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NEWSLETTER

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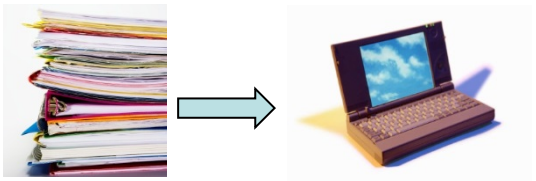
IRB Proposal in India: Implementation of an IT-enabled system for submission of clinical trial information

The Central Drugs Standard Control Organization (CDSCO) in New Delhi, India has recently proposed for the creation of an information technology (IT)-enabled system to submit clinical trial information to regulatory authorities. According to the CDSCO, the overall goal of this system is to increase transparency and patient safety, which will ultimately improve the quality of clinical trials in India and ensure accountability among stakeholders.

With this IT-enabled system, the sponsor/applicant, investigators, ethics committee, and patients all input information into a common database before, during, and after a clinical trial (summarized in Table 1).



Once the information is put into the database, a unique identification number (UIN) specific to the particular trial will be generated and shared among the sponsor/applicant, investigators, and ethics committee to ensure prompt updates of any part of the trial. These updates include details of enrolled patients and serious adverse events (SAEs), the minutes of ethics committee meetings, and specific guidance for sponsors and investigators throughout the trial. The CDSCO will also use the UIN to keep track of the trial information in the system and may temporarily suspend trial recruitment or execute disciplinary action on the sponsor, investigator, or ethics committee (depending on who is accountable) if the database is not updated properly.■

Table 1. Summary of information submitted before, during, and after a clinical trial.

Before
• Trial identification
• Sponsor identification
• Investigational product information and description of each product used
• Authorized sites responsible for the release of the investigational product
• General trial information (specific medical condition or disease studied, scope of the trial, trial type and phase, trial design and compensation policy)
• Subject population (age gender, health status, planned number of subjects and names of other participating countries if applicable).
• Information on the investigator(s) and ethics committee
• Informed consent document
During
• Trial initiation date
• Data safety monitoring board (DSMB) details
• Name and contact information of the trial monitor
• Ethics committee opinion, date of clinical trial approval/rejection
• Amendments to protocol or requests
• Trial subject details, including actual number, age, gender and population of subjects enrolled and randomized
• Details of trial subjects and any SAEs
After
• Declaration of the end of the clinical trial
• Inspection of the clinical trial site
• Inspection of the investigational product manufacturer/importer
• Patient-wise details of significant adverse events

FDA Issues Memo: Informed consent and individual provisions for IRBs

All FDA-regulated clinical investigations involving human subjects (with the exception of certain limited circumstances) require that the subject or the subject's legally authorized representative (LAR) provide informed consent before participating. The FDA has recently updated its guidelines on the informed consent process to specifically address IRB provisions necessary for ensuring the process meets FDA regulatory requirements.

Basic elements of an informed consent document include a description of the clinical investigation; risks, discomforts, and benefits of participating; alternative procedures and treatments; a statement of confidentiality; information on compensation and medical treatment in case of an injury or adverse event; contact information for subjects to

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address pertinent questions or trial-related adverse events; and a statement clarifying that participation is voluntary.

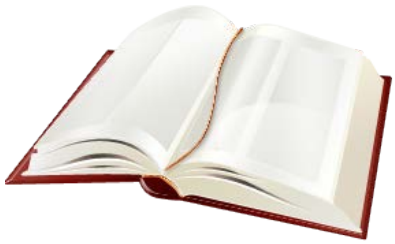
However, informed consent is more than simply obtaining a signature. Informed consent also involves providing the subject or LAR with enough information to make an informed decision with minimal coercion or undue influence. Informed consent should answer questions, allow sufficient time for the subject to consider participation, and continue to provide information to the subject as the situation requires. The language of the informed consent form must be understandable to the subject or LAR and cannot indicate that the subject's legal rights are waived by participating in the study.

IRBs play an essential role in facilitating ethical and productive clinical trials. They must review and approve, request modifications, or disapprove of all research activities covered by IRB regulations. A major component of this role is ensuring the informed consent process meets FDA regulatory requirements. Thus, the recently updated FDA guidelines recommend IRBs employ the following provisions:

1) Review of Informed Consent Materials. IRBs must review all materials used to obtain informed consent, including recruitment materials and documents providing supplemental information. The wording, length, and presentation of information must be adequate and appropriate for the potential subjects.

This may require explanation or substitution of technical or scientific terms with common language, or use of pictures or diagrams to improve understanding.

The IRB must also address institutional requirements and applicable federal, state, and local laws and regulations. Thus, institutions may develop a standard language or format to use in parts of all consent forms.



2) Review of Consent Process. IRBs are responsible for ensuring the materials and procedures used for subject recruitment and informed consent allow sufficient time for subjects to consider the information, ask questions, and decide whether to participate. IRBs should inquire who will conduct the consent interview, the procedures they will use, and if necessary, require the use of a third party to observe the consent and research procedures to enhance subject protection.

Additionally, IRBs must ensure recruitment incentives are appropriate for the time commitment and study procedures without being unduly influential to potential subjects. For clinical investigations, the IRB must ensure that informed consent is obtained and appropriately documented from each subject or LAR.

3) IRB Review Procedures. Changes in the research information or the clinical investigation may affect subject rights or welfare. IRBs should implement timely and effective review procedures to review and approve any changes to the consent form and to ensure that subjects receive new information relevant to their participation. IRBs should also use a mechanism, such as date stamping the consent form, to ensure the most recently approved version is used for all future subject consents. ■

Fun Fact: ***Your body gives off enough heat in 30 minutes to bring half a gallon of water to a boil.*** If you've seen the Matrix you are aware of the energy potentially generated by the human body. Our bodies expend a large amount of calories keeping us at a steady 98.6 degrees, enough to boil water or even cook pasta.

Contact IRBco.

Interested in learning more about IRBco? Our team is ready to answer your inquires regarding your organization's specific IRB needs.

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