HRPP Newsletter – July 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 (Human Research Protection Program)</th>
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<td>HIPAA / Privacy</td>
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<td>Congratulations to Juli (Gardner) Wessel, who is now the KUMC Privacy Official. She can be reached at (913) 588-0940 or <a href="mailto:jgardner3@kumc.edu">jgardner3@kumc.edu</a></td>
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Human Subjects Protection Training
KUMC is now using CITI (Collaborative Institutional Training Initiative, housed at the University of Miami) for the Human Subjects Protection Training and some training required by other compliance areas. Individuals who need to take the training by September 16, 2014 include:

1. Personnel who have never been certified in human subjects protection at KUMC (either through Chalk or CITI), or
2. Personnel whose certification through KUMC was completed prior to July 1, 2012, or
3. Persons affiliated with research at KUMC, but not employed or enrolled at KUMC.

For more information and instructions, please visit our Human Subjects Protection Training screen.

Volunteers working in Research areas
Please remember that there is a KUMC policy on volunteers which includes compliance / HRPP procedures. This applies to non-KUMC students and other volunteers. For more information, see the Policy on Volunteers in the Workplace on the Human Resources Administration webpage. In HR, contact Jodi Robinson, 913-588-5086, jrobinson5@kumc.edu

Volunteers working on KUMC research must complete the HR requirements for being on campus. They also must fulfill requirements related to human research by being:

1. Current on human subjects training and COI disclosures; and
2. Covered by either an IRB Reliance Agreement or an Unaffiliated Investigator Agreement.

If the volunteers are non-KUMC students who are obtaining course credit related to the research, then we will work with their home institution to negotiate an IRB Reliance Agreement to cover their activities. On the other hand, if they are volunteering for their own professional development, then they should be covered by an Unaffiliated Investigator Agreement. Please contact the IRB office with questions at 588-1240 or humansubjects@kumc.edu
Website
We have made SEVERAL updates to our website in the past 2 months. Among the highlights are:
• Updated Q & A Consent Template for Clinical Trials – FDA Studies on Consent Templates screen.
• Added Emergency Use of an Investigational Drug or Biologic to the Topical Guidance screen.
• The KUMC Protocol Template is here! Refer to the Initial Study Submission page, Step 1.
• REVISIONS to the Full Committee, Expedited and Exempt project descriptions on the Initial Study Submission page, Step 3.

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 588-1390.

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)

**Using the approved consent documents**
Make sure you and your study team members only use the finalized, stamped consent documents, which can be found on the main screen of the study under the Documents tab. Use the clean copy listed under the column labeled Final.

**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.

**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

**COI Updates** (Conflict of Interest)

Sunshine Act/Open Payments Announcement – FOR PHYSICIANS ONLY!!
Open Payments program (previously known as the Sunshine Act) offers patients the opportunity to know if their doctors have a financial relationship with companies that make or supply medicines,
medical supplies or devices, and the biological products used in their care. The CMS user registration portal for physicians opened June 1st. Additional Information is available on the KUMC COI Webpage.

**COI Contact Information:** 588-1288, 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.