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: Providing Ancillary care to the clinical trial subjects- 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 finalised by the Ministry of Health & Family Welfare.

In pursuance to above, with regard to Providing Ancillary care to the clinical trial subjects, it has been decided that there should be provision for providing ancillary care to patients suffering from any other illness during the trial.

In view of above, all Sponsors / Manufactures/Clinical Trial Applicants are hereby advised that such ancillary care should be provided to the clinical trial subject for brief illness in the same hospital/trial site, wherever required.

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

To:

IDMA / IPA / OPPI / ISCR / ACRO

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