**Study title**:

**Analysis of Audiovisual Consent Process Records Submitted to the**

**Institutional Ethics Committee of a Tertiary Care Hospital: ARetrospectiveStudy**

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# Institutional Ethics Committee

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**Introduction:**

On October 21, 2013, a directive from the Supreme Court of India mandated audiovisual (A-V) recording of the informed consent process for all clinical trials. The national regulatory body for Indian pharmaceuticals and medical devices, Central Drugs Standard Control Organization (CDSCO) together with Drugs Technical Advisory Board (DTAB) then issued an order on November 19th 2013 stating that A-V recording of the informed consent process (in addition to obtaining written informed consent)must be conducted for each study participant for all clinical trials.[1]Many guidelines were issued during the same period and one among them was on A-V recording of informed consent.[2] The original order was subsequently modified making A-V consent legally binding only in cases of vulnerable populations involved in research on new chemical entities. A section was added in the same notification that, only audio consenting (not A-V consent) was needed in patients with HIV and leprosy.[3] The purpose of the order on A-V consent recording was to bring in transparency towards the process of consenting.The A-V recording of the informed consent was then made mandatory, including the preservation and archival of the A-V recording while adhering to the principles of confidentiality. Thishas been reinforced in the recent New Drug Clinical Trial Rules released on 19th March 2019. [4]The process of audio-visual recording of informed consent is unique to India. However, the uniqueness does not invalidate its utility. The utility of this process can only be ascertained by critically examining it from the perspective of all stakeholders.[5]Allthe stakeholders (investigators, sponsors,regulators, and ethics committees) will face challenges while executing and monitoring the A-V consenting process. There is already a study published mentioning the challenges faced by the stakeholders with A-V consenting.

There are many operational challenges like infrastructure issues, ideal duration of A-V consent process, visibility of the physician and participant in the same video frame, breach of confidentiality of participants etc.[6] Concerns were expressed by investigators and sponsors regarding the process of A-V consenting, maintaining records and their accessibility to the stakeholders. In a study which recorded the perceptions of Indian investigators regarding the impact of new regulatory guidelines, 50% of them disagreed with the introduction of A-V recording of the informed consent.[7]On the contrary, another study from North India reported good experience with A-V consenting process in a vaccine trial.[8] A study from KEM Hospital, Mumbai showed that A-V recording of the informed consent process in a clinical trial appeared to improve the understanding of participants compared to those who were administered the written informed consent alone.[9]Along with the directive for A-V consent, there were expectations that investigator sites will formulate standard operating procedures (SOP) to execute to AV consent process keeping in mind the infrastructure requirements. A guidance document was also issued by CDSCO regarding conduct of A-V consent process[10], which requires IEC to ensure and monitor that the investigators for regulatory studies meet the requirements. Based on this guidance, Institutional Ethics Committees (IEC) of KEM created a checklist for monitoring A-V consenting [11].

The IECof KEM Hospital receives around 50 regulatory trials every year for review. As a part of continued oversight, IECs conduct routine and ‘for cause’ monitoring of the regulatory studies by visiting sites. With the new requirement of A-V recording of consent process, IEC members had to review A-V recordings too. It was of interest to find out how the investigator sites were implementing the new directive regarding A-V consent recording. We could not find any similar study wherein experiences of EC (Ethics Committee) members with respect to monitoring of A-V consent process were reported. It was perceived that sharing our experiences of A-V consent process monitoring will add value and make the stakeholders aware of the challenges faced by the investigators. Hence, the present study was undertaken as a retrospective analysis of A-V consent videos submitted to IEC for monitoring.

Objective of the study was to assess whether A-V recording, as well as storage and archival were performed in compliance with the existing regulatory requirements.

**Methodology:**

The current study was a retrospective study, exempted from review byIEC (IECII/OUT/324/17). The studies that were ongoing, required A-V recording of consent process and scheduled for IEC monitoring were included. The recordings of the studies conducted between October 2013 and February 2017 were analyzed. Or from Oct 2013 till Feb 2017. Strict confidentiality was maintained regarding the study protocols, details of the investigators, sponsors and IEC monitorswhile reviewing the data.The A-V consent monitoring checklist prepared for this studywas based on the CDSCO guidance document and SOP no. 15 of IEC. [10-11].It was prepared by one of the authors, was reviewed and finalized by the other two co-authors. The checklist included the following points: 1. Number of A-V consents monitored for each project.2.Adequacy of A-V recording: frame, video, and audio clarity 3. Number of relevant persons (from the studyteam) in the video – their appropriateness.4.Elements of informed consent document (ICD) covered as per Schedule Y 5. Review of confirmation of knowledge gain on the given trial by the participant. 6.Time taken to complete the procedure 7. Issues regarding maintenance of confidentiality and whether there was a need to re-consent due to amendment in protocol/ICD.

The data was entered inan adapted MS excel sheet, GraphPad InStat 3.10 Version. Data was analyzed by descriptive statistics. Association between the number of pages of the Patient Information sheet (PIS) and consenting time was analyzed by Pearson correlation. p<0.05 was considered as statistically significant.

**Results:**

A total of 23 regulatory studies were activefrom to 2013 till February 2017. When the regulation came into force in 2015,10/23 did not require A-V consent,6/23 were not recruiting.IEC had monitored only 7 eligible studies which involved A-V consent procedures.The 7 clinical studies which were monitored focused on the following therapeutic areas:-chronic non-infectious uveitis, pulmonary Hypertension, Polycythemia vera, Chronic diabetic ulcer, Cushing syndrome, Healthy infants (vaccine study), Pregnant women with Rh incompatibility(Anti D study). All of these were Phase III pharma-sponsored studies. Table 1 depicts the number of A-V consents monitored and the number of participants approved by IEC for the study.

**Table 1 – Number of A-V consents monitored and number of participants approvedby the IEC**

|  |  |  |  |
| --- | --- | --- | --- |
| Sr no | Area of Research | Reports of AV Consent Monitoring (n=85) | No. of Participants Approved by IEC (n=251) |
| 1. | Chronic non-infectious uveitis | 2 | 6 |
| 2. | Pulmonary Hypertension | 3 | 12 |
| 3. | Polycythemia vera | 3 | 4 |
| 4 | Chronic diabetic ulcer | 4 | 10 |
| 5 | Cushing syndrome | 5 | 12 |
| 6 | Healthy infants (vaccine study) | 48 | 167 |
| 7. | Pregnant women  Rh incompatibility | 20 | 40 |

The number of A-V consenting reports monitored by viewing the compact disk (CD) was 86. The authors reviewed 85, as one report was missing. 22 re-consents wereavailable and were reviewed from 5 studies. The investigators stated that there was only 10% refusal rate as found in the monitoring report.The A-V recording permission wasspecifically sought in 49 cases and it was missing in 36 cases, in the facility where the A-V consenting was taken, a dedicated room was visible in 54 of the consents while in the other 31,the consent was taken in the office/ward/OPD.

In avaccine study (n=48 A-V consent reports)where pediatric patients were recruited, the setup was not adequate in 46% cases (22/48 consents), as there was no play area for elder children. The child as participant was not seen in the frame and multiple people were seen in the room (neighbor, mother in law, husband and wife with their children).In 22% of the A-V consent frames, privacy was not maintained,especially in the study with vulnerable participants study (pediatric vaccine study).In 40/48consents,mothers posed as legally acceptable representatives (LAR)who were accompanied by their mother-in-law, and when asked about the nominee,in 20/40 caseswomen gave their name and rest of the times, they gave the husband’s name. But in 8/48 consents, where both the parents were seen in the frame, father was the LAR, the nominee there was always the father.The placement of the camera was not constant. It was flexible and the angle changed frequently. In 15/85 (18%) cases, the frame was seen upside down. The video was clear in 81/85and the storage of A-V consent was adequate as per regulatory requirement in 71/85. However, the audio was not clear in22/85(26 %) cases. There should be formal introduction of each person (person conducting the informed consent discussion with the participant/ LAR/ impartial witness) involved in the informed consent process and information about necessity for audiovisual recording. Table 2 depicts the lacunae in this aspect.

**Table 2- Findings regarding Clinical Team information and Choice of Language**

|  |  |  |
| --- | --- | --- |
| Sr no | Information | Number of Deficient Reports (n=85) |
| 1. | Name and designation of the investigator | 5 |
| 2. | Role of the investigator in the clinical trial | 10 |
| 3. | Date and time not visible on the video | 38 |
| 4. | Identity of videographer | 37 |
| 5. | Language comfortable to participant | 30 |

The Patient information sheet is an important document, which the patient should read, understand and comprehend and then volunteer to participate in the study. The studyinformation was given to the patient in an inappropriate manner in 36/85 cases and some elements were missing in 49/85as depicted in Table 3.

**Table 3 Findings regarding Lapses in Consent Process in AV Recording**

|  |  |  |
| --- | --- | --- |
| Sr no | Information | Number of Deficient Reports (n=85) |
|  | Explanationregarding the study not given | 22 |
|  | Consenting language mismatch | 13 |
|  | Information on confidentiality and privacy not given | 30 |
|  | Information on data sharing not told | 43 |
|  | Risks /compensation to be paid for study related injury | 5 |
| 6. | Right to withdraw | 3 |
| 7. | Contact details of Principal Investigator | 30 |
| 8. | Contact details of IEC | 25 |
| 9. | Nominee name missing | 20 |
| 10. | Mismatch with the actual information mentioned in ICD | 6 |

A-V recording was individualized in 74/85cases. In 50% of cases, the participant read the consent document and ample time was given to think and consent. Doubts were answered satisfactorily in 50%, and in 75 % the process of obtaining signatures is seen. But in 44% cases, patient understanding was not checked. The time required for signature ranged from 0.42 mins to 12.18 mins.

The duration of consent was 20.03 ± 10.83 minutes (N=85) and the number of pages were 14.24 ± 7.52. There was a weak correlation between the pages of consent and the duration of consent (R= 0.29 p = 0.041). The duration of re-consent was also 5.99 ± 3.3 minutes (N=22).In 21 cases more than one session was undertaken (range 2-7)sessions. In 22 cases, there was re-consenting, non-maintenance of privacy was not maintained (2) and the reason for re-consenting was not explained (1). In rest of the cases (n=19), the reconsent was satisfactory as per the checklist.

**Discussion:**

This was aretrospective analysis of A-V consent monitoring reports of an IEC working at a tertiary care hospital. TheIEC had monitored all the studies involving A-V consent procedures. This highlighted the due diligence on the part of IEC which continued to monitor conduct of research studies.There were lots of reservations when the gazette notification regarding A-V consent requirement came into force. There were issues regarding its feasibility to Principal Investigator(PI) and acceptability to participants.Nowhere in the world,A-V consent is mandated except in the US, wherein video recording is required only when the participant is illiterate(12).Few thought that it is a boon as it safeguards both the participants and the investigators(13). The authors had assumed that there would be refusal to participation as found in a study from South India,wherein 39% refused A-V consenting (14). However, in the present, the refusalwas in 10% as was reported by another study in North India (8).

Only 85/251 samples from the 7 approved studies were monitored during the study period. All the consents were not monitored, because it was not feasible for the ECs. Only a few random samples of A-V consents were monitored. Nearly 50% of the samples recruited were monitored to get to know what exactly was the situation at site when there were no guidelines published regarding the site requirement during A-V consenting, time duration to be followed as so forth during 2017. There were 5 studies in which reconsenting was done by A-V process in 22 patients. Maximum patients monitored were in pediatric vaccine trial (n= 48) and pregnant women tested for Anti -D drug (n=20).In vaccine study, we found male preponderance while giving the name for nominee and found that women were uncomfortable or were interrupted by the husband while asking questions, reflecting the principle of autonomy. In pregnant women study, the patient information sheet was read from the start to the end without anything being explained.At the end,the participant was asked for comprehension and signature. The women never questioned the investigator.There can be two possibilities in such a scenario, firstthat the women understood everything or second that she is so inhibited or over drawn to ask questions. Ideally before the commencement of A-V recording, investigator needs to take consent and the same should be recorded and seen in the video, however 42% of the times consent was not taken as depicted in the video. It is possible the PI had taken permission before starting the recording. As per the regulatory requirement, a dedicated room has to be given for A-V consenting, wherein a camera is permanently fixed for recording. In this study, the authors noted that in 36% cases, the room was not constant in pediatric trial which can take a toll on participant privacy, while in other studies the setup was adequate. The setup was again not adequate in pediatric study, because they could not engage the elder child which could have come in the way of consenting procedures. Multiple people related to the patient were seen in the frame,which can impinge on the issue of confidentiality. The child as participant was not seen in frame and as per the guidelines, everyone involved in the trial – participants, their LAR and impartial witness should be seen in the frame. The study by Shetty etal has mentioned in their A-V consenting experience that this may not always be possible with a sick or irritable child and that can preclude A-V consenting [6], but the argument in such cases would be anyway that a sick child is never included in a vaccine study and if we want to show the child in the frame,it can be for a moment and then the child can be on his own or handed over to the relatives. In 22% of the A-V consent frames, privacy was not maintained especially in a study with vulnerable participants. This was happening because there was no dedicated place for consenting and every time the place changed. There were intrusions from residents, staff, MBBS students,other patients and relatives. As per A-V recording guidelines, the audio-visual recording should be conducted in a room conducive for recording with disturbance-free audio and video of the consent process should be undertaken. During thevideography process, care should also be taken not to include unrelated persons/patients at the hospital within the field of vision.

A good practice was that the video was clear and stored properly,so the regulators and EC could monitor whenever they wishedand it was as per the regulation. Another good practice was the individualization of A-V recording in 74 cases. But the audio was not clear, which again doubts the credibility /quality of 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. There should be formal introduction of each person (person conducting the informed consent discussion participant/legally acceptable representative (LAR) / impartial witness) involved in informed consent process and information about requirements for audiovisual recording ‐ by name, designation and his/her role in the research, current date and time, identity of videographer. Consideration for language comfort which was missing in the study.The AV recording frame also did not have date and time which leaves scope for manipulation. Complete information should be given to the participants, based on which he /she will comprehend and volunteer to participate in the study. There were many missing elements in the patient information sheet which were not conveyed to the patient. The participant autonomy and decision-making capacities are based on the information provided. The basic elements of autonomy, voluntariness and factors governing patient safety were not properly handled in the study. 50% of the times the participant read the consent document and ample time was given to think and consent, doubts were answered satisfactorily, and in 75% cases signature procedure was seen. But in 44%, patient understanding was not checked which is mandatory as the guidelines. The time required for signature ranged from 0.42 seconds to 12.18 mins. The consenting time depended on the number of pages of ICD. When number of pages and consenting time was correlated, there was weak correlation between the pages of consent and duration of consent. It means that the timing was not according to number of ICD pages since the pages ranged from 7 to 21,so the minimum time required should be atleast 30 min to 1 hour, but it was 20.03 ± 10.83min. Also, in one study it was seen that the investigator gave the ICD to the patient, and the patient read the ICD in 2 minutes and then signature was asked bythe PI and the participant obliged. There was absolutely no conversation between the PI and the participant (n=4, Chronic diabetic ulcer study). This again bringsthe scope of creating site specific SOPs for A-V consenting, training the team in consent process, creating site facility and participant sensitization in A-V consenting as emphasized in KEM study (6). In 21 cases, more than one session was required (2-7), which means that adequate time was given to the participant to comprehend and participate in those studies. Grady etal(15) had raised concerns regarding the feasibility in time, sessions,visibility of face,audio recording and maintenance of privacy during the A-V consent process and we found lot of deviations in all these aspects.In 22 cases, there was reconsenting, but privacy was not maintained in 2 cases and reason for re-consenting was not explained. Atleast here the investigator had understood about the situations where re-consenting has to done.Ganguly (16) and Ghooi (17) had concerns regarding execution of A-V consenting, but our study reports a good experience.

**Best Practices**

Post law amendment in A-V consenting, the stakeholders namely, the PI andthe IECwere accountable and responsible in undertaking A-V consenting in studies with vulnerable population and new chemical entity as well as in archiving and allowing monitoring by IEC and regulator.

**Research Agenda**

We assessed whether Audio-Visual (A-V) recording, storage and archival are performed in compliance with the existing regulatory requirements and tried to find the investigator’s hurdles in undertaking it. Based on this study,IEC has made a checklist conducive to the investigators and included it in the IEC SOP. The investigators sites with good practices were sent appreciation letters and the sites with issues were sent rectification letters. Regulators might take a note of it.

**Educational Implications**

A-V consenting came into existence for increasing reliability, transparency, & improving the quality of conduct of informed consent process and increasing society’s faith in clinical research. IEC and investigators are meant to follow this rule and because of this study, we have recommendations specific to each stakeholder. For investigators - creating site specific SOPs,training the study team to conduct A–V consent process, maintaining site facility and sensitizing participant to AV consent process. For IEC - SOP for A-V consenting review process, regular monitoring of the studies which involve A-V consenting along with appropriate actions to be taken against defaulter with investigator education. Recommendations for regulators - preparing checklist for AV consenting process and providing it to investigators and IECs to maintain uniformity, monitoring of the studies which involve A-V consenting, taking appropriate actions against defaulters and investigator and IEC.

**Conclusion:**

There was an attempt to follow the A-V consenting regulation, but we found deficits in facility, execution of consent process with regards to giving information, lending timeand maintaining privacy and confidentiality.

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