From: irb@umassmed.edu
To: Blodgett, Allison
Subject: 2018 Regulations Update, Today - Capacity to Consent Webinar
Date: Thursday, January 18, 2018 12:04:54 PM

Dear Research Community,

Late yesterday, the federal government issued a six-month delay in the revised human subjects regulations. The notification explicitly acknowledges that the consent form changes are consistent with the existing regulations, and UMMS will continue to require all new studies to use the new template that was posted 12/20/2017. UMMS will also move ahead with three-year approval periods for some minimal risk new studies. Research that is FDA regulated or has any federal funding or support will continue to have a one-year approval period.

What do you need to do right now?

1. Make sure that the Funding Sources for your research are appropriately captured in eIRB. If you are part of a multi-site study and the overall project has federal funding or support, it is important to list that federal funding or support in eIRB.
2. Continue to obtain prior IRB review and approval for all human subjects research — including research that fits one or more of the exemption categories.
3. Download all forms and templates fresh from the IRB website.
4. Note the expiration dates indicated in your approval letters. Create a reminder system to ensure timely submission of continuing reviews and study closures.
5. Submit a closure to the IRB when your research is completed, even if it's deemed exempt.

Over the coming week, we will be updating the one- to two-page summaries of key topics related to the 2018 Regulations -- including the "Who What When Where Why How."
https://www.umassmed.edu/ccts/irb/what-you-should-know-about-the-2018-regulations/

To read the HHS Press Release about the delay in the New Rule, visit
https://www.hhs.gov/ohrp/interim-final-rule-common-rule.html

We invite you to join us today for a PRIM&R Webinar. The speakers include an education and outreach specialist from the University of Minnesota, an institution which has been through a high-profile case related to informed consent and vulnerable populations. (http://www.sciencemag.org/news/2015/03/human-subjects-protections-under-fire-university-minnesota) Although in-person attendance is required, preregistration is not. For more information on the webinar itself, please visit https://www.primr.org/webinars/

Title: Capacity to Consent to Research: Assessing and Improving your HRPP's Strategy
Date: January 18, 2018
Time: 1:00 -2:30pm
Location: Amp III S6-102

We look forward to continuing to work with you during this time of transition.

Sincerely,
Allison Blodgett, PhD, CIP
Director of IRB Operations