From: irb@umassmed.ed

To: Blodgett, Allison

Subject: IRB Updates: Fact Sheet, Basic Coordinator Course, Short WIRB Survey, & More Date: Monday, February 12, 2018 1:21:49 PM

Dear Research Community,

1. The Fact Sheet's back and it's better than ever, hey la, hey la, the fact sheet's back: As part of the transition to the Revised Common Rule, an updated fact sheet template has been posted to Forms and Templates: https://www.umassmed.edu/ccts/irb/forms_templates/ Existing approved consents and fact sheets are not required to convert to the new templates. As always, be sure to download templates fresh from the IRB website when preparing a new submission

- 2. A Basic Clinical Study Coordinator Training Course will be held on Wednesday, March 14, 2018 from 9AM-1PM on ACC 7th floor. This introductory course is geared toward new study coordinators and will introduce basic concepts related to human subject research. Topics will include: IRB policies and procedures, informed consent guidelines, research team roles and responsibilities, trial master file organization, and adverse event reporting. Space will be limited. If you would like to attend this class, please email anne.roussell@umassmed.edu with the following: attendee name, title, department, and name of supervisor. If you have a colleague who may be interested in attending, please feel free to forward this email to them.
- 3. Representatives from Western IRB (WIRB, https://www.umassmed.edu/ccts/irb/submission/western-irb-wirb/) have asked whether there is interest in on-site training in early April. If you are interested in possibly attending a WIRB training, or have any general feedback or questions for the IRB, please let us know by completing a short survey by close of business this Thursday, 2/15: https://arcsapps.umassmed.edu/redcap/surveys/?s=7FFNKFADH4
- 4. Need CE credit? Want to learn more about FDA's Expanded Access Program with a Focus on Individual Patient Expanded Access? Sign up for their free webinar to be held 2/20/18 from 1pm to 2pm:

https://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm

- 5. A new listing of 27 social-behavioral research (SBR) laws, regulations, and guidelines around the world is now available on the OHRP website: https://www.hhs.gov/ohrp/international/social-behavioral-research-standards/index.html
- 6. We invite you to join us Thursday 2/22 for an IRB drop-in session, being held 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

February's remaining date is 2/22 (12:30 to 2:00pm)

March dates are 3/8 and 3/22 (12:30 to 2:00pm)

Sincerely.

Allison Blodgett, PhD, CIP

Director of IRB Operations