iTOO™

In association with Hollard.

PROPOSAL FORM
Medical Malpractice Clinical Trial

Hollard.

Underwritten by The Hollard Insurance Co. Ltd, an authorised Financial Services Provider

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ITOO is an Authorised Financial Services Provider. FSP No. 47230

Please answer **ALL** questions completely
Should any question or part thereof not be applicable, please state "N/A"
Should insufficient space be provided, please continue on your company letterhead

Each Clinical Trial is to comply with all current recommendations as set forth in the "Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa," as issued by the South African Department of Health, and any subsequent amendments

Kindly include the following documents when submitting the proposal form

- Protocol
- Research Subject Information and Consent Form
- Hold Harmless/Indemnification Agreements

1. Name of Insured _____

2. Has the Insured ever carried out medical services under a different name **Yes** ☐ **No** ☐

   *If **YES**, please provide details*

3. Head office physical and postal address _____

   _____

4. Location of branch offices _____

5. Telephone Number _____

6. Email Address _____

7. Does the Insured have any subsidiary companies that you require cover for **Yes** ☐ **No** ☐

   *If **YES**, please provide details*

8. VAT Number _____

9. Company Registration Number _____

10. Date of first commencement of clinical trials undertaken by the Insured _____

11. Please advise your involvement in the trial to be insured

12. Title of Trail

13. Kindly attach proof of approval from the Medicines Control Council and Ethics Committee
*If approval has **NOT** been granted, please explain*

14. Will the trial be conducted in full accordance with applicable Government Department, Medical Body or Pharmaceutical Industry Body guidelines and requirements *If **NOT**, please explain*

15. Specify the funding/budget applicable to this trial

16. Who will be providing the funding for the trial

17. What is the experience of the stakeholders with clinical trials

18. Where will the trial be conducted (City/province/country/hospital/university, etc.)

19. Total number of Research Subjects involved in or being recruited for the trial

20. Number of batches of research subjects

21. Will there be double blind testing conducted	**Yes**		**No**	

22. Characteristics of participant population e.g., gender, physical condition, etc.

Please indicate whether the following Research Subjects will participate in the trial (Research Subjects under the age of eighteen years; Pregnant Research Subjects; Research Subjects that require additional attention as outlined in Section 2.3 of the "Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa," as issued by the South African Department of Health)

23. Phase of trial	
24. Commencement date of trial	
25. Planned end date of trial	
26. Expected length of trial	
a. Per research subject	
b. Length of intervention/treatment period	
c. Length of "follow-up" period	
d. Time-frame between each batch of Research Subjects	

27. Type of testing

a. Phase 1 (Human Pharmacology)	**Yes**		**No**	
b. Phase 2 (Therapeutic Exploratory)	**Yes**		**No**	
c. Phase 3 (Therapeutic Confirmatory)	**Yes**		**No**	
d. Phase 4 (Therapeutic Use)	**Yes**		**No**	

28. Nature and purpose of the trial

29. Name of the drug/product /device being tested

30. Describe the intended purpose of the drug/product and how it will be used when approved

31. Describe how the drug/product has been used in other applications

32. Is the drug/product registered in North America or elsewhere. If so, what is the FDA (Food and Drug Administration) classification

33. Give details of previous testing on the drug/product including toxicity studies and explain any problems or adverse events which resulted in death, injury, illness, disease (physical or mental) to Research Subjects

34. Describe any losses including reserves/payments incurred during previous testing

35. What part of the body or body system will be affected

36. What are the possible or known side effects or complications

37. What harm might occur if the drug/product did not work as intended

38. How will the drug/product be administered

39. Will any of the functions during the trial be outsourced or sub-contracted

    Please provide full details of the contractor and exactly what functions they will be performing, together with confirmation that they have their own clinical trial cover in place

GENERAL INFORMATION

40. List all circumstances/complaints/claims of professional negligence, error or omission or public liability that have been made against the Practice or any of the present or past Principals or employees, whether insured or not, in the past 5 years

41. Are any of the Principals or Employees of the Practice, after enquiry, aware of any circumstances that may give rise to a claim for professional negligence, errors or omissions or public liability

Yes		No	

*If **YES**, please provide details*

42. Has any application for insurance of this nature (made on behalf of the Practice or their predecessors in business or by any of the present Partners) ever been declined, cancelled or has renewal been refused or have special terms been imposed

Yes		No	

*If **YES**, please provide details*

LIMIT OF INDEMNITY

	Option 1	Option 2
Annual aggregate (Minimum of R1, 000, 000)		
Sub-limit per research subject (Maximum of 10% of Limit of Indemnity)		
Deductible (Minimum R20, 000)		

DECLARATION

I/We, the undersigned, declare that the statements set forth in this proposal form together with any other information supplied are true and correct and that I/we have not misstated or suppressed any material facts.

I/We agree that this proposal form together with any other information supplied by me/us shall form the basis upon which the contract of insurance is concluded and shall be incorporated therein.

I/We further undertake that in the event that the information provided changes between the date of this application and inception of cover, I/We will notify ITOO of such changes as soon as reasonably possible.

_____ _____

Name (duly authorised) Designation

_____ D D M M Y Y Y Y

Signature Date