HRPP Newsletter – June 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”

Office of Compliance Updates

You’re invited to an open house at our new office space on Wednesday, June 10 between 3 and 4:30 pm.

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 as listed below:

HRPP
- HRPP Director: Karen Blackwell (913) 588-0942 kblackwe@kumc.edu
- HRPP Assistant Director: Kyle Stephens (913) 588-1240 kstephens3@kumc.edu
- HRPP Coordinator: Diane Etzel-Wise (913) 588-1390 detzel-wise@kumc.edu
- IRB Administrator: Jennifer Pennington (913) 588-5712 jpennington2@kumc.edu

IRB Generalists
- Katie Kosfeld (913) 945-7742 kkosfeld@kumc.edu
- Christopher Griffith (913) 588-1379 cgriffith@kumc.edu
- Melody Solace (913) 588-1493 msolace@kumc.edu

Quality Assurance Monitor
- Kris Whitaker (913) 945-6760 kwhitaker@kumc.edu

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 anyone 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)

Exempt Studies
All open exempt studies, past and future, are now housed in eCompliance. If you are applying for an Exempt Protocol, you will upload your protocol and project description in the electronic system the same way you would upload and submit documents for other types of protocols.
Non-Human Subjects Determinations and Quality Assurance / Improvement Determinations
Requests for determination of Non-Human Subjects or Quality Assurance/Improvement protocols should be downloaded from our Initial Study Submission webpage, Step #3. Complete and save the request form, scan it, and email it to humansubjects@kumc.edu We will process it and communicate with you via phone and email on the status. These determinations will not be stored in eCompliance at the current time.

Training
KUMC partners with CITI (Collaborative Institutional Training Initiative at the University of Miami) to provide Human Research Protection training and other types of training to our research community. If your last Human Subjects course was completed prior to July 1, 2013, it will be time to complete your training in CITI this summer or early fall. If you have taken training through another institution more recently, send a completion report to humansubjects@kumc.edu. Important to note: the completion of GCP can NOT be substituted for the Human Subjects Research requirement.

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, or
• 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.

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.kumc.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 Emergency Use Instructions and form on Topical Guidance webpage
• Updated Collaborations and IRB Reciprocity webpage to include FAQs about and Requests templates for IRB Reliance.
• 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.

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.
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

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

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