

CASE STUDY

Insurance and Indemnity for Clinical Trials in the Developing World: a case from Chile.

In January 2007 a randomised clinical trial was presented for approval to the director of one of the largest district hospitals of Santiago de Chile. The trial sought to demonstrate the non-inferiority of a non-registered drug, in phase III, for Diabetes Mellitus. The trial was sponsored by a private pharmaceutical company and had been previously approved by an ethical review committee. The protocol considered an insurance policy that was issued by an insurance company whose headquarters was based in Geneva, Switzerland. This company had no representative in Santiago de Chile. The insurance policy was written in English and mentioned in its text a number of provisions that were not disclosed at the moment of applying for approval. The insurance policy covered only non-negligent harm and established no indemnity for damages arising out of negligent behaviour of the researchers. The protocol was rejected by the Head of the hospital due to the lack of adequate insurance. The contract research organisation acting as operator of this trial expressed that they were surprised because the same protocol had been already approved in a hospital of a similar size hospital in Santiago de Chile. It should be noted that no general indemnity exists in Chile for negligent harm in public hospitals. No general policy exists either, concerning the requirement of insurance policies and indemnity for harm arising out of clinical research.

Recommendations are currently being written and discussed by the Ministry of Health of Chile, in order to regulate this requirement. Some concern has been expressed by non-commercial researchers and universities, because no local insurance companies offer these kinds of policies at affordable prices. They say that a different policy should be applied to commercial and non-commercial research. This problem has not yet been solved by the regulatory authority.