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Subject: CoR NEWS and Request for Volunteers: Human Subjects Regs proposed changes
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CoR NEWS

(10-2-15)
To: APLU Council on Research
From: APLU Staff

As you likely know, the U.S. Department of Health and Human Services (HHS) and 15 other federal agencies and departments recently announced proposed revisions to the "Common Rule," the regulations that govern research involving human subjects.

APLU is working with the Association of American Universities (AAU) to respond to this Notice of Proposed Rulemaking (NPRM). We seek some volunteers from our campuses to help us in this process. This joint APLU-AAU working group will help identify issues of concern and provide needed expertise and feedback as we draft our comments. If you or someone expert in human subjects protection at your institution would like to be a part of this ***working*** group, please contact Genevieve Croft (gcroft@aplu.org) as soon as possible. In addition to human subjects research and IRB expertise, it will be helpful to have a general counsel or two involved as well as someone who has strong privacy knowledge. The estimated commitment would be for three one-hour conference calls and email communication over the next 2 months. Additionally, even if you are not available to help on this working group, we welcome your thoughts about what our comments should address.

You may recall that APLU and AAU sent joint comments (attached) in response to the 2011 Advance Notice of Proposed Rulemaking on updating the Common Rule. The expertise and input from our institutions was very helpful in that process and we know it will be needed again now as we seek to respond to the NPRM.

Comments are due by December 7, 2015. APLU joined the Council on Governmental Relations and AAU in requesting an extension of the comment period until January 6, 2016 but we are not optimistic the comment period will be extended as there is much interest at HHS to finalize the Common Rule revisions prior to a change in administration.

See below for more information from HHS about the proposed revisions.

The regulations that currently protect individuals who participate in research, have been in place since 1991 and were developed at a time when research was predominantly conducted at universities, colleges and medical institutions, and each study generally took place at a single site. The expansion of research into new scientific disciplines, such as genomics, along with an increase in multisite studies and significant advances in technology, has highlighted the need to update the regulatory framework. Notably, a more participatory model of research has also emerged, with individuals looking for more active engagement with the research enterprise.

The protection of research participants is of paramount importance. Medical advances would not be

possible without individuals who volunteer to participate in research. This NPRM proposes to modernize the current regulations by enhancing the ability of individuals to make informed decisions about participating in research, while reducing unnecessary burdens by streamlining the regulatory requirements for low-risk research.

Changes proposed in the NPRM issued today include:

- Strengthened informed consent provisions to ensure that individuals have a clearer understanding of the study's scope, including its risks and benefits, as well as alternatives to participating in the study.
- Requirements for administrative or IRB review that would align better with the risks of the proposed research, thus increasing efficiency.
- New data security and information protection standards that would reduce the potential for violations of privacy and confidentiality.
- Requirements for written consent for use of an individual's biological samples, for example, blood or urine, for research with the option to consent to their future use for unspecified studies.
- Requirement, in most cases, to use a single institutional review board for multisite research studies.
- The proposed rule would apply to all clinical trials, regardless of funding source, if they are conducted in a U.S. institution that receives funding for research involving human participants from a Common Rule agency.

To view the NPRM, click here. HHS will take public comment on this NPRM for 90 days, beginning Sept. 8.