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May 7, 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FDA-2015-D-0390, Comments on "Use of an Electronic Informed Consent in Clinical Investigations: Questions and Answers; Draft Guidance for Industry, Clinical Investigators, and Institutional Review Boards" (80 FR 12496)

The Association of American Medical Colleges ("AAMC") appreciates the opportunity to comment on the draft guidance issued by the Food and Drug Administration ("FDA") on the use of an electronic informed consent in clinical investigations. The AAMC is a not-for-profit association representing all 141 accredited U.S. allopathic medical schools, nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers, and 90 academic and scientific societies. Through these institutions, the AAMC represents 128,000 faculty members, 75,000 medical students, 110,000 resident physicians, and thousands of graduate students and post-doctoral trainees in the biomedical sciences.

The AAMC has long supported efforts to ensure that the process of informed consent is one that provides potential research subjects with meaningful awareness about what participating in a clinical trial would entail. In a September 15, 2014 letter responding to the FDA's draft guidance entitled ''Informed Consent Information Sheet: Guidance for IRBs, Clinical Investigators, and Sponsors'' (79 FR 41291), the AAMC stated: "As informed consent documents have increased in length and complexity, the research community should be addressing how to provide a potential research subject with clear and meaningful information, with the appropriate context to make the decision about whether or not to participate in the trial, and in a format and medium that facilitates learning and understanding. The FDA has the opportunity to take the lead in this effort by encouraging alternative formats for conveying critical information…and providing flexibility to investigators, IRBs and sponsors in designing a process that enhances understanding and can be tailored to individuals or specific populations."

The AAMC applauds the movement to release guidance on electronic informed consent, which includes the use of interactive websites, graphics, video, and other forms of electronic media.

Incorporating these mediums into the informed consent process has the potential to significantly increase participant engagement and to facilitate the process of dynamic consent, whereby there is ongoing interaction between a research subject and investigator and the continued exchange of information related to a research study. The use of electronic informed consent could also provide potential research study participants with the ability to review the material outside a research site, which could allow for careful deliberation, consultation with family, and time and reflection to make an informed decision. The AAMC recognizes, and encourages the FDA to state explicitly in final guidance, that the use of any technology to improve of facilitate informed consent process is merely a tool, and does not guarantee meaningful understanding about research participation.

In an October 25, 2011 response to the Advanced Notice of Proposed Rulemaking related to proposed changes to 45 C.F.R. Part 46 (76 FR 44512), the AAMC stated: "the current system [of regulations for human subjects research]...is not easily applied to a research system that has changed significantly in breadth, approach, technology and complexity." The use of electronic informed consent is particularly relevant in the context of this changed research enterprise, which increasingly includes new methods of data collection through sensors, smartphones, and other digital means. The lack of guidance in this area has been seen as a barrier to implementing potentially improved and innovative means of communicating with subjects.

As recognized by the FDA, a truly effective electronic consent framework would not be limited to obtaining the consent of participants, but should have the capability to serve as a conduit for information throughout the research study. Ideally, this would not only provide an intuitive format for researchers to relay relevant changes or updates to the participant, but would also allow the participant to find out how to contact investigators or answer questions that arise during the course of the research. An electronic format may also assist in overcoming barriers in understanding related to reading comprehension through the use of graphics or video, and provides the ability for the participant to demonstrate or test their understanding via interactive questions during the informed consent process. We recommend that the scope of the guidance be broadened slightly to include the recruitment process, as this is an important precursor to informed consent and may especially be impacted by the use of electronic media. **We also strongly encourage the FDA to engage with the research community to assess the effectiveness and appropriateness of electronic informed consent, developing an evidence base for the circumstances and types of research for which such a format is most effective.**

The AAMC recognizes the benefits to having an electronic record of information and consent, but also recognizes that this creates additional security and privacy concerns which must be adequately addressed. We acknowledge the FDA's concern expressed in the draft guidance that there should be a method to ensure that the person signing the informed consent is the subject who will be participating in the research. **We recommend that the FDA provide some**

examples of how an investigator or IRB might ensure that the electronic signature is from the subject or the subject's legally authorized representative.

Finally, the AAMC commends the efforts of the FDA to create a harmonized guidance with the Office of Human Research Protections ("OHRP") to enhance human subjects protection and decrease regulatory burden. **We encourage the FDA to revise this draft guidance with OHRP and reissue it as a draft joint document for comment. We further recommend that such a joint guidance document include specific sections for FDA-regulated clinical investigations which are not subject to 45 C.F.R. Part 46 and explicitly state that those sections only apply to FDA-regulated trials.** In particular, we note that many of the sections of the draft guidance reference 21 C.F.R. part 11, which has not been adopted by agencies in the Department of Health and Human Services other than the FDA.

The AAMC is appreciative of the FDA's commitment to engaging affected stakeholders to assist it in improving this draft document so that it provides the necessary guidance on the process of electronic informed consent. We support the release of guidance documents which provide clarity to investigators and promote well-designed, ethical research. The AAMC additionally commends the efforts to create a harmonized regulation with OHRP, and have attached our comments in response to OHRP's proposal for the release of a joint document to this letter. We would be happy to provide any further assistance in this process. Please feel free to contact me or Heather Pierce, Senior Director for Science Policy and Regulatory Counsel at hpierce@aamc.org or (202) 478-9926 with any questions.

Sincerely,

Ann C. Bonham, Ph.D.
Chief Scientific Officer