



Clinical Trial Addendum

Attaching to and forming part of the proposal for Medical Liability Insurance.

Name of Institution to whom this addendum refers.

1. How long have you participated in clinical trials?

_____ Years

2. For whom do you conduct the clinical trials?

- Pharmaceutical Companies: Yes No
- Charities: Yes No
- Research Foundations: Yes No
- Medical device manufacturers: Yes No
- Other: Yes No

If Other, please provide details.

3. Do you receive full indemnity from your principals in all cases?

Yes No

If No, please provide details of indemnities received.

4. Do you require all volunteers to sign an Informed Consent Form?

Yes No

If No, please advise what procedures you have in place.

5. Do you have procedures in place to ensure family members are informed of the trial & potential affects?

Yes No

6. Do any of the trials involve minors or females of childbearing age? Yes No

If Yes, please provide full details of these trials.

7. Please advise the annual revenue received from clinical trials.

\$

8. Please advise the number of clinical trials in which you were involved:

(a) During the past 12 months.

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(b) Estimated for the next 12 months.

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9. Please advise the total number of volunteers who participated in each trial:

(a) During the past 12 months.

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(b) Estimated for the next 12 months.

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10. Do you conduct trials in any of the following fields?

Organ Transplants

Yes No

Human Embryo Research

Yes No

Artificial Organs

Yes No

Surgery

Yes No

Obstetrics

Yes No

Genetic Engineering

Yes No

Cloning

Yes No

If the answer to any of the above is Yes, please provide full details.

DECLARATION

I the undersigned, **after enquiry**, declare as follows:

- (1) I am authorised by each of the persons or entities in the definition of “You” in clause 7 on page 2 of the proposal to make this statement.
- (2) I understand that, up until a contract of insurance is entered into, I am under a continuing obligation to immediately inform the insurers of any change in the particulars or statements contained in the proposal or in the accompanying documents.

Although the signing of this addendum does not bind the applicants to effect insurance, I acknowledge that the particulars and statements contained in this proposal and in the accompanying documents shall be the basis of the contract if a policy is issued. I also acknowledge that the proposal and the accompanying documents will be incorporated in the contract of insurance.

Name of Business or Practice:

Signature (Partner, Principal or Director): _____

Name of Signatory (Please Print): Date