Quorum REVIEW IRB

When Performance Matters

eConsent in Clinical Research.

Considerations When Planning eConsent Implementation.

When considering the use of eConsent processes and systems in clinical research, early planning and close coordination is important. A carefully planned implementation process involves choosing the eConsent approach that works best for the study, the sites and the patients involved, and working closely with the IRB to understand the review processes for using eConsent, including how the eConsent system may impact IRB review and steps involved in meeting documentation requirements.

To have a smooth IRB review, talk to the IRB about review and documentation requirements for eConsent and the IRB's background in reviewing eConsent materials and documentation.

Questions to Consider When Talking to the IRB:

- Has the IRB reviewed eConsent previously?
- What additional documents or forms does the IRB require to review eConsent?
- What additional information does the IRB require to review eConsent?
- How will the IRB review the eConsent?
- What file requirements (format and size) does the IRB have?
- What are the expected timelines for review of the eConsent? Will it take longer than the review of a paper consent?
- Does the IRB have any specific restrictions or requirements related to eConsent that we should be aware of?

> "The informed Consent process is more than just a signature... It is a process of information exchange... IRBs, clinical investigators, and research sponsors all share responsibility for ensuring that the informed consent process is adequate... The consent document should be the basis for a meaningful exchange between the investigator and the subject."
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> – FDA Information Sheet, "A Guide to informed Consent," available at: www.fda.gov/RegulatoryInformation/Guidance/ucm126431.htm.

1501 Fourth Avenue, Suite 800 | Seattle, Washington 98101
T 206.448.4082 | F 206.448.4193 | QuorumReview.com

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