HRPP Newsletter – January 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”

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<th>IRB Tips and Updates</th>
<th>(Institutional Review Board – Human Subjects Committee)</th>
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**Take Advantage of IRB Reciprocity**

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. During the month of January, we will be expanding our Collaborations webpage, so stay tuned for more information!

**Revised Guidance on Protocol Deviations and Monitoring Reports**

All study personnel who conduct clinical trials are asked to review our updated SOP 17.1 that discusses reports of non-compliance. Reportable events are outlined in section 17.1.II. This revised section gives examples of the types of problems to report to the IRB, and it also outlines a new standard for submitting monitoring reports for clinical trials. Monitoring reports should be submitted to the IRB if the industry sponsor determines the findings could affect the safety of participants or influence the conduct of the study. This change in our reporting standards aligns with accreditation requirements for study contracts, and it also helps investigators and the HRPP focus on potential problems that require corrective action plans.

**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

**PI Proxy Policy**

The PI proxy has always had the ability to submit personnel changes, which is now reflected in the policy on our website.

**Adding and Updating Study Personnel**

To ensure that the correct research personnel are recorded in IRB, please submit a modification when someone is added to a study or leaves a study team. For information on this process, visit the Modifications webpage.
Human Subjects Protection Training
While it’s important to complete your CITI training for Human Research Protections, Conflict of Interest, or Good Clinical Practice in a timely manner, we ask that you wait until you have access to eCompliance at https://ecompliance.ku.edu/ before you log into CITI. Once you are able to log into eCompliance, please visit our Human Subjects Protection Training screen for the most up-to-date information.

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

HIPAA Updates
Are you using medical information to identify subjects that might qualify for your research project? If so, the person reviewing the medical information must have an existing treatment relationship with the individual. Otherwise, a partial HIPAA waiver for recruitment purposes must be approved by IRB prior to accessing this information. Once a waiver has been approved, the researcher can then access medical information to identify subjects. Once a potential subject has been identified, the initial contact to the potential subject must come from an individual or group who has an existing treatment relationship with the potential subject. Partial HIPAA waivers can be found on our website at: http://www.kumc.edu/compliance/hipaa/research.html

If you have questions, feel free to contact Juli Wessel, KUMC Privacy Official at 913-588-0940.

COI Updates

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. Individuals who need to take the training are:
1. Personnel who have a role in research which meets the definition of an Investigator according to Federal regulation, and
2. The sponsor is the Public Health Service or a PHS Compliant Entity

The KUMC IRB and COI Committee honors COI training for four years.

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.

**COI Contact Information:** 588-1288, or coi@kumc.edu. View more info at the COI Training Website

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**Website**

Updates to our website in the past two months include:

- Posted 2015 IRB Meeting Dates on several pages and [HRPP Events Calendar](#)
- Creation of an easy to find “How to Submit to the IRB” at the top left panel on every IRB screen
- Update to our [Standard Operating Procedures](#) documents. They are now bookmarked and searchable in PDF format!

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.

**eCompliance Information**

**General eCompliance Access**

If you are with the 95% of the KU-KUMC community affiliated with only one campus, your user name and password will still work in the normal log in space at eCompliance. With individuals in several departments holding dual campus identities, we’ve adapted eCompliance log in to assist you in choosing your user name and password that corresponds with either KU or KUMC. When this feature goes live on the site, you will see the following screen at [https://eCompliance.ku.edu](https://eCompliance.ku.edu). If you have a dual appointment, please choose the campus with which a specific project is associated and then log in with those credentials.

Be sure you clear your browser cache periodically for the most up-to-date information on ALL websites. For eCompliance access issues, please contact University Customer Support at 588-7995.
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.