



Full Length Review Article

NEW AUDIO VIDEO CONSENT GUIDELINES: ELEMENTS FOR INFORMED CONSENT PROCESS FOR CLINICAL TRIALS IN INDIA

Shekhar Goyal, Indra Bhadu, *¹Dr. Akhil Kapoor and ²Surender Beniwal

Department of Clinical Operations, SIARAM Clinical Research Centre, Bikaner, Rajasthan

¹Department of Radiation Oncology, Acharya Tulsi Regional Cancer Treatment and Research Institute, Sardar Patel Medical College and AG of Hospitals, Bikaner, Rajasthan, India

²Department of Medical Oncology, Acharya Tulsi Regional Cancer Treatment and Research Institute, Sardar Patel Medical College and AG of Hospitals, Bikaner, Rajasthan, India

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ABSTRACT

As per the clinical research guidelines, every adult volunteer must agree to participate in a clinical trial and proper consent must be taken for the same. As per the schedule Y, in all trials, informed, written consent, free from any physical, psychological or economic points. After highlight of the order of the Hon'ble Supreme court, CDSCO dated 19 November 2013, has made it mandatory for all clinical trials to conduct audio video (AV) recording of the informed consent process along with written consent of each trial subject. AV consent is the best mechanism intended to improve the quality of Informed Consent Process (ICP). AV consent of the informed consent process will protect both the subjects and the investigators. AV consent will also work as a safeguard for the industry as well as investigators from future litigations, media and socialists' false claims. This article highlights the AV consent elements procedures according to present guidelines.

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INTRODUCTION

Voluntary participation in research strengthens ethical conduct, making comprehensive informed consent documents a critical component of research. For good clinical practice (GCP), essential elements of informed consent process and documents should be incorporated. However, there are still instances where the process is not properly conducted either intentionally or due to ignorance and subjects are found to have poor comprehension of the information provided leading to recruitment of incompetent participants. (Kulkarni *et al.*, 2014) There are some issues regarding enrollment of vulnerable subjects, illiterate participants or those who don't understand any language or investigator does not know the local language. Indian regulatory authority has taken the strict decision to increase the confidentiality, protection of human subjects, and the transparency of the clinical research.

*Corresponding author: Dr. Akhil Kapoor

Department of Radiation Oncology, Acharya Tulsi Regional Cancer Treatment and Research Institute, Sardar Patel Medical College and AG of Hospitals, Bikaner, Rajasthan

The Central Drugs Standard Control Organization (CDSCO) issued the gazette of India notification dated 7th June 2013 and proposed to draft a rule to make AV recording of the informed consent process of individual participants by an investigator. (<http://www.cdsc.nic.in>) Final decision has been taken by Supreme Court, CDSCO vide F. No. GCT/20/SC/Clin./2013/DCGI dated 19 November 2013 in which directives have been issued that "in all clinical trials, in addition to the requirement of obtaining written informed consent, AV recording of the informed consent process of each participant trial subjects, including the procedure of providing information to the subjects and his/her understanding on such consent is required to be done while adhering to the principles of confidentiality. Such audio video recording and related documentation would be preserved by site for least five years." (CDSCO 2014) A video tape recording of the consent interview is also recommended by United States Food and Drug Administration (US FDA 2014) for illiterate participants who can understand and comprehend spoken English but are physically unable to talk or write. (<http://www.fda.gov/regulatoryinformation/guidances/ucm126431.htm>)

This guideline is applicable for all Indian as well as global clinical trials which are conducted in India.

Elements of Informed consent Process (AV ICF Process)

For every participant/patient before enrollment in the study, Principal Investigator (PI) has to provide the individual or group presentation in the presence of witness or legal acceptable representative (LAR) in an understandable language or local language without using much more scientific words to the patients in a proper manner. PI should explain the following required Elements for AV consenting:

- Topic of the study, aims and objectives of the study
- Study duration with scheduler and number of participants
- Protocol design, selection criteria and timelines with follow up and investigation list
- Foreseeable risk and benefits of the study with discomfort
- Alternative treatment source and procedures
- Data confidentiality and accessible details
- PI and study team contact details
- Aware about adverse effects (AE), serious adverse effects (SAE) and SAE medical management and compensation details in cases of life threatening illness and death.
- Statement that participant is voluntary in the study and agree for AV consenting
- About prorate payment
- Subject responsibilities (reporting of new finding, any AEs and withdrawal from the study anytime, regular follow up, previous results)

In case patient is unconscious or mentally ill/unable to give informed consent, then above mentioned information should be provided to the LAR. If the subject and LAR both are illiterate, then, impartial witness (IW) should be present during the AV ICF process. All the communications between investigator and patient / LAR should be recorded in proper way without any restriction in AV process. AV consent should be taken in a disturbance free room. Investigator should resolve all the queries generated by the patient or LAR during the AV consent. ICF hard copy is also given to the subjects for deep analysis, after that process should be started with the elements and ended with sign/ thumb impression in proper section by subject/ LAR, IW and investigator.

Protocol of AV recording

At the start of the consent process, investigator will identify the patients/LAR (in case IW required, then IW presence is necessary during the process). Investigator communicates to the patient in his/her understandable language otherwise interpreter is arranged for communication. All elements points should be communicated during the informed consent procedure and final affirmation of the subject, certification that he is in complete knowledge of the study and all the queries are clarified. Patient identity proof is also documented. AV process has adequate capability to capture the facial details of subject, LAR, IW (if any), investigator during the consent process without any hurdle in a peaceful place. This consent should be taken by orally in front of video. This consent procedure is kept as source documentation preferably in form of compact disc.

Merits

Saves investigators from future litigations

AV consent process is designed to safeguard the interests of both the participants and investigator in clinical trials. It is a legal document that can show that all relevant information was provided to the subjects before enrollment after which the subject agreed to take part in the study. In case of any issue or dispute, the sponsor will have solid evidence to support that adequate measures were taken to obtain consent instead of simply written ICF.

Provides transparency

AV consent process should increase the transparency ration of the IC process in clinical trials; it will enhance the confidence level of the clinical trial societies and institutions. (Ghooi 2014) AV recording could be used as an evidence in the court of law provided and written process is followed for recording and maintaining the records which may helpful to reduce the false claims in the compensation process of SAEs.

Protects vulnerable subjects from risk

After taking AV consent process, vulnerable and illiterate subjects can be protected as investigator will carefully explain each and every elements of the study. So, they can know about the study and study procedures.

Simple and improved ICF process

Previously monitor needed to work on ICF documentation and make out the narratives to reconstruct the ICF process many times. The expectation of the documentation and detailed narrative languages continuously increases for the site and can make issues. Current process will be recorded for patient as well as investigator to ensure that before participation in the clinical trials, participant knows about the trial and all the elements of the study are discussed; doubts and queries raised by participants/ LAR are resolved. It will also highlight those investigators who are not following the IC process properly.

Demerits

Additional step and responsibility to do this work

Audio video process is an additional step for site. The investigator may counsel or resolve all the queries and doubts. Investigator will have to give more time to obtain IC process from each participant through AV consent process. This will increase the volume of work at the site due to recording, storage, conduct of videography, etc.

Maintain the confidentiality and long term storage

Investigator and study team should keep confidentiality of AV consent process; AV data cannot be utilized or opened by any third party or sponsor/CRO. It will be used only by regulatory body or ethics committee as evidence or resolving ethical issues.

Indian Culture

Indian has traditional culture especially in rural India. Indian women wear *ghungat* or *burkas* to cover their head and face to avoid eye contact with men. Thus, AV process can be time consuming and uncomfortable in such cases. Subjects who do not want to show their face can refuse to give consent which may negatively affect the recruitment of the study.

Language barrier

India has 26 different languages spoken in different regions. If inspector or auditor wishes to check the AV process, it might be difficult to know whether the process was adequately performed or not.

Unconscious and serious ill patients

Some studies are related to seriously ill patients or unconscious patients; in that case AV recording of the consent process to enroll the subjects will be a big issue.

Cost burden

This process has a dramatically increased the clinical trial budget. In a study with large sample size and high screen failure rate, each and every IC process should be AV recorded and stored, whether the participants agree or refuse the consent at the end of the discussion. This will be raise the cost and unnecessary load.

Conclusion

Audio video recording and elements of the consent process would be helpful to investigators to take AV consent in a methodical way and can save them from future litigations at the cost of increased work load and cost.

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