

POLICYI014 COMPENSATION POLICY

Manual: Policies	Document ID: PI014	Date Created: Jul 04
Section: Investigator	No. Pages: 2	Review Date: Dec 16
		Future Review Date: Dec 18

PURPOSE

To describe the requirements for the Participant Information Sheet and Consent Form (PISC) in regard to compensation.

The following clause or its equivalent is required to be included in the PIS (incorporating the bolded print).

Sample Compensation for Injury Clause for Participants – Clinical Drug Trials

If you are injured as a result of your participation in this trial you may be entitled to compensation.

Sponsors of clinical trials in Australia have agreed that the guidelines developed by their industry body, Medicines Australia, will govern the way in which compensation claims from injured participants are managed by sponsors.

However, as guidelines, they do NOT in any way dictate the pathway you should follow to seek compensation. The sponsor is obliged to follow these guidelines.

These guidelines are available for your inspection on the Medicines Australia Website (www.medicinesaustralia.com.au) under Policy – Clinical Trials – Indemnity & Compensation Guidelines. Alternatively, your study doctor can provide you with a hard-copy of the guidelines.

It is the recommendation of the independent ethics committee responsible for the review of this trial that you seek independent legal advice before taking any steps towards compensation for injury.

Sample Compensation for Injury Clause for Participants – Clinical Device Investigations

If you are injured as a result of your participation in this investigation you may be entitled to compensation.

Sponsors of clinical investigations in Australia have agreed that the guidelines developed by their industry body, Medical Technology Association of Australia (MTAA), will govern the way in which compensation claims from injured participants are managed by sponsors.

However, as guidelines, they do NOT in any way dictate the pathway you should follow to seek compensation. The sponsor is obliged to follow these guidelines.

These guidelines are available for your inspection on the MTAA website (www.mtaa.org.au) under Policy – Clinical Investigations. Alternatively, your study doctor can provide you with a hard-copy of the guidelines.

It is the recommendation of the independent ethics committee responsible for the review of this investigation that you seek independent legal advice before taking any steps towards compensation for injury.

Non-sponsored Studies/Investigations

If, as a result of your participation in this study, you become ill or are injured, immediately advise your study doctor of your condition. In the first instance your study doctor will evaluate your condition and then discuss treatment with both you and your regular treating doctor.

Since you are participating in a non-sponsored study/investigation any question about compensation must initially be directed to your study doctor who should advise their insurer of the matter.

It is the recommendation of the independent ethics committee responsible for the review of this study/investigation that you seek independent legal advice.