

NIEHS sets the standard for protocol transfers

By Ernie Hood

The NIEHS Human Research Protection Program (HRPP), which encompasses the NIEHS [Office of Human Research Compliance \(OHRC\)](#) and Institutional Review Board (IRB), is currently in the process of working with the National Institute on Aging (NIA), to transfer six of its clinical research protocols to NIEHS for IRB oversight.

A protocol is a predefined, written procedural method in the design and implementation of a research study. A well-written protocol is essential for answering specific research questions, avoiding problems during the study, achieving a high quality research study, and safeguarding the health of participants.

Under the leadership of Joan Pakenham, Ph.D., OHRC director and vice-chair of the IRB, NIEHS is setting the standard for future efforts of this kind. With three of the protocols already transferred and three more in progress, this marks the first time such a transfer has been successfully undertaken. One of the studies, the [Baltimore Longitudinal Study of Aging \(BLSA\)](#), (<http://www.blsa.nih.gov/>) is America's longest-running scientific study of human aging, having started in 1958.

The transfer process is occurring because the NIH [HRPP](#), (<http://ohsr.od.nih.gov/>) which includes all NIH institutes and centers (ICs), is undergoing accreditation by the [Association for the Accreditation of Human Research Protection Programs \(AAHRPP\)](#). (<http://www.aahrpp.org/>) Successful completion of the rigorous accreditation process signifies an organization's commitment to the highest standards of ethics, research quality, and protection of human subjects.

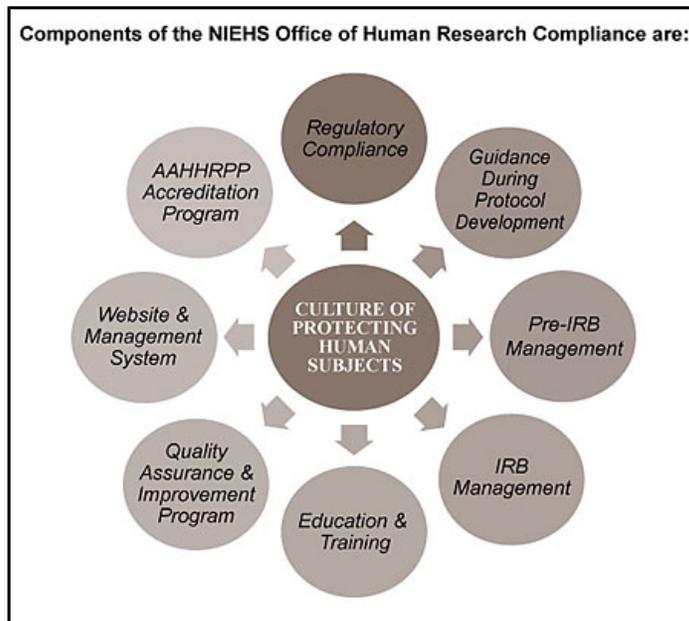
NIEHS and NTP Director Linda Birnbaum, Ph.D., said of the transfer, "Once again, NIEHS is ahead of the curve, with groundbreaking work being performed by our OHRC and being used as a model by other NIH ICs. That's pretty significant, particularly as we are going into AAHRPP accreditation."

With the accreditation process approaching, the NIH Human Subjects Research Advisory Committee (HSRAC) advised NIH Deputy Director for Intramural Research Michael Gottesman, M.D., that any ICs using commercial or external IRBs needed to transfer their protocols in-house to NIH IRBs. Since NIA had been using a commercial IRB, it was necessary for them to transfer their protocols to one of the NIH in-house IRBs. NIEHS received six of the existing NIA protocols.

New ground, new policies

"It was an honor for NIEHS to be selected for the protocols," Pakenham said. "Most of them are epidemiological protocols with minimal risk, so you could say we're serving as an epidemiological thematic IRB. For this type of transfer, we developed standard operating procedures, as well as a transfer agreement, that specifically indicated the necessary criteria for the transfer between NIA and us."

The protocol transfer process is not simple, and this type of transfer is new territory for NIH. Recognizing those challenges, the HSRAC formed a Protocol Transfer Subcommittee (PTS), and, due to the success of the NIA-NIEHS protocol transfer,



Among its several activities, the OHRC manages the NIEHS IRB and oversees interactions with the AAHRPP accreditation program.



"What we have done is a model for the ICs to follow and for NIH to develop policies concerning transfer of protocols," said Pakenham. (Photo courtesy of Steve McCaw)



(Image courtesy of National Institute on Aging)

Packenham was asked to be the subcommittee chair. She has overseen the protocol transfers and formulated many of the new policies and procedures necessary to complete the process.

At the HSRAC meeting June 21 at the NIH Clinical Center in Bethesda, Md., Packenham reported on the subcommittee progress, experiences, and lessons learned. Bethesda, Md.

"There are many different ways that transfers of protocols can occur, and we certainly have to have policies in place to make sure they are done properly, so that regulations and guidance are followed, everyone has the same understanding, and all are in agreement with the process, to insure that research is not affected and participants are not harmed by the transfer," Packenham noted.

Packenham said that the current round of NIA-NIEHS protocol transfers should be completed by the end of the summer, and that the NIEHS IRB expects, in the future, to receive subsequent initial NIA protocols for new studies being started.

(Ernie Hood is a contract writer with the NIEHS Office of Communications and Public Liaison.)



BLSA, the nation's longest-running scientific study of aging, began in 1958, when gerontology was still very much in its infancy. With more than 1,300 volunteers who made a lifelong commitment to be part of the research, BLSA continues to be an innovative and robust study. (Image courtesy of National Institute on Aging)

The Environmental Factor is produced monthly by the [National Institute of Environmental Health Sciences \(NIEHS\)](http://www.niehs.nih.gov/)
(<http://www.niehs.nih.gov/>)

, Office of Communications and Public Liaison. The content is not copyrighted, and it can be reprinted without permission. If you use parts of Environmental Factor in your publication, we ask that you provide us with a copy for our records. We welcome your [comments and suggestions](#).
(bruskec@niehs.nih.gov)

This page URL: NIEHS website: <http://www.niehs.nih.gov/>
Email the Web Manager at webmanager@niehs.nih.gov