

**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)? Which directive?  Yes  No
  - 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:
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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<sup>1</sup> medical devices/implants? Yes No
19. Is the route of administration intravenous/ intra-arteriel/intrathecal<sup>2</sup>? 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.

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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.

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<sup>1</sup> Relating to a technique in which the body is entered by puncture or incision

<sup>2</sup> 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)

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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):

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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