FDA Draft Guidance on Electronic Informed Consent

06-22-15 • alert • katherine leibowitz

If your company will sponsor trials at research institutions using electronic informed consent (eIC), please see the FDA draft guidance entitled, "Use of Electronic Informed Consent in Clinical Investigations; Questions and Answers; Guidance for Industry" released in March 2015. The draft guidance is an effort to harness new technologies to conduct the consent process, such as texts, graphics, audio, video, podcasts, interactive web sites and card readers. It is part of FDA's efforts to work with OHRP to harmonize regulatory requirements and guidance relating to human subject protection.

For clinical trial sponsors, some highlights include:

– eIC is a process, all stages of which must comply with the FDA regulations;

– Electronic signatures must comply with 21 CFR Part 11, a complex regulation that poses logistical problems for many trial sites;

– HIPAA authorizations may also be signed electronically if they are valid under applicable laws and regulations, such as E-Sign (consider whether the eIC process also complies with HIPAA);

– For IDE submissions, sponsors must include copies of all forms and materials provided to subjects as part of informed consent, and this will now include the eIC materials; and

– Subject identity authentication/nonrepudiation, data integrity, privacy and security are paramount for the eIC process.

While eIC should make the consent process more efficient, making sure the research institutions have appropriate measures in place to meet FDA requirements (including this draft guidance and Part 11) and industry standards will be a challenge. Sponsors will want to work with investigators and the institutions, including IRBs that have oversight responsibility for informed consent, to ensure the requirements are met.

If you have any questions or would like more information about these developing issues, please contact the following:

KATHERINE LEIBOWITZ
1-610-896-5788
Katherine.Leibowitz@LeibowitzLawTeam.com