HRPP Newsletter – July 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”

IRB Tips and Updates  (Institutional Review Board – Human Subjects Committee)

Farewell to Diane
Diane Etzel-Wise is leaving KUMC to work at the KU School of Social Welfare in the Center for Assets Education and Inclusion. She will serve as a Research Project Coordinator for longitudinal studies about solutions to generational poverty. We wish her the very best and say thanks for her stupendous contribution to the KUMC HRPP!

IRB Office Hours on Main Campus  NEW!
Starting July 6th, IRB staff will hold office hours on main campus in order to provide consultation to investigators. Feel free to come to G058 Delp during these hours for assistance with choosing the correct IRB application, answering provisos, navigating eCompliance and much more. G058 Delp is the Compliance Conference Room, located on main corridor, ground floor, across from the Mail Room.

1st, 3rd and 4th Mondays: 2 – 4pm
2nd Mondays: 8 – 10am
Wednesdays: 2 – 4pm
1st and 3rd Thursdays: 8 – 10am
2nd and 4th Thursdays: 2 – 4pm

For assistance at other times, call (913) 588-1240, email humansubjects@kumc.edu, contact the IRB coordinator listed on your eIRB submission or stop by our Fairway offices at 4330 Shawnee Mission Parkway, Suite 350.

Training
KUMC partners with the Collaborative Institutional Training Initiative at the University of Miami (CITI) 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 CITI training through another institution more recently, send a completion report to humansubjects@kumc.edu. Important to note: the completion of Good Clinical Practice (GCP) can NOT be substituted for the Human Subjects Research requirement.

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.
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.

**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

**COI Updates (Conflict of Interest)**

**FY16 COI Certifications**
The FY16 Annual COI Certifications will be created in eCompliance as new faculty and unclassified professional staff join the KUMC community beginning July 1, 2015. The new KUMC personnel will be notified of their COI certification’s availability in a system-generated email from eCompliance@ku.edu with a direct link to their specific certifications. To login, individuals use their KUMC network username and password.
The KUMC Compliance window will open for current faculty, staff and research affiliates in late August/early September. Email notifications will be sent during this time. If you do not receive an e-mail with the link to your FY16 certification by September 14, 2015, please contact the COI Office.

CMS’ Open Payments Publishes Data [for Physicians]
On June 30th, CMS published data concerning financial transfers between health care providers and drug and medical device makers on its Open Payment website. Your Open Payments report represents payments and other transfers received during the 2014 calendar year. In comparison, your KUMC COI certification form should reflect financial interests from July of 2014 to present in order to be compliant with University policy.

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

HRPP Updates (Human Research Protection Program)

Website
Updates to our website in the past two months include:
- Revised Instructions for Using Short Form Consent Documentation on Consent of Non-English Speaking Subjects page and added the Russian Short Form
- Revised Retrospective Protocol and Application template on the Forms or Initial Study Submission Step 1 page
- Updated Emergency Use Instructions and form on Topical Guidance webpage
Please give us feedback on how we can make our website more helpful to YOU. Contact Chris Griffith at cgriffith@kumc.edu or 588-1379.

HIPAA

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

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

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