From: irb@umassmed.edu
To: Blodgett, Allison
Subject: eIRB offline 7pm Tuesday 12/5; minor correction to 11/30 update
Date: Monday, December 04, 2017 10:18:52 PM

Dear Research Community,

1. **Please be advised that the eIRB application is scheduled for necessary updating starting at 7pm, Tuesday, December 5**. The **eIRB application will be unavailable for the duration of the update.** Please be sure to **log out of eIRB Tuesday, December 5, before 6:45pm**. We anticipate that eIRB will return online on Wednesday, December 6. Please refrain from logging in to the system until that time. If you experience any problems accessing the eIRB application after this period, please contact the IRB at 508-856-4261 or email us at IRB@umassmed.edu.
2. MINOR CORRECTION FROM 11/30 UPDATE: Changes to the Code of Federal Regulations for Human Subjects Research are scheduled to take effect on **January 19, 2018**, despite a proposed one-year delay that is under review by the Federal Office of Management and Budget. The IRB will be providing detailed updates, training, and revised templates starting in earnest in December. **What do you need to do right now?**
    a. **Watch for messages from the IRB:** https://www.umassmed.edu/ccts/irb/. We recommend that you **refresh your login page for eIRB, which now provides a link to the News and Announcements section of the IRB homepage for easy access to periodic updates:** https://eresearch.umassmed.edu/OVPR/
    b. **Continue to submit to the IRB as you normally would.**
        i. Studies approved before January 19, 2018, will largely stay under today's "pre-2018" regulations and standard operating procedures.
        ii. All human subjects research – including research that fits one or more of the exemption categories – and all Modifications to human subjects research will continue to require prior IRB review and approval, in accordance with *HRP-800 INVESTIGATOR GUIDANCE: Investigator Obligations* (https://www.umassmed.edu/ccts/irb/investigator-guidance/).
    c. **When you need a form or template, download from the IRB website instead of recycling earlier versions.** Changes are coming soon to the consent form template and the study plan instructions.
    d. **Take note of the expiration dates indicated in your approval letters and create a reminder system to ensure timely submission of continuing reviews and study closures.** Starting January 19, 2018, all new non-exempt minimal risk research will have a one-year or three-year approval period. All research – including exempt research – will receive annual reminders of investigator obligations, including the obligation to submit research closures to the IRB.

We look forward to working with you as we transition to the new regulations.
Sincerely,

Allison Blodgett, PhD, CIP
Director of IRB Operations