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Sites Need Strict Rules on Conflicts of Interest

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) will require sites, IRBs and other bodies applying for accreditation to adopt stricter rules on conflicts of interest, an association official says.

The organization will base accreditation on an applicant's ability to separate business interests from ethics review functions, according to draft standards released last week for public comment.

The group defines conflict-of-interest rules in its evaluation instrument, but the draft standards are stronger as they split the problem into institutional conflicts, investigators' financial conflicts and other conflicts, President and CEO Marjorie Speers told *CTA*.

The standards say a corporate sponsor, research institution, contract research organization, IRB or other responsible group has an obligation to draft and follow written policies and procedures to identify financial and other conflicts among investigators and research staff, and ensure that these are managed, minimized or eliminated.

AAHRPP is proposing that no one who serves on an IRB can have any equity in the institution overseen. This would apply to all IRBs, although for-profit boards are a particular concern, Speers said.

Other new elements in the draft standards call for organizations to create policies for periodically or urgently sending data and safety monitoring reports to sponsors and for the organization or researchers to involve community members in the trial design, implementation and dissemination of results.

The draft consists of 15 accreditation standards that are organized into three "domains": organization, IRB or ethics committee (EC), and researcher and research staff.

Because of broad differences between organizational structures, no single solution exists to integrate the domains into a high-quality human research protection program, the draft says. The standards require organizations to:

- Ensure sufficient resources for human research protection programs;
- Establish a systematic, comprehensive program to protect all participants;
- Ensure individual employees are knowledgeable about and follow the subject protection policies;
- Respond to participants' concerns, including establishing a safe, confidential and reliable communications channel;
- Create and follow written policies and procedures to ensure the use of any investigational drug complies with all applicable legal and regulatory requirements;
- Ensure the structure and composition of the IRB or EC is appropriate for the amount and nature of the research;
- Ensure the IRB or EC reviews research projects in accordance with laws and regulations, keeps appropriate documentation and provides additional protection for vulnerable subjects; and
- Incorporate patient protection in research design and implementation and ensure studies meet all requirements and applicable laws, codes, regulations and guidance, as well as the organization's policies and procedures.

"We have been holding institutions to a higher standard than required in the regulations since we first started offering accreditation. Now we will require even more," Speers said.

To review and comment on the draft standards, go to www.aahrpp.org/www.aspx?PageID=296. Comments are due July 30. — Martin Berman-Gorvine

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