INSURANCE APPLICATION FORM - REVISED
LEGAL LIABILITY INSURANCE FOR CLINICAL TRIALS
DATE: ___/___/_____

1. Contracting Party:
   The Sponsor(s) _____ In the capacity of: _____
   _____
   Address: _____
   Telephone:_____ Fax: _____
   Email: _____
   The Investigator(s):_____ In the capacity of: _____
   _____
   Address: _____
   Telephone:_____ Fax: _____
   Email: _____

2. Description of Business: _____

3. Date Business was established: _____

4. Contracting Party acts as agent of another party: _____
   (Indicate if not applicable)

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:_____

7. No. of Trial Subjects: _____

8. Status of Helsinki Committee approvals:
   Local: Approval Date: _____ Expiration: _____
   Ministry of Health Date: _____ Expiration: _____

9. Date the Trial is to begin:_____

10. Date the Trial is to end: _____

11. 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?
    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

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

13. All trials are to be conducted in Israel? ☐Yes ☐No
If not, state other countries in which trials are to take place:
_____

14. Has the study been approved by the national ethical committee in each trial country? ☐Yes ☐No

15. Is the clinical trial drug listed on the attached pharma exclusion list ? ☐Yes ☐No

16. Does the study involve surgical activity? ☐Yes ☐No

17. Inclusion criteria:
    - Does the study include pregnant women? ☐Yes ☐No
    - Does the trial involve women of child bearing potential who are not obliged to take any contraception measures? ☐Yes ☐No
    - Does the study include children (<18 years)? ☐Yes ☐No

18. Is the trial performed with invasive[1] medical devices/implants? ☐Yes ☐No

19. Is the route of administration intravenous/ intra-arteriel/intrathecal[2]? ☐Yes ☐No

20. Does the study involve invasive removal and/or implantation of cells, organic tissue, organs, blood and/or bloodserum (beyond routine withdrawal of blood)? ☐Yes ☐No

21. Does the study involve any viruses, bacteria and/or cells that have been genetically modified? ☐Yes ☐No

22. Does the study involve gentherapy or stem cells? ☐Yes ☐No

23. Comments:
Please provide any additional comments on the trial.

_____

_____

_____

_____

24. Requested Limits of Liability
USD _____ per anyone claim / occurrence
USD _____ in the Aggregate during the period of Insurance.

25. 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.

[1] Relating to a technique in which the body is entered by puncture or incision

[2] Describes the fluid-filled space between the thin layers of tissue that cover the brain and spinal cord. Drugs can be injected into the fluid or a sample of the fluid can be removed for testing.

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

_____
_____
_____
_____

26. 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):

_____
_____
_____
_____

27. 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) (may be in Hebrew)
    C. Patient Information/Explanation and Informed Consent Form to be used in the trial

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.

Note: Attached Pharma exclusion list.

Pharmaceutical products/substances exclusion list

- 8-Hydroxy-quinolines
- Adalimumab
- Alatrofloxacin
- Alosetron
- Amiodarone
- Apomorphine
- Astemizole
- Benzbromarone
- Bromfenac
- Bromocriptine
- Bupropion (also known as amfebutamone)
- Butorphanol
- Celecoxib
- Cerivastatin
- Cisapride
- Contraceptives, side effects
- Dex, -Fenfluramine/Phentermine (PHEN-FEN)
- Diethylstilbestrol (DES)
- Encainide
- Ephedrine / Pseudoephedrine
- Etanercept
- Etoricoxib
- Flosequinan
- Fluoxetine
- Grepafloxacin
- Hormone Replacement Therapeutics (HRT), 'box warning' side effects
- Infliximab
- Isotretinoin
- Itraconazole
- Leflunomide
- Levomethadyl
- Levonorgestrel (marketed as OTC)
- LYMErix vaccine
- Methylphenidate (MPH)
- Mibefradil
- Nefazodone
- Olanzapine
- Parecoxib
- Paroxetine
- Phentermine
- Phenylpropanolamine (PPA)
- Pioglitazone
- Piper methysticum (Kava-Kava)
- Rapacuronium
- Remoxipride
- Risperidone
- Rofecoxib
- Rosiglitazone
- Selective Norepinephrine Reuptake Inhibitors (SNRI)
- Selective Serotonin Reuptake Inhibitors (SSRI)
- Sibutramine
- Sildenafil
- Statins including combined ingestion with fibrates
- Sumatriptan
- Tadalafil
- Temafloxacin
- Terbinafine
- Terfenadine
- Thalidomide
- Theophyllin
- Thimerosal/Thiomersal
- Troglitazone
- Trovafloxacin
- Valdecoxib
- Vardenafil