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

Dated 03.08.2016

Circular

Subject: Requirement of NOC from DCGI for addition of new clinical trial site or investigator-regarding.

To deliberate stake holders concerns and the way forward relating to some issues on conduct of clinical trial 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 and Director General, ICMR and Director General of Health Services were present.

As regards requirement of NOC from DCGI for addition of new clinical trial site or Investigator in clinical trial, it was decided in the meeting that the respective Ethics Committee after due diligence can approve proposals for addition of site(s) and investigator(s) and no NOC from DCGI in the normal course, should be necessary. However, the applicant would inform DCGI about any such addition /deletion and thereafter, if no objection was received from DCGI, it would be deemed to have concurrence of CDSCO.

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. PPS to secretary
II. PPS to DGHS
III. PPS to AS (Food and drugs)
IV. PS to JS (R)