HRPP Newsletter – May 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)

Welcome, Chris Griffith and Ryan Werth
Chris Griffith joined the HRPP team as an IRB Generalist on Monday, April 14. Chris has IRB and eCompliance experience from his position as Assistant Coordinator of the KU-Lawrence Human Subjects Committee. He is a graduate of the KU School of Law.

Ryan Werth joined the Office of Compliance as the COI Manager on Monday, April 28. Ryan earned a JD from Washburn University School of Law and a Masters in Health Services Administration here at KUMC.

Website
We have made SEVERAL updates to our website in the past month. Among the highlights are:
- Link on the COI Resources webpage to the April 23 CTELS presentation on the Sunshine Act by Peter Griffith
- Updated HRPP Contacts list
- Step-by-step instructions for Initial Study Submissions and Modifications
- Additional Quick Start Guides on Answering Provisos, Setting or Changing the Primary Contact

Watch for a KUMC Protocol Template, coming soon to the Initial Study Submission page!!! Please feel free to give us feedback on how we can make our website more helpful to YOU. Contact Diane Etzel-Wise, detzel-wise@kumc.edu or 8-1390.

Please remember to use the HRPP Suggestion Box and take advantage of our Consultation Services!

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

Summarizing the Modification
When you are creating a modification to your study, please assist the Committee by answering these questions under the text box “Summarize the Modification:”
   1. In lay terms, summarize the key changes being proposed.
   2. Summarize the reason for the changes.
   3. List the documents included in the submission. Please make sure that any revised documents are in track-changes mode or otherwise highlighted so that changes are clear.
Modification submissions without this information may be returned for clarification.
Response to Clarifications Requested and Modifications Required
If your study is in the state of Clarifications Requested or Modifications Required (see below), please note that adding a comment does not push the study back to the IRB office for review. The PI still needs to Submit Changes by hitting that action link in the left panel under My Current Actions in order to move forward with the IRB review. Once you have submitted the changes, the dark blue bubble will move to the top row (Pre-Review, IRB Review, or Post-Review) which indicates IRB staff action is needed.

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.

Adding and Updating Study Personnel
If you are submitting a modification in which you have selected “Study team member information,” you will need to verify that the Financial Interest and Involved in Consent questions have been answered for each member of the study team before you can successfully submit the modification for IRB review. This action is required even if the study team members weren’t new additions to the study. Use the “Update” button in front of his/her name to answer these two questions on each member. If you are having difficulty with this feature, please contact us at 8-1240.

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

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Students and KUMC affiliates will ONLY need to complete a Conflict of Interest Certification IF they are currently listed on a research project as study team personnel.
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 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

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

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