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”

HRPP Newsletter – October 2014
Human Research Protection Program at KUMC
http://www.kumc.edu/compliance/human-research-protection-program.html

Do you need help with IRB, COI or eCompliance?
We offer many avenues to assist you and your study team members with the study submission process, follow-up submissions, COI reporting, and working in the electronic system. These services include face to face or phone assistance, group training and a plethora of information on the HRPP website.

1. You can arrange for Consultation and Pre-Review Services
2. You can review the step-by-step guide to Initial Study Submission, which includes decision trees, protocol templates, project descriptions, forms, Quick Start Guides, and screen shot guides.
3. You can review the step-by-step guide for Modifications to Your Study, which includes Quick Start Guides for specific modifications and how to respond to provisos.
4. You can review FAQs and the step-by-step guide to Continuing Review, which includes the required Continuing Review Supplement and screen shot guide to closing a study.
5. You can sign up for one of our helpful technical assistance sessions through the HRPP Events and Training Calendar OR an HRPP staff member will assist you at your desk.
6. You can sign up for a Study Coordinator Orientation / Training through the HRPP Events and Training Calendar

Website
Highlighting our Important Links box on the right hand panel on each screen of our site! You can find:
  - Contact Information for all HRPP staff
  - Consultation Services to assist investigators, coordinators, residents, and students with pre-review and other questions about HSC submissions
  - Suggestion Box to provide ideas and feedback for any area of HRPP
  - HRPP News to access past editions of this newsletter

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, checking training dates, and printing your completion reports
- Added a page devoted to Consent of Non-English Speaking Subjects with short forms in six languages
- Updated User Guides on the COI User Guidance screen
- In development: Recruitment Resources page and a Retrospective Protocol Template!

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.
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 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, new personnel, and continuing reviews, training must be current (completed after July 1, 2012) for all study team members before IRB approval is granted.

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.

How to Check Training Date for Human Subjects Training
• If you have completed your human subjects training through KUMC Chalk or CITI through KUMC sign on, log into eCompliance and click on your name in the upper right hand corner. On your Properties tab, select the view "Research Profile." Refer to "2. Training data" where you will find the title of the course and the date on which you passed it.
• If you have completed your human subjects training through CITI prior to your KUMC position, log into CITI through your previous affiliation and go to My Reports page. Click the "View" link under Completion Report. You may also view your expirations and scores from this page. If you prefer, you may be able to transfer your modules for credit to KUMC on the CITI website or request assistance from CITI staff.
• If you require a copy of your completion report in CITI, please see “Obtaining a copy of your CITI completion report” on our Human Subjects Protection Training screen

For more information and instructions, please visit our Human Subjects Protection Training screen or contact Diane Etzel-Wise at detzel-wise@kumc.edu

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

Continuing Review Tip
When creating a Continuing Review, please make sure to check the list of study team members and make changes if needed by choosing Modification and Continuing Review. Be sure to choose Study Personnel Changes as the Scope of the Modification (and Other Parts of the Study if you have additional changes). Removing personnel that are no longer working on the study (and possibly no longer with the institution) will help keep you from receiving unnecessary provisos for training.
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*, NOT the draft column.

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

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**Compliance Window**
FY15 Conflict of Interest Disclosure Certifications were created the week of August 25, 2014 and distributed via a system-generated email from eCompliance@ku.edu. Completion of the annual COI disclosure is a requirement for the conduct of human subjects research AND a requirement for most University employees per the Kansas Board of Regents. If you have NOT received your system-generated email with the link to your FY2015 COI certification, please contact us at coi@kumc.edu as soon as possible. FY2015 COI certifications must be completed within 30 days of receipt of email notification. NOTE: New studies, continuing reviews, and personnel modifications cannot be approved until study team members have completed their FY2015 COI certifications.

For more information on Conflict of Interest reporting, please view **Reporting in eCompliance**

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

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**General eCompliance Access**
Be sure you clear your browser cache periodically for the most up-to-date information on ALL websites. For eCompliance access issues, please contact University Customer Support at 588-7995.

**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