Clinical Trial ... and Error

Clinical Score leads the industry as a "voice of the sites" by gathering front-line opinions and observations from Study Coordinators and other Clinical Professionals.

Using Correct Consent Form Versions

The Situation This morning an asthmatic patient visited his regular pulmonology clinic. After discussing his treatment options with his medical care team, he was consented to participate in a clinical trial testing the efficacy of an investigational steroid regimen. The research nurse consented the patient using a version of the consent form that she printed out 3 months ago and left in a file on her desk. Unfortunately, this version of the consent form was now obsolete.

During the previous month an amendment was released by the Sponsor, significantly changing the risk profile of the investigational agent. It was subsequently approved by the local IRB which issued a revised version of the consent form.

The Corrective and Preventative Action Plan Consent form version control is an essential part of good clinical practice and regulatory oversight. The most important next step in this scenario would be to contact the patient as soon as possible to discuss the new risks of the investigational drug regimen. Then (assuming the new risks are not a deterrent for the patient to stay on trial) obtaining signatures on the appropriate consent form as soon as practical. After the patient is correctly consented, the IRB should be notified of this error in the consent process.

To prevent future consent form issues, the following strategy should be employed: The use of the current IRB approved consent form should be utilized in all patient interactions. Consent forms should not be copied in bulk but individually in real time, ideally by the team member who is responsible for the regulatory coordination of the trial. If an online portal is utilized, a confirmation discussion of the correct version should take place between a clinical team member and regulatory team member prior to the patient visit. If investigators and other clinical staff are insistent on keeping a copy of the consent form in the patient office, then the recommendation would be to provide the consent form without the signature page. A successful strategy can be obtained with effective internal communications.

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