AGENT NAME : _____

NUMBER : _____

INSURANCE APPLICATION FORM

LEGAL LIABILITY INSURANCE FOR CLINICAL TRIALS

1. Named Insured:
   I.D. Number :
   Address:
   Telephone: Fax:
   Email:
2. Description of Business:
3. Date Business was established:
4. Other parties to be covered by the Policy:
5. Hospital(s) and/or Institution(s) where the trials are to be performed:

6. Title (s) of the Trial(s) for which insurance is sought:

   Phase: I___ II ____ III ____ Other:
   Protocol Number:
7. No. of Trial Subjects:
8. Minimal age of Trial Subjects:
9. Status of Helsinki Committee approvals:
   Local: Approval Date: ____ Expiration: _____
   Ministry of Health Date: _____ Expiration: _____
10. Date the Trial is to begin:
11. Date the Trial is to end
12. Time of Trial per participant: days/weeks/months

13. Are all trials are to be conducted in full accordance with:

(please give full details if any reply is "No"):

a. Public Health Regulations (Medical Experiments Involving Human Subjects)--1980? ☐Yes ☐No

b. Protocols approved by the relevant Helsinki Committee(s) including any special conditions required by a committee as a condition of approval? ☐Yes ☐No

c. Ministry of Health--Pharmaceutical Division Guidelines of September,1999? ☐Yes ☐No

d. Any directive on Good Clinical Practice (GCP)? ☐Yes ☐ No

Which directive? _____CE MARK, MDD 93/42 EEC Annex X, EN 540 _____ (indicate F.D.A., I.C.H., etc.)

e. A Consent Form to be signed by each Trial Subject conforming to those set forth in the:

Ministry of Health—Pharmaceutical Division Guidelines of 1999? ☐Yes ☐No

14. If a medication, pharmaceutical or medical device is being investigated in the Trial(s), is product liability insurance in force? ☐Yes ☐No

15. All trials are to be conducted in Israel? ☐Yes ☐No

If not, state other countries in which trials are to take place:

_____.

16. Requested Limits of Liability $

17. Give details of incidents during the last 5 years resulting in death, injury, disease or illness (physical or mental) to patients or volunteers participating in similar or related clinical trials, and any circumstances which might give rise to a claim for compensation against the Contracting Party, the Sponsor, the Investigator or the manufacturer of the medication or device which is to be investigated in the Trial for which coverage is sought.

Include date of event, date of claim, description of injury, amount of claim, status and outcome. (Attach a separate page if necessary)

_____

_____

_____

_____

18. If not included in the Protocol to be submitted with this application, provide summary of similar or related Trials/Studies performed in the last 12 months. Include the dates, a description, the Phase of the Trial and the number of patients or volunteers participating. (Attach a separate page if necessary):

_____

_____

_____

_____

_____

19. For each trial to be insured, you must attach a copy of:

    A. Protocol or Summary of Protocol. (Must be provided in English)

    B. Helsinki Committee (s) Approval (s).

    C. Patient Information/Explanation and Informed Consent Form to be used in the trial. (Please provide in English, if possible)

I hereby declare that all of the answers above are correct, complete and straightforward and that I have not concealed any material facts relating to the trial(s) to be insured or the assessment of the risks involved. I hereby acknowledge and agree that the information provided above will be relied upon by the insurance company and shall serve as a basis of the policy.

Signed on behalf of the Contracting Party:

Name:

Date: Position:

This proposal is subject to review and written confirmation on behalf of the insurers and shall not be construed as an offer to insure.