Delay in Implementation of 2018 Common Rule (IRB) Changes

One year ago, the U.S. Department of Health & Human Service (DHHS) announced that a new 2018 Common Rule (new IRB rules affecting Human Subject Research) would go into effect nationally on January 19, 2018. In response, the MCW/FH Human Research Protection Program (HRPP) Office worked out plans to implement these changes on the effective date.

In a last-minute decision made late on Jan. 17, 2018, DHHS announced a six-month delay of implementation of the 2018 Rule. The new deadline for implementation is July 19, 2018. The last-minute timing of the announcement and its regulatory implications has created a particular headache for some investigators.

Had it been implemented on Jan. 19, 2018 as originally planned, the 2018 Rule would have required that MCW/FH investigators in the process of initial IRB review "switch" from the long-standing consent form templates to new 2018 templates. Our IRB Office been working with the affected investigators to accomplish this change. This recently announced implementation delay means that investigators can continue to use the pre-2018 consent form templates. The IRB office is notifying all investigators in the process of initial application that they NO LONGER are required to switch consent form templates, and that the long-standing (pre-2018) template will be sufficient for now.

The HRPP office will still proceed to post the new 2018 Rule consent form templates. Though the long-standing template will be accepted for the next six months, investigators should begin using the new templates in anticipation of the July implementation of the 2018 Rule.

This delay does not change the new NIH policy regarding single IRB implementation.

Additional information will be provided by the HRPP office through the usual avenues. Our IRB office can be reached at IRBoffice@mcw.edu.

David C. Clark, PhD
Director, Human Research Protection Program
Professor of Psychiatry and Behavioral Medicine

Ann B. Nattinger, MD, MPH, MACP
Associate Provost for Research
Professor of Medicine