

Compliance for Grants Administration

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Today's Speaker

Summer Buchanan is a Supervising Senior Auditor responsible for leading and conducting audits of the medical center operations. Prior to joining the Office of Internal Audit in 2015, she worked in public accounting performing audits of companies in a variety of industries including manufacturing, not-for-profit, governmental and educational entities. Summer then worked for many years doing Corporate Reporting at both ServiceMaster, LLC and FedEx. She received her BBA in Accounting from the University of Memphis, and lives in the Nashville area with her husband of 20 years and two teenage daughters.

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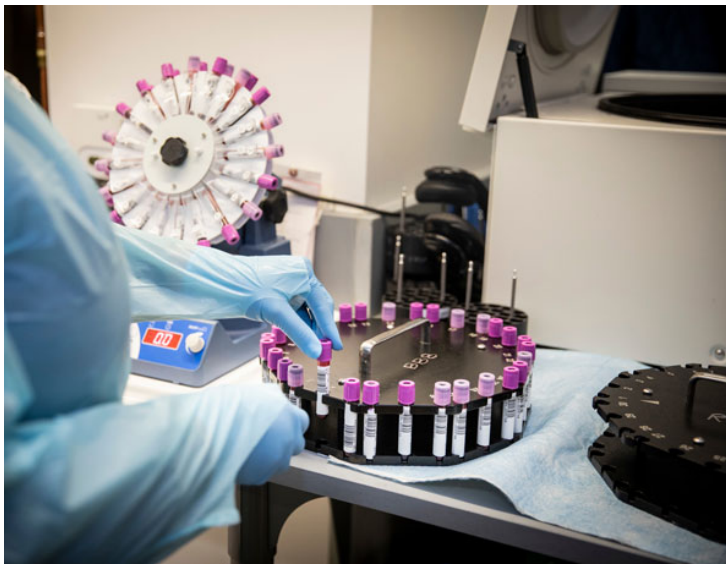
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Vanderbilt University Medical Center



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What do we know about Research??

Almost 25% of medical center individuals consider research their primary focus

In 2021, Vanderbilt and VUMC received more than 3,100 external awards totaling over \$1,000,000,000.

BioVU, VUMC's genetic database, is the world's largest DNA bank based at a single academic institution

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Today's Objectives



Understand the various phases of the grant life cycle



Identify key risks in post-award management



Discuss various audit procedures to implement in your organization



Review case study examples of non-compliance

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Internal Audit's Role in Grant Management



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Engagement Planning Steps

1. Understand the context and purpose of the engagement
2. Gather information to understand the area or process under review
3. Conduct a preliminary risk assessment
4. Form engagement objectives
5. Establish engagement scope
6. Allocate resources
7. Document the plan

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Post Award
Management
– Key Risks

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Cost Principles

Direct Costs and Facilities & Administrative Costs

Cost Transfers

Allocation of Costs

Allowability of Costs/Activities



NIH Grants
Policy Statement
Section 7 – Cost
Consideration

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Expense-Testing

- **Become familiar with internal policies and procedures and grant requirements**

- For direct charges:

- Ensure each charge is reasonable, properly classified, allocable, consistent, properly documented and approved and that sponsored funds are available

- Cost transfers:

- Ensure each transfer is appropriate, properly supported and approved in accordance with internal P&P and federal guidelines

- End of the grant period purchases

- Administrative and Clerical Costs



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Two Case Studies

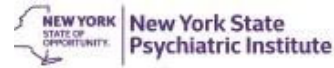
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Columbia University – The Facts

From July 1, 2003, through June 30, 2015, Columbia applied its on campus direct cost rate, instead of the much lower off campus rate

Impacted 423 NIH grants where research was performed primarily off campus

Columbia failed to disclose to NIH that they did not own or operate the facilities, and that they did not pay for use of the space for most of the period



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What did it cost??



In July 2016, Columbia University agreed to a settlement of \$9.5 million, one of the largest False Claims Act settlements

Payment was in exchange for a release from civil liability for the impacted grants

Columbia claims that it did not over-bill intentionally and stated that “Columbia believed in good faith that it was appropriate to apply an on campus indirect cost rate to research performed by Columbia faculty in certain buildings owned by the state or city that are located on our medical center campus.”

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University of California – San Diego

Objective of the OIG review was to determine whether the University claimed reimbursement for nonpayroll administrative and clerical costs charged directly to HHS awards in accordance with Federal regulations and applicable guidelines.

Reviewed covered nonpayroll costs of \$26.9M from October 1, 2008, to September 30, 2010.

Reviewed a stratified sample of 142 nonpayroll administrative and clerical transactions. Determined that 125 were allowable, but 17 sample transactions totaling \$56,375 were not allowable



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UC San Diego provided supplemental information and documentation which made OIG later allow one more of the transactions, reducing the repayment

Using the basis of the sample results, the OIG estimated that the University claimed at least \$202,401 in unallowable costs and recommended a refund in that amount to the federal Government.

Recommended that the University also reclassify maintenance and repair costs as a capital expenditure.

Stated a need for the University to enhance oversight of nonpayroll administrative and clerical costs charged directly to HHS awards to ensure compliance with federal regulations.

Results of the Audit

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Personnel Costs-Regulations

- Key Personnel
 - Principal Investigator
 - Co-Investigator
 - Collaborator
- Significant reduction in effort
- Salary cap

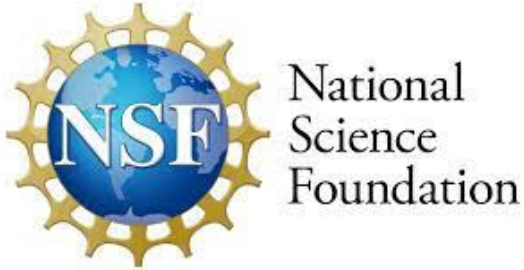
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Testing Labor Charges

- Effort Allocations and Certification
 - Perform effort interviews, including faculty members and staff
 - Processes for oversight and monitoring of effort allocations
 - Ensure guidance includes expectations for timeliness, approvals, training, etc.
 - Reasonable effort allocation percentages (i.e., 100% charged to federal projects)
- Review of salaries in excess of NIH salary cap guidelines
- Key Significant Personnel
 - Verify employees listed on NOA match effort allocations and labor charges
 - Ensure that any reduction in effort of 25% or more was approved by the appropriate federal agency
- Subcontractor expenses
 - How is effort monitored and managed for subawards
- Required training by employees

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University of California – Santa Barbara



External OIG audit of cost transfers for the period January 1, 2008, to December 31, 2010

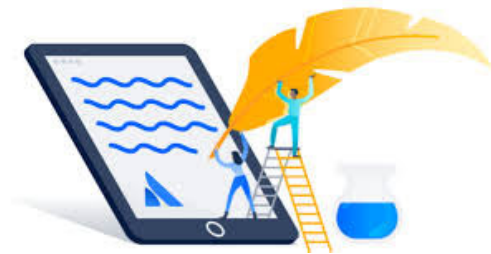
National Science Foundation (NSF) identified \$6.3M in questioned costs, made up of summer salaries, unfulfilled cost sharing, cost transfers, indirect costs, unallowable costs and fellowship funds

After review of documentation provided by the University, NSF allowed \$5.8M of the questioned costs and only \$43,551 was deemed disallowed

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What did we learn??

DOCUMENT
DOCUMENT
DOCUMENT



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Required Reporting-Regulations

Research Performance Progress Report (RPPR)

Federal Financial Report (FFR)

Annual Invention Utilization Report

Conflict of Interest Report

Institutional Review Board (IRB) Approval – human subjects

Institutional Animal Care and Use Committee (IACUC) – animal research

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What if we miss a report?

Closer monitoring by the NIH

Delay in issuance and funding of continuation award

Withholding or removal of certain NIH standard terms of award



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Memorial Sloan Kettering Case Study

Memorial Sloan Kettering Leaders Violated Conflict-of-Interest Rules, Report Finds

NY Times - April 4, 2019



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What happened?

Review conducted by law firm Debevoise & Plimpton and jointly reported by *The New York Times* and *ProPublica*

Jose Baselga, former Physician-in-Chief and CMO of Memorial Sloan Kettering Cancer Center resigned from his position in September 2019 after failing to disclose his company ties in dozens of articles in medical journals, including *The New England Journal of Medicine*

His omissions reportedly included payments totaling millions of dollars

Beginning in 2014, senior executives were no longer required to vet financial relationships with a conflict of interest advisory committee because the hospital felt the committee should not make decisions about executives to whom it reported

Dr. Baselga also stepped down from the boards of the drug maker Bristol-Myers Squibb and Varian Medical Systems, a radiation equipment manufacturer

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The Sunshine Act

- Goal: Increase transparency and accountability in healthcare
- Requires drug, medical supplies, and medical device companies to report all payments to health care professionals over \$10

Sloan Kettering's Response

Hired outside firms to conduct inquiries

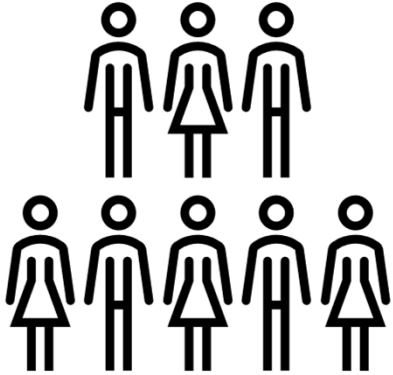
Major overhaul of policies governing employees' relationships with outside companies

Barred top executives from serving on corporate boards of drug and health care companies



Annual Report on Possible Research Misconduct

Suspect Fraud or Misconduct?



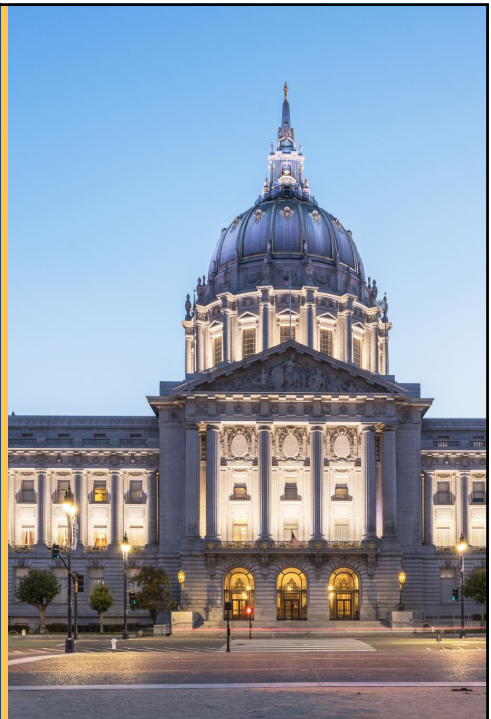
Internal Policy for Responding to Allegations of Research Misconduct

False Claims Act and Whistleblower Protection Policy

Confidential Integrity Hotline

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Duke University – A study of fraud, research misconduct, and the biggest fine in university research history



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What Happened?

In 2013, a biologist named Erin Potts-Kant, working at Duke was arrested and fired for embezzling \$25,000 on Duke credit cards. The \$25,000 had been stolen between 2008 and 2012 and spent at Walmart, Target, Restaurants, and other locations. The biologist worked in a well-funded Duke laboratory for a well-respected Duke PI.

In 2014, another Duke biologist named Joe Thomas, who worked with Potts-Kant left the university and filed a lawsuit alleging Duke was aware of research misconduct by the arrested researcher and covered it up. The allegations were associated with \$200 million in grant funded projects. (Martin, 2019)

Potts-Kant was an expert on conducting tests related to mouse lungs and contaminants. She had been able to achieve results no other technician in the lab was able to achieve. Joe Thomas had reported concerns that her data was too good, but he was ignored by researchers reliant on the amazing results.

Duke fights the lawsuit for four years, during which the PI of the lab retired. A three-year Duke investigation finds extensive fraud and triggers the retraction of publications and data. (Martin, 2019)



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Outcomes

- Duke agreed to pay \$112M, including \$34M to Joe Thomas
- The researcher who falsified data lost her job and the PI of the project retired
- As part of the settlement Duke lost expanded authorities for federal grant management
- Duke hired its first Vice President for Research, implemented a new data system, hired many new grant administrators, and expanded training for research ethics

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Questions

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