HRPP Newsletter – February 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.

“We partner with our investigators to ensure safe and ethical research”

General eCompliance Access

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

Office of Compliance Updates

Save the Dates!
Cookies and Compliance, a four-part series to highlight various compliance units, will be presented in February 2014 on consecutive Thursdays from 1-2 pm in Wahl Hall West auditorium. No signup required, and cookies for the first 50 attendees will be provided.

Feb. 6: Overview, annual compliance window, Institutional Opportunity Access, and employee accommodation
Feb. 20: Conflict of interest and environment, health and safety
Feb. 27: Vendor relations, export controls, research integrity

For more information, contact Pat Dean-Love, business officer, at 588-5079.

HRPP Updates (Human Research Protection Program)

We are in the process of revamping our website. Although we have a plethora of great info to share with you, we want our website to be user friendly and functional. We want YOUR advice and suggestions on improving our web-based communications to our customers: the research community at KUMC!

Contact: Diane Etzel-Wise, detzel-wise@kumc.edu or 588-1390

IRB Updates (Institutional Review Board – Human Subjects Committee)

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.

Closing a Study
To close a study in the electronic system, you will select “Create Modification / CR” on the Study’s home page and select “Continuing Review” as the purpose of this submission. Continue to the next screen and fill in all boxes for Question 1. If your study satisfies the first four Research milestones in Question 2, the study may be closed. The four research milestones are as follows:

☐ Study is permanently closed to enrollment
All subjects have completed all study-related interventions
Collection of private identifiable information is complete
Analysis of private identifiable information is complete

These four choices MUST be selected in order to close a study. Complete the remaining information on the screen, click “Finish,” and submit or have the PI submit the Continuing Review.

Proxy Policy for Electronic IRB Submissions
KUMC institutional review boards (IRBs) allow designated individuals to serve as “PI Proxy” for minor changes and updates to human subjects research managed through the electronic IRB system. At any given time, one individual can be designated as the PI proxy. If the principal investigator will be temporarily unavailable for an extended period, a sub-investigator can be designated as a proxy.

Studies that are managed by the KUMC Research Institute or the University of Kansas Cancer Center may only have a proxy from those regulatory offices. For other studies, proxies must be a member of the study team, and the request must be submitted by the principal investigator.

Proxy requests can be emailed to the IRB office at humansubjects@kumc.edu

A PI proxy may submit the following items:

- Minor consent form changes on approved studies if the changes do not involve increased risk or changes to study design (e.g., small increase in payment; minor clarifications or corrections; new contact information)
- Proviso responses when the study has been conditionally approved. If the proxy submits the proviso response, the study team is responsible for maintaining documentation that the principal investigator has reviewed and approved the submission.
- Administrative or other minor changes to the protocol (e.g., editorial corrections; new sponsor contacts; additional questions or new versions of a previously-approved survey)
- Updated Investigator’s Brochures that do not necessitate protocol or consent form changes
- Recruitment/retention materials

If the IRB office determines the changes are not minor, the submission will be returned for PI submission.

The Principal Investigator must submit the following items:

- Initial submissions
- Proviso responses when the proposal is deferred
- Changes to the protocol or consent form that are being made because of new safety concerns or changes to study design, aims or methods
- Continuing Reviews
- Study Closure requests

Additionally, principal investigators will be asked to acknowledge their awareness when a Report of New Information (RNI) is referred to the convened committee for review. Convened committee review is required when an RNI indicates a new safety concern or serious non-compliance.

For questions about the PI Proxy policy, please contact us at 913-588-1240.
eCompliance Assistance with IRB
You can sign up for one of our helpful technical assistance sessions through the [IRB website](http://example.com), in the HRPP Events and Training Calendar.

**IRB Contact information:** 588-1240 or [humansubjects@kumc.edu](mailto: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.

**Students and COI certifications**
A student will only need a COI certification **IF** he/she is currently serving on a research study.

**Other COI info**
If you’d like to meet with the COI Committee, please contact Juli Gardner, COI Manager at [jgardner3@kumc.edu](mailto:jgardner3@kumc.edu) or the phone number below to schedule your appointment.

If you have questions about completing your Conflict of Interest report, please see our informative [COI website](http://example.com) 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.

**COI Contact Information:** 588-0940, 588-1390 or [coi@kumc.edu](mailto:coi@kumc.edu)

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<th>HIPAA Updates</th>
<th>(Health Insurance Portability and Accountability Act of 1996)</th>
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**Contact Information:** 588-0940

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Newsletter is archived at [HRPP News](http://example.com)
Contact [detzel-wise@kumc.edu](mailto:detzel-wise@kumc.edu) to be added to the distribution list.