

Elements for an informed consent process for clinical trials



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Audio video consent Guidelines

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Abstract:

Clinical research guidelines require that every adult volunteer must agree to participate in a clinical trial after given the consent. As per the schedule Y, in all trials, a freely given, informed, written consent, free from any physical, psychological or economic points. After highlight the order of the Hon'ble Supreme court, CDSCO dated 19 Nov. 2013 has passed that all clinical trials should be audio video recording of the informed consent process along with written consent of each trial subject. Audio video consent is another best mechanism intended to improve the quality of ICF. An audio video consent of the informed consent process will protect both the subjects and the investigators. AV consent will also work as a safeguard for industry as well as investigators for future litigations, media and socialist false claims. This article highlights the audio video consent elements procedures according to present guidelines.

Keywords: AV process, Clinical trials, consent, Elements, audio video

Introduction:

Voluntary participation in research strengthens ethical conduct, making a 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 intentionally or due to ignorance and subjects were found to have poor comprehension of information provided or incompetent participants were recruited. There are some issues going on when study enrolls vulnerable subjects, illiterate participants or those who don't know understandable language or investigator don't 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. CDSCO issued the gazette of India notification dated 7th June 2013 proposed to make the draft rule that audio – video (AV) recording of the informed consent process of individual participants by an investigator. Final decision has been taken by Supreme Court, CDSCO vide F. No. GCT/20/SC/Clin./2013/ DCGI dated 19 Nov. 2013 has issued the directions that in all clinical trials in addition to the requirement of obtaining written informed consent, audio-video (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 at least 5 year.

A video tape recording of the consent interview is also recommended by United States Food and Drug Administration (US FDA) in case of illiterate participants who can understand and comprehend spoken English but are

physically unable to talk or write. 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):

Every participant/ patient before participant in the study, Principal Investigator should have provide the individual or group presentation in presence of witness or LAR in a 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 and aims & objective of the study
- Study duration with scheduler & number of participants
- Protocol design, selection criteria & timelines with follow up & investigation list
- Foreseeable Risk & benefits of the study with discomfort
- Alternative treatment source and procedures
- Data confidentiality & accessible details
- PI & study team contact details
- Aware about AE & SAE & SAE medical management & compensation details in case of:
 - Seriousness of illness
 - If 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 unconscious or mental illness/ unable to give informed consent process then above mentioned information should be provided to the legal acceptable representative (LAR). If the subjects or LAR both are illiterate then use the impartial witness should be present during the audio video ICF process.

All the communications between investigator and patient / LAR should be recorded in proper way without any restriction in audio video process. AV consent should be taken at disturbance free room. Investigator resolves all query generated by patient and patient LAR during the audio video consent. ICF copy also given to the subjects for deeply gone through, after that process should be started with the elements and ended with sign/ thumb impression in proper section by subject/ LAR, impartial witness and investigator.

Previously without AV process, consent had been taken in written format, but after stringent law to tighten the regulatory framework around clinical trials & same documented should be in the form of audio video which one recorded by site / investigator for each participant trials subjects.

Protocol of AV recording:

At the initial of the consent process, investigator will identify the patients/LAR (in case impartial witness (IW) required then IW presence is necessary during the process). Investigator communicate to the patient,

his /her understandable language otherwise interpreter arrange for inter-communication. All elements points should be communicate during the informed consent procedure & Final affirmation of the subject and certify that he is in complete knowledge of the study and all the queries are clarified. Patient ID proof also documented. Audio video have adequate capability to capture the facial details of subject, LAR, IW (if any), investigator during the consent process without any hurdle in peaceful place. This consent should be taken by orally in front of video. This consent procedure kept as source documentation or further record purpose.

Merits:

Saves investigators from future litigations:

Audio video consent process should be safeguarding of the participants subjects in clinical trials. AV process also safeguard to investigator and show that all relevant information was provided to the subjects after that subjects 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 informed consent form.

Provides transparency

Audio video consent process should increase the transparency ration of the informed consent process in clinical trials; it will enhance the confidence level of the clinical trial societies and institutions.

AV recording could be used as an evidence in the court of law provided & 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 subjects and illiterate subjects have protected and those subjects who are not understandable medical terminologies. AV consent patient & investigator recording and investigator explain the each & every elements of the study. So vulnerable subjects and illiterate subject know about the study & study procedures.

Simply and improved ICF process:

In previously, monitor 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 continuous increase for the site & make issues.

Current process will be recorded for patient as well as investigator to ensure that before participant the clinical trials, participant know about the trial and all elements of the study are discussed and doubts and queries raised by participants/ LAR are resolved. It will also highlight those investigators who are not following the informed consent process properly.

Demerit:

Additional step and responsibility to do this work:

Audio video process is an additional step for site. The investigator may counsel or resolve the all queries and doubts. Investigator will be given his more time to obtain informed consent process from each participant through AV consent process. This will enhance the volume of work at the site such as recording, storage, conduct the videography etc.

Maintain the confidentiality and long term storage

Investigator and study team should be keep confidentiality of audio video consent process, AV data could not utilized or open by any third party or sponsor / CRO. It will be used by regulatory body or EC in case of evidence or Ethical issues.

Indian Culture:

Indian has traditional culture especially in rural India. Indian women's wear *ghungat* or *burkas* to cover his head & face to avoid eye contact with men. When investigator or site staff goes for audio video consent then it will be time consuming and uncomfortable. Subjects who are not want to show her face, she refused to give her consent which may affect the recruitment of the study & bias.

Language barrier

Indian has 26 types of languages speak out from different regions. When inspections or auditor want to gone the audio video process then it will be become difficult for auditor or inspector to know the process was adequately performed or not? Because he or she not familiar with the language.

Unconscious & 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 consent should be audio video recorded or stored, whether the participants agree or refuse the consent at the end of the discussion. This will be raise up the cost & unnecessary load.

Conclusion:

Audio video recording and elements of the consent process would be helpful to investigators to take AV consent in proper way. Best point to transparent the data which is helpful to regulatory body.

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