HRPP Newsletter – March 2014
Human Research Protection Program at KUMC
http://www.kumc.edu/compliance/human-research-protection-program.html

Monthly publication of the Human Research Protection Program at KUMC to keep our investigators and research partners informed on HRPP news, policies, processes, and procedures.

“Partnering with our investigators to ensure safe and ethical research”

HRPP Updates (Human Research Protection Program)

Volunteers helping with Research
KUMC has a new policy about volunteers on campus. The Policy on Volunteers in the Workplace is posted on the Human Resources website. Please be aware that non-KUMC student volunteers who want to help with human subjects research also must be approved by HSC. Additionally, volunteers will need an affiliate account to access their required Conflict of Interest Report and training in the Chalk system per HR and HSC policies. To request an affiliate account, the university department sponsoring their volunteer experience has a designated account requestor to assist. See the department’s administrative specialist for more information.

Website
We are in the process of revamping our website. Although we have a plethora of great info to share with you, we want this info to be at your fingertips / easy to find. Please feel free to give us feedback on how we can make our site more helpful to YOU. Contact Diane Etzel-Wise, detzel-wise@kumc.edu or 8-1390.

IRB Tips and Updates (Institutional Review Board – Human Subjects Committee)

Where is my “official letter?”
If you are seeking your IRB approval letter for your initial study submission, subsequent modifications, or continuing reviews in eCompliance / eIRB, you can locate the letter at the top right side of the respective screen. You can access that screen by going into the main study, locating the symbol in front of the closed (approved) transaction and clicking on the link following that symbol.

Changing the PI on a Study
To change the PI on a study, the study team should select “other parts of the study”, not study team. The PI is listed on the Basic Information tab, not in the personnel list.

New CR Supplement Form
Make sure you are referring to the Continuing Review screen on our website for the current Continuing Review Supplement and information. We have updated the form most recently to include conflict of interest questions, FDA progress, device logs, non-English consent form submission, and reporting adverse events.
Study Expiration
If you are informed that one of your studies has expired, you should contact the IRB (HSC) immediately if the expiration affects subject safety. Investigators may request continuation of protocol-related activity they deem necessary to ensure subject safety. If you believe that some or all subjects may be harmed by study expiration, you must submit written documentation to the IRB chair, including a list of affected subjects. The IRB chair may determine that the specified activities may continue for affected subjects. At his/her discretion, the IRB chair may consult individual IRB members or the entire committee when making the determination. The IRB chair will provide written documentation to the investigator about the study activities that may continue for affected subjects. Regarding the timeline:

- If the lapse is less than 60 days, the investigator must submit a letter with the continuing review application summarizing any study related activities that occurred during the lapse.
- If the lapse is 60 days or longer, the investigator must submit a new application for approval to the HSC. The submission will be reviewed in accordance with SOP 2.0. When requesting a new application, the investigator must also include a letter summarizing any study related activities that occurred during the lapse.

Project Descriptions
To make sure that you are using our most current forms, please download Project Descriptions and other IRB forms directly from our webpages, especially at Initial Study Submission or Forms.

Study Staff and Coordinator Orientation
Kris Whitaker, Quality Assurance Coordinator, offers orientation to general research administration processes for University, Hospital, and KU Physicians staff. You can sign up on our HRPP Calendar or contact Kris at 945-6760 or kwhitaker@kumc.edu for additional information.

IRB Contact Information: 588-1240 or humansubjects@kumc.edu

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<th>COI Updates</th>
<th>(Conflict of Interest)</th>
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Supervisor Action Needed
If you are a Supervisor, please be sure to check your COI Inbox in eCompliance for any FY14 Certifications of your employees / faculty members which might require your review.

Other COI info
If you have questions about completing your Conflict of Interest report, please see our informative COI website and be sure to check the User Guides. Don’t forget to check the box and click finish at the Assurance and Certification screen; otherwise your report will remain in draft status.

Keep your Disclosures current! Please “Create an Update Certification” in eCompliance if you have a new entity to disclose or make changes to your existing disclosures within 30 days of the change.

COI Contact Information: 588-0940, 588-1390 or coi@kumc.edu. View more info at the COI Website

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<th>HIPAA Updates</th>
<th>(Health Insurance Portability and Accountability Act of 1996)</th>
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Contact Information: Juli Gardner Wessel, 588-0940
eCompliance Information

General eCompliance Access
For eCompliance access issues, please contact University Customer Support at 588-7995.

eCompliance Assistance with IRB and COI
You can sign up for one of our helpful technical assistance sessions through the HRPP website, in the HRPP Events and Training Calendar. OR an HRPP staff member will assist you at your desk. Contact Diane Etzel-Wise at 588-1390 or detzel-wise@kumc.edu

Office of Compliance Updates

Anonymous Reporting
The Compliance Helpline provides a way to report suspected non-compliance in a manner that facilitates resolution and assures non-retaliation. The Helpline is part of KUMC's Compliance Program. The Helpline is available to any person in the KUMC research community, or other interested parties who know about or suspect illegal, unethical or questionable activity. To confidentially report noncompliant conduct, please call (913) 588-5757 or toll free (877) 588-5757

Environment, Health and Safety Office
Drug disposal instructions are displayed on the EHS webpages. Be sure to review these instructions for Human Subjects Research on DEA and Non-DEA regulated drugs when applicable. Contact EHS at EHS@kumc.edu or 588-1081

Newsletter is archived at HRPP News
Contact detzel-wise@kumc.edu to be added to the distribution list.