Electronic informed consenting: A boon to modernize consenting process

The informed consent process is essential to the ethical conduct of clinical research of new medicinal products. It is an ongoing conversation between the human research subject and the researchers that begins before consent is given and continues until the end of the subject's involvement in the research. There are various tools for the investigator to use to optimize this conversation, but the most important feature of informed consent is the investigator commitment to the process.

In March 2015, US Food and Drug Administration (USFDA) released a draft guidance document with recommendation for clinical investigators, sponsors, and Institutional Review Boards (IRBs) on the use of electronic media and processes to obtain informed consent for clinical investigations of medicinal products.[1] As per this guidance, electronic informed consent (eIC) refers to using electronic systems and processes that may employ multiple electronic media including text, graphics, audio, video, podcasts and interactive web sites, and card readers, etc., to communicate information related to the study and to obtain and document informed consent.

This initiative is certainly going to improve the understanding of the study by the patients before agreeing to participate in a study. The guidance also includes recommendations on procedures to help ensure protection of the rights, safety, and welfare of human subjects. This guidance is an effort to enhance human subject protection and reduce regulatory burden.

As per this guidance, the system that supports e-IC must be secure with restricted access and should include suitable methods to ensure confidentiality regarding patient's identity. It recommends that subject's information within the system must be encrypted unless it is precisely documented why encrypting is not reasonable in the specific case and circumstances.

FDA recommends that e-IC process should incorporate procedures to ensure that electronic documents can be archived appropriately, and all versions can be retrieved easily. The system should also have audit trail capability.

An e-IC is bound to streamline enrolment, provide real-time enrolment statistics, and greatly improve quality and ethics concerns.

An e-IC process often uses interactive interface, which substantially enhance the subject's ability to understand, retain, and comprehend the study information. The use of technology brings immense strength, insight, and integrity to the consenting process.

An e-IC process using web applications or electronic tablet devices such as an iPad is growing in popularity. Three key stakeholders in developing e-IC include sponsor, vendor, and IRB. Vendor plays an important role in making the tool simple and easy for the patients enrolled in clinical research.

Good news is that technology savvy vendors are ready with products for making this happen as soon as a sponsor would decide to shift to the new e-IC process. Many innovative technology companies are into pioneering patient-centered technologies that enable people to participate in clinical trials in a better informed and more convenient way. Such products have to be validated for compliance with United States of America's Code of Federal Regulation 21 Code of Federal Regulations part 11 requirements for electronic records and signatures.[2] Gateway technology that allows critical disclosure information to be converted into an easy to understand digitized format using animation, interaction, and visual imagery are being used by some vendors while developing suitable quality products.

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Western Institutional Review Board (WIRB) reviews E-informed consent technologies during development as well as in their final form to ensure that they meet the regulatory requirements, and the key elements, and documentation of consent.[3]

FDA regulations require that IRB/Independent Ethics Committee review and have the authority to approve, instruct revision or modification, or disapprove a study. Sponsors and investigators considering E-consenting option have to obtain IRB/Ethics Committee approval of the consent document text prior to developing the electronic consent tool. Revisions based on IRB feedback are easier to implement before E-consent programming, and animation has begun. For a typical E-consent IRB submission, the sponsor and E-consent vendor should jointly prepare the IRB submission of materials. Typical submissions include scripts for any video or audio files, a guide for researcher's storyboards for any planned video creation, content for any screens on the E-consent tool that will be viewed by the patient.

The IRB's decision to conditionally approve versus defer will depend on the extent to which the draft version reflects the content of the final electronic version. If the bulk of the electronic process has been provided in draft text or in storyboards, then the IRB can conditionally approve the consent form. However, if there is still substantial content to be developed, then the IRB may defer the consent form for future board review. Sponsors typically should ascertain how much time and resource they need to commit to developing an electronic consent before seeking an IRB decision. The most optimal process is for the sponsor to provide in writing to the IRB a complete description of the electronic consent process, with storyboards for videos if applicable. Then the IRB will likely be able to provide conditional approval and have a single individual review of the final product. If the final step is solely the transfer of the IRB approved consent form to the tablet, without any modification of the text wording, the IRB does not have to conditionally approve the consent form and does not have to review the final version of the consent form on the tablet. The IRB can issue a final approval of the consent form. If there are photos or audio materials to add to the final version, then the IRB should review the final electronic version.

In India, we have a big debate about several ethical and practical issues in audio visual (AV) recording of consent. Kulkarni *et al.*,[4] have enumerated their opinion on advantages and challenges of recording of consenting process. Advantages listed by them include safeguarding the participants, simplification, reliability, and transparency of the informed consent process. The challenges listed includes lack of infrastructure at government institutions, interpretation of patient's behavior on camera, compromising confidentiality, and the record being vulnerable to tampering and cost implications.

One noteworthy feature of this USFDA guideline is the format. The guidance document includes 14 key questions which may crop up while implementing the e-IC process. This augurs well for the stakeholders for the easy implementation of this guidance. Central Drugs Standard Control Organization (CDSCO) can adapt such a format and provide guidance on the process of AV recording of consent. CDSCO would be doing a yeomen service to all stakeholders if it follows this approach while introducing new regulatory requirements. This would not only result in faster implementation but also would save a lot of time and energy of all stakeholders including CDSCO officers as holding meetings to provide clarification on guidelines would no longer be required.

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