

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: Approval of academic Clinical Trials- 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.

In pursuance to above, it is stated that academic clinical research may be approved by the Institutional Ethics Committee (IEC). However, if a new drug is being evaluated or a new use for an existing drug is being evaluated, then approval of the DCGI is needed as per Drug & Cosmetic Rules.


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

To:

All Concerned / MCI / IMA

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