

Recommendation

It is recommended that the Bill is amended accordingly.

**Clause 31      Personal injury caused by medical misadventure**Submissions

The Health Research Council Ethics Committee (116) has noted that the term "clinical trial" has not been defined. Interpretation of "clinical trial" varies depending on the context of the trial (i.e. a drug trial, a particular type of health research study, or a randomised clinical trial excluding healthy volunteers). The Committee is concerned that healthy volunteers could be excluded from cover because of the particular interpretation given to the clinical trial they participated in. They suggest that the term "clinical trial" is replaced with the term "research study" and they propose a definition for this.

Comment

Clause 31(3)-(5) amounts to a definition of clinical trial for cover purposes.

Recommendation

No change is recommended.

Submission

The Health Research Council Ethics Committee (116) is concerned that coverage for personal injury caused as a result of participation in a research study is inappropriately tied to medical error or medical mishap in clause 31(3). They are concerned that these requirements are too restrictive and are contradictory to the spirit of the International Ethical Guidelines for Biomedical Research involving Human Subjects that are issued by the Council for International Organisations of Medical Sciences in collaboration with the World Health Organisation (1993). These guidelines require participants to be "entitled to such financial or other assistance as would compensate them equitably for any temporary or permanent impairment or disability". They suggest either amending the clause to remove the requirement that it be tied to medical error or medical mishap or removing clause 31(3) and establishing a new clause which allows for all personal injury as a result of participation in a research study to be covered. They maintain that this clause is in direct conflict with international obligations and is unsatisfactory, unethical and unfair.

Comment

Clause 31(3) restricts cover for personal injury caused as a result of a clinical trial to medical error or medical mishap, and only if the conditions in clauses 31(4) and (5) are met. The purpose of excluding cover more generally for these injuries is to ensure that researchers remain liable for the cost and consequences of their research; the costs of willing participants should not be borne by the Corporation (except where the trial they are participating in is (a) not a drug trial and (b) is approved by a health ethics committee). In any event if cover does not exist, the right to sue does, so ensuring that international standards are met.

Recommendation

No change is recommended.

Submission

The Health Research Council Ethics Committee (116) said that personal injury caused by an abnormal reaction to treatment and/or caused by a complication suffered later should be included as a personal injury caused by medical misadventure as part of a clinical trial. Currently these types