UA Seeks Accreditation for the IRB

UA has started the process of seeking voluntary external accreditation for its IRB from the Association for the Accreditation of Human Research Protection Programs (AAHRPP), pronounced “A-HARP”. AAHRPP was founded by several leading research universities and clinical research agencies out of concern about rising public mistrust of research. It functions very much like SACS accreditation, requiring a self-assessment, meeting of specific performance criteria, and a site visit. Very importantly, AAHRPP’s standards have an organization-wide perspective rather than a sole focus on the IRB. The University is required to document institutional commitment to the ethical treatment of persons, a much broader perspective than just the ethical treatment of research participants. UA must also increase educational outreach to investigators, faculty teaching research ethics and the responsible conduct of research, and to the non-university community about their rights and responsibilities in research studies. Therefore, the evaluated unit is called the Human Research Protection Program rather than merely the IRB. Both terms will be used, depending on whether one is talking narrowly about the IRB or broadly about the entire institutional commitment.

A subcommittee of the IRB is now conducting a self-assessment of our IRBs and developing policies, procedures, and educational materials to meet AAHRPP’s standards. Following a site visit and a written response to site visitors’ observations, UA may receive full or qualified accreditation or could be required to start over.

Once accredited, this status must be maintained. AAHRPP requires annual reporting that includes an evaluation of the HRPP and IRB and a plan for continuous quality improvement based on that evaluation.

The accreditation effort will take at least two years. The Accreditation Subcommittee is chaired by Dr. Sharol Jacobson. The members are John Dew, John Higginbotham, Tom Stem, Deidre Leaver-Dunn (Faculty Senate representative), Carmen Taylor, Michael Spearing (University Legal Counsel), Bishop Earnest Palmer (community representative), and Tanta Myles, Research Compliance Officer.
Great Resource for Teaching Research Ethics, IRB Issues

The library now has provided us with online access to the Journal of Empirical Research on Human Research Ethics (JERHRE pronounced “Jerry”). This peer-reviewed, interdisciplinary journal focuses on improving ethical problem solving in human research through empirical research. Investigators will find much practical guidance. The “Educational Advantage” feature presents teaching strategies for ethical content and, often, complete student assignments based on JERHRE articles. If you use or adapt their assignments, please let the Research Compliance Office know how you liked them. Educators are also invited to submit learning activities using JERHRE articles to the journal for possible publication.

E-Protocol Is Here!

It had to happen—the process of submitting and tracking research protocols in IRBs has gone electronic. After reviewing many products and conducting a local pilot study with several willing investigators, UA has selected e-Protocol as its electronic human subject research management system. It is now available campus-wide.

E-protocol is a total web-based system that automates the IRB approval process by allowing investigators, the IRB, and the research compliance staff to process IRB protocols online. The new system is expected to strengthen the human subjects research environment and increase compliance with ethical standards and regulatory requirements.

E-Protocol offers some important advantages to investigators. The system includes a checklist that can serve to alert investigators to matters that will need to be explained in the protocol, such as the use of investigational drugs or devices or the use of a vulnerable population. Based on this checklist, the system will not allow submission of an application until all questions have been answered. This should reduce the need for IRB staff to contact investigators for additional information. Lastly, investigators will be able to determine exactly where their protocols are in the system.

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