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Informed Consent on Camera

Sir,

Informed consent (IC) is one of the most important components of ethical research in human participants. Even though it is mandatory to obtain a freely given "written IC" from each study participant before he/she is enrolled in a clinical trial, which includes explaining pros and cons of participation, currently there is no objective measure to ensure that the same has been followed in letter and spirit. Often researchers do not obtain proper IC, because they just see it as a signature at the bottom of the form and not a partnership.[1] The gravity of the situation further increases in a scenario where majority of the research participants are not properly educated, they may lack understanding and comprehension and hesitate to ask questions even if they are not satisfied.[2]

With the aim of improving this situation, recently India's Drug Technical Advisory Board for clinical trials proposed that the investigator should make audio/video recording of the procedure of obtaining IC of the individual subject and maintain it for record.[3] The board after deliberations have agreed to the following amendment in Schedule Y of the Drugs and Cosmetics act.

"In sub-para (4) under the caption "Informed Consent", under para 2. Clinical trials, the following clause may be inserted: "An audio/video recording of the informed consent process of individual subject including procedure of providing information to the subject and his understood consent shall be maintained by the investigator for record."[3]

Such a step will help to verify that at the time of enrolling the participant in a clinical trial, he/she was well-informed about the positive and negative aspects of such participation.

This amendment in the process of IC made by the regulatory authorities appears to be interesting and it seems that this will certainly be useful in resolving various concerns that are currently raised about the IC process. On the contrary, certain issues may arise as a result of this amendment which needs to be considered.

First, video recording of the consent process involves identification of the participant.[4] This may be objectionable considering that maintaining confidentiality of research participants is one of the prerequisites of clinical research. It is essential to maintain the dignity and welfare of participants and there may be a possibility of stigma and other social problems if confidentiality is not maintained. But this can be resolved if confidentiality of records (audio/video) is properly maintained and they are available only to concerned authorities. Only audio recording of the IC process would have the advantage that it is difficult to identify people from voice recordings which would help in maintaining confidentiality of the participant but at the same time since it is easy to tamper with voice recordings authenticity of the evidence can be questionable.[5] Video recording has a clear advantage in this respect.

Second, sometimes even a video recording may not be able to identify whether the participant understood the research study or not.[4] Though the amendment states "understood consent," it is difficult to have any objective evidence for the same. The video recording may show that the participant has actually understood but even this can be based on what he/she has been told to speak in front of the camera, prior to the recording. This may be particularly applicable in scenarios, where majority of prospective research participants are poor, needy, and illiterate people who may be easily lured into clinical trials for meager incentives which may be more important for them than health and hence, they may be only interested in what monetary returns they are getting rather than knowing the details of the research process. Studies have reported that even after using various audio-visual aids to explain the research process to the participants majority of research participants who have given IC have not actually understood their rights as participants or the methods of their treatment allocation in the trial.[6] This indicates that simple audio/video recording of the IC process cannot be an evidence of an "understood consent." Hence, the method of obtaining an "understood consent" needs to be specified.

Thus, many issues may remain debatable, but it is certain that this new amendment will help to document the process of IC as it will provide direct evidence about how the clinical trial was actually presented to the potential participants.[4] This seems to be an interesting exercise which would to a certain extent help in restricting unethical practices in biomedical research. In spite of all pros and cons, this appears to be a crucial step which will be of great consequence as far as ethics in clinical research is concerned.

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