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Managing Research in the Changing World of Healthcare

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Session Participants

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Director of Regulatory Affairs
Georgetown University
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Issues and Challenges

- How to pay for the increasing costs associated with the conduct of research?
- What responsibilities do you have to your community?
- Should you conduct federal as well as privately-sponsored research?
- Do individuals have “rights” to conduct research at your institution?

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External Environment

Clinical

- Open-ended reimbursement to rigorous cost control
- Increased complexity of care
- shortage of nurses and ancillary personnel
- Increased documentation requirements-E&M, teaching physicians, etc.

External Environment

Research

- Burgeoning fundamental science-the genome etc.
- Increased industry support, basic and clinical
- Increased Federal spending-NIHx2
- Increased public expectations

Internal Environment

Institutional

- Post-Medicare expansion of academic medical practice
- Cross subsidy of research (and teaching)
- Increased regulatory requirements
 - Human subjects protection
 - OSHA
 - Animal Care
 - Responsible research conduct training
 - Privacy and confidentiality

Internal Environment

Institutional

- **Red ink all over!**

Internal Environment

Health Professionals

- Increased specialization
- Increased length of training
- Increased indebtedness
- Increased attraction to academic careers and the decline of the physician-scientist

Coping with Change

Institutional

- Expanded affiliations and networks
- Reduced affiliations and networks
- Purchase of healthcare facilities & physician practices
- Spin-off of healthcare facilities & physician practices

Coping with Change

Institutional

- Consolidation and merger of healthcare institutions
- Dissolution of mergers
- Separation of healthcare entities from academic institutions

Coping with Change

Institutional

- Sale of healthcare institutions to investor-owned entities
- Explicit mission-based management
- All of the above

Coping with Change

Individual

- Escape to clinical practice
- Increased entrepreneurism
- Early retirement
- Decreased involvement in research, teaching and mentoring

Managing Clinical Research

Improved Infrastructure

- Information technology
- Instrumentation
- Rigorous training models
- Debt forgiveness
- Improved linkages with basic research
- Access to population base

Actions Taken

- NIH Director's Advisory Panel
- Clinical Research Summit
- AAMC Task Force on Clinical Research
- FASEB Conference on the Physician-Scientist
- IOM Clinical Research Roundtable

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Ignorance is not Bliss!

- Health care organizations should consider conducting compliance risk assessment of medical research activities
- Health care organizations also must stay abreast of the many regulatory changes and developments affecting medical research

Benefits of Compliance Risk Assessment

- Reduce risk of liability
- Avoid jeopardizing research programs
- Improvement of operations

The Audit Process

- Assembling the compliance risk assessment team
 - Compliance Officer
 - IRB Administrator
 - IRB Chair
 - In-House/Outside Counsel
 - Financial/Billing Personnel

The Audit Process

Preliminary Issues

- Conducting review through legal counsel
- Internal review
vs.
Use of outside firm

The Audit Process

- Interviews of relevant personnel
- Review of existing policies and procedures
- Sampling procedures
 - Protocols
 - Billing/accounting records

General Areas for Compliance Risk Assessment

- Human Subject Protections
- Financial/Billing Issues
- Stark/Anti-Kickback Laws
- HIPAA

Response to Audit Findings

- Institution must address audit findings of non-compliance
- Prompt and appropriate corrective action is essential

Compliance Training

- IRB members
- IRB administrators and staff
- Principal investigators
- Billing personnel

Ongoing Assessment of Research Compliance

- Periodic monitoring of research activities
- Follow-up on identified deficiencies
- Role of institution's compliance department

Ongoing Assessment of Research Compliance

- Periodic review and updating of policies and procedures
- Stay current with relevant regulations and disseminate information regarding regulatory changes
- Ongoing training

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Research Facts

Children's Hospital & Regional Medical Center

- Since 1990, research funding increased by over 160% and number of projects has doubled
- Currently 146 research projects being conducted
- Research support in excess of \$13 million (combination of external grants and 38 foundation research grants)

Less Research Intensive Institutions

- Small organizations have complicated relationships with larger research centers
- Growth in multi-center drug trials, patient registries, large population-based studies
- Explosion in start-up biotech companies means they are looking for research venues
- All adds up to a complex environment for the small organization

Issues Affecting Similar Institutions

- Human subject review processes
- Indirect costs
- Conflict of interest policies and implementation
- Training requirements -- RCR and others
- Multiple reporting relationships for PIs
- “Credit”
- Culture clashes

Issues

- **IRB issues:**
 - Reciprocity, avoiding multiple reviews
 - Balanced against special expertise and different organizational cultures
 - No PI really likes IRB review anyway
- **Indirect Costs:**
 - Pressures to hold down indirect rate
 - Pressures to waive indirects to be competitive
 - Indirects on subcontracts used to transfer \$\$\$

Issues

- **Conflict of Interest Issues**
 - Differing organizational policies may reflect cultural differences
 - Some state laws stricter than federal rules
- **Training Requirements**
 - RCR: daunting task for small organization
 - Limited resource to create a program
 - Reliance on bigger partners may not work

Issues

- **Multiple Reporting Relationships**
 - Is it faculty or organizational research?
 - Relationships with Schools
- **“Credit”**
 - Who takes it, who gets it
- **Culture Clashes**
 - Partnerships among academia, health care and biotech create strong tensions requiring vigilance and management

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Director of Regulatory Affairs
Georgetown University
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Partnerships, Mergers and Acquisitions

Case Study:

- Georgetown University and
- MedStar Health, Inc.

Georgetown University

- Undergraduate and Graduate Programs
- Law School
- Medical Center
 - Research enterprise
 - School of Nursing
 - School of Medicine
 - Basic Science Faculty*
 - Clinical Faculty >50% research effort*
 - Clinical Faculty <50% research effort*
 - Georgetown University Hospital (GUH)
 - Community Practice Network
 - Faculty Practice Group

MedStar Health, Inc.

- Washington Hospital Center
- National Rehabilitation Hospital
- Franklin Square Hospital Center
- Good Samaritan Hospital
- Harbor Hospital
- Union Memorial Hospital
- Medlantic Research Institute

Partnership Agreement

Georgetown

- Undergraduate and Graduate Programs
- Law School
- Medical Center
 - Research enterprise
 - School of Nursing
 - School of Medicine
 - *Basic Science Faculty*
 - *Clinical Faculty >50% research effort*

MedStar Health, Inc.

- *Clinical Faculty <50% research effort*
- *Georgetown University Hospital (GUH)*
- *Community Practice Network*
- *Faculty Practice Group*

Oversight Documents

- Academic Affiliation Agreement
- Research Affiliation Agreement
- Shared Services Agreements

Academic Affiliation Agreement

- GUH space would continue to be available for teaching and research
- University retains responsibility over matters traditionally part of academic governance
 - Curriculum
 - Faculty appointments

Academic Affiliation Agreement

- Georgetown University faculty status is retained by MedStar physicians located at GUH
 - Continue teaching responsibilities
 - Serve on University committees

Research Affiliation Agreement

- For all research that is conducted at GUH for which the PI is a MedStar employee/faculty member, the University shall be accountable for sponsored programs
 - Receive direct and indirect dollars
 - Responsibility for managing the funds

Research Affiliation Agreement

- All research will be conducted in accordance with The Ethical and Religious Directives for Catholic Health Care Services
- From the perspective of sponsors (such as NIH), the research activities of Georgetown Faculty are conducted as if the Medical Center was a single entity

General Compliance Issues

- MedStar and Georgetown agree to honor all compliance requirements applicable by law, regulation and sponsor requests
- MedStar and Georgetown agree to cooperate to ensure that their respective employees are trained to fulfill this responsibility

Specific Compliance Issues

- IRB
- Animal Care
- Radiation Safety
- Biohazards
- Conflict of Interest
- Research Integrity
- Technology and Intellectual Property

Institutional Review Board

- Cooperative Amendment to the Multiple Project Assurance submitted by both Georgetown University and MedStar Health
- Georgetown IRB will review all human subject research performed at GUH facilities
- If the PI is an employee of MedStar, MedStar reserves the right to insist on separate review by its own IRB
- However, Georgetown University IRB is the final authority
- Both IRBs will include appropriate representation from the other entity

Animal Care

- Georgetown University Animal Care and Use Committee must approve all vertebrae animal procedures

Radiation Safety

- GUH and Georgetown University each have a separate license approved by the NRC
- GUH license - MedStar RSO is responsible for all clinical activities including clinical research
- Georgetown license - Georgetown RSO is responsible for the use of radioactive materials in non clinical research

Conflict of Interest/Research Integrity

- All faculty, regardless of employer, follow the policies described in the Georgetown University Faculty Handbook

Biohazards

- MedStar is responsible for compliance of GUH with federal, state and DC regulations
 - Governing disposal of hazardous wastes
 - Protection from bloodborne pathogens
 - Protection from bacterial and other infections
- Georgetown Biosafety Committee will review proposals dealing with recombinant DNA, gene transfer etc.

Technology and Intellectual Property

- All Faculty members have the rights described in the Georgetown University Faculty Handbook
- University shall own all patent rights

Summary

- Partnerships, Mergers and Acquisitions will increase dramatically over the next decade
- It is imperative that all compliance issues be identified and dealt with prior to conclusion of the partnership
- Don't assume that the other partner has the responsibility!

Thanks

- David Perlman, PwC Philadelphia

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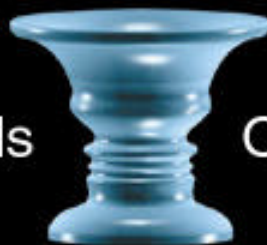
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Your worlds



Our people