

File No. 12-01/14-DC Pt.47
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
FDA Bhawan, Kotla Road, New Delhi-110002

Dated: 03.07.2014


ORDER

SUBJECT: Clinical trial - Compensation in case of injury or death discerned at a later stage- regarding

The Ministry of Health & Family Welfare had constituted an Expert Committee under the Chairmanship of Prof. Ranjit Roy Chaudhury to formulate policy and guidelines for approval of new drugs, clinical trials and banning of drugs. The Expert Committee submitted its report to the Ministry of Health & Family Welfare. The actions proposed to be taken on the recommendations of the Expert Committee were finalized by the Ministry of Health & Family Welfare.

Pursuant to above, with regard to the compensation in case of injury or death discerned at a later stage, it has been decided that compensation in case of injury or death discerned at a later stage should be paid to the trial participant / his / her nominee as the case may be, if any drug-related anomaly is discerned at a later stage and accepted to be drug related.

In view of above, all Sponsors / Manufactures/Clinical Trial Applicants are hereby advised to provide compensation to the trial participant / his / her nominee as the case may be, if any drug-related anomaly is discerned at a later stage and accepted to be drug related injury or death.


(Dr. G. N. Singh)
Drugs Controller General (India)

To:

IDMA / IPA / OPPI / ISCR / ACRO

CC to: US(D), Ministry of Health and Family Welfare