**Insurance Application Form**

**Legal Liability Insurance for Clinical Trials**

1. Named Insured: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. I.D. Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Telephone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3. Description of Business: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4. Date Business was established: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5. Other parties to be covered by the Policy (Medical Centers, CRO if applicable, etc.): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

6. Hospital(s)and/or Institution(s) where the trials are to be performed:

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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 Protocol number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phase: I\_\_\_ II \_\_ \_\_ III \_\_\_\_ Other:       N/A

8. No. of Trial Subjects: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

9. Minimal age of Trial Subjects: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

10. Status of Helsinki Committee approvals:

Local: Approval Date: \_\_\_\_\_\_\_\_\_\_\_\_ Expiration: \_\_\_\_\_\_\_\_\_\_\_\_

 Ministry of Health Date: \_\_\_\_\_\_\_\_\_\_\_\_ Expiration: \_\_\_\_\_\_\_\_\_\_\_\_

11. Date the Trial is to begin: \_\_\_\_\_\_\_\_\_\_\_\_ Date the Trial is to end: \_\_\_\_\_\_\_

12. Expected duration of the Trail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (months).

13. Time of Trial per participant: Days / Weeks / Months

14. 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 Administration, Guidelines for Clinical Trials in Human Subjects, 2014? Yes [ ]  No [ ]

d. Any directive on Good Clinical Practice (GCP)? Yes [ ]

 Which directive? \_\_\_\_\_ N/A

e. A Consent Form to be signed by each Trial Subject?

yes [ ]  No [ ]

15. If a medication, pharmaceutical or medical device is being investigated in the Trial(s), is product liability insurance in force? Yes [ ]  No [ ]  N/A

16. All trials are to be conducted in Israel? Yes [ ]  No [ ]

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

17. Requested Limits of Liability: $\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

18. 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)

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19. 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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20. 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 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.**

|  |  |  |  |
| --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Date | Full Name of Signature | Title | Signature & Stamp |

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