From: irb@umassmed.edu
To: Blodgett, Allison
Subject: Important IRB Changes & Ask-An-Expert Reminder Today 11/30 12:30-2pm
Date: Thursday, November 30, 2017 9:20:31 AM

Dear Research Community,

Please see below for important updates from the IRB.

1. The IRB is continuing to offer its drop-in sessions as part of the Library's "**Ask an Expert**" initiative.
    - **Who** will be available? Representatives from IACUC, IRB, Library, CCTS, QMC, Capstone, and Sponsored Programs
    - **Where** will sessions take place? Library computer classroom, the "C" computer section and consultation rooms
    - **When** can people stop by? Typically the 2nd and 4th Thursday of each month from 12:30 to 2:00pm
    - November's remaining date is **today 11/30 (12:30 to 2:00pm)**.
    - December's dates are **12/14** and **12/28 (12:30 to 2:00pm)**.
2. **Please be advised that the eIRB application is tentatively 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.
3. 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 minimal risk research –including exempt research – will have a one-year or three-year approval period.

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

Sincerely,

Allison Blodgett, PhD, CIP

Director of IRB Operations