

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

Nirman Bhawan,  
New Delhi, dated the 6<sup>th</sup> 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:

<b>Dr. V.M. Katoch, Secretary, Department of Health Research, and Director General, ICMR</b>	<b>Member</b>
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<b>Dr. Jagdish Prasad, Director General of Health Services.</b>	<b>Member</b>
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<b>Dr. A.K. Panda, Joint Secretary, Ministry of Health &amp; Family Welfare</b>	<b>Member Secretary</b>
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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.

<b>1. Dr. Jagdish Prasad,</b>	<b>Chairman</b>
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**Director General of Health Services.**

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, Puducherry-605006.	Member
4.	Dr. Vinod Raina, Prof. & Head, Department of Medical Oncology, AIIMS, 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, AIIMS, New Delhi.	Member
8.	Dr. Kamlakar 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

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.

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(Shailendra Kumar)  
Director  
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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, DteGHS / PPS to AS&DG(CGHS) / PS to JS(AKP)