**Compensation for injury to participants**

**Form B: Declaration of provision of compensation for injury for participants in a research study for a pharmaceutical company or any other company involved in health research**

This form is to be completed and the statutory declaration signed by the applicant. It should be forwarded to the appropriate ethics committee together with the documents seeking ethical approval for the proposed study and appropriate assurance from the pharmaceutical company or any other company involved in health research.

The information provided must be sufficiently detailed to enable the ethics committee to be satisfied that:

* the proposed research is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out
* participants in the proposed research project will receive an acceptable level of compensation from a pharmaceutical company or any other company involved in health research in the event of injury to participants resulting from their involvement in the proposed research study.

Note:

1. Researchers and institutions have indemnity cover to provide an acceptable level of compensation in the event of injury to participants resulting from any researcher or research staff deviating substantially from the trial protocol.
2. Applicants applying for approval for a research study that is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out should complete Form A.

**Declaration B trials: to be included on information sheet under the heading “Compensation”**

The (insert name of committee) Ethics Committee has certified that this clinical trial is being conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which this trial is being carried out. This means that **if you suffer injury as a result of your participation in this trial, you will not be eligible for cover under accident compensation legislation**. Compensation, however, will be provided by (insert name of company) in accordance with the *New Zealand Researched Medicines Industry Guidelines on Clinical Trials: Compensation for injury resulting from participation in industry sponsored clinical trials*.

These Researched Medicines Industry (RMI) Guidelines are only guidelines, and until your claim is assessed by the insurers of (insert name of company) it cannot be said with any certainty exactly what type or amount of compensation you will receive if you suffer injury as a result of your participation or what sort of injury will be covered. The guidelines require that compensation be provided by (insert name of company) where the injury you suffer is serious and not just temporary and is one caused by the trial medicine or item or where you would not have suffered injury but for your inclusion in this trial.

The guidelines require that the compensation you receive be appropriate to the nature, severity and persistence of your injury. This means that you will be unlikely to receive compensation from (insert name of company) unless your injury is serious and not just temporary.   
  
You will also not receive compensation from (insert name of company) in this trial if (include other exclusions, for example, if mental injury is excluded this must be stated). You might not receive compensation from (insert name of company) if your injury was caused by the investigators, if there is a deviation from the proposed plan of research, or if your injury was caused solely by you. If you are injured as a result of the trial, but your injury was caused by the investigators (or the institution/hospital where the trial took place) or as a result of a deviation from the proposed plan of research, you will **not be covered by** ACC and may have to pursue a civil action against the investigators (or institution). Ethics committees require that researchers and their institution have indemnity cover for such risk.

You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation.

Note: If the trial includes placebo/standard treatment, the investigators will need to check with the company whether there is compensation for participants using placebo treatment. If there is no compensation for this, it should be stated in the last sentence of paragraph four of the declaration above. The declaration should also make it clear why participants on placebo are not covered, for example, because there are not the same risks involved.

**Form B: declaration of provision of compensation for injury for participants in a research study for a pharmaceutical company or any other company involved in health research**

**Instructions:** This form is to be completed and the statutory declaration signed by the applicant. It should be forwarded to the appropriate ethics committee together with the documents seeking ethical approval for the proposed study and appropriate assurance from the pharmaceutical company or any other company involved in health research. The information provided must be sufficiently detailed to enable the ethics committee to be satisfied that:

* the proposed research is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out
* participants in the proposed research project will receive an acceptable level of compensation from a pharmaceutical company or any other company involved in health research in the event of injury to participants resulting from their involvement in the proposed research project.

Note: researchers and institutions have indemnity cover to provide an acceptable level of compensation in the event of injury to participants resulting from any researcher or research staff deviating substantially from the trial protocol.

**Details of proposed research study**

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| Title of research project: | |  | |
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| Name of research director/investigator: | |  | |
|  | |  | |
| Location(s) of proposed study: | |  | |
|  | |  | |
| Number of participants: | |  | |
|  | |  | |
| Organisations providing support (in money or kind) for the direct and indirect costs of the research *(please provide names of organisations and details of the type of support provided)*: | |  | |
|  | |  | |
| Relationship of proposed research to the pharmaceutical industry or other company involved in health research *(please describe the involvement of industry in your proposed research and provide details of support to be received from them*): | |  | |
|  | |  | |
| Details of compensation to be provided to participants in the event of injury *(documents signed by the sponsoring pharmaceutical company or other company involved in health research must be attached)*: | |  | |
| Statutory declaration  I (name) of (town/city) solemnly and sincerely declare that as director of the proposed research, the proposed study is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out and that in the event of injury arising from participation in the research, an appropriate level of compensation, in line with the *New Zealand Researched Medicines Industry Guidelines on Clinical Trials – Compensation for Injury Resulting from Participation in Industry Sponsored Clinical Trials,* will be provided by (name of pharmaceutical company or another company involved in the research project) as detailed in the attached documents, unless the injury is a result of a significant deviation from the study protocol. I confirm that I, my research staff and the host institution have indemnity insurance that covers injury as a result of significant deviation from the study protocol. I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957. | | | |
|  | |  | |
| Name *(please print)* | Signature | | Date |
|  |  | |  |
| before me |  | |  |
| Name of witness *(please print)* | Signature | | Date |
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| a Justice of the Peace, or |
| a Solicitor of the High Court |
| or other person authorised to take a statutory declaration |

**Warning:** It is an offence under part VI subsection 111 of the Crimes Act 1961 to make a false statutory declaration. **Note:** Applicants conducting a research study that is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out should complete Form A.