

HHS–OIG Draft Compliance Program Guidance for Research Awards

Overview

Compliance Program Guidance (CPG)– Background

- Issued a draft CPG for Research Awards in November 2005
- Purpose:
 - Assist entities in developing and evaluating an effective compliance program
 - Encourage the use of internal controls to effectively monitor compliance
- Guide includes 8 fundamental elements of an effective compliance program

Compliance Program Guidance (CPG)– Background

- ❑ OIG has issued numerous CPGs for other healthcare industries receiving federal funds
- ❑ Influenced by Changes in Corporate Culture (i.e Sarbanes Oxley Act)
- ❑ Consistent with Federal Sentencing Guidelines elements of an effective compliance program

8 Fundamental Elements

1. Implementing written policies and procedures
2. Designating a compliance officer and committee
3. Conducting effective training
4. Developing effective lines of communication
5. Conducting internal monitoring and auditing

8 Fundamental Elements

6. Enforcing standards through well publicized disciplinary guidelines
7. Responding promptly to detected problems and undertaking corrective action
8. Defining roles and responsibilities and assigning oversight responsibility*

* *OIG views as especially significant for a research institution*

"Takeaways"

- ❑ CPG not mandatory
- ❑ The Guidance does not establish any additional program rules or regulatory requirements
- ❑ Goal of an effective compliance program should focus on ensuring good stewardship of federal funds
- ❑ No single best compliance program; characteristics of institution will determine best approach

MIT's Research Administration Compliance Efforts

Research Administration Improvement Initiatives
(RAII)
Research Administration Compliance Program
(RACP)

Background

□ The Environment at MIT

- MIT campus had \$570 million in research volume for FY 2005
- Estimated 1500* people involved in research administration related activities at least part-time
 - Titles vary from dept to dept
 - Commitment to research administration varies...from small percentage of effort to 100%

*Includes Professors, DLC and central admin.; does not include research staff (Post-Docs, Research Scientists, etc.)

Background

- Administration of research has become more complex and challenging at MIT
 - More research volume
 - Changes in funding/regulatory environment
 - New major enterprise administrative systems (SAP, COEUS, Data Warehouse)
 - Migration to “Grants.Gov” (electronic instead of paper)
- Need for improvement to help faculty, administrators, and MIT overall
 - Improve efficiency and effectiveness (staff isn't increasing)
 - Greater expectations regarding accountability

Background:

MIT Compliance Efforts

- ❑ Driven by increased emphasis on research compliance issues nationwide
- ❑ Strong emphasis on training and process improvement
- ❑ Overall goal is to help Departments meet regulatory requirements and strengthen controls
- ❑ *Partnership/Common goals*

MIT's Balanced Approach toward Compliance:

RAII

- ❑ Committee with Broad Representation
- ❑ Working Group Sub-Committees
- ❑ Institute-wide Policy Issues
- ❑ Process Improvement
- ❑ Training
- ❑ IT Solutions

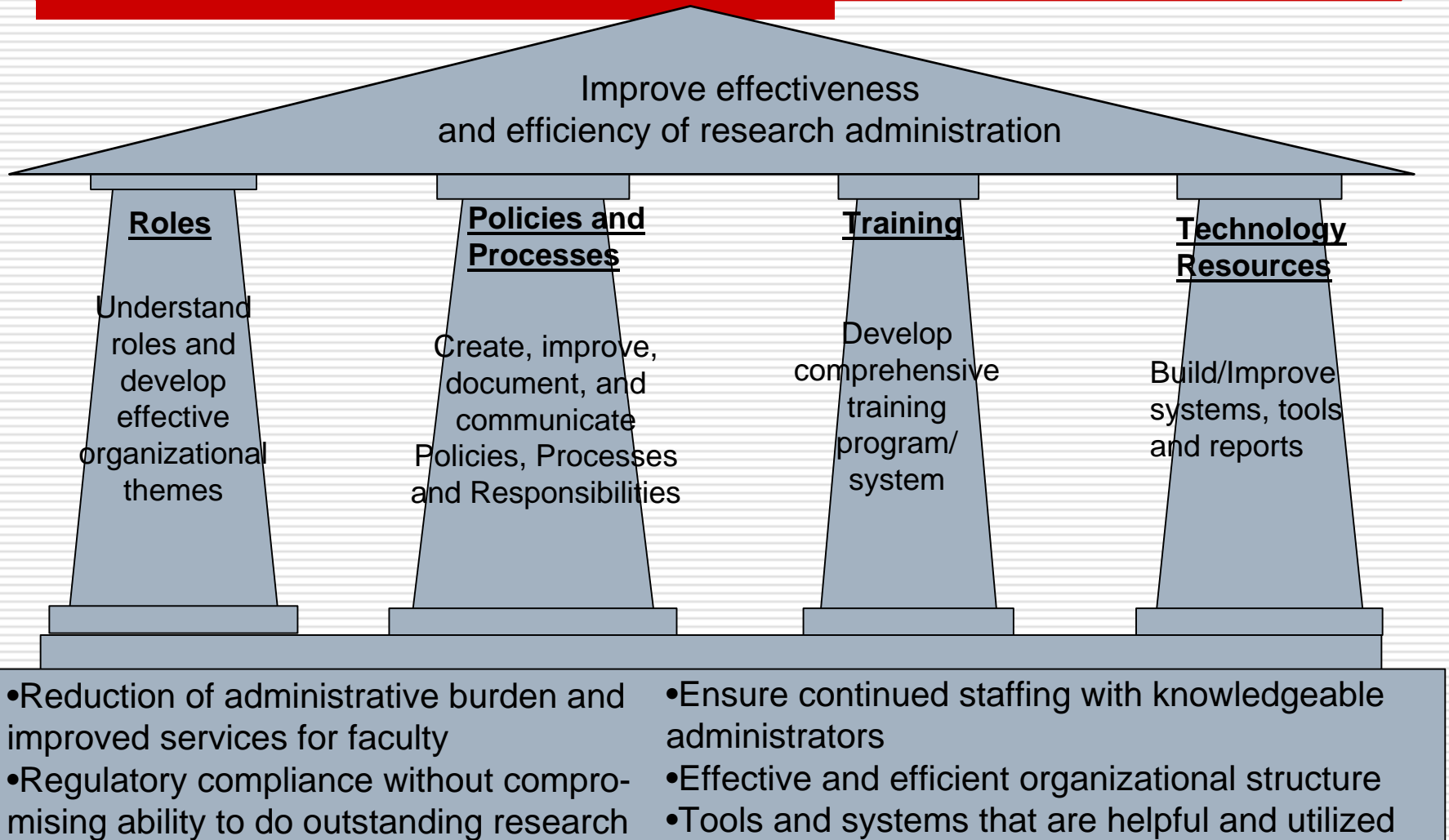
RACP

- ❑ Function within Audit Division
- ❑ Department Level oversight
- ❑ Site Visits/Control Assessments
- ❑ Compliance Monitoring
- ❑ Data Collection/Outreach for RAI
- ❑ "Boots on the Ground"

MIT
Research Administration
Improvement Initiative
RAII

RADG Meeting
4.27.06

RAII: Objectives



RAII Team Structure

Steering Committee

Co-Chairs: Patrick Fitzgerald (OSP), Ron Hasseltine (Science)

- John Donahue (OSP)
- Robin Elices (ASO)
- Gill Emmons (CAO)
- Deborah Fisher (Audit)
- Tim Gordon (Audit)
- Sheila Kanode (Engineering)
- Colleen Leslie (Center Cancer Research)
- Diane MacDonald (Broad Inst.)
- Doreen Morris (Provost)
- Eileen Nielsen (OSP)
- Charlene Placido (Provost/Research)
- Marilyn Smith (Provost/Research)
- Judith Stein (HR)

Sponsors

- Alice Gast
- Sherwin Greenblatt
- Rafael Reif

Faculty Advisory Committee

- Steve Buchwald
- Steve Eppinger
- Karen Gleason (Chair)
- Jackie Lees
- Ken Oye
- Miklos Porkolab
- Alex Slocum
- Larry Vale
- Jacob White
- Victor Zue

Sub-teams

1. Roles and organizational structure

2. Policies and processes

3. Training

4. Technology Resources

- Team lead for each sub-team from Steering Committee
- Sub-team members comprised of Steering Committee members as well as other community members

Project administrator: Kristen Shikes

Project manager: Cecelia Wardle

RAII Sub-Team Activities:

□ Roles and Organizational Structure

- Develop roles and responsibilities accountability matrix
- Analyze life of grant segmented in 12 phases
- Develop framework for characterizing existing Research
- Administration departmental models
- Develop recommendations for enhancements to existing organizations and structures
- Review report with Steering Committee and Sponsors and develop action plan/next steps

□ Policies and Processes

- Compile RA policies, understand and prioritize gaps
- Develop recommendations to create new or improve existing RA policies and processes
- Catalog (on website), document, and communicate existing policies

RAII Sub-Team Activities:

Technology Resources

- Develop and improve tools that support RA (e.g., forecasting, COEUS, Research Administration portal)
- Integrate research data and develop standard reports

Training

■ General

- Assess overall RA training needs and curriculum outline
- Develop new courses and non-course training materials

■ "STAR" Program

- Create web based fundamentals training – "Specialized Training for Administrators of Research"
- Develop training manual for more experienced staff
- Develop implementation plan

Faculty Advisory Committee

Role of the Faculty Advisory Committee

- Faculty input is critical to success of initiative
- Act as resource to RAII Steering Committee
 - Help identify, prioritize and advise on opportunities for improvement in research administration
 - Meet periodically to provide input
 - Provide input through email if needed

Example of a RAI “spin-off” project:

- Mechanical Engineering (ME) Department
- Background
 - Ocean Engineering merged with ME in Jan 05
 - New Department has 75 faculty and \$25 million in research volume
 - “Decentralized” model for Res Admin support
 - Faculty heavily involved in Res Admin activities

Example of a RAI “spin-off” project

- New Organizational Model for Mechanical Engineering (ME) Department
 - Satellite office of central OSP located in dept
 - Dual reporting: OSP Director and Dept Head
 - Manager and Departmental Research Administrators dedicated to support of ME faculty
 - Full-time Research Admin specialists replace part-time support staff

Research Administration Compliance Program (RACP)

Overview

RACP Overview

- ❑ Replaced “Black Hat” Audit Approach
- ❑ Strong Emphasis on providing value-added service and on-the-job training
- ❑ Promote Self-Assessment activity and provide applicable Tools
- ❑ “Find and Fix” approach to instances of non-compliance
- ❑ Identify and Channel broader compliance issues to appropriate groups (i.e. RAI)

RACP: Objectives

- ❑ Site Visit/Internal Control Assessments - Identify *and address* control weaknesses within the Departments through on-site visits/assessments.
- ❑ Monitoring Program – Designed to detect specific exceptions, identify potential problems and provide trend data for assessing the effectiveness of internal controls.
- ❑ Consultation – Assist Depts in process improvement initiatives and corrective action measures

Site Visits:

- Control Assessment Interview
- Review pre-run monitoring reports
- Perform limited manual testing
- Focus on training and awareness
- Issue an observation memo to department
- "We are here to help!"*

Monitoring Program

- Series of Data Warehouse Reports
- Uses:
 - As part of Site Visits
 - On-going Institute-wide Monitoring Program (Semi-annual testing and quarterly reports)
 - Self Monitoring
 - Executive Information System (EIS)
 - Quarterly Monitoring Reports

EIS - Dashboard

Brio Intelligence - [0_version2.bqy]

File Edit View Insert Format EIS Tools Window Help

Process

EIS

RACP

Research Administration Compliance Program
Massachusetts Institute of Technology

1. Choose a Report Type

Federal Reports

- Account Balance Report-Federal
- Cost Transfers on Federal Awards
- Delinquent Financial Close Out - Federal
- Equipment Purchased At End of Period
- Period of Availability - Pre Award
- Period Of Availability - Post Award

Institute Reports

- Unallowable GL Account Charges
- Fabricated Equipment - Unallowable Expenses
- Fabricated Equipment - Open Accounts
- Credit Card - Violations
- Credit Card - Swept Charges
- Miscellaneous Revenue

Select from one of the following options

- School & Profit Center
- Profit Center

2. Choose a School & Profit Center

VP Research

P246000 - Center For Matl Science And Engineering

3. Chose WBS ID

All

- 1268500 - Materials Research Science And Engineeri
- 1268600 - Materials Research Science And Engineeri
- 1268700 - Microfabrication Facility (Sef)
- 1268800 - Nist/Structural Analysis Fac (Sef)

Generate Report

Local Area Connection is now connected
Speed: 100.0 Mbps

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Beth Israel Deaconess
Medical Center



A teaching hospital of
Harvard Medical School

PAY NOW OR PAY LATER

One Institution's Approach

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Beth Israel Deaconess Medical Center

Today's Topics

- What's the Big Deal?
- The OIG's Draft Guidance and BIDMC's Program
 - BIDMC's Infamous History
 - What BIDMC Changed
- A Day in the Life of Research Compliance at BIDMC



What's the Big Deal?

- The False Claims Act
 - Used to protect public against abuse and fraud in government contracts.
 - Violations
 - Knowingly submit
 - Deliberately ignorant
 - Recklessly disregard
 - Consequences
 - Triple Damages
 - Suspension/Disbarment
 - Criminal Charges
 - Qui Tam



What's the Big Deal?

- SETTLEMENTS!!!
 - BIDMC – 1999, 2002, 2004 (with Harvard)
 - Northwestern – 2003
 - Johns Hopkins/Bayview Med. Ctr – 2004
 - U. of Alabama Birmingham – 2005
 - Mayo Foundation – 2005
 - Weill Med. College of Cornell – 2006
 - U. of Connecticut – 2006
 - Rush University Medical Center - 2006



What's the Big Deal?

- United States Sentencing Commission - USSC §8A1.2
 - Guidelines developed for mitigation of fines and penalties
 - Became basis of all compliance programs
 - Part of OIG Compliance Guidance



OIG Guidance & BIDMC's Approach

- 1. Written Policies and Procedures
 - Code of Conduct
 - Compliance Program – Guiding Principles for Researchers
 - Compliance Program Policy Manual for Research Activities
 - Policies & Procedures for the Management & Administration of Sponsored Projects
 - CCI Policy & Procedure Manual

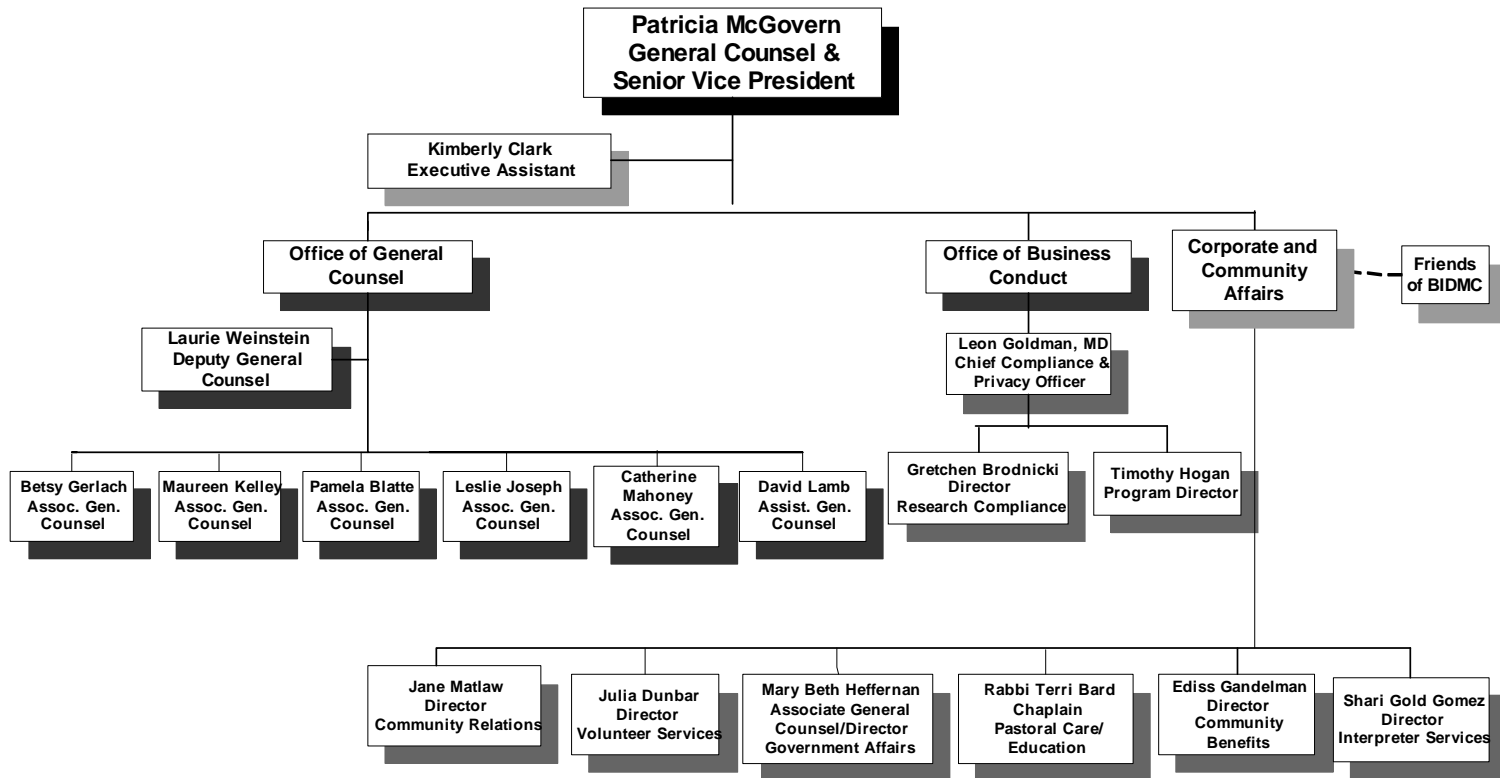


OIG Guidance & BIDMC's Approach

- 2. Designate Compliance Office and Compliance Committee
 - Office of Business Conduct
 - (it's not just about compliance!)



Office of the General Counsel & Corporate and Community Affairs



OIG Guidance & BIDMC's Approach

- 3. Conduct Effective Training and Education
 - For all Research Staff
 - Research Compliance, Lessons Learned
 - Clinical Research Basics
 - Responsiveness
 - HIPAA for Research
 - Investigational Drug & Device Billing
 - Research Compliance Update (T&E, COI)
 - Responsible Conduct in Research
 - PI Grants Management Training
 - Animal Research Training
 - Laboratory Safety Training



OIG Guidance & BIDMC's Approach

- 4. Effective Lines of Communication
 - Email: conduct@bidmc.harvard.edu
 - Confidential Report Line
 - 888-753-6533
 - Non-Retaliation Policy
 - It's not enough
 - Culture
 - Leadership
 - Accessibility



OIG Guidance & BIDMC's Approach

- 5. Internal monitoring/auditing
 - Internal Audit Program
 - Grants Management
 - Clinical Trials Billing
 - Q/A in Clinical Trials
 - For Cause
 - Not-for cause
 - Risk Assessment



OIG Guidance & BIDMC's Approach

- 6. Enforcing standards through disciplinary guidelines
 - Privacy Violations
 - Policy Violations
 - Action



OIG Guidance & BIDMC's Approach

- 7. Responding promptly/corrective action
 - Detect
 - Investigate
 - Act

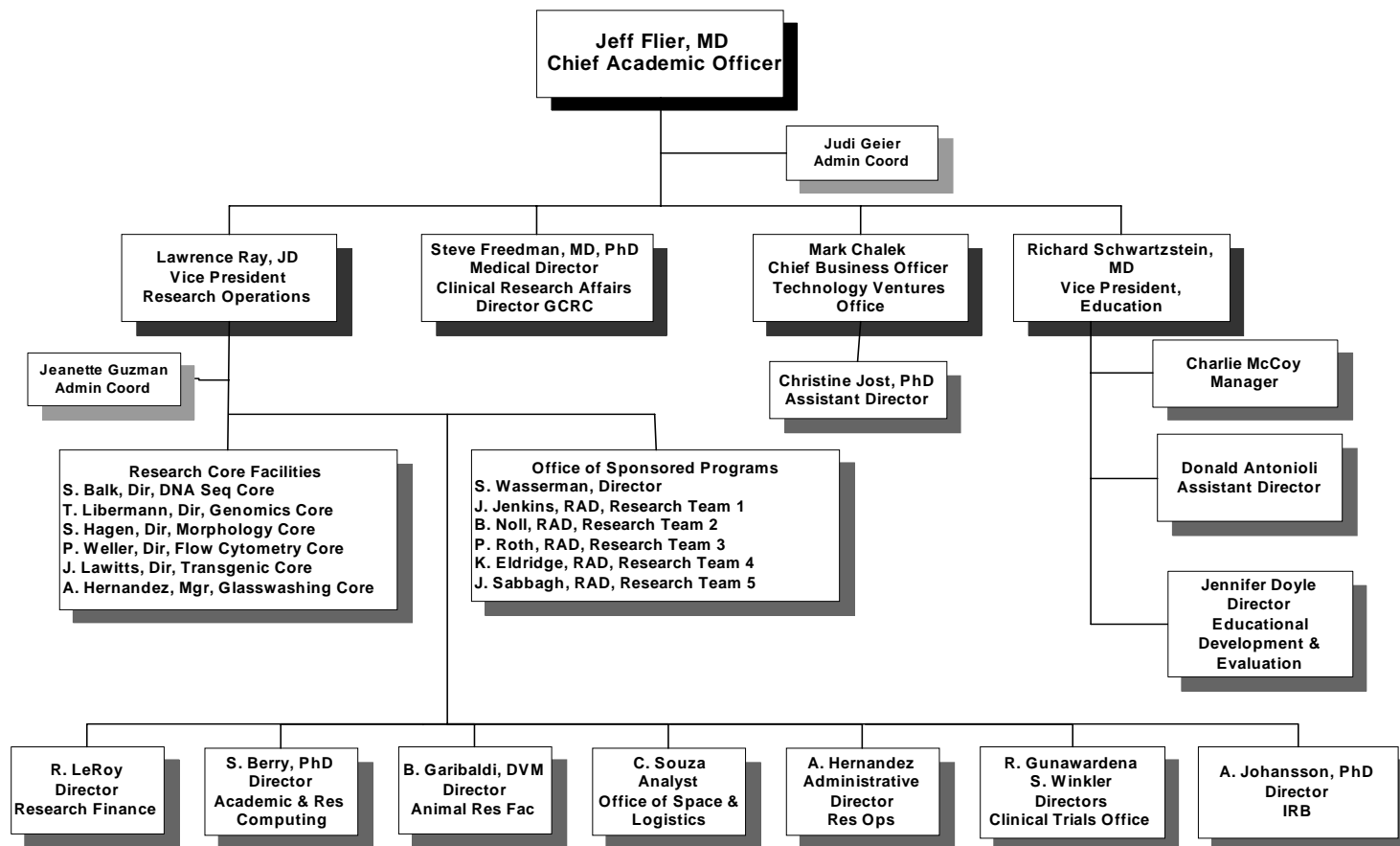


OIG Guidance & BIDMC's Approach

- 8. Defining Roles and Responsibilities



Research & Academic Affairs



A Day in the Life

- Conflict of Interest
- Gifts
- Vendor Relationships
- HIPAA
- Professional Behavior
- Grants Management
- Time & Effort
- Cost Sharing
- Cost Transfers
- Grant Preparation
- Post Award
- Subcontract
- Ts, Ks, (ABCs)



A Day in the Life, cont

- IRB
- Quality Assurance
- Data Monitoring
- INDs/IDEs/HDEs
- Informed Consent
- Scientific Misconduct
- Billing
- Coding
- Contracting
- Good Clinical Practice
- Federal Wide Assurance
- AAHRPP
- IACUC
- Lab Safety
 - BPHC
 - Fire Department
 - State



Questions?

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