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President

January 10, 2008

BY ELECTRONIC MAIL: impairedcapacityohrp@hhs.gov

Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

**Re: Request for Information and Comments on Research That Involves Adult
Individuals with Impaired Decision-making Capacity
[Federal Register: September 5, 2007 (Volume 72, Number 171), FR Doc. E7-17490]**

Dear Office for Human Research Protections:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to comment on the notice issued by the Office for Human Research Protections (OHRP) entitled "Request for Information and Comments on Research That Involves Adult Individuals with Impaired Decision-making Capacity."

The Association of American Medical Colleges is a nonprofit association representing all 126 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 68 Department of Veterans Affairs medical centers; and 89 academic and scientific societies. Through these institutions and organizations, the AAMC represents 109,000 faculty members, 67,000 medical students, and 104,000 resident physicians. The Association appreciates the opportunity to respond to the Request for Information and Comments.

We acknowledge and appreciate the effort of the OHRP to define the population and protect the rights and welfare of adult individuals with impaired decision-making capacity, and strongly support the position that "research involving adults with impaired decision-making capacity is important and necessary in order to improve the health and well-being of such individuals."

The request seeks information and comments on a number of specific questions and issues concerning the review, approval, and conduct of research involving decisionally impaired adults as it is currently conducted at research institutions. The AAMC's membership is in an excellent position to respond directly to OHRP's specific inquiries based on the individual experiences and

practices of their IRBs and investigators, and we expect that our constituent organizations will provide this information. However, the request also seeks comment on the more general question of whether the current human subject protection regulations adequately address research involving adults with impaired decision-making capacity, and whether additional federal regulations or guidance are needed with respect to this population.

For the reasons indicated below, **the AAMC believes that additional regulations or changes to existing regulations are not needed at this time** to adequately protect adult individuals with impaired decision-making capacity. Additional regulation could unnecessarily conflict with duly established state or local procedures that already secure the rights of such individuals, and would impede research progress and unnecessarily increase administrative costs and regulatory burdens.

IRBs, institutions, and investigators currently rely on models provided under the existing federal regulations, in combination with relevant state and local laws and practices, to evaluate the key legal and ethical questions raised by this research. The current structure, while by definition subject to some local variation, provides necessary flexibility to address the full range of potential participants who may be considered “decisionally impaired” and the full spectrum of issues that may arise as a result of this heterogeneity in the potential subject population. It also permits IRBs to take advantage of well-established local expertise on surrogate decision-making and consent in the clinical context. In this environment, IRBs are able to develop responsible approaches for evaluating and ensuring protection of participants and prospective participants in this important research.

Moreover, OHRP has already addressed in an online FAQ¹ one of the key questions that institutions may encounter, namely, who may act as a legally authorized representative (LAR). “Some states have statutes, regulations, or common law that specifically address consent by someone other than the subject for participation in research. Most states have no law specifically addressing the issue of consent in the research context. In these states, law that addresses who is authorized to give consent on behalf of another person to specific medical procedures, or generally to medical treatment, may be relevant if the research involves those medical procedures or medical treatment.”

Nevertheless, some institutions and organizations conducting medical research involving adult individuals with impaired decision-making capacity may find such local determinations more problematic for a variety of reasons. For such institutions, guidance on the definition and role of a legally authorized representative (LAR) may be useful, provided that the guidance has necessary qualifiers and boundaries.

¹ http://answers.ohrp.hhs.gov/cgi-bin/answers_ohrp.cfg/php/enduser/std_adp.php?p_faqid=1319
Accessed Nov. 29, 2007.

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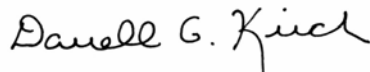
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AAMC proposes that OHRP issue guidance that further clarifies the definition and role of an LAR **that may be (but would not have to be) considered** by an IRB in making its determinations. Such guidance could be used when in the judgment of the institution, the applicable law and policy of the jurisdiction in which the research is being conducted (e.g., local or state law) does not provide sufficient guidance regarding the determination of a legally authorized representative. Such guidance would also be exceptionally useful in the context of multi-center, multi-state trials.

OHRP might also wish to consider providing additional guidance in the form of points to consider when reviewing research that involves decisionally impaired individuals (e.g., fluctuating competence, means of assessing competence, and limitations on risks when there is no possibility of direct benefit). Such a list will help IRBs determine the important issues they need to consider while retaining flexibility to consider relevant state and local laws and practices in their decision making. Because SACHRP has already convened a subcommittee devoted to this topic, this subcommittee should be a good resource for developing such guidance.

Thank you in advance for consideration of our comments. Please contact Irena Tartakovsky (itartakovsky@aamc.org; 202-862-0481) of AAMC staff for questions or clarification of these comments.

Sincerely,



Darrell G. Kirch, M.D.