Save the Date for the Office of Compliance Open House!
You’re invited to an open house at our new office space on Wednesday, June 10 between 3 and 4:30 pm. More information will be coming soon! The IRB Office and other units in the Office of Compliance have moved to the Fairway North Office Building. Those staff units include Conflict of Interest, HIPAA, Equal Opportunity, Export Control, and the Associate Vice Chancellor for Compliance. Our physical address is 4330 Shawnee Mission Parkway, Fairway, Kansas 66205, with IRB occupying Suite 350 and the Office of Compliance situated in Suite 330 just across the hall. Our phone numbers and email addresses remain the same.

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)
Reliance Request Q&A
KUMC researchers are entering into increasing numbers of collaborative arrangements. Researchers may request an IRB reliance agreement to streamline the review process.

What is an IRB reliance agreement?
An IRB reliance agreement allows one IRB to review research that is occurring at multiple sites or research that involves personnel from multiple institutions. The reliance agreement avoids duplication of effort by establishing an arrangement for one IRB to review the research on behalf of other IRBs. IRB reliance means that instead of the KUMC IRB reviewing the research, we rely on the review of another IRB.

When are reliance arrangements applicable?
There are two circumstances where reliance requirements apply:
- When KUMC investigators conduct research at non-KUMC locations and external personnel are part of the study team, or
- When external personnel participate in KUMC research on our campus

Why are reliance agreements necessary?
Each institution is responsible for research conduct by its own personnel, regardless where the research occurs. When KUMC personnel conduct human subjects research, the institution has only two options:
- Review the research through the KUMC IRB,
• Arrange for another qualified IRB to review the project

KUMC personnel may not conduct human subjects research until approval has been obtained from one of the above reviews and all other institutional requirements have been met. More information about IRB Reliance is available on our Collaborations and IRB Reciprocity webpage.

Training
KUMC has contracted with CITI (Collaborative Institutional Training Initiative at the University of Miami) to offer six different types of training to our community, with five of them directly related to research. These six curriculum areas are: Human Subjects Research, Laboratory Animal Research, Good Clinical Practice (GCP), Responsible Conduct of Research, Conflicts of Interest, and Export Control. The IRB staff track completion of the Human Subjects Research training courses at this time. Other departments on campus track completion of the remaining courses as needed. Important to note: the completion of GCP can NOT be substituted for the Human Subjects Research requirement.

O2 Access
All employees/staff working on any human subject research study needing 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 team. 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 the research QA email at 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 and they can be reached at O2trainingrequests@kumc.edu

If you are not able to log on to O2 using your KUMC user ID and password, please contact Information Technologies Help Desk 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.
Continuing Reviews and QA
The email address for people to submit the last three signed informed consents at continuing review time was changed on 12.4.2014. The correct email address is ResearchQA@kumc.edu

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

HRPP Updates (Human Research Protection Program)

Website
Updates to our website in the past two months include:

- Updated Collaborations and IRB Reciprocity webpage to include FAQs about and Requests templates for IRB Reliance.
- Condensed the Training page to a Q&A section on Training Information and How do you find CITI?
- Added a Recruitment Resources page!
- Added an Overview of Community-based Participatory Research to Topical Guidance – IRB Review
- Added Community Engagement questions to Full Committee and Expedited Project Descriptions and to the Protocol Template on Initial Study Submission page.
- Revised the Administrative Certification and Scientific Review / Administrative Certification to include a more detailed description of departmental support on Initial Study Submission page.

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.

COI Updates (Conflict of Interest)

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 or May. 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.

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

HIPAA Updates

HIPAA Contact Information: Juli Wessel, KUMC Privacy Official at 913-588-0940.

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