F. No. GCT/20/SC/Clin./2013 DCGI
Directorate General of Health Services
Ministry of Health & Family Welfare
Office of Drugs Controller General (India)

Food & Drugs Administration Bhawan,
Kotla Road, New Delhi-110002
Dated: 19 NOV 2013

ORDER

The clinical trials on new drugs are regulated under the provisions of Drugs & Cosmetics Rules 1945 as amended from time to time. The detailed requirements and guidelines for undertaking clinical trials are specified under Schedule Y of the said rules. As per the Rule 122 DAC of the said Rules, clinical trials are required to be conducted in compliance with the approved protocols and Good Clinical Practice (GCP) guidelines published by Central Drugs Standard Control Organization, Directorate General of Health Services, Govt. of India as well as applicable regulations.

As per the Schedule Y, in all trials, a freely given, informed, written consent is to be obtained from each study subject. The Investigator must provide information about the study verbally as well as using a patient information sheet, in a language that is non-technical and understandable by the study subject. The Subject's consent must be obtained in writing using an 'Informed Consent Form'. If the Subject or his/her legally acceptable representative is unable to read/write – an impartial witness should be present during the entire informed consent process who must append his/her signatures to the consent form.

In the case 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, the Hon'ble Supreme Court, has passed an order dated 21.10.2013. As per the said order, in respect of 5 Global Clinical Trials for which approval has been given by this office after 01.01.2013 till 31.08.2013, before the clinical trials are conducted, appropriate provision shall be made or administrative direction shall be issued which ensures that audio- visual recording of the informed consent process of the participants is done and the documentation preserved, adhering to the principles of confidentiality. In other words, the clinical trials in respect of these five cases shall commence after proper framework is in place concerning audio-visual recording of the informed consent process and the preservation of documents while adhering to the principles of confidentiality.

In view of the above, it has been decided with the approval of the Ministry of Health & Family Welfare, that in all clinical trials, in addition to the requirement of obtaining written informed consent, audio-visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her understanding on such consent is required to be done while adhering to the principles of confidentiality. Such audio-visual recording and related documentation would be preserved. This is applicable to the new subjects to be enrolled in all clinical trials including Global Clinical Trials.

All the Sponsors/Investigators/Institutes/Organizations and other stakeholders involved in conduct of clinical trials in the country are hereby directed to adhere to the above requirement of audio-visual recording of informed consent process of trial subjects with immediate effect.

(Dr. G. N. Singh)

Drugs Controller General (India)

To:

All the concerned.