HRPP Newsletter – March 2015
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”

Office of Compliance Updates

Big Move Coming!!
Several units in the Office of Compliance will be moving around April 13 to the Fairway Office Building. Those staff units will include IRB, Conflict of Interest, HIPAA, Equal Opportunity, Export Control, and the Associate Vice Chancellor for Compliance. Phone numbers and email addresses will remain the same. Look for more information in April’s newsletter!

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

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

O2 Access
All employees/staff working on any human subject research study that need access to O2 must do the following:

1. Your Human Subjects Protection training must be current. Please visit our Training page for assistance.
2. Your COI disclosure must be current. This certification is completed in eCompliance. Contact coi@kumc.edu for information and directions.
3. If you are not listed on the study in eCompliance, a modification must be submitted and processed to add you to the study. See our Modifications page for assistance.
4. Access the O2 form at http://intranet.kumed.com/workplace-support/computer-access-request-forms#O2Rev Once this page opens, there are several selections. Go to the- O2/Rev Cycle/ ImageNow access request form, and complete it.

Once all the above steps have been completed, please send an email asking for O2 access with your full name as listed in the KU directory, along with the name of the study and the IRB number of the study to researchqa@kumc.edu

When this is received, verified and processed, IRB permission is sent to O2 affirming that you have completed required IRB steps to gain access to O2. The O2 unit is responsible for the remaining process.

If you are not able to log on to O2 using your KUMC user ID and password, please contact Information Technologies at 913-588-7995.

Retrospective Protocol and Application
Our newest protocol template is now available for your use with a bonus: we have combined the application (project description) with this Retrospective Protocol Template! For submitting a
retrospective research proposal, the study team only needs to upload the combined form into the protocol area Question 8 of the Basic Information screen in eCompliance. Administrative certification and applicable study tools (i.e. data collection sheet or other as needed) should accompany these submissions. Details can be found on our Initial Study Submission site, especially in Step 1.

**Reminder: always find currently approved forms on our website**

We carefully and consistently update our forms to meet your needs, KUMC policies and procedures, and federal and state guidelines. Please don’t save old forms on your desktop as you may complete an outdated form and be instructed to return to our website to retrieve the correct / current form.

**Take Advantage of IRB Reciprocity (Updated on Website)**
The HRPP maintains multiple IRB reciprocity arrangements to avoid duplicative review. Please contact the IRB office if your study involves collaboration with regional institutions, including KU-Lawrence, UMKC, Children's Mercy, St. Luke's or KCUMB. We will help you identify which institution should provide oversight and guide you on the application process so that only one IRB reviews the project. KUMC investigators can also take advantage of our arrangements with Western/Copernicus IRB, National Cancer Institute IRB, NeuroNext and the IRBs affiliated with our PCORI partners. Protocol-specific reciprocity arrangements are available for other projects that involve multiple academic institutions. We expanded our Collaborations webpage, and added External IRB applications under Reliance Request forms for your easy reference and use.

**Revised Guidance on Protocol Deviations and Monitoring Reports**
All study personnel who conduct clinical trials are asked to review our revised instructions on reporting protocol deviations, monitoring reports and other problems. These updated instructions provide clarifications in response to questions from study staff and give examples of the types of problems to report to the IRB. The revisions to our reporting standards align with accreditation requirements for study contracts, and they also help investigators and the HRPP focus on potential problems that require corrective action plans. The same information is also available in our SOP 17.1.II.

**Continuing Reviews and QA**
The email address for people to submit the last 3 signed informed consents at continuing review time has changed effectively immediately (12.4.2014). The new email address is ResearchQA@kumc.edu

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

**HIPAA Updates**

**Secure Email**
When working with sensitive information, we want to protect the privacy and confidentiality of information that is contained in email messages and attachments that are sent over the internet. When sending sensitive information through email, be sure to use the secure email function that will encrypt the message. To send an encrypted email using the secure email system, you simply need to add "[secure]" (without quotes) to the beginning of the subject line of the email. Be sure to include the brackets but do not include the quote marks. The subject of your e-mail message might look something like this: [secure] Here are your lab results

Recipients will need to register and login to the secure email system before being able to view or reply. For additional information, please visit the KUMC Information Resources page on Secure Email.

If you have questions, feel free to contact Juli Wessel, KUMC Privacy Official at 913-588-0940.
COI Updates (Conflict of Interest)

For Studies under an active COI Management Plan
You (Principal Investigators & Primary Contacts) will be receiving a notification from the COI Office beginning approximately 75 days prior to your study’s IRB expiration date. This notification is being sent for the purpose of identifying changes to the study which may impact whether the management plan requires updates or retirement. Timely response will ensure that the IRB and the COIC have accurate information for review and will lessen the need for additional modifications post-IRB approval.

Open Payments for Calendar Year 2014
Physicians may now register in the system so they can be prepared to review any data that may be submitted about them. The review and dispute period for physicians is anticipated to start in April. CMS plans to publish the 2014 payment data and make any applicable updates to the 2013 data in June 2015. More information about the Open Payments is available at: www.cms.gov/openpayments

Updating Your COI Disclosures - - New & Old
In addition to the Annual Reporting window, you are asked to update your disclosures periodically.
1. Please update your COI certification within 30 days of acquisition of a new SFI (e.g., new consulting or speaking fees). If it is for a new entity, you can Add Disclosure. If it is for an existing entity, you can Modify the disclosure
2. You can also remove disclosures that are no longer applicable. For instance, previously disclosed financial interests tied to activities which took place more than 12 months ago can be deleted from your COI certification.

To make updates, login to https://ecompliance.ku.edu/ and click on the Create “Update Certification” button on the left hand margin of the screen.

Financial Conflict of Interest Training
KUMC is now using CITI (Collaborative Institutional Training Initiative, housed at the University of Miami) for COI Training required for key personnel working on studies sponsored by PHS compliant agencies (Public Health Services). Investigators will be apprised of the training requirement through the Research Institute or COI office. The KUMC IRB and COI Committee honors COI training for four years. More information can be found at the COI Training Webpage

COI Contact Information: 588-1288, or coi@kumc.edu

HRPP Updates (Human Research Protection Program)

Website
Updates to our website in the past two months include:
- Updated the types of new information that should be reported on the RNI page
- Added the O2 access information to the IRB FAQs
- Added new Consent Templates for pregnant partners, optional sample storage and future use
- Revamped Collaboration and Reciprocity page to reflect entire list of external IRB in agreements with KUMC at the present time
- Retrospective Protocol Template and Application (combined) posted on Initial Study Submission and Forms pages for your use. Retrospective Project Description no longer needed or available

Please 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.

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