

May 5, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2015-D-0390 -- "Use of Electronic Informed Consent in Clinical Investigations: Questions and Answers" Draft Guidance

Dear Sir/Madam:

The Association of Clinical Research Organizations (ACRO) represents the world's leading, global clinical research organizations (CROs). Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices – from discovery, pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. With more than 110,000 employees engaged in research activities around the world, ACRO advances clinical outsourcing to improve the quality, efficiency and safety of biomedical research.

Each year, ACRO member companies conduct more than 9,000 clinical trials involving nearly two million research participants in 142 countries. On average, each of our member companies works with more than 500 research sponsors annually, and we have a broad and unique understanding of the roles, responsibilities and behavior of all the stakeholders – research sponsors, investigators, Institutional Review Boards, clinical trial participants and ancillary providers of all types – that are part of the research enterprise.

Representing companies that routinely interact with IRBs, clinical investigators and sponsors, ACRO thanks the FDA for the above-referenced draft guidance, which advances two critical components of the mission of ACRO member companies during the clinical trial process: (1) human subject protection and (2) data quality and integrity.

Electronic Informed Consent Draft Guidance Complements the 2014 Informed Consent Information Sheet Draft Guidance

We thank the Agency for this draft guidance on electronic informed consent (eIC), which -- together with the 2014 draft guidance on informed consent information sheets¹ -- provides recommendations for advancing the subject's comprehension of the information presented during the informed consent process. The 2014 draft guidance focused on *the "what"* -- understandability and language. That guidance elucidated the requirement (at 21 CFR 50.20) that the informed consent must be in language, and at a reading level, understandable to the subject -- underscoring the number of adults who have basic, or below basic, health literacy and basic, or below basic, quantitative literacy.

This 2015 guidance on eIC explains *the "how"*—an eIC process that “may facilitate the subject’s ability to retain and comprehend the information.”² We thank the Agency for examining, via these two guidances, how both the *medium* and the *message* are vital to facilitating the subject’s comprehension of the information presented during the eIC process in order to protect the rights, safety, and welfare of human subjects.

In addition to welcoming this draft guidance as another major step in creating a robust, optimized, and modernized informed consent process, ACRO also offers some specific suggestions.

Specific recommendations

Line 36 of the draft guidance discusses how using an eIC can help “*Ensure the subject’s comprehension of the information presented during the eIC process.*” Whether the informed consent process is conducted electronically or via traditional pen-and-paper, the word “ensure” sets a standard that is arguably impossible to meet. We recommend that the word “ensure” be replaced by the word “facilitate” because -- while *neither* traditional pen-and-paper nor electronic consent processes can ensure comprehension -- the uniquely interactive and multi-format capabilities of electronic informed consent may actually facilitate comprehension better than traditional, pen-and-paper consent processes.

Lines 130-132 state “*the computerized system should include a method to ensure that the person signing the informed consent is the subject who will be participating in the research study (or the subject’s LAR).*” The word “ensure” is used again here. As we note in our comment regarding Line 36, whether the informed consent process is conducted electronically or via traditional pen-and-paper, the word “ensure” sets a standard that is arguably impossible to meet. ACRO recommends changing Lines 130-132 from a “method for ensuring” to a “method for attesting:” “. . . *the computerized system should include a method for the person signing the informed consent to attest that he or she is the subject who will be participating in the research study (or the subject’s LAR).*”

¹ “Informed Consent Information Sheet: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors,” July 2014.

² “Use of Electronic Informed Consent in Clinical Investigations: Questions and Answers: Guidance for Industry – Draft Guidance,” lines 84-85.

Lines 173-175 read *“The process should also ensure that the subject or the subject’s LAR signs the amended eIC in a timely manner and the signed amended eIC is archived appropriately.”* ACRO recommends two revisions to this sentence. First, if possible, ACRO believes it would be helpful to present the changes or significant new findings to subjects in summary form and in a comparative (original and revised text) format. In this way, subjects would not be asked to read the entire consent again (which was already agreed to), but would be presented the new information and asked if they agree to continue in the study. If this provision were permitted, it could be accompanied by affirmation that subjects may withdraw at any time. Second, ACRO recommends that the phrase *“and a copy made available to the subject”* be added to the end of this sentence so that it reads: *“The process should also ensure that the subject or the subject’s LAR signs the amended eIC in a timely manner and the signed amended eIC is archived appropriately and a copy made available to the subject.”*

Lines 252-255 state: *“The HIPAA privacy rule requires that when a covered entity seeks an authorization from a subject (or a subject’s personal representative), the covered entity must provide the individual with a copy of the signed authorization; this requirement also applies where a HIPAA 254 authorization is obtained electronically.”* The Guidance does not specify that a HIPAA authorization signed electronically may be sent to the subject as an e-copy as an alternative to a paper copy. ACRO recommends explicitly permitting use of e-copies for the HIPAA authorization if the subject agrees--with the same stipulations as provided in Question 8 of the guidance.

In conclusion, ACRO appreciates this opportunity to comment on this guidance, and we look forward to further dialogue with the FDA about the important issues raised in this Request for Comments.

Respectfully submitted,



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