

*La Cesta Consultants, LLC*  
*Promoting a conscientious culture in human research*

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) has called for public comments on Proposed Revised Accreditation Standards. (1) AAHRPP has developed 5 new standards including elements dealing with both individual and institutional conflicts of interest; community input into research design; implementation and dissemination of results; data safety monitoring, and minimizing risk and maximizing potential benefits. This comment directs attention to fundamental flaws in the Common Rule unaddressed by AAHRPP standards in both the current and proposed revised versions.

The Common Rule permits IRB decision-making in the absence of an unaffiliated member. (2) AAHRPP should establish a standard that closes that regulatory loophole and raises the bar acknowledging that IRB decisions made in the absence of an unaffiliated perspective are ethically unacceptable, constitute a form of institutional conflict of interest and undermine public trust.

The Common Rule defines the elemental IRB as 3 scientists, 1 nonscientist and 1 unaffiliated constituents suggesting, but not mandating, a 3:1:1 ratio of scientists to nonscientist and unaffiliated members. (3) AAHRPP should establish a standard that, at the very least, maintains the proportional representation of scientists to nonscientist and unaffiliated members promoting a diversity of perspectives from nonscientist and unaffiliated members. The effect of this flaw in the Common Rule minimizes input from nonscientist and local, community unaffiliated perspectives and places an unconscionable burden on the single nonscientist and unaffiliated members of IRBs with 10, 15 or 20 scientists.

The combined effect of these fundamental flaws in the Common Rule undermines public trust in the system for human research protection. AAHRPP's mission will be well served by redressing these flaws with standards that require participation of unaffiliated member(s) in decision-making votes and promote, at least, the proportional representation of scientists to nonscientist and unaffiliated members suggested in the Common Rule. Comments to AAHRPP on revisions to standards must be sent no later than July 30, 2009.

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(1) See <http://www.aahrpp.org/www.aspx?PageID=296>.

(2) See [http://hhs.gov/ohrp/humansubjects/guidance/45cfr.htm#46.108\(b\)](http://hhs.gov/ohrp/humansubjects/guidance/45cfr.htm#46.108(b)).

(3) See <http://hhs.gov/ohrp/humansubjects/guidance/45cfr.htm#46.107>.