HRPP Newsletter – August 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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**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.

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 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

**COI Updates** *(Conflict of Interest)*

**Compliance Window**
Your FY15 Conflict of Interest Disclosure Certifications will be created around August 25, 2014 and distributed via a system-generated email from eCompliance@ku.edu This is NOT a spam email address, but the address used by our system housing IRB projects and COI disclosures. After FY15 certifications are created around August 25, new studies, continuing reviews, or personnel modifications will NOT be approved until everyone on the study team has completed their FY15 COI. 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 – August 27, 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

**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

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