

Regulatory Cost Study for Vanderbilt University

Completed by and with the Boston Consulting Group



Methodology Anchored on Defining Scope, Employing Tools and Methods, and Following Principles

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Scope

Categories of regulatory areas

- Research
- Higher education
- All-Sector

Types of costs

- Labor
- Non-labor
- Indirect costs of labor

2

Tools and Methods

Decentralized Costs:
incurred from academic depts. and research centers

Centralized Costs:
incurred from central / admin offices

- Survey instrument with detailed compliance activities and examples
- Select interviews/worksheets
- Interviews with key contacts and worksheets

Salary and benefits data and relevant budgets

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Principles

Principles to determine if an activity is required to comply with federal regulation



Scope of Regulatory Areas Assessed

Research

- Conflict of interest
- Environmental health and safety compliance (related to research)
- Export compliance
- Federal grants and contracts management
- Human/animal research compliance
- Research misconduct requirements
- Technology transfer requirements

Higher education

- Accreditation
- Clery Act
- Drug and alcohol prevention
- Equity in athletics data report (EADA)
- Financial aid
- FERPA
- IPEDS reporting requirements
- Gainful employment
- Sexual misconduct (Title IX)
- State authorization
- Title IX athletics administration

All-Sector

- Anti-discrimination
- Disability
- Environmental health and safety regulations (outside of those related to research)
- Finance
- FISMA
- Immigration
- Other human resources-related requirements



Types of Costs Considered

- **Labor costs:** including activities such as reporting (including data gathering), giving and receiving training, institutional policy development and review, oversight and management (including answering questions from employees, students, parents, etc.), time spent interpreting regulations, preparing and implementing operational changes, responding to potential issues of non-compliance, interacting with regulators and auditors, and any day-to-day activities resulting from the practical impact of regulations.
- **Non-labor operating costs:** including any outsourcing of the above activities to external vendors; external trainings and conferences (including travel costs); materials, supplies, and services to support the above activities (e.g., equipment, facilities); software licensing fees; and fees associated with permits, licenses, applications and registrations. Note that taxes, penalties and benefits paid were not included in cost estimates (e.g., FICA, ACA, ERISA).
- **Indirect costs of labor** were estimated based on labor costs: the ratio of specific categories of indirect costs to total institutional labor was determined and applied to the estimate of compliance-related labor costs. Specific categories of indirect costs included utilities, operating leases, minor equipment (e.g., computers), insurance, professional development, recruitment, travel, telephone, office supplies, computer software, printing, postage, freight and shipping, courier service, direct mail, memberships, and subscriptions.



Methodology for decentralized and concentrated costs varied to determine total cost of compliance

Cost type	Method	Description
Decentralized costs	Surveys	<ul style="list-style-type: none">• Estimated time spent by faculty and admin staff in academic departments on compliance through survey<ul style="list-style-type: none">– 975 responses
	Worksheets / Interviews	<ul style="list-style-type: none">• Gathered decentralized time costs in several areas where information collected centrally (e.g., conflict of interest disclosures, training time in several areas, immigration processes, etc.)
	System data	<ul style="list-style-type: none">• Budget and payroll data
Centralized costs	Worksheets / Interviews	<ul style="list-style-type: none">• Worked with senior administration to validate relevant regulations and to identify pertinent offices• Estimated compliance costs in each relevant office<ul style="list-style-type: none">– Conducted ~150 interviews• Worked with senior administration and relevant offices to follow-up on results and analysis
	System data	<ul style="list-style-type: none">• Analyzed data for certain types of activities (e.g., financial aid)• Budget and payroll data



Regulatory areas categorized by type and nature of costs

Cost concentration

More decentralized

More concentrated

Research compliance

- Environmental health and safety – research
- Export control
- Grants & contracts
- Human/animal research

- Conflict of interest
- Tech transfer
- Research misconduct

Higher education compliance

- Accreditation (regional & programmatic)

- Clery Act
- FERPA
- Title IX (sexual misconduct)

- Equity in athletics (EADA)
- Drug & Alcohol prevention
- Financial aid
- Immigration
- IPEDS reporting
- State authorization
- Title IX (athletics)

All-sector compliance

- Finance (tax, debt, financial solvency)
- FISMA
- HR (FLSA, ERISA, FLMA, labor relations, etc.)

- Disability (ADA)
- Anti-discrimination
- Environmental health and safety – plant operations
- Gainful employment
- Power plant



Principles to Determine if an Activity is Required to Comply with Federal Regulation

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The following principles were used as guidelines to determine if an activity is required to comply with federal regulation:

- The institution would have been ineligible for a U.S. federal program if it had not performed the activity;
- The institution would have stopped receiving a U.S. federal benefit if it had not performed the activity;
- The institution would have risked violation or penalties under U.S. federal law if it had not performed the activity; or
- The institution performed the activity to determine whether any of the above items applied.



Summary findings

Categorized federal regulations based on type (e.g., research, higher ed-specific, all-sector) and nature of cost incidence (decentralized vs. centralized)

Estimated costs through multiple approaches, including conducting ~150 interviews and administering a survey of faculty and admin staff in academic departments with 975 responses

Estimated regulatory cost of compliance at Vanderbilt of ~\$146M or 11% of non-clinical expenditures

- ~70% of costs are decentralized across broad swath of faculty, research staff, admin staff and trainees in academic departments
- ~30% of costs are centralized and contained in specific offices
- Areas with greatest cost burden include grants and contracts, research/human participation, environmental health and safety, and accreditation
- Significant variation in compliance cost between research (17% of relevant expenditures) and non-research areas (4% of relevant expenditures)



Compliance costs estimated at ~11% of total expenditures

	Total cost of compliance estimate (\$M)	% of 2014 VU expenses, non-clinical (\$1,365M ¹)
Centralized compliance costs	~39	~3%
Decentralized compliance costs	~107	~8%
Total	~146M	~11%

1. Total expenses (3,754M) less healthcare services (2,389M)



Significant variation in cost between research and non-research areas

Total compliance cost

Total compliance cost	\$146M
Total FY14 VU expense (non clinical)	\$1,365M ¹
% of total	11%

Research-related compliance cost

Research-related cost	\$117M
FY14 research expense	\$679M
% of research expenditures	17%

Non-research-related compliance cost

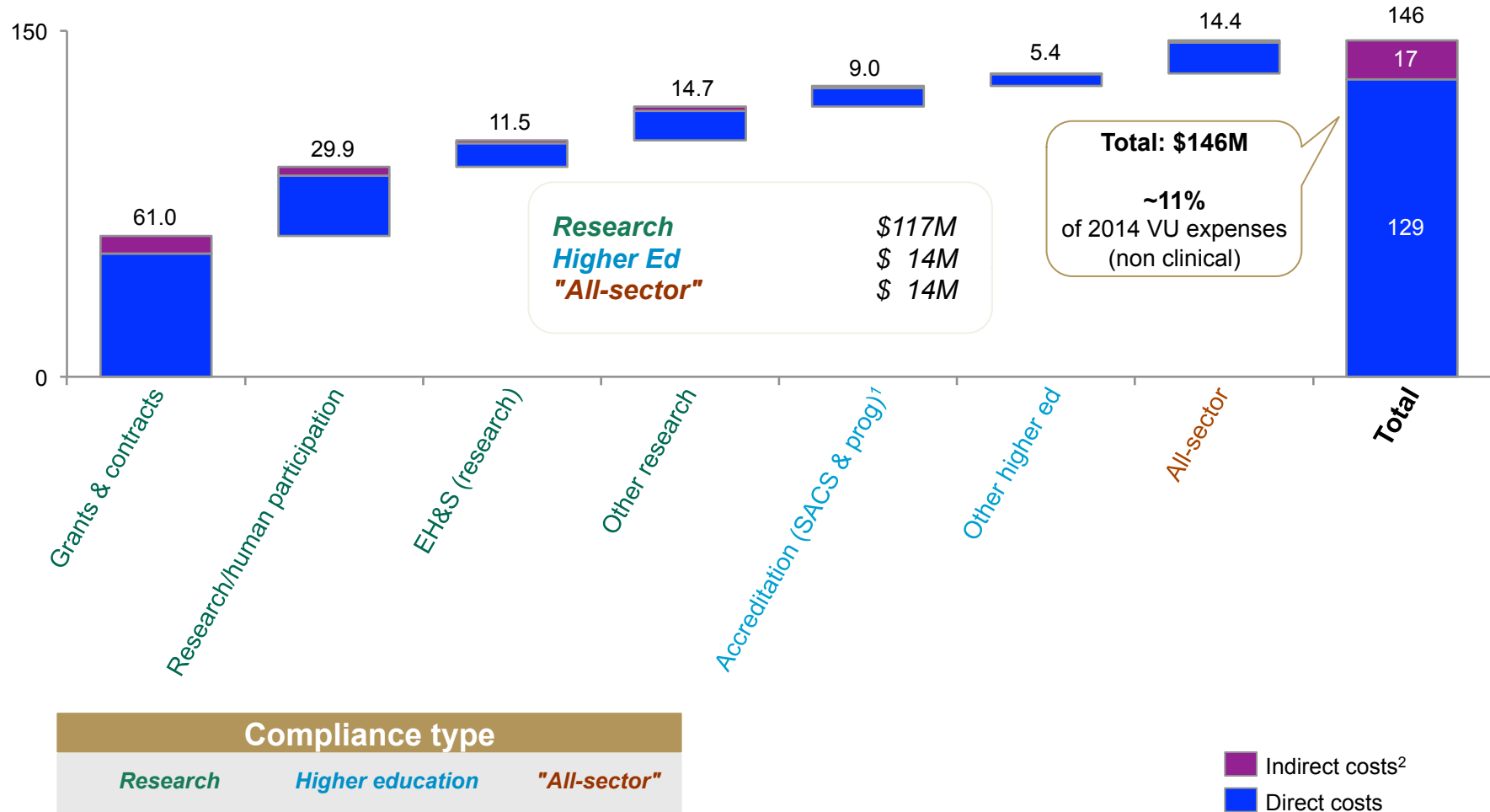
Non-research-related cost	\$29M
FY14 non-research expense ³	\$686M
% of non-research expenditures	4%

1. Total expenses (3,754M) less healthcare services (2,389M)



Research-related areas largest contributors to overall costs

Cost of compliance (\$M)



1. Not all programmatic accreditations are linked to federal regulatory compliance 2. Indirect costs estimated based on labor costs and include facilities and supply
Note: Totals do not tie due to rounding

Appendix – Compliance components



Grants and contracts compliance components

Decentralized Compliance – Faculty, staff and trainee time on managing federal awards

Central grants/contract management – Time spent managing federal awards by:

- OSP¹
- VUMC Finance
- OCM²
- Office of C&G Accounting
- OCRA³

Research-related central offices – Time spent educating on the topic of award management or managing awards by:

- Office of Research
- BRET⁴
- VICTR⁵
- Clinical trial & billing

Other – A-133 audit; Time spent by:

- Senior administration
- General Counsel
- Internal Audit
- Faculty Affairs

1. Office of Sponsored Programs 2. Office of Contract Management 3. Office of Contract and Research Administration 4. Biomedical Research Education and Training 5. Vanderbilt Institute for Clinical and Translational Research



Research/human participation compliance components

Decentralized compliance – Faculty, staff, and trainee time on research/human participation compliance

IRB office costs – Manages IRB processes, training, review committees

IRB reviewers – Review IRB submissions, support faculty

Other HRPP¹ offices – Research support services; Radiation IRB; Accreditation (of IRB)

Faculty and staff – Training for those involved in research/human participation

Other costs – Time spent by:

- General Counsel
- Senior administration
- Internal Audit
- Faculty Affairs



Environmental health and safety (research) compliance components

Decentralized compliance – Faculty, staff and trainee time on EH&S research compliance

VEHS¹ office – Radiation, chemical and biosafety compliance management

Hazardous waste – Hazardous waste disposal

Occupational health services – Federally required occupational health services for non-clinical employees

Faculty and staff – In-person and VandySafe training for faculty, staff and students

Time spent by:

- General Counsel
- Senior administration
- Faculty Affairs
- VICTR²
- Research offices
- IT
- Internal Audit

Safety boards – Required radiation and biosafety boards to maintain oversight

1. Vanderbilt Environmental Health and Safety
2. Vanderbilt Institute for Clinical and Translational Research



Other research compliance area components

- Export compliance activities
- Conflict of interest management
 - Annual disclosure management
 - PHS-grant conflict of interest processes
 - Training
 - Completion and review of annual disclosure
 - PHS-grant processes
 - Committee meetings to discuss cases, review conflicts, maintain oversight
 - Fees paid for external management
 - Research misconduct
 - Course development
 - Time spent by schools/depts on responsible conduct of research oversight
 - Time spent by grad students, post-docs, and others faculty/staff on responsible conduct of research requirements
 - General Counsel
 - Internal Audit
 - Office of sponsored programs, Offices of Contracts Management, Office of Research Administration
 - Senior admin time
- Technology transfer
 - Reporting requirements as per Bayh-Dole Act
 - Medical Device Regulatory Affairs Program (MDRAP) compliance
 - External fees for lawyers/consultants
 - Initial disclosure compliance components
 - Required education time on timely disclosures, regulations
 - MDRAP required compliance
 - General Counsel
 - Internal Audit
 - Senior administrative oversight
- Animal research compliance



Accreditation compliance components

Decentralized compliance - Faculty, staff, and trainee time on SACS and programmatic accreditation

Business office (decentralized) - Effort from business offices to complete annual report for SACS

Central reporting and oversight - Time from:

- Office of the Vice Provost for Faculty
- BRET¹
- VIRG² (for QEP³ data analysis)
- Senior administrative time
- Internal Audit

1. Biomedical Research Education and Training
2. Vanderbilt Institutional Research Group
3. Quality Enhancement Plan



Other higher education compliance area components

- FERPA
 - IT security and infrastructure, e.g.,
 - Encryption, firewalls, incident response, malware detection
 - IT app development and database management
 - FERPA trainings
 - In-person (~400 employees)
 - Online module (~1200 employees)
 - FERPA online acknowledgments
 - Manage student records under FERPA
 - Store records
 - Provide students right to inspect
 - Obtain written consent to release records
 - Provide admin oversight and advise on policies
- Title IX sexual misconduct
 - Respond to charges, complaints, and suits
 - Define and advise on policies
 - External training fees
 - Student accountability - Set policies, investigate complaints
 - Project safe - Student support
 - Residential Ed.
 - Training & reporting
 - Faculty VUceptor training
 - VUPD - Title IX trainings
 - VU IT - VU PETSAA2 module development and maintenance
 - Internal audit
- Federal financial aid
 - Manage federal financial aid transactions (e.g., verify eligibility, originate & disburse funds, counseling)
 - App development and database support for Financial Aid systems
 - Verify and manage eligibility for VA benefits
 - Update and maintain financial aid and enrollment systems (w/ VUIT)
 - Manage Title IV permissions
 - Provide admin oversight and advise on policies
- Clery Act
 - Residential Education
 - Training
 - Reporting
 - Student Accountability
 - Review incidents
 - Investigate cases
 - Dean of Students - Missing persons policy
 - Review, classify, report Clery crimes
 - Create Annual Security Report (ASR)
 - Fire safety report
 - Issue timely warnings
 - Training for CSAs
 - Provide coordination and oversight
 - Review and advise on policies
 - Fee for external training
 - VU IT - Maintain security alert systems (e.g. AlertVU, email lists)
 - Senior leadership time
 - Admin oversight and policy advisory
 - Internal audit staff time
- State authorization
 - Cost to meet State requirements, including: Fees, Surety bonds, Business registrations
 - Time spent meeting State requirements by
 - Office of the Vice Provost for Faculty
 - School of Nursing
 - School of Medicine
- Title IX athletics
 - Admin staff, senior staff time related to Title IX
 - Advise on Title IX related issues, respond to charges, complaints, and suits
- Drug and alcohol prevention (DFSCA¹)
 - Manage wellness program and alcohol education program
 - Administer alcohol and wellness trainings for students
 - Programming related to prevention of alcohol- and drug- abuse
- IPEDS reporting
 - Survey inputs gathered by Vanderbilt Institutional Research Group (VIRG)
 - Additional input provided by Finance and Financial Aid Office
 - Verification of enrollment and graduation data
- Gainful employment

1. Drug Free Schools and Communities Act of 1989 – requires institutions receiving federal financial aid to establish drug & alcohol abuse prevention programs for students and employees



All-sector compliance area components

- HR
 - Manage HR policies related to regulations such as FLSA, ERISA, ACA, minimum wage, W2 reporting, Unemployment
 - Manage policies, and processes for FLMA and unemployment
 - Respond to labor relations issues
 - Fees for external consultants and ER advisors
 - Manage policies and processes related to FLSA and unemployment
- Finance
 - Financial statements - includes cost of 498(c) reporting for financial solvency
 - Incl. VU staff + external auditors
 - Tax team and external auditor time
 - FATCA
 - IRS compliance
 - Tax returns for charitable trusts
 - Deduction calculations
 - Disclosure requirements
 - Tax documentation
 - Bond compliance
- Plant operations
 - Asbestos, pesticide, underground storage tank (UST), air permits, and safety equipment compliance
 - Training and labor time costs
 - VEHS allocated labor time to USTs, pesticide and asbestos removal, water compliance
 - Clean Air Permits
 - Bags for Baghouses
- FISMA
 - Security and infrastructure staff time for activities such as:
 - Firewall management
 - Incident response
 - Malware prevention
 - Equipment and hardware costs, e.g.
 - Firewalls
 - Malware detection and prevention
 - Operational expenses for activities such as:
 - Firewalls
 - Malware prevention
 - Secure File Transfer services
 - Multi-factor authentication services
- Disability-related
 - Coordinate disability support services
 - Monitor accessibility of programs and facilities
 - Investigate complaints
 - Provide trainings
 - Advise on ADA-related regulations and policies
 - Respond to charges, complaints, and suits
 - Answer employee questions
 - Support investigations related to discrimination for disability
 - ADA compliance costs related to construction
- Immigration
 - Fees for:
 - I-9 forms
 - H-1B visas
 - Permanent residency applications
 - Time required to complete
 - Visa req's
 - Permanent residency applications
 - Time on I-9 forms
 - Data mgmt for H-1B holders
 - Compliance support for F and J visa holders (students/ scholars)
 - Support for F/J visas holders
 - Sponsorship for H1-B
 - Permanent residency applications
- Anti-discrimination
 - Develop, implement, evaluate, programs and policies related to Equal Opportunity, Affirmative Action, Recruitment, Workplace conduct
 - Advise on discrimination-related regulations and policies
 - Respond to charges, complaints, or suits related to Civil Rights and discrimination
 - Manage Equal Employment policies related to Compensation & Benefits
 - Support responses to charges, complaints, or suits