



KUMC Research Orientation 2005

Presentation Online

www2.kumc.edu/researchcompliance/education_presentation_archives.htm

Session Goals

- Provide a **high level overview** of the administration of research at KUMC
- Identify resources and contacts for research at KUMC
- Navigate the KUMC Web site to find resources for conducting research

Session Topics

- Research Enterprise
 - Lawrence & Kansas City
 - Research Advisory Council
- Office of Compliance
 - Animal Research Protection Program
 - Human Research Protection Program
- Research Institute
 - Pre- & Post-Award
 - Clinical Trials
- Human Resources

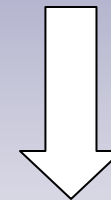
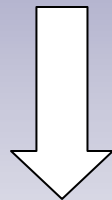
Research at KU & KUMC



Lawrence



KC



Research Advisory Council (RAC)

- Reports directly to the EVC
- Membership includes:
 - School of Medicine (KC & Wichita)
 - School of Nursing
 - School of Allied Health
 - Faculty Assembly Research Committee
 - Basic science researcher
 - Clinical science researcher
 - Graduate student
 - Research Institute

Marge Bott, R.N., Ph.D., Chairperson

- Office of Compliance
- KUMC Research Institute
- General Clinical Research Center

Office of Compliance

- Animal Research Protection Program
- Human Research Protection Program
- HIPAA
- Safety Administration
- Equal Opportunity

KUMC Comprehensive Compliance Program

- Institutional Animal Care & Use Committee (IACUC)
- Human Subjects Committee (HSC)
- HIPAA Compliance Office
- Institutional Research Safety Committee (IRSC)
- Conflict of Interest Committee
- Data & Safety Monitoring Board (DSMB)
- Radiation Safety Committee

KUMC Comprehensive Compliance Program - *Hotline*

- Compliance Hotline
 - Confidential phone line to report suspected compliance violations
 - 8-5757

Animal Research Protection Program (ARPP)

- For those who work with animals in research, testing or teaching, appropriate training is mandated by federal law
- Live Animal Resources (LAR)

ARPP Training for Investigator, Technician Staff

- Laws, regulations & policies
- Authority & responsibility
- IACUC
- Accreditation (AAALAC), every three years
- Annual USDA Inspection for LAR facility
- Personal responsibilities

Institutional Animal Care & Use Committee (IACUC)

- Oversight of animal care and use in research conducted at KUMC
- Required by the Animal Welfare Act and PHS policy
- Follows the *Guide for the Care and Use of Laboratory Animals*
- <http://www2.kumc.edu/researchcompliance/iacuc.htm>

Review Schedule

- Meetings are the 3rd Tuesday of every month
- Submissions are due by Friday
 - (11 days prior to the meeting date)
 - Deliver Animal Care & Use Proposals (ACUP) to G018 Sudler
- Submissions materials
 - www2.kumc.edu/researchcompliance/iacucforms.htm

ARPP Training for Investigator, Technical Staff - *continued*

- Occupational health standards
- Standards for anesthesia, analgesia & surgical procedures
- Standards for euthanasia
- General animal handling & caging maintenance
- Optimum use & interaction with ARPP
- ARPP Standard Operating Procedures

ARPP Contacts

- Jo Denton, MSN, ARPP Director 8-5492
- Latyona Mebane, IACUC Coord. 8-2416
- www2.kumc.edu/researchcompliance/animalsubjects.htm
- www2.kumc.edu/researchcompliance/iacuc

LAR Training

- First step in certification
 - Access to the building & animals will not be granted until training is complete
- ❖ For more information, call 8-7015

LAR Contacts

- David Pinson, Director 8-7351
- Nathan Culley, Assoc. Director 8-7852
- Yolande Cole, Assit. Director 8-7016
- Marcia Helwig, Sr. Coordinator 8-7093
- Barbara Banks, Front Desk 8-7015

- www.kumc.edu/lar
- www2.kumc.edu/researchcompliance/iacuc

Human Research Protection Program

- For those who work with human subjects in research, appropriate training is mandated by federal law
- Human Subjects Committee (HSC)

Human Subjects Committee (HSC)

- KUMC's Institutional Review Board (IRB)
- Committed to ethical, legal & safe conduct in all research involving human participants
- Guided by the Belmont Report & governed by Office for Human Research Protections (OHRP), federal regulations & University policies
- Provides oversight of research & ensures adequate & uniform protections for research subjects
- Serves as KUMC's privacy board

What Is Subject to HSC Review?

- Research conducted by KUMC faculty, staff, students involving human subjects or their data
- Research conducted by KUMC faculty, staff, students at other locations
- Collaborative studies, even if there are no KUMC subjects

Review Schedule

- Meetings are the 2nd & 4th Tuesdays of every month
- Submissions are due by noon on Friday
 - (7 business days prior to the meeting date)
 - Deliver submissions to G006 Sudler
- Submissions materials
 - www2.kumc.edu/researchcompliance/hscsubprocess.htm

HSC Continuing Review *Recertification*

- Annual Review
 - HSC approval is for one year or less
 - Summary Progress Report (SPR)
 - Projects that fail to apply for recertification will be terminated
 - PIs must pay strict attention to effective dates stamped by HSC on consent forms & consent form approval must be current

HSC Review

Additional Requirements

- Adverse Event reporting
- Recruitment information
 - Ads, posters, fliers
- Amendments
 - Changes in protocol, consent form

HSC Training & COI Disclosure

- All research personnel who have any role in research involving humans must complete:
 - Human Subjects Protection & HIPAA tutorials
 - Modules 1-6, Human Subjects Protection
 - Module 7 HIPAA Training for Research Personnel
 - Conflict of Interest Disclosure
- All training can be found on Chalk System
 - www2.kumc.edu/chalk2

HSC Training

- Human subjects projects will not receive initial approval until all training is complete
- For external collaborators, we accept current training from their “home” institution

❖ For more information, call 8-1240

HSC Contacts

- Karen Blackwell, HRPP Director 8-0942
- Dan Voss, IRB Administrator 8-5712
- HSC Office Front Desk 8-1240
- Tom Field, HIPAA Manager 8-0940
- www2.kumc.edu/researchcompliance/humansubjects.htm

HIPAA

- Health Insurance Portability & Accountability Act of 1996 (HIPAA)
- Specialized training for individuals involved in research
 - Human research
 - Animal & basic science research
- All training can be found on Chalk System
 - www2.kumc.edu/chalk2

Safety Administration

- Basic training is required for all employees
- Annual basis
- Research staff may have additional training requirements based on work
- Includes transients in lab environment
- Lab safety
- Lab-specific orientation

Current Issues in Safety

- More government regulation
- Increased accountability & liability
- More accurate inventories
- More guidelines sent to lab administration from Safety Administration
- Lab & building security issues

Safety Administration

In Case of Emergency

- In case of emergency, contact:
 - Occupational Health
 - G110 Delp
 - 8-6512
 - Emergency Room (after hours)
 - Campus Police
 - 911

Safety Administration Contacts

- Ruth Schukman-Dakotas, Director 8-6126
- www2.kumc.edu/safety

The University of Kansas Medical Center Research Institute (KUMC-RI)



- Sponsored Programs Administration (SPA)
- Clinical Research Administration
- Legal Counsel & Contracts Office
- Technology Transfer, Commercialization & Intellectual Property
- Finance & Administrative Services

Research Institute – Five Goals

- To facilitate & assist KUMC faculty in obtaining extramural funding from all sources
- To continue to improve the entire KUMC Research Administration process from proposal development to final grant close out
- To fund an internal grants program for KUMC faculty that will enhance their extramural funding competitiveness

Five Goals - *continued*

- To continue the development of a strong, user-friendly Research Administration program to the benefit of KUMC faculty members
- To promote KUMC research focusing on the various Life Sciences Initiatives in the greater Kansas City community, the states of Kansas & Missouri and the greater Midwest & heartland

SPA Pre- & Post-Award

- Pre-Award Services
 - Funding opportunities
 - Government & non-government
 - Proposal development, preparation & review
 - Award acceptance, prior approval request
- Post-Award Services
 - Sponsored Awards Administration & monitoring

SPA Pre- & Post-Award Contacts

Mei-Shya Chen, Director

- mchen@kumc.edu
- 8-1259

- **Pre-Award Services**

- Jenne Accurso, Manager

- jaccurso@kumc.edu
 - 8-5439

- **Post-Award Services**

- Doug Harris, Manager

- dharris@kumc.edu
 - 8-1260

SPA (Pre-Award) Proposal Development

- Develop profiles to match faculty to funding opportunities
- Notification of funding opportunities
- One-on-one assistance in proposal preparation
 - Contact: Vickie Eaton
6009 Wescoe
8-1239
- Notification of changes in funding source requirements & budgetary restrictions

SPA (Pre-Award) Proposal Preparation

- **BEFORE** you begin to put your proposal together:
 - Contact Sponsored Programs Administration
 - Conflict of Interest Form completed
 - Current application instructions
 - Current forms
 - Understand restrictions of funding agency

SPA (Pre-Award) Proposal Preparation

- Note deadlines
- Note signatures required
- Make copies of materials
- **CALL** Sponsored Programs Administration

SPA (Pre-Award) Proposal Review

- For all funding sources:
 - Analyze solicitation & review proposal
 - Assist in budget preparation & review
 - Ensure commitment letters are obtained for required matching funds, services or support
 - Confirm subcontract commitments
 - Facilitate review of any contract requirements

SPA (Pre-Award) Proposal Review

- Assist with electronic proposal submissions (NSF, Grants.gov, eSNAP)
- Check proposals for compliance
- Provide institutional signature
- Grant no-cost extension
- Process sub-awards/subcontract agreement

SPA (Pre-Award)

- All proposals must be submitted at least 10 working days prior to application due date in submission ready form
- Submit 2 single-sided copies

SPA (Post-Award)

- Sponsored Award Accounting
- Sponsored Award Monitoring
- Finance & Administration Services

Sponsored Award Accounting/Monitoring

- All funded sponsored programs
- Uses PeopleSoft Financial System
- PeopleSoft training is required
- Initial account set up
- Re-budgeting
- Authorization forms

Sponsored Award

Accounting/Monitoring - *continued*

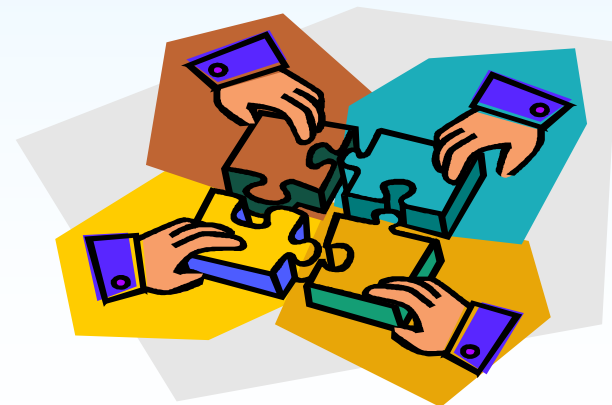
- Receiving funds
- Expenditure monitoring
- Financial reporting
- Grant close out

Finance & Administration Services

- Payments & reimbursements
- Subject payments
- Questions about check disbursements
- Contact: Cody Tully
 8-1241
- RI Accounting Procedures for Grants & Contracts

Clinical Research Administration Services

- Provides supportive services for conducting funded clinical trials at KUMC
- Liaison between funding agencies, HSC and principal investigator



Clinical Research Administration

Service areas include:

- Pre Award
 - Study Recruitment
 - Study Set-up
 - Study Tracking
- Post Award
- Clinical Trials Education

Information for Investigators

Clinical Research Administration

Types of studies in which CRA Division assists:

- Industry (pharmaceutical) sponsored clinical trials
- Privately funded PI initiated clinical trials
- Government funded clinical trial flow thru (money comes to KUMC from another source)
- Government funded clinical trials

Clinical trial processing

Clinical Research Administration

- KUMC agent to post any study, regardless of funding, on www.clinicaltrials.gov
- Clinical Research Administration
- Contact: Laurie Kemble
8-1242

Technology Transfer, Intellectual Property & Commercialization

- Facilitate transfer of technology from the University to the commercial marketplace
- Help faculty protect their ideas
- Preview research plans & strategies when to disclose new inventions
- Review processes for disclosing new inventions, marketing new ideas, patenting & collaborating
- Technology Transfer, Intellectual Property & Commercialization
- Contact: Richard Huston

8-1495

Legal Counsel & Contracts Office

- Review & negotiation of research-related agreements
- Legal Counsel & Contracts Office
- Contact: Arthur Hogg
8-2617
- Read agreements CAREFULLY
- Don't sign anything without legal counsel review and institutional approval
- Provides protection for both the individual & institution

General Clinical Research Center (GCRC) at KU Medical Center

Goals established in 2002

- Provide clinical investigators from the SOM, SON, and SOAH with a modern, state of the art facility in which clinical research can be conducted
- Enhance multidisciplinary research across departments and the three schools
- Enable and train junior faculty and trainees to become more involved in clinical research
- Apply for federal funding to support the GCRC
- Protocol Application and Submission done via GCRC website
- GAC Advisory Committee meets every 4th Wednesday of each month to review protocols

GCRC Contact Information

GCRC Administration

•Richard Barohn, MD

Program Director 8-6094

•Susan Schmitz, RSA, CCRC

Administrative Director 8-0980

•Nicole Ladesich, BS

Administrative Coordinator 8-0970 *GCRC Clinic Phone*

GCRC Nursing

•Judy Otey, RN, BSN

Nurse Manager 8-0984

•Mary Reed, RN, BSN

Research Nurse 8-0977

Location

GH04 DELP Mail Stop 3037

Administrative Offices/Clinic

913-588-0970/0978 fax

*Visit the GCRC Web site at <http://gcrc.kumc.edu>

What the GCRC Can Do

- Space to see patients
- Biostat support – study design
- Data management
- Trained research nursing support
- Specimen collection/processing/storage
- Core labs (exercise physiology, computer lab and metabolic kitchen)
- No cost for above services to PI's on investigator initiated studies
- Industry sponsored with charges for space/resources

GOALS of the GCRC

- Offer an *Introduction to Clinical Research* course (weekly for 3 months) through the GCRC which will be available to students, residents, fellows, and junior faculty
- Work closely with the existing K30 program to train junior clinical researchers
- Work closely with the Research Institute and the Human Subjects committee to develop an seamless mechanism for the facilitation of clinical research

A Visit to the GCRC



Human Resources at KUMC

- Personnel need identified
- Recruitment
- Selection
- New Hire
- Orientation
- Contact: 1024 Murphy
 8-5080

Equal Opportunity

- Rights & responsibilities
- Call with any personnel action
 - Hire, promotion, termination
- Contact: 1040 Wescoe
 8-1206

Research Policies & Procedures

- Handbook for Unclassified Faculty & Staff
- KUMC Research Institute
- Human Subjects Committee
- Institutional Animal Care & Use Committee
- Records Retention Policy

Educational Opportunities

- Educational Opportunities in Research

KUMC Research Orientation

- Laurie Kemble, clinical research contact
 - lkemble@kumc.edu
 - 8-1242
- Mei-Shya Chen, grants contact
 - mchen@kumc.edu
 - 8-1259
- Tom Field, compliance contact
 - tfield@kumc.edu
 - 8-0940

Questions?