

# **AGENDA**

## **RESEARCH ROUNDTABLE REVIEW**

November 15, 2005  
9:00 AM  
Storm Eye Institute Auditorium HA 809

Sponsors:  
Office of Research & Sponsored Programs  
(792-3838)  
Office of Grants & Contracts Accounting  
(792-2850)  
Harborview Tower – 6<sup>th</sup> Floor

### **TOPICS:**

1. Health Insurance for Post-Doctoral Trainees..... Stewart Mixon,  
Chief Operating Officer
2. Research Compliance: Components, Commitment, and Cost..... Cynthia Karr, Office of  
Research Integrity
3. Corporate Interactions Related to Intellectual Property..... Dillard Marshall, ORSP
4. Corporate Sponsorships..... Dillard Marshall, ORSP
5. MUSC / USC Research Foundation..... Dillard Marshall, ORSP
6. Grants.Gov Demo & Update..... Robbie Lee, ORSP
7. F&A Cost Rates Negotiations..... Velma Stamp, GCA
8. Improper Charging of Expenditures..... Velma Stamp, GCA
9. Updates and Reminders..... Mike Bull & Ann Hall, GCA
10. Q & A / Open Forum..... All

**RESEARCH  
ROUNDTABLE**

Grants & Contracts Accounting  
November 15, 2005  
Storm Eye Institute Auditorium

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**Health Insurance for  
Post-Doctoral Trainees**

Stewart Mixon,  
Chief Operating Officer

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**Research Compliance:  
Components, Commitment,  
and Cost**

Cynthia Karr, PhD  
MUSC Research Integrity Officer

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## F&A Cost Rates Negotiation

- Site visit scheduled for December 6-9, 2005.
- DHHS has selected four departments for interviews and walk-through of space.
- After on-site visit, we may still be months away from having rates negotiated.

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## Improper Charging of Expenditures

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## Updates & Reminders

### Federal Per Diems for Charleston

- Used when paying a consultant who isn't a SC state employee.
- For FY06 (10/1/05 to 9/30/06):
  - Lodging \$89 per night
  - Meals \$54 per day
- Website: <http://www.firstgov.gov>
  - Scroll down & click on "Federal Employees"

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## Updates & Reminders

### Subcontract Payment Procedures

- Get a Purchase Order for each subcontract.
- Please send all subcontract invoices to GCA so that costs can be monitored.
- GCA sign-off on invoices is necessary for payment to be made.
- Please close P.O.'s during award closeout.
- Policy - Finance Administrative Policies & Procedures – Chapter 4 - 3.12  
(<http://www.musc.edu/fanda/cfopolicymanual>)

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## Updates & Reminders

### Research Grant Positions & Bridge Funding

- Any funding, other than State Appropriations, can be used.
- HR indicates that bridge funding should not last more than 6 months.
- If grant is not renewed and no other grant is awarded: Research Grant employee must be terminated.

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## Updates & Reminders

### Miscellaneous Items

- F&A (indirect) budget must be adjusted when rebudgeting to/from equipment or subcontracts.
- No-cost extensions must go through ORSP.
- First quarter's Activity Reports due 12/30/05. Reports for the second quarter should be on time.
- Policy - "Transfer of Equipment Purchased under Sponsored Projects" – Chapter 4 - 4.03
  - Policy was revised & clarified to minimize confusion

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## Updates & Reminders

### PhD Student-Employee Health Insurance Reimbursement Procedures

- Sponsored Projects charged 12.1% fringe benefit rate beginning 7/1/05.
- Student is reimbursed from Non-Sponsored departmental funds – charge to account 50229.
- College receives quarterly allocation of 2% of sponsored salaries to fund PhD Health Ins., Term Pay, Sabbaticals, etc.
- College to reimburse Department from College recovery pool - based on student-employee's sponsored funding % for the current fiscal year.

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## Questions?

Contact Info:

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**Section : 4- Grants and Contracts Accounting****Policy/Procedure Number : 4-4.03****Subject : Transfer of Equipment Purchased under Sponsored Projects****Effective Date : 11/01/2005****Responsible Department : Grants and Contracts Accounting**

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**Overview** This policy/procedure provides guidelines for the transfer of equipment purchased with Sponsored Project funds when a Principal Investigator relocates to another institution.

**General Guidelines** MUSC policy is that PIs with active Sponsored Projects may transfer equipment purchased from those Sponsored Projects to whatever institution they are relocated. The State of South Carolina considers this equipment to be Sponsored Project-owned and has given MUSC the authority to transfer such equipment.

Additionally, MUSC policy allows PIs to transfer equipment that is brought with them from a previous institution to yet another institution should the PI leave MUSC for that institution.

State policy and law is that equipment purchased from Sponsored Project funds where the sponsored Project has become inactive becomes State-owned property, just as if the equipment had been purchased with Non-Sponsored Project funds. Equipment purchased even partially with state funds is considered state-owned equipment.

The State Surplus Office regulates the sale or transfer of state equipment. In order to transfer state-owned equipment, MUSC must petition the State Surplus Office and must certify:

1) There is no current or future need for the equipment at MUSC (i.e., the equipment would otherwise be considered surplus equipment).

2) MUSC will receive reimbursement for the equipment at the higher of either the book value or fair value of the property.

Note: State processing of transfer requests normally takes 8 to 10 weeks. Departmental transfer requests should be planned accordingly.

Questions regarding equipment transfers should be addressed to the appropriate Grants and Contracts Accounting Administrator based on departmental assignment (see [Distribution of Grants by Administrator](#)) or at 792-2850.

**Procedures****A. Procedures Applicable to All Equipment Transfer Requests:**

1. PI proposes transfer and follows departmental/college authorization process.
2. Chair/Dean submits transfer request to Property Control.
3. Property Control works with GCA and ORSP to verify:
  - a. Status of Sponsored Project
  - b. Funding source for equipment
  - c. Whether the Sponsored Project was purchased from a Shared Instrumentation Grant.

Follow instructions in B., below if Sponsored Project-Owned Equipment, otherwise, follow C., below.

**B. Additional Procedures for Sponsored Project-Owned Equipment:**

1. Property Control will submit the transfer request form to the Vice President-Finance and Administration (VPFA) for approval.
2. Property Control will notify the PI and the Departmental Administrator regarding the VPFA's approval or disapproval of the transfer request.
3. If the equipment was funded by a Shared Instrumentation Grant, ORSP will survey the other PIs listed on the Sponsored Project to determine any ongoing need for the equipment. Based upon their responses, ORSP will approve or disapprove the transfer of the equipment and notify Property Control.
4. Property Control will follow procedures 1 and 2 above (if approved) or notify the department (if disapproved).
5. The Associate Provost for Research will mediate any researcher disputes over equipment.

**C. Additional Procedures for State-Owned Equipment:**

1. ORSP will determine ongoing need for the equipment, approve or disapprove the transfer request and notify Property Control.

2. Property Control will submit the transfer request to the State Surplus Office (if approved) or notify the department (if disapproved).
3. The State Surplus Office will approve or disapprove the transfer request, and (if approved) will verify the amount that the receiving institution is required to pay for the equipment. Note: State Surplus normally requires 8?to10 weeks to process requests.
4. If approved, Property Control will submit the transfer request to the VPFA for approval. If disapproved, Property Control will notify the PI and Departmental Administrator.
5. Property Control will notify the PI and the Departmental Administrator regarding the VPFA's approval or disapproval of the transfer request any cost of the sale that must be borne by the receiving PI or institution.
6. Upon receipt of the payment, Property Control will notify the PI and department that the transfer can occur.
7. The Associate Provost for Research will mediate researcher disputes over equipment.



## Research Compliance: Components, Commitment, and Cost

Cynthia K. Karr, PhD  
MUSC Research Integrity Officer  
October 18, 2005  
[karrc@musc.edu](mailto:karrc@musc.edu)

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## Research: Definition

“a **systematic** investigation, including research development, testing, and evaluation, designed to develop or contribute to **generalizable** knowledge”

45 CFR 46.102(f)



## Compliance

- Conformity in fulfilling official requirements  
Webster's Dictionary
- Cost of doing business with the government
  - Required
  - Regulated
  - Tough
  - Costs money

Marianne Woods  
The University of Alabama



## Cost: The Association of Academic Health Centers

- Report of survey released 10/03/05
  - \$300,000->\$7 million/year
  - Many said costs rose 300% in last 5-10 years
  - Frequently requirements are unfunded mandates
  - Concern expressed re: Institutional Review Board for Human Research (IRB) costs, conflict of interest (COI), effort reporting



## Compliance: Why?

- Increasing scrutiny e.g. on 9/20/05 two Congressional representatives asked DHHS to:
  - Examine how NIH grantees are spending their money
  - Investigate overcompensation of graduate students at state universities



## Compliance – Why?

- **Right**
- **Reduces consequences of non-compliance**
  - Fines and penalties
  - Loss of research funding
  - Negative press
  - Damaged reputation
  - Incarceration

## ○○○ | Responsibilities of ALL

- **Compliance** with laws, rules, regulations, policies and procedures
  - Federal
  - State
  - Local
  - University
- **Reporting possible non-compliance**

## ○○○ | Compliance Plan: 1

- Strong institutional support starting at the top
- Code of Conduct
- Compliance Officer
- Compliance Advisory Board
- College and Departmental Contacts
  - Faculty Liaison
  - Manager

## ○○○ | Compliance Plan: 2

- Training and tracking (retraining)
- Proactive measures
  - Risk Assessment
  - Monitoring
  - Auditing
- Corrective Measures
  - Including enforcement and discipline

## ○○○ | Code of Conduct: Elements

- Integrity
- Trustworthiness
- Evenhandedness
- Respect
- Stewardship
- Compliance
- Confidentiality
- Reporting possible violations
  - Medical University of South Carolina

## ○○○ | Research Compliance: Components

- Human research
- Animal research
- Biosafety
- Radiation safety
- Controlled substances
- Conflict of interest
- Occupational safety and health
- Human resources
- Procurement
  - And more

## ○○○ | Compliance & Communication

- **Essential** among the various groups involved in research compliance e.g.
- Grants and Contracts Accounting needs to know if approvals have been obtained for research with humans, animals, and biologic agents, radioactive materials
- Institutional Biosafety Committee (IBC) approval is required for approval of human or animal studies involving infectious agents, recombinant DNA or biotoxins



## Means of Communication

- Print
  - Posters
  - Letters and Memos
- Meetings-Orientation, Quarterly roundtables
- E-mail
  - Broadcast messages
  - Listservs
    - And more



## CONFLICT OF INTEREST



## Conflict of Interest: Regulations

- PHS
  - 42 CFR Parts 50 and 94
- FDA
  - 21 CFR Part 54



## Conflict of Interest: Guidance

- Federal Government
  - NIH – 2004 – Human Subjects
- Professional Organizations
  - American Medical Association-2000
  - Association of American Universities – 2001
  - Association of American Medical Colleges-2001 and 2002



## Conflict of Interest: Individual

- Disclose that with real or perceived appearance of biasing the investigator
- >\$10,000/year or 5% equity
- Self and/or family members



## Conflict of Interest - Rules apply to:

- Clinical investigators
- Members
  - IRB for Human Research
  - Institutional Animal Care and Use Committee (IACUC)
  - Committees considering allegations of scientific misconduct

○○○ | **Conflict of Interest:  
Goal**

- Ensure the reliability of research data
- Protect credibility – Institution, faculty, staff
- Maintain public trust and confidence
- Protect human subjects

○○○ | **Conflict of Interest:  
Resolution**

- Reduce
- Manage
  - Committee oversight of a resolution plan
- Eliminate
- Conflict of Interest Committee – Research Administration work together

○○○ | **Effort Reporting:  
OMB Circular A-21**

- Addresses assignment of costs to Federal grants
- Faculty effort allocation is subject to audit
- Individual penalties could include fines, prohibitions from grant submissions and funding (3-10 years), or incarceration
- Institutional penalties too

○○○ | **HUMAN RESEARCH**

○○○ | **Human Research:  
Basic Principles**

- Nuremberg Code – 1949
- Declaration of Helsinki – 1964 (first)
- The Belmont Report – 1979
- 45 CFR Part 46 – Protection of Human Subjects – 1991
- 21 CFR 50 and 56 – FDA Good Clinical Practice (GCP and Clinical Trials)
- International Conference on Harmonization (ICH)

○○○ | **Human Research: Federal**

- Office for Human Research Protections (OHRP)
- Federal wide Assurance (FWA)
  - Replaces Multiple Project Assurance
  - Three year approval
  - Contains multiple terms including written procedures and training

## ○ ○ ○ | Human Research: Regulation

- Federal Policy for the Protection of Human Subjects
  - Known as the Common Rule
  - Covers 17 Federal agencies.
  - requires a written consent with specific content

## ○ ○ ○ | Human Research: Institution

- Components
  - Institutional Review Board (IRB)
  - Clinical Trials
- Regulatory issues for both
  - Membership
  - Education and Training
  - Conflict of Interest
  - Operation

## ○ ○ ○ | Compliance: Good Clinical Practice Audits

- Participant consent
  - Payments to patient per protocol
- Protocol adherence
- Safety monitoring
- Institutional Review Board (IRB)
- Essential documents (study file)
- Drug/Device Accountability/Handling
  - MUSC main topics

## ○ ○ ○ | Human Research: Penalties

- Unauthorized solicitation or inclusion of participants without informed consent is subject to sanctions (institutional or individual) by the USDHHS Office of Human Research Protections (OHRP)
- Others

## ○ ○ ○ | Human Research: Voluntary Accreditation and Assessment

Association for the Accreditation of Human Research Protection Programs (AAHRPP)

- Academic and industrial institutions
- Non-profit
- Application and annual fees based on number of active protocols

## ○ ○ ○ | Health Insurance Portability and Accountability Act (HIPAA)

- Regulation – Standards for Privacy of Individually Identifiable Health Information i.e. the **Privacy Rule**

45 CFR Parts 160 and 164

April 14, 2003

## ○ ○ ○ | HIPAA: Privacy in Medical Research

- Individually identifiable health information contains one or more of 18 personal identifiers
- Accessing medical records and databases preparatory to research i.e. to determine the available patient population - requires approval
- Randomly accessing medical records to recruit individuals – NOT approved

## ○ ○ ○ | HIPAA: Research Participant's Authorization of Disclosure or Release of Records

- Written, signed and dated
- Specifics of information, purpose, those using or disclosing, and recipients included
- Expiration date or event indicated
- Risk of redisclosure included
- May be revoked
- For purposes other than treatment, payment, and healthcare options

## ○ ○ ○ | HIPAA Compliance: Institution

- Institutional oversight provided by:
  - IRB and/or
  - Privacy Board
  - HIPAA Compliance/Privacy Officer

## ○ ○ ○ | HIPAA: Penalties

- 45 CFR Part 160 Subpart E

Unauthorized uses or disclosures of PHI is subject to significant civil penalties by the US Department of Health and Human Services Office of Civil Rights

## ○ ○ ○ | ANIMAL RESEARCH

## ○ ○ ○ | Animal Research: Regulations - 1

- Animal Welfare Act, Public Law 89-544, 1966
  - Implemented by USDA/Animal and Plant Health Inspection Service
    - Annual or more frequent inspections
  - mandates an IACUC
- Health Research Extension Act of 1985, Public Law 99-158, "Animals in Research" – mandates the PHS Policy

## ○ ○ ○ | Animal Research: Regulations - 2

- Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, 1986
- This policy incorporates US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training (9 principles)

## ○ ○ ○ | Animal Research: Compliance

- NIH Office of Laboratory Animal Welfare (OLAW)
  - Administers and coordinates PHS policy
  - Provides guidance and instruction
- Institution
  - Obtains Animal Welfare Assurance
  - Establishes Institutional Animal Care and Use Committee (IACUC)

## ○ ○ ○ | Animal Research: IACUC

- Regulatory agent of institution
- Annual report to OLAW
- Prompt reports of action involving serious or continuing noncompliance, serious deviations, suspensions of activity
- Initial approvals, annual continuing reviews, 3 year renewals
- May suspend approved activities for non-compliance or mistreatment

## ○ ○ ○ | Animal Research : PHS

- Requires the following before awarding funding
  - Approved assurances with OLAW
  - Verification of IACUC approval
- PHS may review, including a site visit, funded institutions at any time
- PHS must investigate all complaints

## ○ ○ ○ | Noncompliance: OLAW Response

- In all instances, errors of fact may be identified before OLAW reports
- In most instances, no action is taken without allowing the institution to explain or take remedial action
- Corrective action to remedy noncompliance and prevent recurrence
- Most resolved at this level

## ○ ○ ○ | Animal Research: PHS Penalties

- OLAW may refer issues to other PHS components, USDA or other Federal agencies
- Lack of compliance with PHS policy may → OLAW to restrict or withdraw approval for Assurance → stoppage of funding for
  - Some research projects
  - **ALL** projects at the institution



### Animal Research: Voluntary Accreditation and Assessment

- o Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC)
- o **In addition** to complying with local, state, and federal laws
- o Application and annual fees based on square feet of animal facility for initial and regular site revisits



### BIOSAFETY



### Research Using Recombinant DNA (rDNA)

- o NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) April 2002 (Current)
- o Contents
  - Scope
  - Safety Considerations
  - Experiments Covered
  - Roles and Responsibilities



### rDNA Work: Federal Agency

- o National Institutes of Health (NIH)  
Office of Biotechnology Activities (OBA)  
Recombinant DNA Advisory Committee (RAC)  
Gene therapy studies



### rDNA: Institutional Oversight

- o Institutional Biosafety Committee (IBC)
  - Members include the Biosafety Officer
  - Must review rDNA research
  - May review other agents e.g. microorganisms, biotoxins, select agents
  - Must submit annual reports to NIH/OBA, update membership, report significant violations and accidents



### NIH Guidelines: Compliance

- o Institutions must ensure that all rDNA research complies with the Guidelines if any NIH funding is received for rDNA work
- o Principal investigator responsible for
  - Full compliance
  - Ensuring that reporting requirements are fulfilled

○ ○ ○ | **NIH Guidelines:  
Noncompliance**

- NIH may propose to suspend, limit, or terminate funding
- The applicable DDHS and PHS procedures are followed

○ ○ ○ | **National Science Advisory  
Board for Biosecurity (NSABB)**

- Initial meeting in June 2005
- Expected to provide guidance/requirements for IBCs in dealing with possible “dual use” research
- Professional codes of conduct
- Instructional material on biosecurity

○ ○ ○ | **Occupational Safety and  
Health: Regulations -1**

- Blood borne Pathogens
  - OSHA Standard 1910.1030
  - Employee health records- 29 CFR 1910.20
- Chemical Hazards
  - OSHA Communication Standard- Material Safety Data Sheets (MSDSs) 29 CFR 1910

○ ○ ○ | **Occupational Safety and  
Health: Regulations – 2**

- Hazardous Waste Management CFR 260-266
- Enforcement statutes-if a violation is not corrected within 30 days of notice
  - Civil penalties of not >\$25,000/day & suspension or revocation of permit
  - Criminal penalty of \$25,000/day and/or one year in prison that double on repeat violations

○ ○ ○ | **Hazardous Materials:  
Shipping**

- CFR 49 identifies these to include infectious substances
- Those handling must be trained, tested and certified
- Violations could →
  - Fines of \$27,000/occurrence
  - Criminal penalties of up to \$500,000 and imprisonment of up to 5 years

○ ○ ○ | **Export Controls:**

- International Traffic in Arms Regulation (ITAR) – US State Dept.
- Export Administration Regulations (EAR) – US Commerce Dept.
- Institution needs to determine if in specified situations materials or equipment will be shipped abroad or if work will be done abroad or by foreign nationals

○○○ | **Controlled Substances:  
Registration**

- Drug Enforcement Administration
  - Principal investigator must register
- SCDHEC Regulation, Section R61-4
- Required documents and records
- Inventory
- Security
- Destruction CFR Section 1307.21

○○○ | **Radiation Safety:  
Regulations**

- Federal and state statutes for use of radioactive material
- Licenses from SCDHEC under auspices US Nuclear Regulatory Commission
- National Council on Radiation Protection and Measurements provides recommendations
- Inspections, audits, training, and monitoring are used to achieve compliance
- Research use of radiation subject to additional review

○○○ | **Research Misconduct:  
Regulation**

- 42 CFR Parts 50 and 93  
PHS Policies on Research Misconduct  
June 16, 2005

Subpart C – Responsibilities of  
Institutions

○○○ | **Research Misconduct:  
ORI Actions**

- Individuals for whom a finding of research misconduct is made
  - Exclusions: Federal funding, serving as an advisor to the PHS
- Institutions for which a finding of noncompliance is made may include
  - Letter of reprimand
  - Recommendation that HHS debar or suspend the entity

○○○ | **WHISTLE BLOWING**

○○○ | **Reporting Non-compliance:  
Requirements**

- Element of regulations
- Mechanisms
  - Institutional officials
  - Independent Hotline/Helpline
  - Federal government officials
    - Office of the Inspector General
    - Office of Research Integrity

## ○○○ | Whistle Blower Protection

- Animal Research
  - PHS policy does not contain explicit protections, but
  - AWAR provides protection for employees & IACUC members
  - There are no Federal laws, regulations, or policies requiring ID of a complainant

## ○○○ | Whistle Blower Protection

- rDNA Research
  - Not addressed in the NIH Guidelines
  - Information should be brought to OBA and the institution
- Research Misconduct
  - Institutions must protect the confidentiality of complainants and to protect them from retaliation if they are acting in good faith (ORI has Guidelines)

## ○○○ | EDUCATION AND TRAINING

## ○○○ | Education and Training: Human Research

- Collaborative IRB Training Initiative (CITI) University of Miami
- University of Rochester
- NIH for Human Research Teams
- Research Coordinators Development Program (MUSC)

## ○○○ | Education and Training: Animal Research

- Laboratory Animal Training Association (LATA)
  - Basic
  - Species specific

## ○○○ | Education and Training: Biosafety

- OSHA
  - Personal protective equipment (PPE)
  - Hazardous and infectious waste disposal
  - Blood borne pathogens (BBP)
  - Hazard Communication (MSDS)
- Additional in conjunction with IBC

## ○○○ | Fundamental Proposition

- Rules – just a small part of the picture
- Alpha and omega-  
**INTEGRITY**  
from which all else will follow,  
Including **COMPLIANCE**

• Daniel Vasgird  
University of Nebraska, Lincoln

## ○○○ | Education for Scientific Integrity: Responsible Conduct of Research (RCR)

- Responsible Conduct of Research Education Consortium (RCREC)
- Office of Research Integrity (ORI)  
Introduction to the Responsible Conduct of Research
- ORI grants for RCR programs for:
  - Graduate Schools
  - Academic Societies

## ○○○ | RCR Topics

- Human Subjects
- Animal Welfare
- Research Misconduct
- Conflicts of Interest and Commitment
- Peer Review
- Collaborative Science
- Mentor/Trainee Responsibilities
- Data Acquisition, Management, Sharing, and Ownership
- Publication/Authorship

## ○○○ | Take home message

- Compliance
  - Costs
  - Complex
- With Commitment
  - Communication
  - Cooperation
  - Education and Training
- Compliance can be achieved

# Corporate Sponsorship

## Review Process

- A. Same as the Federal Process
- B. Information Disclosure is Critical
  - 1. Research Contract Agreement
  - 2. Research/Clinical Protocol
  - 3. Confidential Disclosure Agreement
    - a. Not being submitted. . .
    - b. Investigators are agreeing to some issues with inconsistent standards i.e., export controls, indemnification, other laws than South Carolina
- C. Corrections: This is the sole, complete and accurate agreement and there are no other applicable agreements between the parties.

## Intellectual Property Issues

- A. Depends upon whether the research is PI-initiated or company-initiated
- B. Depends upon the proprietary information being shared
- C. See handout “MUSC/MUSCFRD Interactions Related to Intellectual Property”

## **MUSC/MUSC FRD Corporate Interactions Related to Intellectual Property**

MUSC encourages collaborations of various types between University researchers and corporate partners. It is the intent and practice of the University and the MUSC Foundation for Research Development (FRD), which manages intellectual property generated by MUSC faculty, students and staff, to make intellectual property related to corporate partnerships easily accessible to our partners for development and commercialization.

There are various types of relationships between University scientists and the corporate sector that may lead to intellectual property creation. The nature of the collaboration and the source of funding for the research program resulting in the creation of new intellectual property determine the approach and specifics of how the corporate partner accesses innovations that result from the partnership. Some examples of the types of relationships that occur, and general approaches for management of the intellectual property related to those relationships include:

### 1. Discussions about common research interests

Ownership of inventions conceived during discussions concerning possible research relationships between MUSC investigators and corporate partners is determined by inventorship or authorship; i.e. MUSC retains ownership of intellectual property made solely by MUSC faculty, students and staff. The company retains ownership of intellectual property created by its employees. MUSC and the company share ownership of intellectual property created jointly by their respective personnel. In the case of intellectual property owned in whole or in part by MUSC as the result of such discussions, it is the practice of FRD to offer the company the opportunity to acquire an exclusive or non-exclusive option or license to MUSC's rights in such intellectual property, at the company's discretion. Terms of such options or licenses are negotiated between the company and FRD.

### 2. Sponsored Research Agreements

Companies that support a research program at MUSC through an agreement negotiated between the MUSC Office of Research & Sponsored Programs and the company have, through provisions in the research agreement, an exclusive option to license MUSC's rights in any intellectual property created in the course of that research. The option applies to sole MUSC intellectual property as well as to MUSC's rights in joint intellectual property created by MUSC and company personnel.

### 3. Clinical trials

Intellectual property resulting from corporate sponsored clinical trials at MUSC is handled according to the inputs to the trial that are provided by the company. In the case where significant inputs (for example, a compound or formulation and protocol to be used) are provided by the sponsor, intellectual property is typically assigned to the

company, regardless of who creates the intellectual property resulting from that trial. When MUSC personnel have significant input into design and management of the trial, ownership of resulting intellectual property created by MUSC personnel is retained by the University. In such cases, FRD will seek to negotiate a license to MUSC's interest in the intellectual property, on commercially reasonable terms, with the sponsor.

#### 4. Pre-existing MUSC intellectual property

When a company is interested in intellectual property that has been created without contribution of any kind by a company, FRD determines whether the intellectual property of interest is available to the company. If so, FRD works with the company to establish a mutually acceptable arrangement to allow the company access to the intellectual property. Arrangements may include an option to license or a license to the intellectual property and are determined on a case by case basis through discussions with the company and consider such issues as how much investment will be required to develop and commercialize the intellectual property, how and where the development will take place and the company's resources, as well as other factors relevant to the specific situation. In every case, FRD attempts to make arrangements with commercially reasonable terms.

In any arrangement transferring MUSC intellectual property rights to a company, FRD must be cognizant of laws and policies related to such transfers. Relevant laws and policies generally do not effect financial terms of agreements governing the transfer of MUSC intellectual property, but may impact certain non-financial terms. In such cases, FRD makes every effort to explain the laws and policies so that the partner company understands why FRD establishes positions on effected issues that may not be in keeping with standard industry practices for those issues.

## **MUSC/USCRF COLLABORATIVE PROJECT**

◆ Demonstration of MUSC and USC working together under a Foundation 501(c)(3)

◆ Two major MUSC participants are:

*SC College of Pharmacy*

*Dept. of Biostatistics,*

*Bioinformatics & Epidemiology*

Other departments may  
volunteer

◆ No additional hurdles for the investigator

◆ Director of ORSP, MUSC, is also Director of Pre-award Services, USCRF-Charleston Office

## **Pro's**

- Earn interest on direct and indirect cost.
- Easier collaborations between organizations; issue subaccounts, rather than subagreements.

## **Theoretical Pro's**

- Enhanced reputation on the NSF Science and Engineering; NIH Rankings
- Economies of scale as cost sharing and implementation of Velos (CTMs) and WebBridge (e-IRB)
- Alignment with NIH Roadmap for patient-oriented research and larger translational research projects
- Minor changes to the submission process
- Promote easier collaborations under SC Research Centers of Economic Excellence

### **Cons/Challenges**

- Geography: two hours by automobile
- Different Cultures: Different fringe benefit rates, F&A rates and sharing F&A
- Control: Consists of both Boards of Trustees

Department of Health and Human Services Public Health Services <b>Grant Application</b> <i>Do not exceed character length restrictions indicated.</i>		<b>LEAVE BLANK—FOR PHS USE ONLY.</b>	
		Type	Activity
		Review Group	Number
		Council/Board (Month, Year)	Formerly
			Date Received
1. TITLE OF PROJECT ( <i>Do not exceed 81 characters, including spaces and punctuation.</i> )			
2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION <input type="checkbox"/> NO <input type="checkbox"/> YES (If "Yes," state number and title) Number: _____ Title: _____			
3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR		New Investigator <input type="checkbox"/> No <input type="checkbox"/> Yes	
3a. NAME (Last, first, middle)		3b. DEGREE(S)	3h. eRA Commons User Name
3c. POSITION TITLE		3d. MAILING ADDRESS ( <i>Street, city, state, zip code</i> )  E-MAIL ADDRESS:	
3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT			
3f. MAJOR SUBDIVISION			
3g. TELEPHONE AND FAX ( <i>Area code, number and extension</i> ) TEL: _____ FAX: _____			
4. HUMAN SUBJECTS RESEARCH <input type="checkbox"/> No <input type="checkbox"/> Yes	4b. Human Subjects Assurance No. 4c. Clinical Trial <input type="checkbox"/> No <input type="checkbox"/> Yes 4d. NIH-defined Phase III Clinical Trial <input type="checkbox"/> No <input type="checkbox"/> Yes		5. VERTEBRATE ANIMALS <input type="checkbox"/> No <input type="checkbox"/> Yes 5a. If "Yes," IACUC approval Date
4a. Research Exempt <input type="checkbox"/> No <input type="checkbox"/> Yes	If "Yes," Exemption No. _____		
6. DATES OF PROPOSED PERIOD OF SUPPORT ( <i>month, day, year—MM/DD/YY</i> ) From _____ Through _____		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD 7a. Direct Costs (\$)	
		7b. Total Costs (\$)	
		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT 8a. Direct Costs (\$)	
		8b. Total Costs (\$)	
9. APPLICANT ORGANIZATION Name University of South Carolina Research Foundation Address 901 Sumter Street Columbia, SC 29208		10. TYPE OF ORGANIZATION Public: → <input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Local Private: → <input checked="" type="checkbox"/> Private Nonprofit For-profit: → <input type="checkbox"/> General <input type="checkbox"/> Small Business <input type="checkbox"/> Woman-owned <input type="checkbox"/> Socially and Economically Disadvantaged	
		11. ENTITY IDENTIFICATION NUMBER 57-0967350 DUNS NO. 11-131-0249   Cong. District 1	
12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE Name Robbie Lee Title Sponsored Program Administrator, IT Address Sponsored Awards Management USC Research Foundation 901 Sumter Street, Columbia, SC 29208 Tel: 843-792-7198 FAX: 843-792-6447 E-Mail: sam@gwm.sc.edu		13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION Name Dillard C. Marshall Title Director, Pre-Award Services/Charleston Office Address Sponsored Awards Management 19 Hagood Avenue, 606 Harborview Towers Charleston, SC 29425 Tel: 843-792-3828 FAX: 843-792-6447 E-Mail: marshdc@musc.edu	
14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.		SIGNATURE OF PI/PPD NAMED IN 3a. ( <i>In ink. "Per" signature not acceptable.</i> )	
15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.		SIGNATURE OF OFFICIAL NAMED IN 13. ( <i>In ink. "Per" signature not acceptable.</i> )	
		DATE	
		DATE	



- **The Medical University of South Carolina is already registered as an institution. No additional registration by PI's or business managers is necessary.**
- **Contact your Grants Consultant in ORSP and give them the CFDA number and title of the solicitation, and let them know this proposal must be submitted through Grants.GOV. Hard copies of the proposal must be routed through ORSP with the Proposal Data Sheet.**
- **The application is a package of forms that have to be completed. It is NOT web-based.**
- **ORSP needs the final saved version of the PureEdge file uploaded to [http://erma.musc.edu/grants\\_att\\_flow/upload.cqj](http://erma.musc.edu/grants_att_flow/upload.cqj) no later than three days prior to the submission deadlines.**
- **ORSP must submit the finished PureEdge file proposal package to Grants.GOV.**

### ***TIPS***

1. Use Internet Explorer.
2. You need to enable cookie support and pop-ups.
3. When naming files, don't use spaces, hyphens, special characters in the file names. Avoid long file names.
4. Be sure to read both the agency solicitation AND the Grants.GOV instructions. We have seen numerous mismatches between the two.
5. PureEdge is only a file, not a website. You need to save the file to your hard drive BEFORE you begin entering info into the file. You may also wish to save the file to a shared drive.
6. Complete the 424 or 424 R&R first. It populates other forms.
7. The file doesn't automatically save. You have to click on SAVE to save the data entered.
8. Notify your Grants Consultant in ORSP as soon as you know this is going through Grants.GOV.

### **ORSP Technical Support**

Robbie Lee – ext. 2-7198

[leer@musc.edu](mailto:leer@musc.edu)

Jackie Middleton – ext. 2-7196

[middletj@musc.edu](mailto:middletj@musc.edu)

## Electronic Submission of Federal Grant Applications

Office of Research and Sponsored Programs

November 15, 2005

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## Grants.gov

- Site launched in October 2003
- To date, MUSC has utilized Grants.gov for one Federal submission

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## Grants.gov

- Federal Agencies slowly making conversion to use the Apply feature
- NIH's announcement of conversion timeline will significantly increase our usage of the grants.gov site

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## NIH and Grants.gov

- August 19, 2005
  - NIH Announced Plans to:
    - Transition to the SF424 Research & Related (R&R) Application
    - Utilize Grants.gov for Electronic Submission
  - Published Time Line for Implementation
    - \*Deadline is the end of 2007

\*OMB Clearance for the PHS398 form expires in September 2007

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## NIH Time Line for Implementation

- This Year - 2005
  - December 1
    - Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) Programs (R41, R42, R43, R44)
  - December 15
    - Support for Conferences and Scientific Mtgs. (R13 & U13)

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## NIH Time Line for Implementation

- Next Year - 2006
  - February 25
    - Academic Research Enhancement Awards (AREA) (R15)
  - June 1
    - Small Grant Programs (R03)
    - Exploratory/Development Grant Awards (R31)
  - October 1
    - Research Project Grant Programs (R01)

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### NIH Time Line for Implementation

- 2007
  - Late May
    - Submit all competing mechanisms via Grants.gov

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### Impact of the Conversion

- NIH constitutes 49% of total funding for MUSC
- NIH's plans for using grants.gov "APPLY" feature will have significant impact on internal business processes

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### MUSC Plans for Conversion

- Immediate
  - Schedule training classes for users
  - Create a web site with information and tips

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### MUSC Plans for Conversion

- Intermediate
  - Explore all viable options to overcome the PureEdge platform problem
  - Evaluate commercial software applications for integrated grants management
- Long Term
  - Deploy integrated Electronic Research Administration System

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### Using Grants.gov

- MUSC is already registered as an institution.
- No additional registration by PI's or business managers is necessary.

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### Using Grants.gov

- The application is a file downloaded to your local hard drive and completed. It is NOT a web site.
- ORSP must submit the finished PureEdge file to grants.gov.

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### Using Grants.gov

- Contact your Grants Administrator in ORSP as soon as you know an application is going through Grants.gov
- Give them the CFDA number and title of the solicitation.

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### Using Grants.gov

- ORSP needs the final saved version of the PureEdge file no later than 3 days prior to the submission deadline.
- Hard copies of the proposal must be routed to ORSP with the Proposal Data Sheet.

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