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May 7, 2015

Jerry Menikoff, M.D., J.D.
Director
Office for Human Research Protections
1101 Wooton Parkway, Suite 200
Rockville, MD 20852

RE: Draft Guidance for Industry, Clinical Investigators, and Institutional Review Boards—Use of an Electronic Informed Consent in Clinical Investigations (80 FR 12497)

Dear Dr. Menikoff:

The Association of American Medical Colleges ("AAMC"), a not-for-profit association representing all 141 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and 90 academic and scientific societies, appreciates the opportunity to submit comments on the proposed issuance of a harmonized guidance on electronic informed consent by the Office for Human Research Protections ("OHRP") and the Food and Drug Administration ("FDA"). Through the AAMC member institutions and organizations, the AAMC represents 128,000 faculty members, 83,000 medical students, 110,000 resident physicians, and thousands of graduate students and post-doctoral trainees.

The AAMC commends the development of guidelines for the use of electronic informed consent in research investigations. In particular, there are potential benefits to be found in the use of electronic media in complying with the general requirements for informed consent as delineated in 45 C.F.R. Part 46. A remote, electronic consent process could potentially facilitate the requirement to provide the subject an opportunity to consider their participation in the research in an environment which "minimize(s) the possibility of coercion or undue influence." Additionally, the intent of the regulation to maximize subject comprehension and to convey new information about the research throughout the process is noticeably suited for improvement through the incorporation of innovative electronic methods.

We are encouraged by OHRP's proposal to issue a joint guidance document with the FDA on electronic informed consent for research subject to 45 C.F.R. Part 46. A joint guidance document would clarify rules for investigators and streamline the process of complying with necessary regulations. The AAMC strongly supports efforts for harmonization of regulatory requirements and agrees that a single set of guidance documents that apply to FDA-regulated clinical investigations would be helpful to the research community. **We encourage OHRP to**

work with the FDA to create a joint guidance document based on this draft that can be issued simultaneously by both the FDA and OHRP. 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 also notes that the timeline for reviewing and revising this guidance document is concurrent with the active discussions regarding the revisions to 45 C.F.R. Part 46. Although much of the FDA draft guidance document may be applicable to human subjects research under 45 C.F.R. Part 46 in its current form, we query whether proposed modifications to the rule might change the analysis if new regulations are finalized, and suggest that OHRP consider the potential effect on a new joint guidance document. Given that a proposed rule is expected in a relatively short timeframe, finalizing the document now could quickly lead to outdated and confusing guidance if the references to 45 C.F.R. Part 46 are no longer accurate in six months or a year.

The AAMC is appreciative of OHRP's stated commitment to producing a clear and unambiguous joint guidance document with the FDA on electronic informed consent, if possible. The effort to harmonize research-related guidance is appreciated and long overdue. We encourage continued efforts in this direction to streamline and clarify federal research oversight. The AAMC has also submitted comments to the FDA on its proposed guidance, which are attached here. 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 Bonham

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