances which may result in claims against you? Yes No



I/We warrant that the information contained herein is true and that it shall be the basis of the policy of insurance and deemed incorporated therein, should the Company evidence its acceptance of this application by issuance of a policy.

Signature of applicant: _____

Title: _____

Date: _____

COPIES OF THE FOLLOWING MUST BE SUBMITTED WITH THIS APPLICATION

- Summary of the results of the previous test phase, if applicable
 - FDA Approved Protocols
 - Informed Consent Documents
 - Hold Harmless Agreements
- Most Recent Annual Report/Audited Financial Statement or Form 10K or Most Recent 10Q
- Curriculum Vitae of the Director and Key Personnel

If you want to learn more about the compensation Zurich pays agents and brokers visit: <http://www.zurichnaproducercompensation.com> or call the following toll-free number: (866) 903-1192. This Notice is provided on behalf of Zurich American Insurance Company and its underwriting subsidiaries.