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

Date: 02-08-16

CIRCULAR

Subject: - Restriction of conducting three clinical trials per investigator-regarding.

To deliberate stakeholders concerns and the way forward relating to some issues on conduct of clinical trials in India, two meetings were held on 20.08.2015 and 06.10.2015 under the Chairmanship of Secretary, Ministry of Health and Family Welfare in which experts including Secretary, D/o Health Research & Director General, ICMR and Director General Health Services were present.

As regards restriction that no investigator shall conduct more than three trials at any given period of time, it has been decided to remove this restriction & it is further decided that Ethics Committee after examining the risk and complexity involved in the trial being conducted/proposed shall decide about how many trials an investigator can undertake.

This is communicated for information and necessary compliance by all concerned.

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

To:-

I) All stakeholders through website of DCG (I).
II) Zonal and Sub-zonal offices of CDSCO/ all officers of CDSCO (HQ).

Copy to:-

I) PS to Secretary, Ministry of Health and Family Welfare,
II) PPS to DGHS,
III) PS to AS,
IV) PS to JS(R).