INDIAN DRUG MANUFACTURERS' ASSOCIATION

102, POONAM CHAMBERS, 'A' WING, DR. A. B. ROAD, WORLI, MUMBAI 400 018. INDIA

Phone : 91-22-24974306
91-22-24944824
Fax : 91-22-24950723

E-mail : idma1@idmaindia.com
accounts@idmaindia.com
Website : www.idma-assn.org

PARTNERS IN GLOBAL HEALTHCARE

29th May 2014

The Health Secretary,
Ministry of Health & Family Welfare,
Government of India,
Nirman Bhawan,
New Delhi - 110 011

Sub: **Request for reconsideration of the requirement of Audio-Visual recording of informed consent process in clinical trials**

Dear Sir,

We would like to draw your kind attention to Order No. GCT/20/SC/Clin./2013 DCGI dated 19th November 2013, the DCGI (copy enclosed as enclosure No. 1) whereby all the Sponsors/ Investigators / Institutes / Organizations and other stakeholders involved in conduct of clinical trials in the country were directed to adhere to the requirements **of audio-visual recording** of informed consent process of trial subjects with immediate effect.

It is learnt that DCGI's order dated 19th November 2013 emanates from a guidance issued by the Hon'ble Supreme Court of India. However the perusal of the Hon'ble Supreme Court's order dated 21st October 2013 (enclosed as enclosure No. 2) reveals that this guidance was specific in respect of **5 Global Clinical Trials** for which approval was given by DCGI office after 1st January 2013 till 31st August 2013.

Drawing clue from the Hon'ble Supreme Court's above order, it was decided by the Directorate 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.

It is humbly submitted that universally implementing this audio-visual recording of informed consent process is posing significant impediment in the clinical research due to below cited reasons:

- Sensitive patient groups, especially females, will not be ready to participate in clinical trials in therapy areas like gynecology, genital diseases, HIV, young females for contraception, young females for treatment of acne, etc., as they would not like to be exposed in videography because of the sensitivity involved in such cases.

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- In Indian socio-economic structure, in most of the families, patient will not like to disclose their illness even to the close one in the family (commonly seen in oncology cases). This group even though they may wish to participate but will not be ready to get themselves enrolled for AV recording just for the fear of disclosure of their illness.

- In most of the Govt. Hospitals/Medical colleges in the country, there is dearth of space. Patients are admitted even in hospital corridors. Hence availability of dedicated, isolated room for audio visual recording of informed consent process and proper infrastructure is a big challenge.

- Another critical challenge in the Indian scenario is how to avoid the misuse of these audio-video clippings by hackers and people with bad intentions using some unscrupulous methods and putting those videos in open websites where video clips are stored / played or share with the media/public etc.

- As per the order No. GCT/20/SC/Clin./2013 DCGI dated 19th November 2013 and Schedule-Y requirements, in clinical trials conducted in India both written informed consent and audio-visual recording of the informed consent process is required which **is a duplication of the activity.**

As per United States Food and Drugs Administration (USFDA) guidance document "A Guide to Informed Consent – Information Sheet, Guidance for Institutional Review Boards and Clinical Investigators" (enclosed as enclosure No. 3) a video tape recording of the consent interview is recommended in case of illiterate participants who can understand and comprehend spoken English but are physically unable to talk or write.

As per Indian Council of Medical Research (ICMR) Ethical Guidelines for Biomedical Research on Human Participants, 2006 (enclosed as enclosure No. 4), "when the written consent as signature or thumb impression is not possible due to sensitive nature of the project or the participant is unable to write, then verbal consent can be taken after ensuring its documentation by an unrelated witness. Audio-visual methods could be adopted with prior consent and adequate precaution to ensure confidentiality, but approval of EC is required for such procedures".

The main objective of the order, as we understand, is to ensure safety of the subjects of clinical trials and to avoid any exploitation by the CROs. Clinical trials in India are conducted as per the provisions of Schedule-Y, GCP guidelines issued by CDSCO, and ICMR Ethical Guidelines for Biomedical Research on Human Participants, which is in line with the international standards. The audio-visual recording of informed consent process does not offer any added safety to the patients.

It is worthwhile to mention here that an article published in **The Economic Times dated 22nd April 2014** (enclosed as enclosure No. 5), it has been highlighted that **nearly 30% of patients are walking out of new clinical trials** wary of facing the camera during illness.

Therefore, looking at the importance of clinical trials for introduction of new drugs for treatment of various disease conditions in the country, **we request that requirement for audio-visual recording of informed consent process should be made limited to only illiterate patients which shall be in line with the international practice/guidance.** There is a fear expressed amongst the professionals that informed consent will lose credibility if A-V recording is made the new norm – thereby derailing the process of smooth conduct of studies.

It has been observed that the number of patients wish to participate & get the benefit of study drug as well as special care received in clinical trial. **Due to unwillingness of participation in the rather uncalled for imposed AV recording procedure for ALL, they may lose potential benefit of the new treatment.** We are confident that your timely intervention in this matter by understanding the finer aspects and nitty-gritty involved would lead to an amicable solution to the deadlock.

Thanking you,

Yours sincerely

S.V. Veerramani
President

Copy to:

1. Additional Secretary and Director General (CGHS), Ministry of Health & Family Welfare; Nirman Bhawan, New Delhi - 110 011
2. The Joint Secretary, Ministry of Health & Family Welfare; Nirman Bhawan, New Delhi- 110 011
3. The Drugs Controller General (India),
   Directorate General of Health Services
   FDA Bhawan, CHEB Campus, Kotla Road, New Delhi - 110 002

Enclosures:

1. Copy of Order No. GCT/20/SC/Clin./2013 DCGI dated 19th November 2013 from CDSCO.
2. Copy of Hon'ble Supreme Court order dated 21st October 2013.
3. United States Food and Drugs Administration (USFDA) guidance document "A Guide to Informed Consent – Information Sheet, Guidance for Institutional Review Boards and Clinical Investigators".
4. Indian Council of Medical Research (ICMR) Ethical Guidelines for Biomedical Research on Human Participants, 2006.
5. Article published in The Economic Times on 22nd April 2014.