Opinion

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Ensuring that informed consent is really an informed consent: Role of videography

Abstract

The voluntary consent of a subject participating in research is fundamental to the principle of autonomy. This consent must be free from any coercion, intimidation, falsehood, physical, psychological, or economic pressure. It is in the interest of the subject, the investigator and the sponsor to ensure that informed consent processes conform to the guidelines and regulations, both in the letter and spirit. However, ignorance on the part of investigating team causes deviation from these norms. Videography of the entire process has been suggested as a means to ensure the compliance, and draft rules for the same published. The present article examines how best videography can be introduced in the informed consent procedure without violating other protective mechanisms.

Key words: Confidentiality, ethics, informed consents, subject protection, videography

INTRODUCTION

The concept of informed consent was first introduced by the Berlin Code in 1900,[1] and by the time this was published, Walter Reed had actually used informed consents while studying the transmission of Yellow Fever.[2] The Guidelines for Human Experimentation, Nuremberg Code, the Declaration of Helsinki, and all ethics guidelines that followed made voluntary informed consent a precondition to recruitment of subjects.

Regulators across the globe have identified essential elements for the informed consent documents and incorporated them in their good clinical practices. To a conscientious investigator, this is adequate to administer the consent in a fair and just manner. 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,[3] or incompetent participants were recruited.[4] There are special problems of informed consent when trials include illiterate participants,[5] or those who are not conversant with the languages known to the investigating team.[6]

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The problems of informed consent are acute in India where investigator apathy[7] is compounded by lax regulatory oversight.[8] As a result participants in trials are not clear about confidentiality, compensation, and protection of human subjects.[9] There are problems with the conduct of the process,[10] and despite the essential elements being present in the informed consent form (ICF), there are doubts if subjects are provided with adequate information.[11]

In response to public outcry over alleged unethical practices of clinical research in India, the regulator has taken a host of measures to increase the transparency of research, and enacted three amendments to the Drugs and Cosmetics Rules of 1945. A proposal for videotaping the entire process has been under consideration, and draft rules for the same have been published.[12] The final rules will be passed 45 days after the publication, a period that has already lapsed, and the rules can be expected any day now.

The draft rule is a simple sentence stating: *"An audio-video recording of the informed consent process of the individual subject, including the procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record."*

As expected there is a furore among investigators, Institutional Review Board (IRB) members and trial managers, all hotly contesting the proposal. The proposal is opposed on the grounds that it will lead to logistic problems, lead to refusal of consent by many subjects, increase costs of trials, and violate confidentiality. Past experience with draft rules is variable. The government may or may not make changes while finalizing the rules based on the draft. In the eventuality of this draft rule too being finalized without change, the stakeholders should be ready to implement it in a manner that will take care of problems that may crop up.

Videotaping

Videotaping of consents is commonly done for transplants,[13] but not of those for research. The fact that the process is being videotaped will make both the informed consent process administrator and the participant careful. Elsewhere videotaping has been found to increase the conformation to norms,[14] hopefully the same may happen here. The investigative team member will ensure that no mistakes are made, since the process is being recorded. Videotaping may thus prove to be a deterrent to any violation that would have otherwise taken place.

Subjects' opposition

An important apprehension of trial managers and investigators is that some participants may not agree to be videotaped. In private consultations, minority (14.1%) of patients have been shown to refuse consent for video recording; younger patients and those with mental health problems were more likely to do so.[15] In another study, 11% patients objected to video recording of their consultation.[16] Thus, fear that subjects may object to video recording is well-founded, and needs to be addressed.

The person administering the informed consent will need to convince the subjects that video recording is meant for the subject's safety. Subjects should be informed that their consultation, or physical examination by the physician will not be recorded, but only the discussion that leads to consent will be. New strategies will have to be developed to allay the fear of subjects, assuring them of confidentiality of the video records. The subjects may have to be reassured that video recording is commonly resorted to and that there is no reason to fear it.

In most cities today, public places like airports, railway stations, cinema halls and shopping centres have installed close circuit televisions (CCTV). Their recording is used to increase safety of the people, and reduce crime. There does not seem to be any apprehension among people while entering such places, and hopefully resistance to video recording consents may not be there.

The draft rule does not specify how the recording is to be made. It is not clear whether the intent is to identify each and every subject, or is it to verify if consent process is proper? It is not specified if the full face of the subject should be captured or a silhouette, a profile or even a shot from the back will do? A clarification on this will make it easy to implement the rule.

Expense

Clinical trial sites are worried about the increased cost due to videography. In photography, the maximum expense was due to the recurring expense on film, but the newer digital recording devices have made the expensive film redundant. The cost of cameras has come down significantly and webcams are now available for a few hundreds. Most new models of laptops come with built in webcams and security cameras have been installed in homes, shops, and community centers. Thus, while additional expense will be required of the sites, this will be very minor compared to trial related expenses. Many hospitals are already under electronic surveillance, and all that is required is to wire the room/rooms where informed consents are administered.

Confidentiality

Photographs of all sorts often find their way on the internet. Though they are valuable, they are a potentially harmful resource.[17] Photography is routinely used in dermatology, and it has been reviewed for its potential for abuse and found to be safe.[18] Video recording of numerous procedures is now being made and archived for teaching and quality assurance purposes.[19,20]

The fear that video recording will violate confidentiality is valid, but there are ways and means of protecting confidentiality. The most effective method will be to control access to recorded informed consent process. The video recording should be stored on password protected CDs, which would be in the charge of the Principal Investigator. Access to these CDs should be restricted to three sets of people only, namely

- Members of the IRB, that granted the approval for the trial
- Designees of the regulator who has approved the invesitgational new drug (IND)
- Courts whose jurisdiction cover the trial.

Monitors or auditors should have no access to these CDs, but they will continue to have access to ICFs signed by the subjects.

Access control of CDs in which informed consent has been recorded will protect the confidentiality of the participants, preventing accidental or intentional disclosure. The records will also provide evidence that the informed consent was conducted as per the guidelines, and will protect both the participants and the investigators from allegations of unethical conduct.

Advantages

Cameras have moved out of studios and into hospitals long back, though the ethics of their use is hotly debated.[21,22] A framework for evaluating their efficacy, associated ethics, and concerns of informed consent has already been worked out.[23] Videos have been demonstrated to improve the decision capacity of patients undergoing elective surgery.[24] A video record of the informed consent process will protect both the subjects and the investigators.

Disadvantages

Video recording has not been used anywhere for recording the interactions between the subjects and the investigator during consent process. It is hoped that it will improve the robustness of the process, but there is no hard evidence that it will do so. There also exists a possibility that some subjects my refuse to consent, thus affecting recruitment.

CONCLUSION

Videography of informed consent is another mechanism intended to improve the quality of informed consent process. Though it might be difficult to monitor the process through videotaping, it may prove a deterrent to investigators who violate the laid down procedures. Before adopting this procedure, a few measures to protect confidentiality of the subjects need to be taken. Once the videotaping of consents begins, new problems may crop up which will have to be addressed. The regulators should keep an open mind, to tweak the rule if necessary and abandon it if it does not improve the quality of the informed consent process.

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