Human Research Report
PROTECTING RESEARCHERS AND RESEARCH SUBJECTS
Volume 30, No. 6 ISSN 0885-0615 June, 2015

"Slow Down, You Move Too Fast," Says National Committee About IRB Changes

As we presented in some detail in the March HRR (pp. 1-3), a recent proposal by the National Institutes of Health (NIH) could have a profound effect on numerous Institutional Review Boards (IRBs). The proposal is titled "Draft NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research." The draft policy was initially issued on December 3 of last year in the NIH GUIDE as Notice No. NOT-OD-15-026 with a public response deadline of January 29, 2015 (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-026.html). The policy would affect all research funded by NIH.

Although virtually all U.S. institutions have access to the NIH GUIDE, NIH inexplicably (as far as HRR is concerned) waited until January 6, 2015, to announce the same policy and comment deadline date in the FEDERAL REGISTER (80 Fed. Reg. 511-512). Thus, persons who may have only noticed the FEDERAL REGISTER announcement had a mere 3 weeks to respond to the NIH proposal.

Regardless, public response was swift. For example, the Association of American Universities (AAU) and the Association of Public and Land-Grant Universities (APLU) quickly submitted comments that -- in HRR's view -- were generally negative. For example, both groups want the NIH to slow down its policy-making process on this issue (see March HRR, pp. 1-3).

National Committee Advises Same Thing: Slow Down Until We Get More Information

Similarly, the influential national committee known as the Secretary's Committee for Human Research Protections (SACHRP), closely tied to the federal Office for Human Research Protections (OHRP), has submitted its own input to NIH. We are always interested in SACHRP's views since its input -- and that of predecessor committees/commissions -- have led to mandatory regulations and policies on the protection of human research subjects.

Perhaps the single most clear and strong message expressed in SACHRP's announced input to NIH is much like that of AAU, APLU, and others; i.e., slow down!

> "There are many research focused committees, departments and offices that play a role in the pre-approval review of human subjects' research. These include, but are not limited to, radiation safety, pathology, pharmacy, nursing, institutional bio-safety, billing, grants and contracts. Mandating single IRB review for domestic multi-site studies is not the appropriate solution to improve turn-around time for human subject's research.

While the use of single IRBs may be effective and efficient in some circumstances, SACHRP believes that it is premature at this time to man-

NOTE #1: Quoted materials in this newsletter appear exactly as originally published in source documents, including any misspellings, grammatical errors, missing words, etc.

NOTE #2: Articles may be continued in subsequent issues.

ALSO IN THIS ISSUE

Published monthly by The Deem Corporation, P.O. Box 451117, Omaha, NE 68145. Editor and Publisher: Dennis M. Maloney, Ph.D.