

of personal injury are excluded from medical misadventure, unless they involve medical error or mishap at the time of the treatment.

Comment

Clause 31(2) limits cover for personal injury to medical error or medical mishap that occurs at the time of the treatment. This means that medical misadventure can occur in these circumstances in respect of later reactions or complications as long as the error or mishap concerned occurred at the time of the clinical trial. Limiting personal injury for medical misadventure in this way is relevant to clinical trials because it creates the right incentives for researchers to ensure the safety of the trial for participants.

Recommendation

No change is recommended.

Submission

The Health Research Council Ethics Committee (116) recommends that the word 'approved' be replaced with the word 'accredited' in clause 31(5)(b). This would avoid confusion with 'approved' as used in 31(5)(a)(i), and the reference to 'approval' which appears later in same sub-clause.

Comment

The term approval is consistent with 'approval' used in section 25(1)(c) of the Health Research Council Act 1990. There is no confusion with using the same word twice in clause 31 as it has similar intent in both instances. The Health Research Council approves the ethics committee and the ethics committee in turn approves the trial.

Recommendation

No change is recommended.

Submissions

Three submitters (03 37 120) said delete clause 31(7): delay or failure due to resource constraints in the health system should not be a ground for denying cover to a person who would otherwise qualify on grounds of medical misadventure.

Comment

Clause 32(1)(c) has a new provision for medical error that now includes an organisation or person responsible for all or part of the treatment. However, the phrase 'resource constraints of health system' is very difficult to interpret operationally and the intent is not clear. It is important to limit cost-shifting from the public health system to the Corporation because of public policy decisions about what and how health services are funded.

Recommendation

It is recommended that clause 31(7) be omitted and that resource constraints be included as one of the factors to consider when deciding to grant cover under clause 32.

Submissions

The NZ Medical Association (50) opposes the terminology 'medical misadventure' on the grounds that it is misleading. The submitter suggests 'provider misadventure' or 'misadventure under treatment' as alternatives.