## Guidance

The following clauses or their equivalent are required to be included in the PICF (incorporating the bolded print).

**Sample clause for participants – clinical drug studies**

***Compensation for injury***

If you are injured as a result of your participation in this study, you may be entitled to compensation. There are two avenues that may be available to you to seek compensation.

1) Sponsors of clinical studies 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 and Compensation Guidelines. Alternatively, your study doctor can provide you with a hard copy of the guidelines.

2) You may be able to seek compensation through the courts.

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

**Sample clause for participants – clinical device investigations**

***Compensation for injury***

If you are injured as a result of your participation in this investigation you may be entitled to compensation. There are two avenues that may be available to you to seek compensation.

1) 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 (https://www.mtaa.org.au/clinical-investigation-research-agreements) under Policy – Clinical Investigations. Alternatively, your study doctor can provide you with a hard copy of the guidelines.

2) You may be able to seek compensation through the courts.

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.

**Non-clinical studies**

If, as a result of your participation in this study, you become ill or are injured inform the Principal Investigator as soon as possible and they will advise you of the appropriate course of action to take.

Any question about compensation should be directed to the Principal Investigator who should advise their insurer of the matter. For sponsored studies, the Principal Investigator should also advise the sponsor.

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

**Studies involving Children -Parent/Guardian Consent**

When your child reaches 18 years of age, they may have their own rights in relation to making complaints or claims for compensation in relation to participation in this study.

It is the recommendation of the independent ethics committee responsible for the review of this study/investigation that if this occurs then they seek independent legal advice before taking any steps towards compensation for injury.

**References**

BA G5 Participant Information & Consent Form Development