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# University of Kansas Medical Center

## 2006 Research Orientation



KUMC Office of Compliance & KUMC Research Institute



# Session Goals

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- 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

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- Office of Compliance
  - Animal Research Protection Program
  - Human Research Protection Program
- Research Institute
  - Pre- & Post-Award
  - Clinical Trials
- General Clinical Research Center (GCRC)
- Human Resources Issues

# Office of Compliance

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- Animal Research Protection Program
- Human Research Protection Program
- HIPAA
- Environmental Health & Safety
- Equal Opportunity

# Comprehensive Compliance Program Committee Oversight

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- Institutional Animal Care & Use Committee (IACUC)
- Human Subjects Committee (HSC)
- HIPAA
- Institutional Research Safety Committee (IRSC) –  
*Biosafety issues and more*
- Conflict of Interest Committee
- Data & Safety Monitoring Board (DSMB)
- Radiation Safety Committee

# Animal Research Protection Program (ARPP)

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- For those who work with animals in research, testing or teaching, appropriate training is mandated by federal law
- Live Animal Resources (LAR)
- <http://www2.kumc.edu/researchcompliance/arpp.htm>

# Institutional Animal Care & Use Committee (IACUC)

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- 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

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- Meetings are the 3<sup>rd</sup> 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

# ARPP Training for Investigator & Technician Staff

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

# ARPP Training for Investigator & Technician Staff - *continued*

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- 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

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- Jo Denton, MSN, ARPP Director 8-5492
- Latyona Mebane, IACUC Coord. 8-2416
- [www2.kumc.edu/researchcompliance/arpp.htm](http://www2.kumc.edu/researchcompliance/arpp.htm)
- [www2.kumc.edu/researchcompliance/iacuc.htm](http://www2.kumc.edu/researchcompliance/iacuc.htm)

# Live Animal Resources (LAR) Training

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- First step in certification
- Access to the building & animals will not be granted until training is complete
- Visit the [LAR Web site](#)
  
- For more information, call 8-7015

# LAR Contacts

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- 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](http://www.kumc.edu/lar)

# Human Research Protection Program (HRPP)

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- IRB - Human Subjects Committee
- HIPAA
- Conflict of Interest Committee
- Data and Safety Monitoring Board
- Radiation Safety and Biosafety
- Compliance enforcement

# Human Subjects Committee (HSC)

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- Committed to ethical, legal & safe conduct in all research involving human participants
- Provides oversight of research & ensures adequate & uniform protections for research subjects
- Serves as KUMC's privacy board

# What Is Subject to HSC Review?

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- 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

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- Meetings are the 2<sup>nd</sup> & 4<sup>th</sup> 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](http://www2.kumc.edu/researchcompliance/hscsubprocess.htm)

# HSC Review:

## *Investigator Responsibilities*

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- Obtain approval from HSC prior to study initiation
- Submit recruitment information for approval
  - Ads, posters, fliers
- Seek prior approval for any changes to the study plan (except in an emergency)
- Report any problems
- Re-certify annually, or as required

# HSC Training & COI Disclosure

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- 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](http://www2.kumc.edu/chalk2)

# HSC Training

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- 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

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- Karen Blackwell, HRPP Director 8-0942
- Dan Voss, IRB Administrator 8-5712
- HSC Office Main Number 8-1240
- Tom Field, HIPAA Manager 8-0940
  
- [www2.kumc.edu/researchcompliance/humansubjects.htm](http://www2.kumc.edu/researchcompliance/humansubjects.htm)

# Health Insurance Portability & Accountability Act of 1996 (HIPAA)

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- 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](http://www2.kumc.edu/chalk2)
- For more information, call 8-0940

# Safety

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- 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

# Environmental Health & Safety

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- Kevin Dirks, Director 8-5165
- *In case of emergency*, contact:
  - Occupational Health
    - G110 Delp
    - 8-6512
  - Emergency Room (after hours)
  - Campus Police
    - 911

# Compliance *Helpline*

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

# KUMC Research Institute (KUMC-RI)

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



# Research Institute: Five Goals

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- 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*

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- 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-Award

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- Funding opportunities
  - Government & non-government (including for-profit companies)
- Community of Science
- Grants.gov
  - Federal government's single, online portal to allow any individual, business or state government to electronically submit grant applications through a common web site
  - Find funding opportunities posted by 26 federal agencies
  - Submit federal grant applications through Grants.gov
  - Training
- Proposal development, preparation & review
- Award acceptance, prior approval request



# SPA Post-Award

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- Sponsored Awards Administration & monitoring

# SPA Pre-Award Proposal Development

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- Use Community of Science to develop profiles 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

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- **BEFORE** you begin to put your proposal together:
  - Contact Sponsored Programs Administration
  - eRA Commons account set up
  - Grants.gov training
  - Conflict of Interest Form completed
  - Current application instructions
  - Current forms
  - Understand restrictions of funding agency

# SPA Pre-Award Proposal Preparation

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

# SPA Pre-Award Proposal Review

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- 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

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

# SPA Pre-Award

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- All proposals must be submitted at least 10 working days prior to application due date in [submission ready form](#)
- Submit 2 single-sided copies
- Email e-application package to [spa@kumc.edu](mailto:spa@kumc.edu)

# SPA Post-Award

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

# SPA Pre- & Post-Award Contacts

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Mei-Shya Chen, Director

- mchen@kumc.edu
- 8-1259
- Pre-Award Services
  - Jenne Accurso, Associate Director, Pre-Award/ERA
    - jaccurso@kumc.edu
    - 8-5439
- Post-Award Services
  - Doug Harris, Manager
    - dharris@kumc.edu
    - 8-1260



# Sponsored Award Accounting & Monitoring

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- 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*

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

# Finance & Administration Services

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

# Clinical Research Administration Services (CRA)

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

# Clinical Research Administration

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Service areas include:

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

[Information for Investigators](#)



# Clinical Research Administration

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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

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- KUMC agent to post any study, regardless of funding, on [www.clinicaltrials.gov](http://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

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- Review & negotiation of research-related agreements
- [Legal Counsel & Contracts Office](#)
- Contact: Cydney Rabourn  
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)

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- Provide clinical investigators with a modern, state-of-the-art facility in which clinical research can be conducted
- Enhance multidisciplinary research across departments & 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 Web site
- GCRC Advisory Committee meets every 4th Wednesday of each month to review protocols

# GCRC Goals

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- Expand research education: Currently offering an *Introduction to Clinical Research* course (weekly for Fall semesters) through the GCRC which is available to any student, resident, fellow, and faculty from KUMC (Kansas City and Wichita), KC VA, CMH, St. Luke's/UMKC, and KCUMB
- Work closely with the existing K30 program to train junior clinical researchers (Research Seminar Series held monthly)
- Work closely with the Research Institute and the Human Subjects committee to develop an seamless mechanism for the facilitation of clinical research (The GCRC meets monthly with HSC to review future GCRC projects)

# What the GCRC Can Do

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- Space to see patients
- Biostatistics 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

# GCRC Contacts

- GCRC Administration

- Richard Barohn, MD

- *Program Director* 8-6094

- Judy Otey, RN, BSN

- *Administrative Director* 8-0984

- Nicole Ladesich, BS

- *Senior Coordinator* 8-0976

- GCRC Nursing

- Jody Mahan, RN

- *Nurse Manager* 8-0970

Location

GH04 Delp Mail Stop 3037  
Administrative Offices/Clinic  
913-588-0970/0978 fax

*GCRC Clinic Phone* 8-0970

*WEBSITE:* <http://gcrc.kumc.edu>

# Human Resources at KUMC

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- Personnel needs
- Recruitment
- Selection
- New hire
- Orientation
- Contact: 1024 Murphy  
8-5080

# Equal Opportunity

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

# Research Policies & Procedures

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

# Educational Opportunities

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- CTEs, *sponsored by the Research Institute*
- CELPs, *sponsored by the Office of Compliance*
- Educational Opportunities in Research

# KUMC Research Orientation Contacts

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

# Questions?

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- *Questions are always welcome by the KUMC Office of Compliance the KUMC Research Institute and the other offices and departments involved in research at KUMC.*