HRPP Newsletter – April 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”

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<th>HRPP Updates</th>
<th>(Human Research Protection Program)</th>
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<td><strong>Kris Whitaker and Quality Assurance</strong></td>
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<td>Kris Whitaker is changing the focus of her position effective April 15, 2014. She will no longer be processing Reviews, but focusing on Quality Assurance full time. QA, as Kris reminds us, is a process of self-improvement for better research. The QA process is an educational one that provides monitoring and guidance on potential problem areas of the studies. Kris’s career has spanned 44 years in the medical / health care field. Her expertise in QA comes from 16 years in clinical research, first as a data coordinator, then trainer, then traveling monitor. Kris’ QA activities at KUMC focus on routine audits, informed consent review, and study coordinator training. Her two favorite QA quotes are: “There is no such thing as a dumb question” and “Notes to file are your friends.”</td>
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<td>Kris is available for new study coordinator orientation and training for current study coordinators. To sign up for or schedule a training session, see the HRPP Calendar or contact Kris at 945-6760 or <a href="mailto:kwhitaker@kumc.edu">kwhitaker@kumc.edu</a></td>
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**Website**

We have made SEVERAL updates to our website in the past month. Among the highlights are:

- Policies on PI Proxy and Genome Wide Association Studies and updates to our Standard Operating Procedures (SOPs) posted on our Policies, Guidelines and Regulations page
- Fact Sheet on FDA Requirements for IVD Device Studies at Topical Guidance
- Step-by-step instructions for Initial Study Submissions and Modifications
- Additional Quick Start Guides on Answering Provisors, 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!
**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.

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**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.

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**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 Affiliates**

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 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

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

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