HRPP Newsletter – September 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”

COI Updates (Conflict of Interest)

Compliance Window
Your FY15 Conflict of Interest Disclosure Certifications was created the week of August 25, 2014 and distributed via a system-generated email from eCompliance@ku.edu. Completion of the annual COI disclosure is a requirement for the conduct of human subjects research. FY2015 COI certifications must be completed within 30 days of receipt of email notification. NOTE: New studies or personnel modifications cannot be approved until study team members have completed their FY2015 COI certifications.

For more information on Conflict of Interest reporting, please view Reporting in eCompliance

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 review and dispute period for the Open Payments system is underway. Physicians have from July 14 – September 10, 2014 to review and dispute information about payments from industry before it is published. 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

HRPP Updates (Human Research Protection Program)

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 17, 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.

NOTE: For new studies or new personnel, training must be current (completed after July 1, 2012) for all study team members before IRB approval is granted. The compliance window closes on September 17, 2014 at which time all researchers must have current training.
Investigators who are transferring to KUMC from another institution may be able to transfer their completed current CITI modules to the KUMC courses. Alternatively, they may email their current certification to humansubjects@kumc.edu if they have already completed the appropriate CITI Basic Course through a previous institution.

How to Check Training Date for Human Subjects Training

- If you have completed your human subjects training through KUMC Chalk or CITI through KUMC sign on, log into eCompliance and click on your name in the upper right hand corner. On your Properties tab, select the view "Research Profile." Refer to "2. Training data" where you will find the title of the course and the date on which you passed it.
- If you have completed your human subjects training through CITI prior to your KUMC position, log into CITI through your previous affiliation and go to My Reports page. Click the "View" link under Completion Report. You may also view your expirations and scores from this page. If you prefer, you may be able to transfer your modules for credit to KUMC on the CITI website or request assistance from CITI staff.

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

Website
We have made SEVERAL updates to our website in the past 2 months. Among the highlights are:

- Updated User Guides on the COI User Guidance screen
- Updated our Human Subjects Training page to reflect information about / instruction for accessing CITI
- 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.

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)

Important information about IRB
Please refer to the COI section of this newsletter for important information about FY15 certifications and your studies.

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.

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

### eCompliance Information

#### General eCompliance Access

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.

#### 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

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HRPP Newsletter is archived at [HRPP News](#)

Contact [detzel-wise@kumc.edu](mailto:detzel-wise@kumc.edu) to be added to the distribution list.