HRPP Newsletter – June 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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**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 is now open as of **June 1st**.

It is vital that you take this important first step to ensure that manufacturer and industry data regarding your financial interactions with them in the last five months of 2013 is accurate. Select the “New User Registration” link at [https://portal.cms.gov/](https://portal.cms.gov/). Refer to the CMS step-by-step registration guide and allow sufficient time to register. Phase 1 requires you to complete a two-part process:

- Step 1- register as a new user
- Step 2- request access to the system

Timely registration and request for access to the system will make it easier for you to review and dispute inaccurate payments once Phase 2 is underway (likely to begin sometime in July). Phase 2 will be open for only 45 days, so please initiate your review and dispute as early as possible.

**Remember, failure to register will result in a lost opportunity to dispute and correct data that will be subject to public disclosure.**

Please ensure that the information in the Open Payments database corresponds to your current KUMC Conflict of Interest Disclosure form in the eCompliance system. To update your KUMC disclosure, access the eCompliance system at [www.ecompliance.ku.edu](http://www.ecompliance.ku.edu)

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

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

• 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.
• Link on the COI Resources webpage to the April 23 CTELS presentation on the Open Payments / Sunshine Act by Peter Griffith and other materials. More guidance at the Physician Payment Sunshine Act / Open Payments screen.

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 8-1390.

Please remember to use the HRPP Suggestion Box and take advantage of our Consultation Services!

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**Adding External Study Personnel**
If you want to add an individual affiliated with research through KUMC, but not an employee or student at the University, please refer to this decision tree on Adding External Study Personnel. Contact the home department of the PI (principal investigator) of the study for an account requestor.

**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.

**Response to Clarifications Requested and Modifications Required**
If your study is in the state of Clarifications Requested or Modifications Required (see below), please note that adding a comment does not push the study back to the IRB office for review. The PI still needs to Submit Changes by hitting that action link in the left panel under My Current Actions in order to move forward with the IRB review. Once you have submitted the changes, the dark blue bubble will move to the top row (Pre-Review, IRB Review, or Post-Review) which indicates IRB staff action is needed.
Where is my “official letter?”
If you are seeking your IRB approval letter for your initial study submission, subsequent modifications, or continuing reviews in eCompliance / eIRB, you can locate the letter at the top right side of the respective screen. You can access that screen by going into the main study, locating the symbol in front of the closed (approved) transaction and clicking on the link following that symbol.

**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.