File No.18-02/2010-DC
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 29 AUG 2012

OFFICE MEMORANDUM

Subject: Constitution of an expert committee for finalization of the Draft notification GSR no. 40 (E) dated 19.01.2011 regarding amendment of the Drugs and Cosmetic Rules for Registration of Clinical Research Organization conducting clinical trial and introductory of schedule Y 1 giving requirements and guidelines for the purpose-regarding.

The Government of India, Ministry of Health and Family Welfare published a Gazette notification GSR no. 40 (E) dated: 19.01.2011 on the recommendations of DTAB, inviting objections and suggestions from public for the amendment of the Drugs and Cosmetics Rules for Registration of Clinical Research Organization conducting clinical trial and introductory of schedule Y 1 giving requirements and guidelines for the purpose.

A large number of comments were received on the proposed draft rules. The Ministry of Health desired that a committee having balanced representation of all stakeholders may be constituted and meeting convened at its earliest for finalization of the draft rules.

In view of the above a committee having the following members has been constituted to examine the various provisions of the proposed amendment in the light of comments received from the public on the draft rules published for the purpose.

Composition of expert committee:

1. Dr. Y.K. Gupta, Prof. & Head, Department of Pharmacology, AIIMS, New Delhi
2. Dr. Vinod Raina, Prof. & Head, Deptt. of Oncology, AIIMS, New Delhi.
3. The Chairman, Ethics Committee C/o Medical Superintendent, MAMC, New Delhi.
4. Dr. Amit Sengupta, Delhi Science Forum, Delhi.
5. Dr. S. K. Gupta, Prof. & Emeritas Head, Clinical Research, DISPAR, New Delhi
6. Mr. C. M. Gulhati, Editor, MIMS India, Delhi.
7. Dr. Usha Rani, Prof. of Pharmacology, NIMS, Hyderabad
8. The Chairman, Ethics Committee C/o Medical Superintendent, RML Hospital, New Delhi
9. Dr. Bikash Medhi, Additional Prof. Department of Pharmacology, PGIMER, Chandigarh
10. Dr. Vijay Kumar,Scientist 'F', Division of BMS-Co-Ordinator, ICMR, New Delhi
11. Dr. Mira Shiva, Director, Initiative for Health Equity & Society, New Delhi
12. Dr. Sarojini N. (Sama), Sama – Resource Group for Women and Health, 2nd Floor, B 45, Shivalik Main, Malviya Nagar, New Delhi -110017.
13. Dr. Amar Jesani, Indian Journal of Medical Ethics, Mumbai
14. Ms. Neha, Madhiwala, Centre for Study in Ethics and Rights, Mumbai
15. Shri S. Srinivasan, LOCOST, Baroda
16. Dr. Sujith Chandy, Chrisitian Medical College and Hospital, Vellore, Tamil Nadu
17. Dr. Santanu Tripathi, Calcutta School of Tropical Medicine, Kolkata
18. Dr. B. Dinesh Kumar, General Secretary, Indian Pharmacological Society, Hyderabad
19. Representative, Organisation of Pharmaceutical Producers of India, Peninsula Chambers, Ground Floor,GanpatraoKadam, Marg. Lower Parel, Mumbai 400 013
20. Representative, Indian Drug Manufacturers Association, 102-B, Poonam Chambers, Dr. A. B. Road, Worli, Mumbai - 400 018
21. Representative, Indian Pharmaceutical Alliance (IPA), Vision Consulting Centre, 201-Dharvesh Chamber, Mumbai-52
22. Representative, Associations of CROs
23. Representative, Indian Society for Clinical Research, c/o, Pfizer Centre,5, Patel Estate, S.V.Road, Jogeshwari(West), Mumbai-400 102.

Terms of Reference:

1. The committee will examine the various provisions of the proposed amendment in the light of comments received from the public on the draft rules published for the purpose and suggest the draft for final notification.
2. The TA/DA shall be paid to non-official members as per applicable TA rules of Central Government.

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

To,

1. The Members of Committee