

**DRAFT GUIDELINES
ON
AUDIO-VISUAL RECORDING OF
INFORMED CONSENT PROCESS
IN CLINICAL TRIAL**

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GUIDANCE DOCUMENT

*Comments/ suggestions, if any, may please be submitted to the
office of Drugs Controller General India*

latest by 16th January 2014

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

DIRECTORATE GENERAL OF HEALTH SERVICES

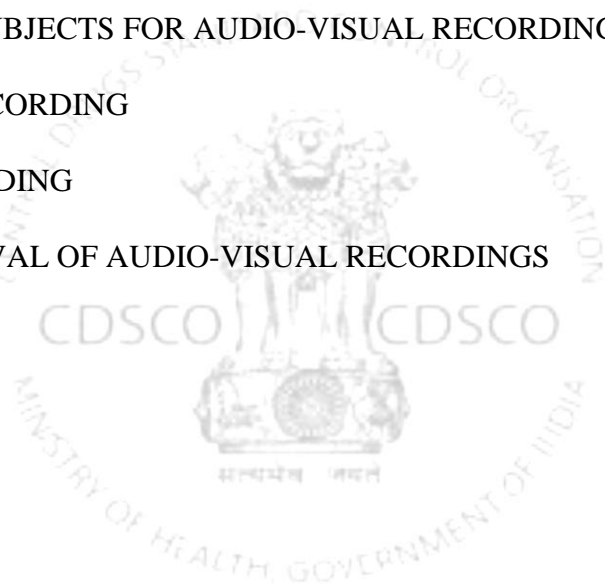
MINISTRY OF HEALTH & FAMILY WELFARE

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GUIDELINES ON AUDIO-VISUAL RECORDING OF INFORMED CONSENT PROCESS IN CLINICAL TRIAL

1. BACKGROUND

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, 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 was given by CDSCO 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 light of the above order of the Hon'ble Supreme court, CDSCO vide F. No. GCT/20/SC/Clin./2013 DCG1 dated 19.11.2013 has issued direction 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.

This document has been prepared to provide guidelines for the stakeholders for the audio-visual recording of informed consent process in clinical trial as per the above direction.

2. INFORMATION FOR PROSPECTIVE STUDY SUBJECT

Before requesting an individual's consent to participate in clinical trial the Investigator must provide the individual with the following information in a language that is non- technical and understandable by the study subjects and the same shall be recorded through audio-visual means.

(A) Essential elements:

1. Statement that the study involves research and explanation of the purpose of the research
2. Expected duration of the Subject's participation
3. Description of the procedures to be followed, including all invasive procedures
4. Description of any reasonably foreseeable risks or discomforts to the Subject
5. Description of any benefits to the subject or others reasonably expected from research. If no benefit is expected subject should be made aware of this.
6. Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
7. Statement describing the extent to which confidentiality of records identifying the subject will be maintained and who will have access to subject's medical records
8. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)
9. Statement describing the financial compensation and medical management as under:

- a. In the event of an injury occurring to the clinical trial subject, such subject shall be provided free medical management as long as required.
 - b. In the event of a trial related injury or death, the Sponsor or his representative, whosoever has obtained permission from the licensing Authority for conduct of the clinical trial, shall provide financial compensation for the injury or death.
10. An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury
 11. The anticipated prorated payment, if any, to the Subject for participating in the trial
 12. Subject's responsibilities on participation in the trial
 13. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled
 14. Any other pertinent information
- (B) Additional elements, which may be required:
1. Statement of foreseeable circumstances under which the subject's participation may be terminated by the Investigator without the subject's consent.
 2. Additional costs to the subject that may result from participation in the study.
 3. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by subject.
 4. Statement that the subject or subject's representative will be notified in a timely manner if significant new findings develop during the

course of the research which may affect the subject's willingness to continue participation will be provided.

5. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or foetus, if the subject is or may become pregnant), which are currently unforeseeable.
6. Approximate number of subjects enrolled in the study.

Where a subject is not able to give informed consent (e.g. an unconscious person or a minor or those suffering from severe mental illness or disability) the above information should be provided to the legally acceptable representative (LAR). If the subject or his/her legally acceptable representative is unable to read/write – an Impartial witness (IW) should be present during the entire informed consent process.

The Investigator has the duty to communicate to the subjects/LAR/IW, all the information necessary for informed consent. There should not be any restriction on subject's right to ask any questions related to the study as any restriction on this undermines the validity of informed consent. Details of such questions if any, asked by the subject/LAR/IW and his/her understanding on consent are also to be recorded through the audio video means. The process of signing/putting thumb impression by the subject/LAR/IW should also be video recorded.

3. PRINCIPLE OF PRIVACY AND CONFIDENTIALITY

During the audio-visual recording of informed consent process, the identity and records of the trial subjects are as far as possible kept

confidential; and that no details about identity of said subjects, which would result in the disclosure of their identity, are disclosed without valid scientific and legal reasons which may be essential for the purposes of therapeutics or other interventions, without the specific consent in writing of the subject concerned, or someone authorised on their behalf, and after ensuring that the said subject does not suffer from any form of hardship, discrimination or stigmatisation as a consequence of having participated in the trial.

The Investigator must safeguard the confidentiality of trial data, which might lead to the identification of the individual subjects. Data of individual subjects can be disclosed only in a court of law under the orders of the presiding judge or in some cases may be required to communicate to Drug regulatory/ Health authority.

In order to maintain the confidentiality, the videographer should be engaged as part of the study team. Prior to initiation of the study, the Investigator should define and allocate the activities of audio-video recording of informed consent process to the respective identified person as videographer. The Investigator shall maintain the details of the person to whom he has delegated the duties of audio video recording.

4. CONSENT OF THE SUBJECTS FOR AUDIO-VISUAL RECORDING

Prior consent of the subject should be taken for audio-visual recording of informed consent process and the same should be documented by the

Investigator. Such consent may be taken orally. Only those subjects who give the consent for the AV recording shall be included in the clinical trial.

5. PROCEDURE OF AUDIO-VISUAL RECORDING

At the beginning of the video recording process, the Investigator will identify the protocol, the subject/LAR/IW and the language understood by the subject/LAR/IW. If the Investigator does not know the language of the subject/LAR/IW a member of the study team who understands the language, would become the interpreter.

In order to identify the subject/LAR/IW his/her photo ID may be documented. The video camera for the audio-visual recording should be of adequate capability to simultaneously capture the facial details of subject, LAR/Impartial Witness (if any), Investigator/authorised person present during the consent process. The audio-visual recording should be conducted in a room conducive to recording of disturbance-free audio and video of the consent process. During the videography process, care should also be taken not to include unrelated persons/patients at the hospital within the field of vision.

6. QUALITY OF AUDIO-VISUAL RECORDING

The Video recording of informed consent may not serve the intended purpose if the quality of the recording fails to meet a minimum standard required for the purpose. The video recording should be done

using video camera of appropriate resolution and in a room free from any disturbance to ensure that the image is recognizable and the audio is clearly audible.

7. STORAGE & ARCHIVAL OF AUDIO-VISUAL RECORDINGS

Audio visual recording of informed consent process and other related documents should be preserved safely after the completion / termination of the study for at least a period of 5 years if it is not possible to maintain the same permanently.