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Ask the Experts: IRB View of eConsent and eSignatures

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This monthly feature presents questions from clinical trial professionals with answers from experts. In this issue, we feature insights from WCG IRB Chair Erin Brower on the differences between eConsent and eSignatures.

Question: *What does eConsent mean to IRBs?*

Answer: eConsent can refer to the process by which a participant's signature is obtained and documented electronically, and it can also refer to other aspects of the informed consent process. eConsent can describe the exact representation of the IRB-approved document on an electronic device as well as refer to a consent process using electronic devices and audio-visual aids. HHS's Office for Human Research Protections and the FDA have issued a joint guidance titled Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers.

Question: *Is there a difference between eConsent and eSignatures? Is it the same as remote consent?*

Answer: There is a difference between eConsent and eSignatures, but often the terms are used interchangeably, which can lead to confusion. eSignature is specific to the documentation of consent, while eConsent refers to the process of consent that includes technology and can support or replace a face-to-face, wet-ink signature process.

In the draft guidance, "Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions and Answers," the FDA defines eSignature as "a computer data compilation of any symbol or series of symbols executed, adopted or authorized by an individual to

be the legally binding equivalent of the individual's handwritten signature." The FDA does not define eConsent.

eConsent can be used as part of a remote consent process, but remote consent does not necessitate that eConsent is utilized. For example, informed consent obtained via a telephone conversation with a paper copy of the signed consent mailed to the research site would be an example of remote consent that is not eConsent.

Question: *Does eConsent or remote consent require IRB review and approval?*

Answer: Yes. The consent process and any modification to the prior approved consent process must be submitted to the IRB for review and approval. Additionally, the IRB must review and approve the eConsent materials, including consent language and any modifications to the eConsent materials that the participant will view or receive.

The IRB must also review any eConsenting tools used in conjunction with a paper or eConsent, such as questions or methods used to gauge participant comprehension of key study elements. If an approved static consent form will not be altered, but will be uploaded to an electronic platform, the document does not need to be submitted as an eConsent. However, if additional technology is used to obtain consent when a static consent form is used, the process is considered eConsent, and how eConsent will be utilized in this scenario must be reviewed by the IRB.