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Video consent to be mandatory for CROs in India

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New Delhi: The Indian health ministry will soon amend the Schedule Y of Drugs and Cosmetics (D&C) Rules to make a provision for audio and video recording of the informed consent in clinical trials. Once the necessary amendments are done by the ministry in this regard, the audio and video recording of informed consent will become mandatory in the country.

Furthermore, the audio and video recording of the informed consent process of individual subject, including procedure of providing information to the subject and his understood consent, should be maintained by the investigator for record.

Aimed at ensuring proper care for the clinical trial participant, the video consent will record that the subject has been well informed about the pros and cons of the clinical trial and that participation is voluntary. This will also serve as a proof in case there is any trial death issue later on.

The Drugs Technical Advisory Board (DTAB), the highest authority in the union health ministry on technical matters, has already given its approval to the proposal of the Central Drugs Standard Control Organization (CDSCO) to amend Schedule Y of the D&C Act to insert a clause, "An audio and 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."

Although it is mandatory under Schedule Y of the Drugs and Cosmetics Rules to obtain a freely given informed, written consent, from each study subject before he is enrolled in a clinical trial, in the absence of audio and video proof, there have been complaints of misuse of this provision by the companies who are engaged in clinical trial business. There were reports that many times the informed consent was taken from the participating subjects without informing them the pros and cons of the trial.