From: irb@umassmed.edu
To: Blodgett, Allison
Subject: Important eIRB Changes & Ask-An-Expert Reminder Thursday 12/14 12:30-2pm
Date: Wednesday, December 13, 2017 2:04:29 PM

Dear Research Community,
In addition to sending a reminder for tomorrow's Ask-An-Expert session, we are writing to share several key changes from last week's eIRB update.
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
December's dates are **12/14** and 12/28 (**12:30 to 2:00pm**).

Conflict of Interest: In coordination with the Conflict of Interest Committee, the prompts in eIRB regarding financial conflict of interest have been updated to clarify that:

- Questions regarding conflict of interest pertain to investigators, study staff, or their immediate family
- "Immediate family" includes spouse, domestic partner, and (their) parents, children, brothers, and sisters

For example, you will see prompts like the following: "To their knowledge, do any investigators, study staff, or their immediate family have a financial interest related to the research?" Corresponding changes are being implemented in materials on the IRB website.
We encourage you to take this opportunity to review the following:

- HRP-800 INVESTIGATOR GUIDANCE: Investigator Obligations (https://www.umassmed.edu/ccts/irb/investigator-guidance/)
- UMMS Conflict of Interest website (https://www.umassmed.edu/research/compliance/financial-conflict-of-interest/overview/)
- UMMMC Policy 1120 (https://ournet1.umassmemorial.org/Resources/Policies/UMMMC%20Center%20Wide%20Policies/Administrative/Document%20Library/1120%20Conflict%20of%20Interest.pdf#search=conflict%20of%20interest%20policy).

With respect to human subjects research, there are Investigator Obligations to disclose financial interests at initial review, continuing review, and within 30 days of discovering or acquiring a new financial interest that would have required disclosure on initial review. Investigators and study staff are responsible for completing the disclosure process and providing written determinations from the COI review process to the IRB.
Devices: There are now prompts to complete the Device section and to provide a Humanitarian Device Exemption (HDE) number if the submission involves administering a Humanitarian Use Device (HUD) for clinical treatment.

Continuing Reviews:

- There is now a prompt at continuing review to indicate whether there have been any federal progress reports. When research is federally funded, please upload a copy of the progress report with your continuing review or briefly explain why a progress report is not available.
- It should now be possible to create Continuing Review and Modification submissions for studies that have Lapsed in approval rather than Continuing Reviews only.

Notification Templates: There have been minor administrative edits to email notification templates.

If you have any problems accessing or using the eIRB application at this point in time, please contact the IRB at 508-856-4261 or email us at IRB@umassmed.edu .

Additional updates regarding the 2018 regulations are coming soon.

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