

No.12-01/12-DC (Pt-133)/DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan,
New Delhi, dated the 6th February, 2013

ORDER

Subject: System for supervising clinical trials on new chemical entities in the light of directions of the Hon'ble Supreme Court of India on 03.01.2013 – regarding.

The Hon'ble Supreme Court of India, vide its order dated 03.01.2013 in the matter of W.P. (C) No. 33/2012 of Swasthya Adhikar Manch, Indore & Anr Vs. Ministry of Health and Family Welfare & Ors. with WP(C) No. 779/2012 regarding clinical trials, had directed that until further orders by this Court, clinical trials of new chemical entity shall be conducted strictly in accord with the procedures prescribed in Schedule Y of the Drugs and Cosmetics Act, 1940 under the direct supervision of the Secretary, Ministry of Health and Family Welfare, Government of India. In view thereof the following two Committees are hereby constituted by the Ministry:

A. An Apex Committee comprising following members under the Chairmanship of Secretary, Health and Family Welfare:

Dr. V.M. Katoch, Member
Secretary, Department of Health
Research, and Director General,
ICMR

Dr. Jagdish Prasad, Member
Director General of Health
Services.

Dr. A.K. Panda, Member Secretary
Joint Secretary,
Ministry of Health & Family
Welfare

The Apex Committee will meet every month to take stock of new approvals. Secretary (Health & Family Welfare) will take the assistance of the Technical Committee to supervise and monitor the conduct of the clinical trials in the country.

B. A Technical Committee comprising following experts to give input related to clinical trials to the Apex Committee for supervising and monitoring the conduct of clinical trials in the country.

1. Dr. Jagdish Prasad, Chairman

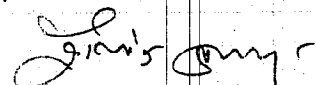
Director General of Health Services.

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| 2. | Dr. Ranjit Roy Chaudhury,
National Professor of Pharmacology,
Former Member, BOG - MCI
Y-85, Hauz Khas, New Delhi-110016 | Member |
| 3. | Dr. Ashok Kumar Das,
Director - Professor of Medicine &
Medical Superintendent,
JIPMER, Puduchery-605006. | Member |
| 4. | Dr. Vinod Raina,
Prof. & Head,
Department of Medical Oncology,
AllMS, New Delhi | Member |
| 5. | Dr. Sanjay Tyagi,
Prof. & Head, Dept. of Cardiology
GB Pant Hospital, New Delhi | Member |
| 6. | Dr. Jaspal Sharma,
Prof. & Head, Dept. of Cardiology,
PGIMER, Chandigarh. | Member |
| 7. | Dr. Nikhil Tandon,
Professor, Dept. of Endocrinology &
Metabolism, AllMS, New Delhi. | Member |
| 8. | Dr. Kamalakar Tripathi,
Prof., Dept. of Medicine,
Institute of Medical Sciences,
Banaras Hindu University,
Varanasi - 221005. | Member |
| 9. | Dr. Shashank V. Parulekar,
Prof. & Head, Dept. of Obstetrics &
Gynecology, Seth GS Medical
College & KEM Hospital, Parel,
Mumbai-400012 | Member |
| 10. | Dr. Debasis Basu,
Prof. & Head, Dept. of Neurology,
Kolkata Medical College, Kolkata. | Member |
| 11. | Dr. P.K. Dalal,
HOD, Dept. of Psychiatry,
CSMU Medical College, Lucknow. | Member |

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| 12. | Dr. Rajutitus Chacko,
Prof. & Head,
Dept. of Medical oncology,
CMC, Vellore. | Member |
| 13. | Dr. S.N. Gaur,
Professor & Head, Dept. of
Respiratory Medicine,
VP Chest Institute, New Delhi. | Member |
| 14. | Dr. B.L. Sherwal,
Director-Professor, Dept. of
Microbiology, LHMC & Associated
Hospitals, New Delhi | Member |
| 15. | Dr. Nandini Kumar,
Former Deputy Director General Sr.
Grade, Co-Investigator, NIH Bioethics
Project, National Institute of
Epidemiology, ICMR, Chennai | Member |

The Technical Committee will meet every month to oversee the conduct of clinical trial in the country and give its recommendation to the Apex Committee for taking further appropriate action. The list of clinical trials alongwith title & objective of the study, name of the applicant and other details, permitted by DCG(I) shall be submitted to the Technical Committee on monthly basis for the said purpose.

2. Honorarium and TA/DA will be paid to the Experts as per the Central Government Rules from the budgetary allocation of CDSCO.


 (Shailendra Kumar)
 Director
 Telefax. 23061656

1. Drugs Controller General (India), FDA Bhavan, Kotla Road, New Delhi - for conveying this Order to the Chairpersons and all members of the Expert Committees.
2. Principal Accounts Office, Ministry of Health & Family Welfare, Nirman Bhavan, New Delhi
3. Pay & Accounts Office, DteGHS, Nirman Bhavan, New Delhi
4. IFD / Budget Section
5. PPS to Secretary (H&FW) / PPS to DG, Dte.GHS / PPS to AS&DG(CGHS) / PS to JS(AKP)