

## **Florida Department of Health: First State Health Department to receive Full Accreditation of its Human Research Protection Program**

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The Florida Department of Health has become the first state health department to receive Full Accreditation of its human research protection program which encompasses the Institutional Review Board and all members of the Florida DOH research community. The IRB reviews research involving human subjects for all of the 67 county health departments in Florida, and at other Department facilities, such as the A. G. Holly State Tuberculosis Hospital. The Florida DOH currently has more than 250 ongoing clinical research studies, epidemiological studies, and studies examining the social and behavioral determinants of health.

The accrediting organization, the Association for Accreditation of Human Research Protection Programs (AAHRPP), is a nonprofit organization that accredits organizations that can demonstrate they provide participant safeguards that surpass the threshold of state and federal requirements (<http://www.aahrpp.org>). The DOH believes accreditation of its human research protection program is crucial to insuring the integrity of research and to fostering public trust in research at the Department.

Research oversight in the United States has come under intense scrutiny, with accreditation seen as one strategy to help institutions improve their programs, achieve regulatory compliance, and advance research quality (Institute of Medicine, 2004; Epstein, 2007; Mather and Hartnett, 2008; Speers, 2004). Nevertheless, researchers express concerns about Byzantine IRB forms, bureaucratic customer service, and inconsistent and time-consuming delays, particularly when they conduct research at multiple locations, or involve multiple community partners. To address such concerns, in 2006 DOH embarked on a “make-over” of its human research protection program, with the support of senior leadership. Changes were made to program structure, to policies, and to the practice of research review, including implementation of an electronic system.

Research ethics oversight, which had been under the responsibility of a contractor, was brought back within the DOH in early 2006. New staff were added and the program reorganized as the Ethics and Human Research Protection Program, in recognition of DOH’s commitment to ethical issues in research and public health practice. New program staff contacted researchers, county health department directors, and solicited--and received--both candid criticisms and significant support for attempts to improve the IRB function, including offers by several individuals to serve on the IRB.

The initial contacting of researchers and listening to their concerns served as an important step in program improvement. The program conducted a formal self-assessment of its policies and review practices using an evaluation instrument available from AAHRPP. After identifying opportunities for improvement in policies and practices, the program reviewed policies and practices used by existing accredited organizations and revised or implemented new policies. Whenever possible the program incorporated best practices from accredited organizations, adapting them to the needs of the DOH.

As part of these program improvements, the DOH implemented the first electronic IRB application system in Florida. This made the process of applying easier for researchers, facilitated review by IRB committee members distributed around Florida, and improved documentation and regulatory compliance. Adopting an electronic system served as an opportunity to substantially revise IRB application forms. The electronic system was implemented quickly--from purchase to implementation in less than 6 months. However, unlike other program changes, this dimension was implemented without substantial opportunity for comment from researchers or committee members. There was resistance and frustration, particularly on the part of IRB members, about the process by which these changes were implemented. IRB members expressed concerns about the importance of communication and transparency.

The “make-over” also involved changes in the practice of how research protocols are reviewed. Changes in practice have taken longer to develop than changes in policies, or the change from a paper to an electronic system. To facilitate changes in review practices, such as the use of a written reviewer comment form to document review and organize comments prior to meetings, the program emphasized education and training.

In addition to sending IRB Chairs to national research ethics meetings and staff to annual AAHRPP conferences, program staff have provided education at IRB meetings. The program developed an education strategy for researchers, adopting as a baseline the Collaborative IRB Training Initiative (<http://www.citiprogram.org>), a web-based online program developed by the University of Miami, and has hosted IRB 101 for researchers and study staff. As part of its commitment to education, all central-office leadership and epidemiologists completed the CITI course to better understand the requirements for review of research, and the differences between research and public health practice.

Accreditation at the DOH has been a team effort, involving many people across the DOH. Perhaps the most important successes in the accreditation process were those that successfully communicated the process and succeeded in eliciting comments and improvements from researchers, IRB members, and staff. Possibly the most important opportunity for improvement as the program moves forward, is in continuously improving communication in order to learn from researchers and IRB members ways in turn to continuously improve the Ethics and Research Protection Program, insuring the integrity of, and trust in, research at the Florida Department of Health.

*\* Robert Hood serves as Assistant Director, Office of Public Health Research, where he is responsible for the Ethics and Human Research Protection Program.*

*Conflict of Interest Declaration: Hood serves as a site visitor for the Association for Accreditation of Human Research Protection Programs.*

## **Sources**

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