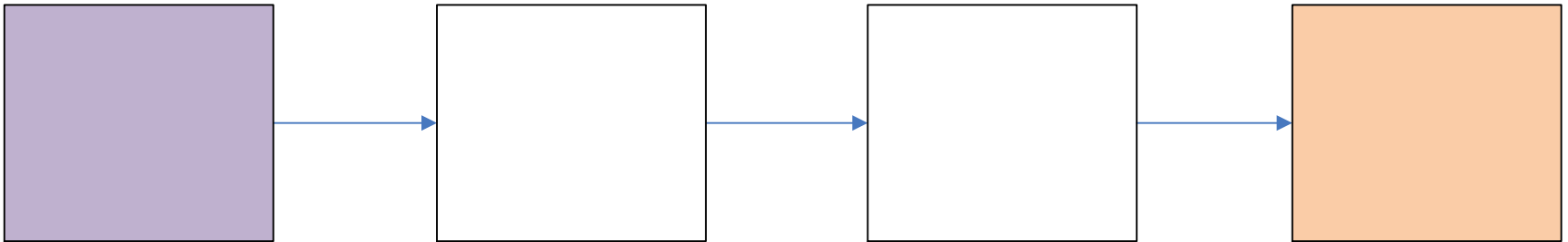




APR – Research & Grants Projects
Project #1: Award Setup

APR Forum Oct 14, 2009

High Level View of Award Setup



Project Scope Boundaries:

Starting Point → Terms & Conditions Finalized

End Point → Bill Plan Set Up (Invoices can be sent out)

Baseline: 113 days

Goal: Reduce by 50%

Notice of Award

Costs of Current State

113 days

- Research delays
- “Temporarily” parked charges
- Delays to financial reports
- Invoices cannot be generated
- Delayed payments from sponsors

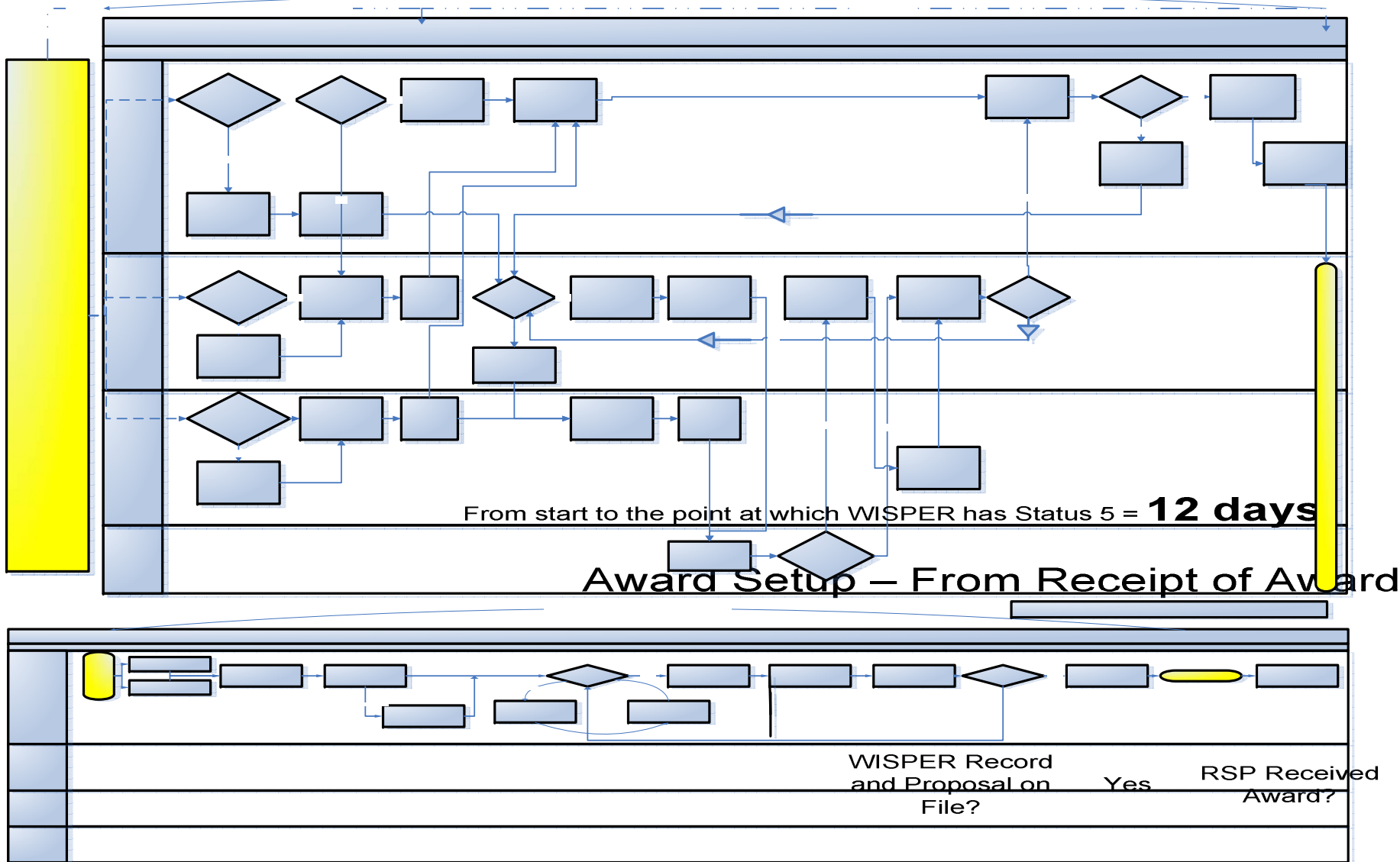
80%
reduction

19 days

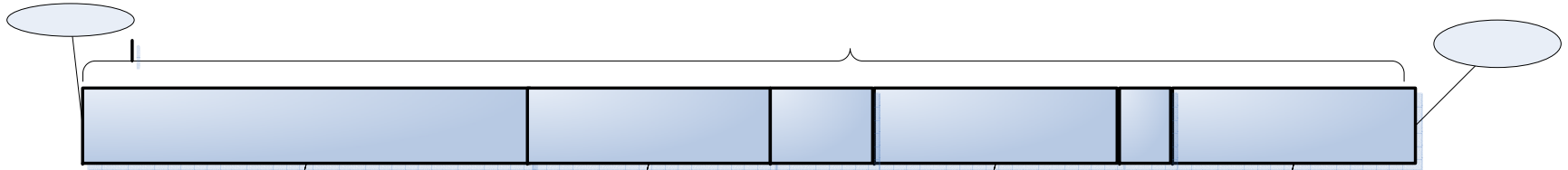
- Fewer research delays
- Fewer cost transfers
- Timelier financial reports
- Timelier invoices and sponsor payments
- Easier closeouts

Current Process:

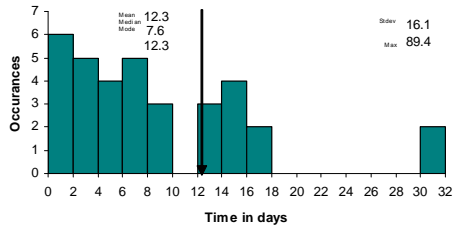
Front End = 34 Days / Back End = 79 Days



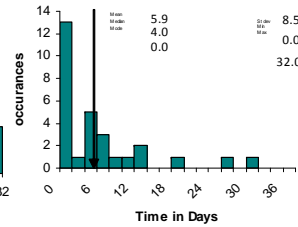
Detailed Process Map with Measurements



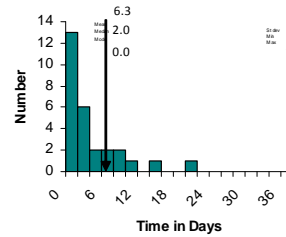
Histogram - Award receipt to Status 5



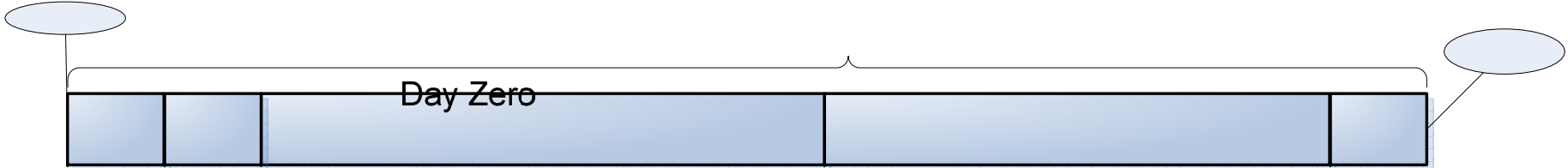
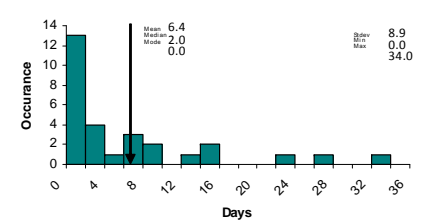
RSP to Deans Setup Approval



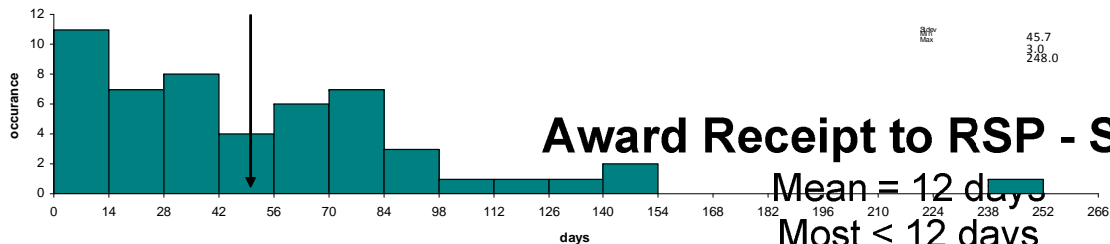
Dept. Approval back to Dean's



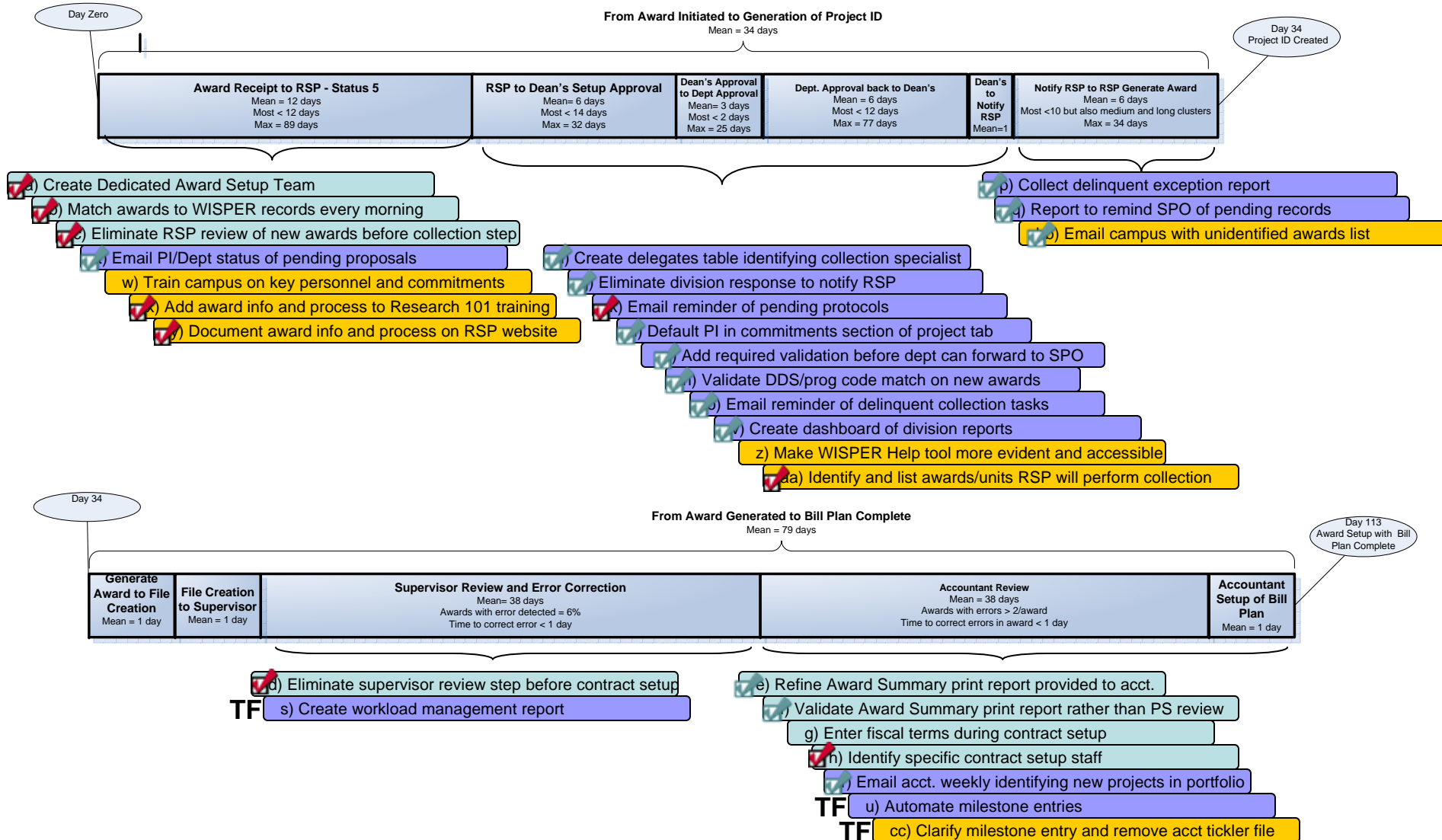
From RSP Notified to Award Generated



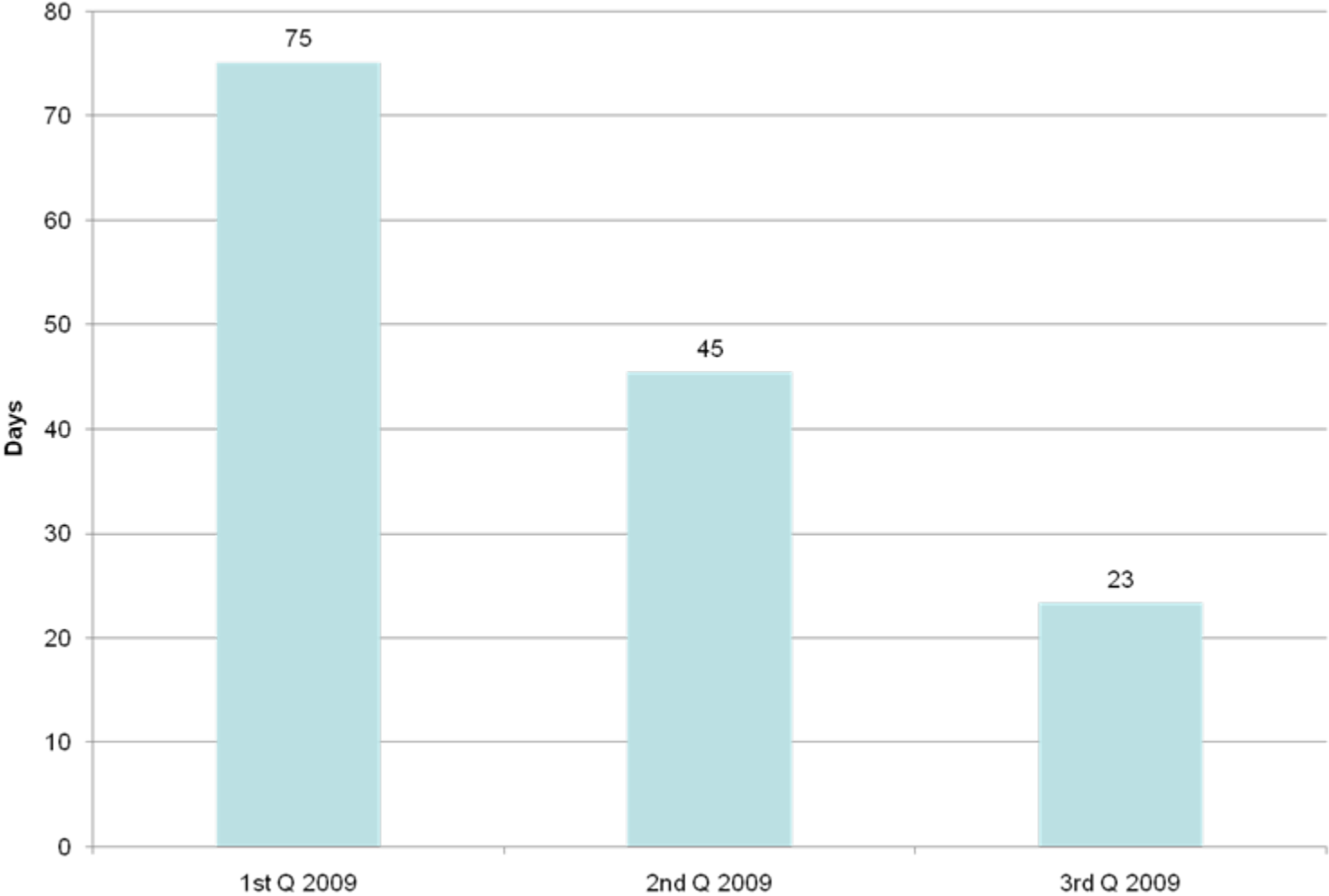
Histogram of Supervisor and Accountant Review Time



How Solutions Fix the Current Process



Average Award Setup Time



APR – Research & Grants Projects
Project #1: Award Setup

Next Steps

Continue
Implementation



Monitor
Sustainability



Report to
Deans'
Council

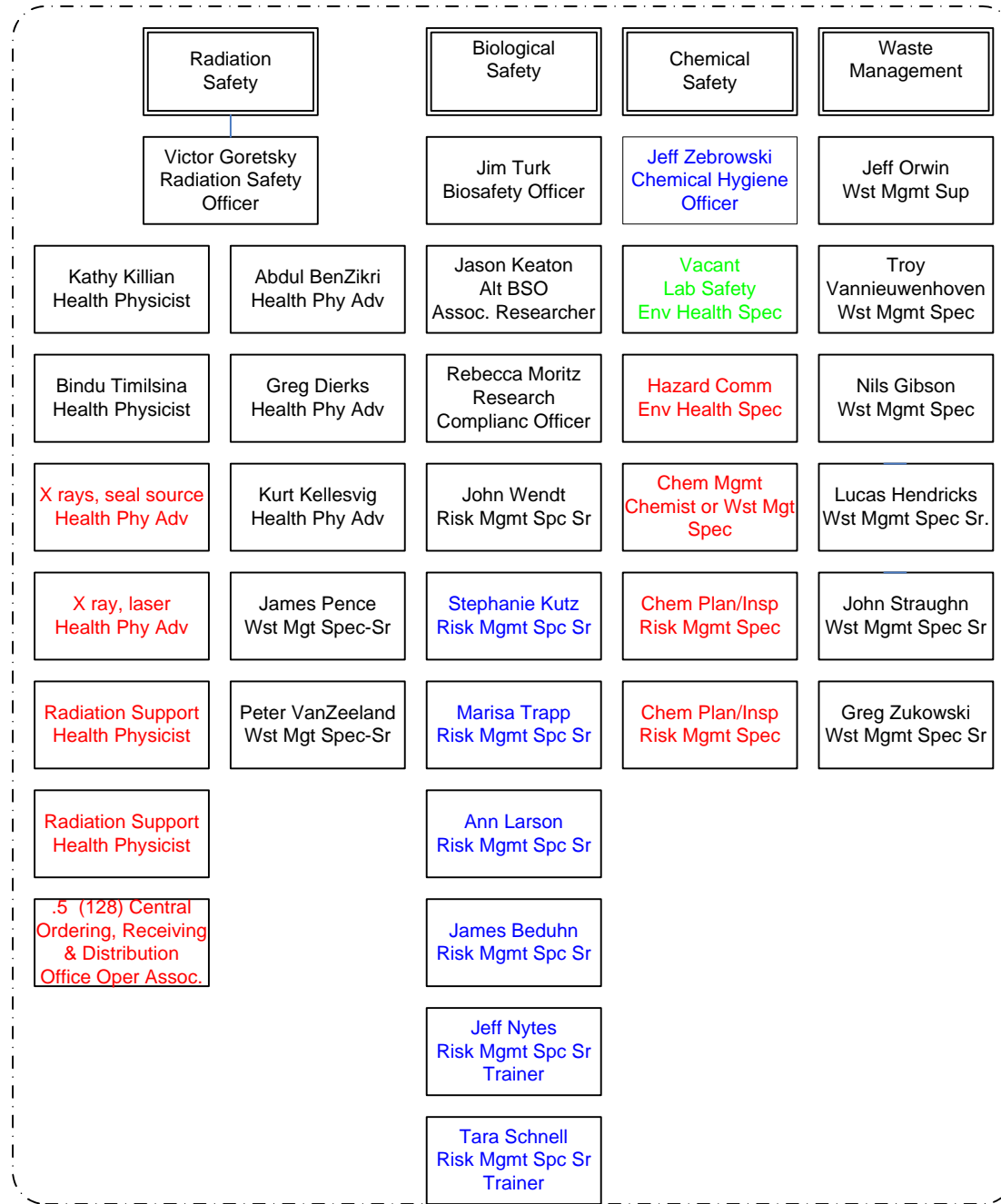
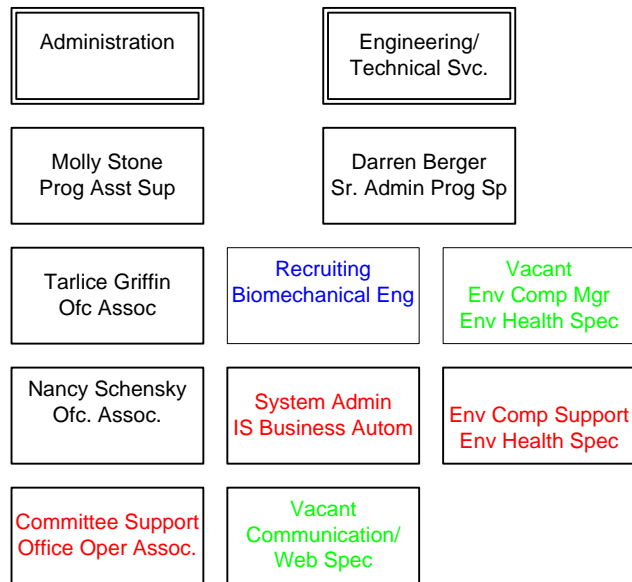
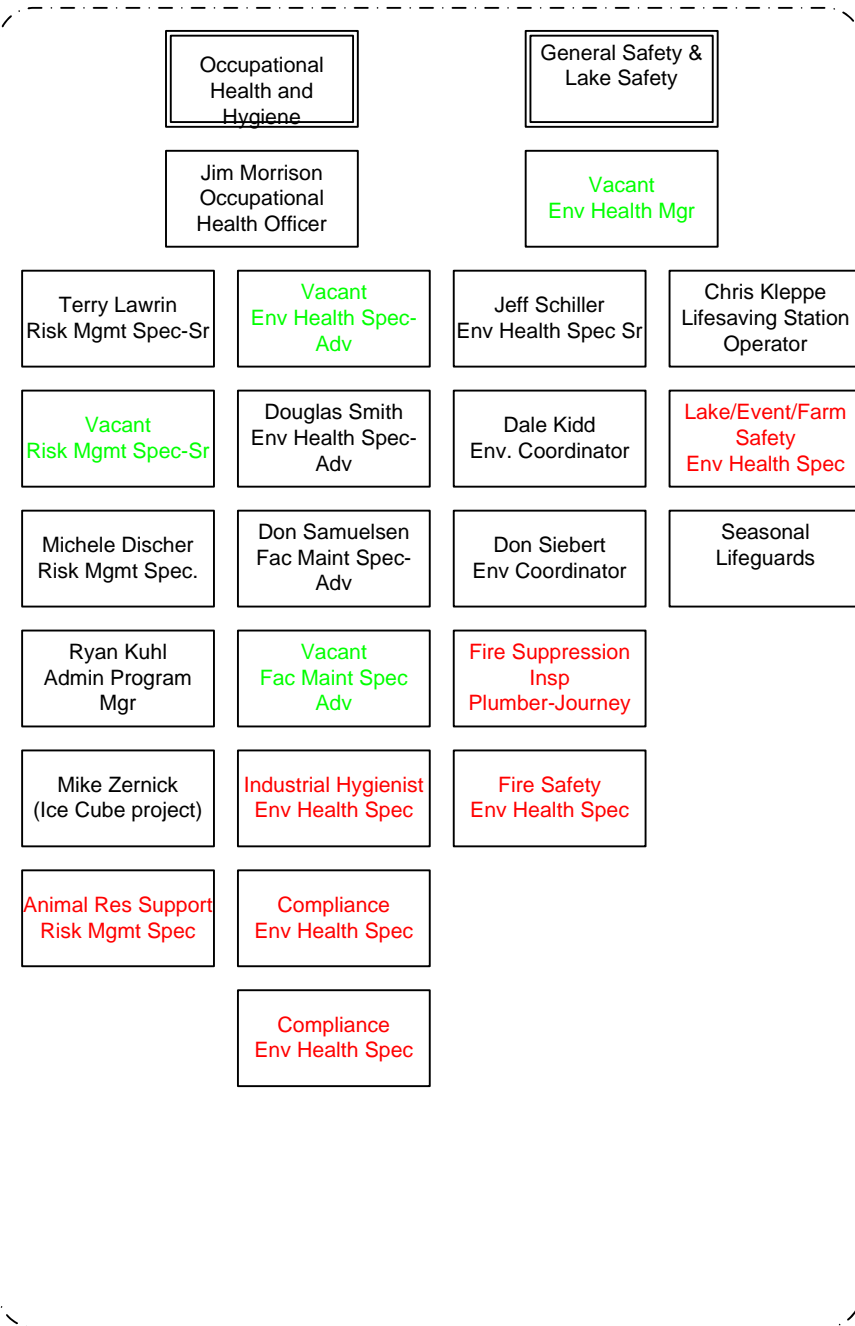
**Environment, Health and Safety
Resource Needs
November 4, 2009**

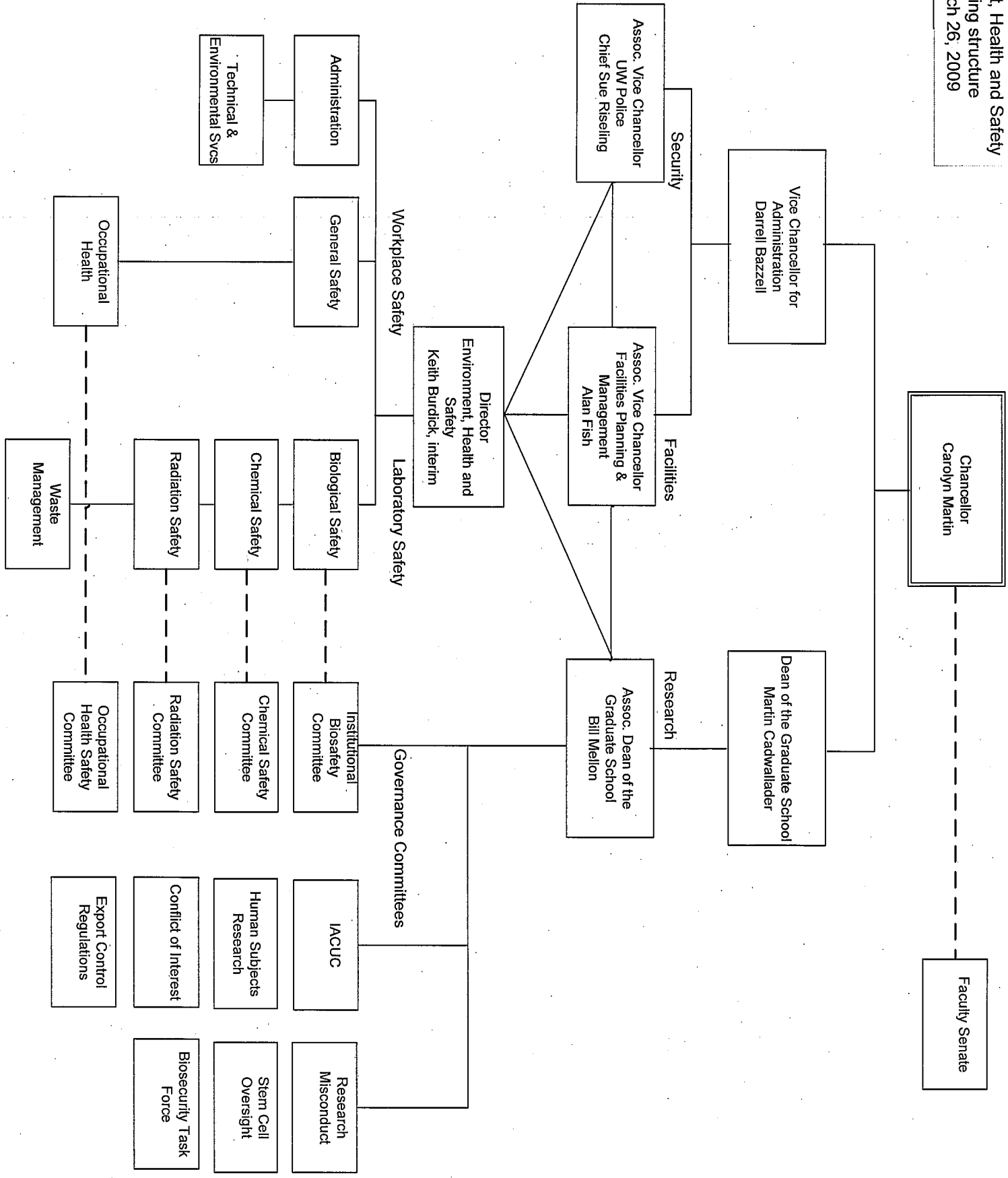
Red – Proposed
Blue – added FY9
Green - vacancy

Keith Burdick
Interim Director

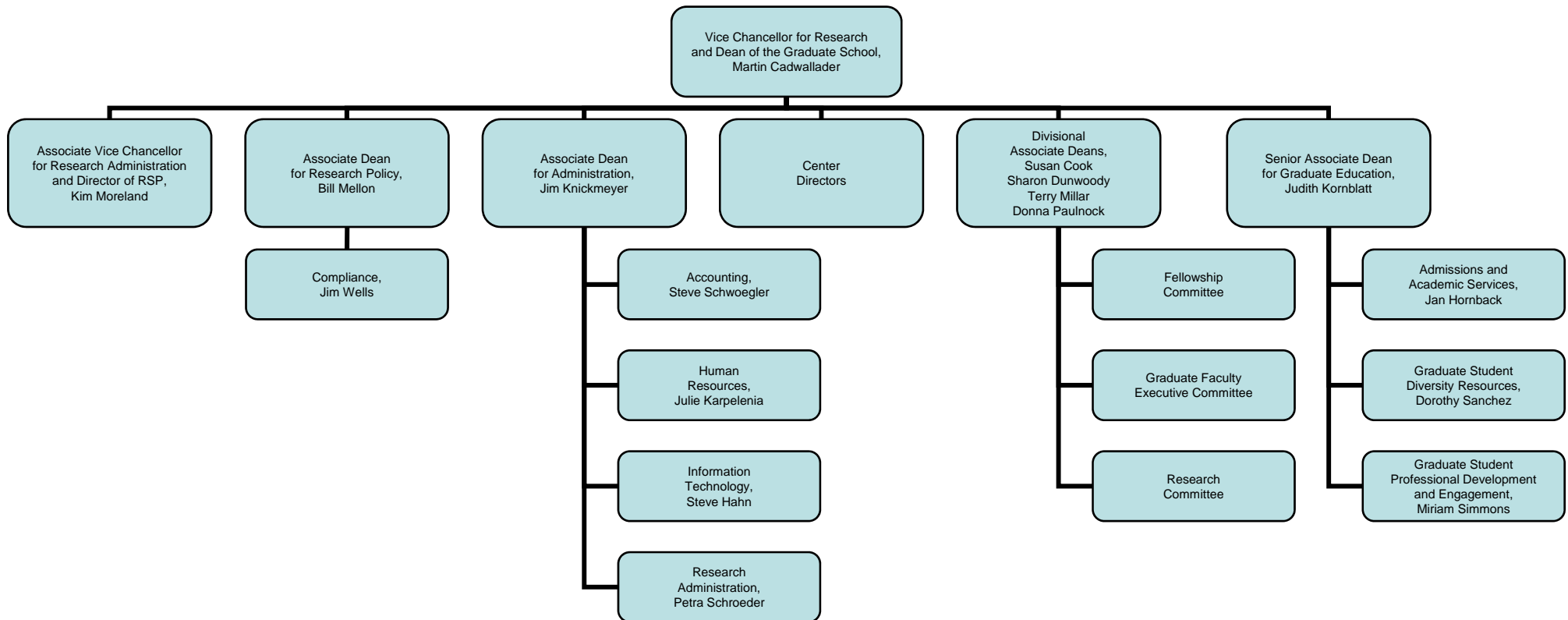
Workplace Safety & OSHA Compliance

Laboratory Safety and Compliance





Graduate School Organization Chart



RSP: A Time of Transition

Kim Moreland
 ASEC Ad Hoc Committee on the Research Enterprise
 November 10, 2009

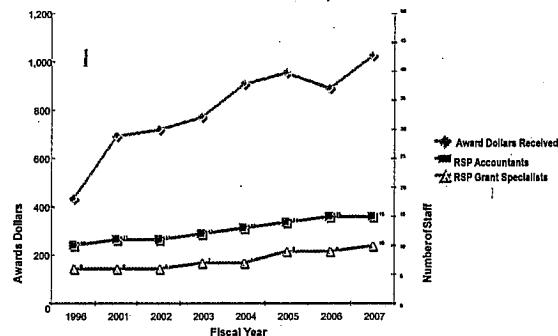
The Problem

- Inability to deliver critical services to researchers, staff, and sponsors
 - Delays in processing proposals and awards
 - Overdue financial reports
 - Slowdowns with billing and invoicing
 - Need to learn new, complex systems
 - RSP staff frustration at not being able to deliver consistently good service

How did RSP get there?

- Many years with no significant investments in research infrastructure
- Rapid growth in UW sponsored programs
- Increasing complexity in grants and agreements
- Exponential growth in financial regulatory environment

RSP Staff vs. Annual Awards, 2007



2007 Benchmarking with Big Ten Universities

Category	RSP	Big 10 Average
Proposals per FTE	225	127
Awards Set Up per FTE	440	143
Subcontracts by FTE	38	17
Research Expenses per FTE	\$41 M	\$19 M
Awards Managed per FTE	334	148

Critical Contributing Factors

- Three systems implementations in three years
 - Cayuse for proposal submission
 - ECRT for Effort Reporting
 - PeopleSoft Grants Management System
- Dramatic change in managing effort reporting
- Proliferation of audits, including NSF OIG Effort Audit

Industry Contracting

- 2005 Report of the Ad Hoc Committee on Industrial Contracting urged:
 - Staffing
 - Restructuring
 - Streamlining
- Requests for funding never approved

2008 Strategic Request

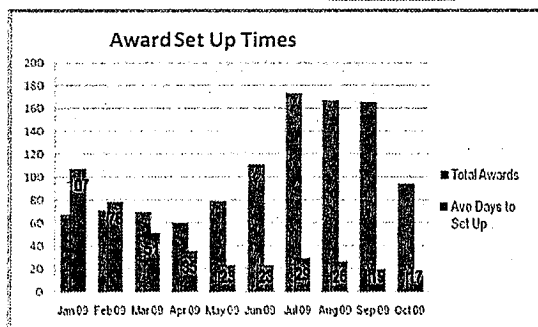
- Goals
 - To improve operational support for the UW research enterprise
 - To deal with immediate NIH backlog problem
- Request to Chancellor Wiley
 - RSP reorganization to target critical areas
 - Additional staffing
 - Financial reporting assistance

Today: Significant Progress

- Additional staff approved for RSP
- Award set up times
- ARRA set up times
- ARRA reporting – minimal impact on PI's
- RSP Customer Contact Initiative
- APR committees
- WISPER, Cayuse: e-tools for campus
- NSF OIG Effort Audit: No fines
- Closed 1800 open projects last summer

Award Set Up – Much Improved

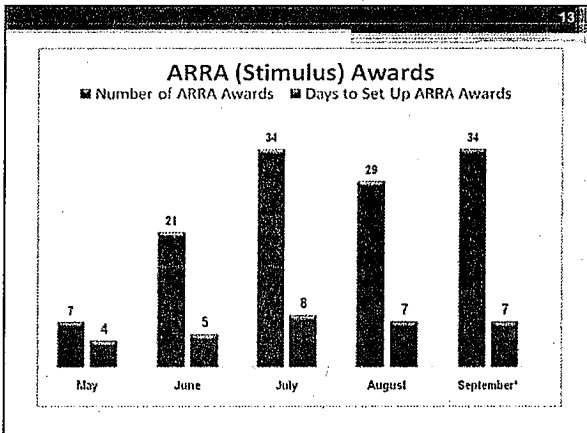
- 70% of all awards are set up in 15 days or less
- Typical delays in set up include:
 - Approvals of protocols
 - Confirming new budgets with PI's
 - Collecting cost sharing and effort commitments



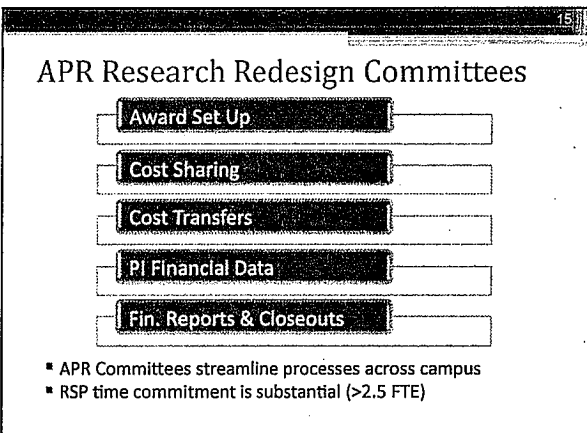
Average Time to Set Up an Award = 17 Days in October

RSP Reporting for Stimulus Awards

- Goal: Minimize the need for PI input
- Confirmation or updates from PI on 3 data elements only:
 - Abstract/Description
 - Percent Completion
 - Project Classification
- Future input from PI: Quarterly activities
- All other data collected and verified by RSP



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- ### RSP Customer Contact Initiative
- Launched in summer 2009
 - Responsive to questions within one business day
 - Coordinates a full resolution of the issue
 - Captures information about the nature and location of problems
 - Very positive response from campus



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- ### NSF OIG Effort Audit: Success!
- No fines or penalties
 - We agreed to:
 - > Set up a schedule for Internal Audit review
 - > Write a definition of "suitable means of verification"
 - > Review our practices of the NSF 2/9 Rule
 - > Offer a refresher training course
 - > Resolve \$2,941 (out of \$31 M) in questioned costs

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- ### Continuing Challenges
- ARRA award management
 - > COGR estimates ARRA reporting requires 46 hours/award. At UW that means 5.5 FTE.
 - Concerns that ARRA reporting will be extended to other grants and contracts
 - Significant Backlogs
 - > Financial reporting
 - > Billing and invoicing
 - > Award closeouts

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- ### Challenges
- Audit environment – 17 current audits underway
 - Time for training and recruitment
 - > 50% of RSP staff have been in the office less than a year
 - Making the transition from a crisis-driven environment to a fully functional, service-driven office
 - The resources provided to RSP have resulted in significant improvements, but there are still unmet needs.

INDUSTRY AGREEMENT STUDY GROUP

Final Report

Study Group Members

Diane Barrett
Deanna Dietrich
Steve Harsy
Carol Hillmer
Kathy Irwin
Dave Kettner

Kim Moreland (chair)

Facilitators: Maury Cotter and Nancy Thayer-Hart

October 2005

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- #2. Agreement Processing by College and Agreement Type
- #3. Common Negotiation Delays
- #4. Benchmark Data – Other Leading Research Institutions

3. Roles and Responsibilities

Current Negotiation Activities across Campus

Planning for Improved Services

1. Study Group Recommendations

2. Organizational Structure for an Industry Contracting Group

Executive Summary

The Industry Agreement Study Group was constituted by Martin T. Cadwallader, Dean of the Graduate School, to identify an approach for negotiating agreements with industrial sponsors that would improve and shorten the process. The Study Group has held a series of meetings over the last eight months to discuss the current procedures for managing industry agreements and to make recommendations for a revised, streamlined approach.

The Study Group initially collected information from key stakeholders about the activities associated with industry research and identified current concerns about the process. There is substantial evidence of overlapping roles, lengthy delays, and uncertainty about the application of University policy to specific situations. The Office of Research and Sponsored Programs (RSP) provided data on the processing time for industry agreements by school and college. In addition, there is information about the negotiation timelines by the type of sponsor, including industrial (for-profit) sponsors, and the recurring points of delays along the path to a fully executed agreement. As expected, the data indicate significant negotiation delays by every participant: RSP, the sponsor, dean's office, the principal investigator, compliance offices, Legal Counsel, and WARF. The data collection process also examined the placement of industry negotiations at seven research institutions with active industry partnerships and found five of the seven universities established the negotiation function within a central office of sponsored programs.

The Study Group reached consensus on the need to create a dedicated function for handling industry agreements; to improve communications with the participants, including the development of training programs; to request additional resources to facilitate an industry focus; and to identify measures of success for an improved process. The Study Group also determined there was a need for a new organizational structure to support negotiation activities.

Throughout its discussions, the committee recognized that the volume of industry agreements for the College of Engineering and the Medical School merited a different treatment and greater autonomy. A subcommittee met with Deans Cadwallader, Paul Peercy, and Paul Deluca to explore options for managing the current and increasing volume of industry research with engineering and medicine. With that meeting the Study Group's goal of shortening and streamlining the process came into focus with an approach centered on the concept of a high-level decision-maker heading an office of industry contracting and located within RSP. As part of this plan, Engineering and the Medical School would have unique relationships with the industry group and considerable negotiating authority while still adhering to University policies and standards.

This Report of the Study Group contains the materials collected during deliberations and explicates the recommendations for improving the University's approach to negotiations with industrial sponsors.

INTRODUCTION

The relationship between universities and corporations has been the subject of broad national discussion during the last decade. Some commentators and public figures have stressed the need for stronger collaborations with corporations as a means to develop university technologies and take products to the marketplace. The cyclical flattening of the Federal budget for research has encouraged the belief that universities must forge a bond of shared research interests with our industrial sponsors as a principal means of counteracting reduced public funds and increased, costly, and burdensome Federal accountability requirements.

On the other side, critics have suggested that universities have sold-out their values, identities, and even their research through the establishment of ongoing arrangements with industrial sponsors. Those observers note the “corruption” of higher education by catering to the vested interests of the private sector and by the academy’s emulation of a business model of institutional management.

Amidst this ongoing debate, the University of Wisconsin-Madison is directing its attention to the balance between those two contradictory viewpoints. The University must continue to focus on the policies that protect the interests of the University and its researchers while also recognizing the need for industrial partnerships. These relationships are vital to advance our research programs and to assist in developing University technologies for public use. There is clear recognition that University research is often enhanced by close relationships to the corporate sector and the subsequent access to such resources as critical technologies developed by corporations, state-of-the-art instrumentation, scientific expertise, and skills at research and development activities.

The Industry Agreement Study Group was formed to investigate a prevailing concern that the University’s relationships with industry, as represented by our various research agreements, are in need of attention and improvement. As funding for the research infrastructure has lagged far behind the growth of research grants and contracts, the campus has somewhat neglected our industrial sponsors and the faculty who find considerable success with them. It is time to turn our focus to our corporate interactions.

Throughout the meetings of the Study Group, the central question has been, “How can we improve the negotiation of industry agreements?” Our response is multifaceted and reflects the complexity of the University’s culture and processes as well as the particular nature of industrial sponsors. This document begins by providing a number of pieces of information that describe what we are doing now, and then it turns to several models for future directions.

A solution for this campus, one that will improve our relationships with industrial sponsors, cannot overlook the differing approaches to research across our colleges and

schools. The magnitude of industrial research varies significantly among campus units, and dissatisfaction is strongest in those colleges where the volume of industrial research is highest. There is certainly a need to maintain common policy interpretation and some points of intersection, but it may not be possible for each college to operate in precisely the same manner. It will be no surprise, then, to find the Study Group has tried to identify solutions that allow optimal flexibility within the new model.

Throughout the discussions of the Study Group, one theme has been repeated: the need for good communications. The Study Group is clear that underlying any organizational model for industry contracting is the critical necessity of establishing and maintaining relationships – with faculty, the colleges, and industrial sponsors. A good negotiation requires sound knowledge of the researcher's goals, the mission and priorities of the individual colleges and the University and the specific interests of the industrial partner in each setting. Without a serious, engaged understanding of the perspectives of all the participants in industry research, a new approach cannot be widely accepted.

Summary of Current Issues

Study Group Observations

The Study Group has heard from PI's, departments, schools and colleges, sponsors, and other interested stakeholders that the current process for negotiating agreements with industrial sponsors is complicated, inefficient, slow, and frustrating to University participants and industry sponsors. A significant amount of staff time is devoted to the protection of the University's long-term interests with respect to research policy and intellectual property rights, but the process does not contribute to enhancing relationships with corporate sponsors. This draft proposal is designed to address the issues and concerns arising from the following contributing factors:

- Good communications are at the heart of a successful experience, and current models need improvement.
- The negotiation process varies among schools and colleges.
- Processing time for agreements needs to be shortened.
- Roles and responsibilities are not clearly defined.
- There may be several levels of review and numerous handoffs with considerable duplicative effort.
- "Expertise" exists in different functional areas across the University.
- Agreements are not logged into the electronic tracking system until after several levels of review.
- Multiple levels of review are involved in the negotiation process and multiple people are contacting the sponsoring companies.

Stakeholder Needs

Everyone involved in industry negotiations brings a different perspective, contributing to the complexity of the process. The sponsor, principal investigator, academic department, Dean or Director's office, RSP, Legal Counsel, and WARF all have a stake in the way the process works and the outcomes it produces. Each party has somewhat different goals for the process. The ideas discussed in Study Group meetings about the stakeholder needs are summarized below:

Sponsor	PI	School/College/Dept	UW/WARF
<ul style="list-style-type: none"> ✓ Consistent policy ✓ Speed ✓ Consistent contact person ✓ Access to the decision-maker ✓ Personal relationships ✓ Both Sponsor and University to understand the importance of the issues and of having common goals and expectations ✓ Agreement meets the industry standard of fairness 	<ul style="list-style-type: none"> ✓ Funding for research ✓ Speed ✓ Protection of publishing and IP rights ✓ Building block for additional research ✓ Knowledge of the contract terms (e.g., invoicing) ✓ Limitations and rights related to obligations to UW 	<ul style="list-style-type: none"> ✓ Act as liaison between RSP and PI ✓ Consistent campus rules ✓ Know their role ✓ Understand what campus needs ✓ Good relationship with sponsor ✓ Sound fiscal management of project ✓ Risk protection ✓ Scope of project consistent with mission 	<ul style="list-style-type: none"> ✓ Consistent application of policy ✓ Develop and disseminate knowledge ✓ Obligations fulfilled ✓ Protect and advance intellectual property for UW ✓ Protect and advance the University's research goals

Data Tables

The information on the following pages has been compiled for review. Please note that only the colleges with significant volume of industry agreements are specified; other colleges are presented in the aggregate. All data are for FY05:

Table #1: Agreement Processing by Type of Agreement

Table #2: Agreement Processing by Type of Sponsor

Table #3: Common Negotiation Delays

Table #4: Benchmark Data – Leading Research Institutions

Table 1: Agreement Processing by Type of Agreement
FY 2005*

College	CALS	ENGR	GRAD	L & S	MED	OTHERS	Totals
Research Agreements							
Total Agreements	160	134	66	122	212	125	819
Total Days Processing	125	100	146	85	60	72	92
RSP Days Processing	79	42	96	52	20	29	47
Days Agreement on Hold	46	58	50	33	40	43	44
Confidentiality Agreements							
Total Agreements	9	54	24	3	126	15	231
Total Days Processing	61	51	33	54	61	66	56
RSP Days Processing	9	4	6	8	6	3	5
Days Agreement on Hold	52	47	27	46	55	63	51
Clinical Trial Agreements							
Total Agreements	0	0	3	0	218	23	244
Total Days Processing	0	0	80	0	153	339	11
RSP Days Processing	0	0	4	0	22	11	20
Days Agreement on Hold	0	0	76	0	132	327	150
Material Transfer Agmnts							
Total Agreements	71	2	28	5	154	39	299
Total Days Processing	106	21	57	101	66	73	76
RSP Days Processing	10	4	5	12	6	5	7
Days Agreement on Hold	96	17	52	89	60	67	69
Miscellaneous Other							
Total Agreements	21	22	8	25	83	121	280
Total Days Processing	37	90	25	107	36	62	65
RSP Days Processing	3	8	6	35	6	8	10
Days Agreement on Hold	33	81	20	72	30	70	55
All Agreements							
Total Agreements	265	215	129	157	796	325	1887
Total Days Processing	113	86	95	88	84	93	91
RSP Days Processing	56	29	51	47	14	16	27
Days Agreement on Hold	58	57	45	41	70	77	64

Table 1 Notes: See next page

Table 1 Notes:

This Table does NOT include any data about Federal grants.

Research Agreements includes all contracts and sub-contracts, including industry-sponsored research agreements, as well as subawards stemming from grants. They do NOT include any Federal grants. The category DOES include Federal contracts and Federal flow-through funds the University receives from third-parties in the form of subawards and sub-contracts.

Miscellaneous Other category includes agreements which do not fall in the other categories, such as purchase orders, fee-for-service and non-monetary agreements. Examples include awards to the State Lab of Hygiene and contracts to the Wisconsin Veterinary Diagnostics Lab.

Total Agreements means the number of Agreements completed, signed by the sponsor, compliance approvals in place, and a permanent account created in FY 2005.

Total Days Processing means the average number of days from the time an agreement was logged into the PALS tracking system in RSP until it was signed by the sponsor, all compliance approvals were in place, and a permanent account was created.

RSP Days Processing means the average number of days, including partial days, RSP performed some activity on the agreement or was preparing to work on the agreement.

Days Agreement on Hold refers to the average days an agreement is outside of RSP, that is, the days RSP is waiting for a response from another participant, including sponsors, PI's, deans' offices, etc.

* Data are for FY 2005 YTD through June 27, 2005. Agreements are not tracked until they reach RSP. Due to rounding and the use of partial days, the numbers in the table may not always add to the totals. Source of Data: PALS Database

Table 2: Agreement Processing by Type of Sponsor
FY 2005*

College	CALS	ENGR	GRAD	L & S	MED	OTHERS	Totals
For-Profit Sponsors							
Total Agreements	56	107	41	21	386	90	701
Total Days Processing	78	84	63	115	97	118	94
RSP Days Processing	16	25	20	51	13	7	16
Days Agreement on Hold	62	59	43	64	84	111	79
Non-Profit Sponsors							
Total Agreements	67	42	39	61	172	79	460
Total Days Processing	114	86	105	68	63	70	78
RSP Days Processing	56	30	71	40	14	19	31
Days Agreement on Hold	58	56	34	29	49	51	47
Public Sponsors							
Total Agreements	119	49	40	59	163	109	539
Total Days Processing	128	97	123	103	48	69	86
RSP Days Processing	78	43	73	56	12	21	40
Days Agreement on Hold	50	54	50	47	37	48	46
All Agreements							
Total Agreements	265	215	129	157	796	325	1887
Total Days Processing	113	86	95	88	84	93	91
RSP Days Processing	56	29	51	47	14	16	27
Days Agreement on Hold	58	57	45	41	70	77	64

Table 2 Notes

This Table does NOT include any data about Federal grants.

For-profit sponsor simply means an organization established or operated with the intention of making a profit. These sponsors are business or industrial sponsors, such as Pfizer, General Motors, Genentech, etc.

Non-profit sponsor may be formally incorporated as a not-for-profit corp or it may be a foundation, charity, or association. Examples include American Cancer Society, Wisc. Carrot Growers, etc.

Public sponsors are governmental agencies, such as NIH, NSF, State of Wisc, etc. If funding originates with a public entity but flows through a private entity to UW, the award is treated as Public in this database.

Total Agreements means the number of Agreements completed, signed by the sponsor, compliance approvals in place, and a permanent account created in FY 2005.

Total Days Processing means the average number of days from the time an agreement was logged into the PALS tracking system in RSP until it was signed by the sponsor, all compliance approvals were in place, and a permanent account was created.

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Due to rounding and the use of partial days, the numbers in the table may not always add to the totals.

* Data are for FY 2005 YTD through June 27, 2005. Agreements are not tracked until they reach RSP.
Source of Data: PALS Database

Table 3: Common Negotiation Delays

The PALS (Pre-award Login System) database in RSP collects information about all the stages of agreement negotiation from the time an agreement is received in RSP. Once an agreement is logged in, RSP tracks its path as it moves among the participants in a negotiation. The list of participants may include, in addition to RSP, the PI, department, dean's office, WARF, Legal Counsel, various compliance offices, and, of course, the sponsor.

While there is evidence of a significant number of hand-offs for any single agreement, the tracking information is maintained only by RSP and therefore does not necessarily provide a record of the activity in other offices. For example, RSP may send an agreement with complex IP requirements to WARF for review and comment. The PALS system will record that the project is on hold and then count the days until the agreement comes back to RSP. However, there is no ability for WARF to note the activity WARF initiates once an agreement is received from RSP. Common causes of delays in this example might derive from the need for the PI and the sponsor to review and comment on a proposed amendment.

Given the limitations of the current tracking system, the Study Group believes the best recognition of the categories of delays is simply a record of the principal points where an agreement may stop along its path to completion. The following locations are those where an agreement may be reviewed and a delay will ensue:

- Sponsor
- Compliance offices
- Dean's Office
- Principal Investigator
- Office of Clinical Trials
- Legal Counsel
- WARF

Table #4
Industry Agreements at Selected Universities

Univ. (Industry Rank)	R&D Volume *	Industry Negotiations	Reporting Lines	Agreements Handled	Staff
Duke (1)	\$99,807	Office of Research Services Office of Science and Technology	Vice Provost for Research Dean of Medical School	All except MedSchool and MTAs All MTAs for campus, all negotiations for the Medical School	3 ?
MIT (2)	\$88,626	Industrial Negotiations group in OSP	OSP reports to the Vice President for Research	All research agreements and all CDAs. MTAs are handled jointly with IP Counsel. MIT does clinical research but not clinical trials.	5 in IND group
Georgia Tech (4)	\$55,802	Industry Contracting Office in OSP	ICO is part of OSP, which reports to the Assoc. Vice Provost for Research. Office of Technology Licensing also reports to AVP for Research. All these offices are part of the Ga. Tech Research Corporation, which handles all sponsored programs for Ga. Tech	Research agreements, CDAs, MTAs. No mention of CTAs.	5.0 in ICO
Washington (7)	\$46,702	Office of Sponsored Programs	Vice Provost for Research	Research agreements, CTAs and MTAs related to funded projects.	32 - 1.5 dedicated to CTAs
Stanford (8)	\$39,110	Industry Contracts Office OSP	Office of Technology Licensing	Research agreements, MTAs CTAs	4 in ICO
UC San Francisco (9)	\$33,577	Division within Office of Sponsored Programs	Executive Vice Chancellor	Research agreements, CDAs, MTAs, CTAs	7+Mgr
Minnesota (19)	\$26,572	Sponsored Projects Administration	Office of the Vice President for Research	Research agreements, CDAs, MTAs, CTAs	4.5

*Volume is based on 2002 NSF R&D expenditures by source of funds (dollars in thousands)
In 2002 UW ranked #34 with industry expenditures of \$16.746 M.

Current Roles and Responsibilities

Negotiation Activities Currently Performed by Each Identified Unit

This chart illustrates where various steps and reviews are performed. Points to note include:

- The number of steps that are duplicated by the Colleges and Schools, RSP and WARF
- The variation among the three main colleges. The other colleges present an additional level of variation. Variation adds complexity to a process. Standardization simplifies the process, although we recognize there may be valid reasons for some variation.

		CALS	COE	MED	RSP	WARF
RESEARCH/TECHNICAL ISSUES						
	Proposed type of agreement is appropriate to proposed research	X	X	X	X	
	Research is appropriate in nature and scope	X	X	X		
	Scope consistent with the departmental and institutional mission	X	X	X		
	Qualified personnel and adequate space are available	X	X	X		
	Adequate and accurate budget to accomplish the scope of work	X	X	X		
	Risk/safety	X	?	X		
ADMINISTRATIVE/BUDGET ISSUES						
	Sponsor deadlines	X	X	X	X	
	Cost sharing/matching funds	X	X	X	X	
	Indirect cost rates, waivers	X	X	X	X	
	Sponsors' terms and conditions for grant administration	X	X	X	X	
	Performance clauses (Includes technical reports, professional staff hourly reports, deliverables, termination conditions)	X	X	X	X	
	Assignment of account number in advance of receipt and acceptance of official award document (Form 88-1)	X	X	X	X	
COMPLIANCE ISSUES						
	Small Business/Minority Subcontracting Plans	X			X	
	Equity/Diversity	X			X	
	Project PI status	X	X	X		
	Human subjects protocols	X		X	X	
	Research animals protocols	X		X	X	
	Biosafety hazards protocols	X		X	X	

	CALS	COE	MED	RSP	WARF
Export controls	X	X		X	
MATERIAL TRANSFER AGREEMENTS					
Is the material available commercially or from another source?	X		X	X	X
Can material be obtained independently of provider through synthesis, biological culture or breeding, or fabrication?	X		X	X	X
Source of funding will be used to support the research to be conducted with this material	X		X	X	X
Will the material be used in combination with another material which was received under an MTA?	X		X		X
Will the material be used in combination with a material under management by WARF, or in a project providing data for an invention being patented by WARF?	X		X		X
Intended use of the material - clinical trial only?			X		X
Does the research involve (or potentially involve working with reagents, antibodies, cell lines or animal models developed using federally sponsored dollars?	X		X	X	X
Will the research possibly create derivatives (new material that contains or incorporates the requested material)? Will the research explore a new use for or improvement to the material?	X		X		X
Is researcher willing to forego financial gain in order to obtain this material?	X		X	X	X
Will the material be used in conjunction with any other material(s) being provided under other MTAs?	X		X		X
Could researcher's willingness to forego financial gain have a potential impact on others in the laboratory?	X				X
Is ability to negotiate IP terms limited by federal funding in the lab that may find its way into the proposed research?	X		X	X	X
Type of material: <ul style="list-style-type: none"> o marketed drug o developmental drug o research chemical or biological material o cell line or organism o piece of equipment 	X		X		X
Proprietary status of the material: <ul style="list-style-type: none"> o Under patent o Trade secret o Non-proprietary 	X		X		X
"CONTAMINATION" OR CONFLICT OF INTEREST ISSUES					
Federal regulations regarding disclosure of potential conflicts	X	X	X	X	X
Are federal funds supporting any other research in the laboratory (including salaries of researchers)?	X	X	X		X
Conflicting agreements and obligations	X		X		X

UNIVERSITY POLICY ISSUES					
Internal approvals (T-Form)	X	X	X	X	
Publication restrictions	X	X	X	X	
Transfer of data ownership	X	X	X	X	
Classified research	X	X	X	X	
Appropriate indirect cost rates	X	X	X	X	
Audit requirements	X	X	?	X	
Payment terms and schedules	X	X	X	X	
Report forms	X	X	?	X	
Financial report schedules	X	X	?	X	
Level of detail	X	?	?	X	
Receipt of confidential/proprietary information	X	X	X	X	
Cost-sharing, tuition remission	X	X	X	X	
Equipment and supplies: record-keeping, disposition	X	X	X	X	
Loaned property: tracking, insurance coverage	X	X		X	
Termination provisions	X	X	X	X	
Performance guarantees	X	X	X	X	
Travel policy and reporting	X	X		X	
Withholding of payments	X	X	X	X	
UW as recipient/signatory to award/contract	X	X	X	X	
Publicity restrictions	X	X	X	X	
Endorsement of products/services	X	X	X	X	
LEGAL ISSUES (STATE LAW)					
Sovereign immunity	X		X	X	
Indemnification	X	X	X	X	
Jurisdiction outside of Wisconsin	X	X	X	X	
Binding arbitration	X	X	X	X	
Certificate of insurance	X	X	X	X	
Open records	X	X	X	X	
Records retention	X	X	X	X	
Non-disclosure	X	X	X	X	
Export control	X	X		X	
IP ISSUES					
Royalties	X	X	X	X	X
Future research rights	X	?	X	X	X
Potential for patent disclosure	X	X	X	X	X
Exclusive vs. nonexclusive license	X	X	X	X	X
Commercialization rights (Sponsor)	X	X	X	X	X
Limitations on sublicensing	X	X	X	X	X
Shared sponsorship	X	X	X	X	X
SPONSOR ISSUES					
Commercialization rights	X	X	X	X	X

Study Group Recommendations

The Study Group has arranged our recommendations into five categories and provided information supporting each decision. The complexity of negotiating agreements with industry is aggravated at the University by the severe budgetary stresses on the research infrastructure and the campus culture of local autonomy in managing grants and contracts. The Study Group has considered those issues and accounted for them in its recommendations wherever possible.

Recommendation #1. There is a need for a dedicated staff, headed by a person with the authority to make decisions and help establish policy, to act as the primary managers for the negotiation of industry agreements. A functional group within RSP with a focus on industry negotiations will have the time, skills, and motivation to streamline and improve the process. An individual heading the group must be empowered to make decisions about the application of University policy to industry agreements and to sign off on the agreements.

A significant role for this group is to establish several sets of industry-specific terms and conditions acceptable to the University and to the industrial sponsor for utilization with particular types of research projects. This set of boundaries would assist all parties involved in the negotiation in understanding negotiation parameters. With those boundaries in place, University negotiators would have flexibility to negotiate contracts within those boundaries and would seek input when terms outside those boundary conditions were needed.

The Study Group suggests several additional strategies to reduce the time required for negotiations:

- Begin the negotiations at the earliest practical point
- Engage in a more proactive exchange with industry representatives
- Revisit University policies on intellectual property and the impact these policies have on negotiations
- Develop a negotiation strategy for industry agreements
- Use dedicated staff to assume responsibility for the process, including such activities as follow-up calls on lagging responses from campus or industry
- Work with Legal Counsel and WARF to increase access to negotiation advice
- Develop an approach to achieve an interactive, engaged relationship with WARF, Legal Counsel, RSP, and UW colleges
- Develop a sophisticated processing checklist for staff working on industrial agreements
- Establish a web-based Negotiation Manual for staff reference
- Focus attention on industry agreements and streamline processes

The Study Group further stresses the need for a comprehensive educational effort to offer guidance to faculty and administrative staff involved in research with industry. Once staff can be dedicated to working with our industrial partners, an educational program for the campus becomes part of their responsibility. An educational program might include:

- Work with Legal Counsel to establish a recurring course for campus on legal issues in research
- Work with WARF and Legal Counsel to establish joint, recurring workshops for campus on IP issues, including downstream effects
- Develop web-based training materials addressing key issues, policy guidance, and the negotiation process for faculty and staff
- Develop or enhance web-based materials for industrial partners that describe the University's mission and provide contractual language for key issues
- Work with Colleges and Schools that are less experienced to increase their knowledge and understanding on key contractual issues.

Recommendation #2. Communications among the University participants and the industry sponsor are critical to the success of negotiations and long-term relationships. There must be a concerted effort to understand the institutional and industrial environments for research, the expectations of the parties, the special interests of the participants, and the criteria for success of the project.

The Study Group has noted several key factors that contribute to good communications and stronger relationships in the negotiations process:

To Enhance UW's relationship with Industry Sponsors, a dedicated Industry Group would:

- Act as the principal point of contact for research agreements at the UW
- Respond more quickly to industry requests
- Provide greater flexibility and creativity in crafting contract language
- Build a network of frequent contacts in the industry sponsor's negotiation team

To Enhance Relationships with the University Stakeholders, the Group must:

- Commit to the achievement of an interactive, engaged relationship with WARF, Legal Counsel, RSP, and UW colleges through a variety of approaches, including dedicated, scheduled time with the stakeholders in their facilities.
- Create personal working relationships with each principal investigator

- Develop electronic tools to simplify the exchange of information among stakeholders
- Make negotiation status immediately available to WARF and campus participants with UW's negotiation tracking database
- Work with WARF to integrate database systems, so that WARF and the Industry Group can easily exchange negotiation information and anticipate IP conflicts.
- Establish a presence in the key colleges using mechanisms appropriate to each college
- Develop an understanding of each College's research portfolio and its particular approach to industry research

Recommendation #3. Significant improvements in the negotiation of industry agreements will require additional resources, in order to provide the dedicated expertise outlined in Recommendation #1. While the current process can certainly be refined and refocused, any major and immediate progress will need adequate staffing and some system improvements.

The Study Group did not reach a conclusion on the level of staffing required for a dedicated unit, but there was clear consensus on the need for staff whose skill set is more directed towards industry agreements. The credentials of staff hired for the Industry Group will contribute to the credibility of the Group and its ability to achieve successful negotiations. The list below includes key elements that should be represented within the Group:

- Technical understanding of work being negotiated
- Experience in negotiation with for-profit entities
- Experience with technology licensing
- Understanding of contract law and IP law
- Understanding of University policy issues
- Advanced degree or commensurate experience (JD, MS or PhD in a technical field, MBA, university administrative experience, industry experience)
- Broad knowledge and experience in the field of research administration

To maximize simultaneous processing and ensure that the process is completed in a timely and orderly manner, the following technology enhancements are recommended:

- Establish a system that makes negotiation notes readily available to WARF, Legal Counsel, RSP, and select Dean's offices
- Upgrade UW electronic systems so that campus can enter basic data electronically through on-line Extramural Support Transmittal Form
- Improve campus access to basic PI intellectual property information
- Institute optical Imaging capability for transferring documents received in hard copy

- Utilize a seamless database that allows for access and updating by all internal stakeholders, thus streamlining the process and allowing negotiations to proceed in parallel where possible

Recommendation #4. Establish a structure for a Contracting Group for Industry Collaborations. In order to accomplish the recommendation for dedicated functions outlined in this report, an alternative structure will be needed. The organizational chart that follows recognizes the need for different treatment of agreements within the College of Engineering and the Medical School, while still placing signature authority in a Contracting Group within RSP.

The following criteria were used in considering various structures for the new group:

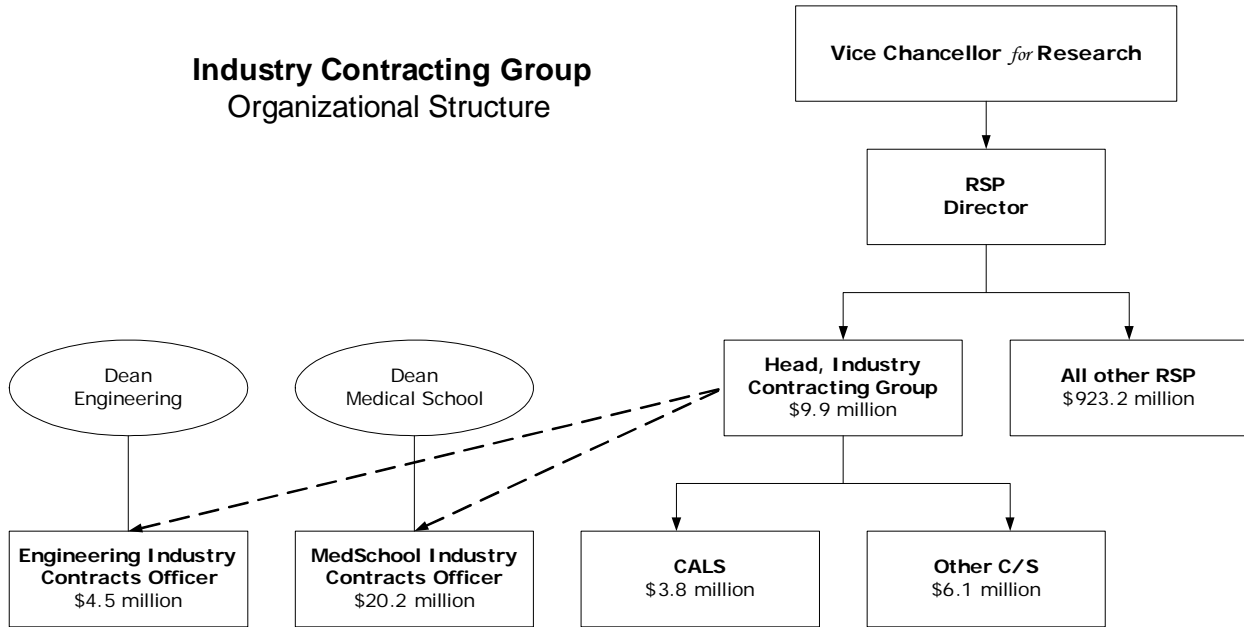
Criteria for Evaluating an Organizational Structure

- Reduces the time needed for negotiations
- Applies University policy consistently to research agreements
- Reduces number of handoffs
- Reduces overlap in what is being reviewed
- Meets needs of different types of agreements
- Reduces negotiation delays
- Improves relationship between schools and colleges and the negotiating unit
- Addresses individual needs of schools and colleges
- Facilitates good communication with PI
- Enhances relationship with industry sponsors and provides single point of contact for industry
- Facilitates post-award tasks
- Is financially viable

Recommendation #5. Determine reasonable measures for evaluating the success of any change in the process for handling industry negotiations so that information beyond anecdotal exchanges is available for a review of the dedicated unit. Measures might include:

- Reduction in time required to negotiate agreements
- Increase in industry funding
- Satisfaction of researchers
- Reduction in negotiation holds and time of holds
- Success rate for completion of agreements
- Increase in the number of agreements and fewer missed opportunities with industry
- Satisfaction within the Industry Study Group

Industry Contracting Group Organizational Structure



¹**Confidential Document (4/19/06)**
OVERVIEW OF RESEARCH POLICY AND COMPLIANCE
UNIVERSITY OF WISCONSIN-MADISON

Submitted by
William S. Mellon
Associate Dean for Research Policy

The formal crafting of the position of Associate Dean for Research Policy and Compliance (previously as the Associate Vice Chancellor for Research Policy) in the Graduate School codifies the creation of an over-arching policy and compliance structure for research activities. The overall structure for research policy and compliance within the university is shown in the figure labeled as **Appendix A**. The solid lines indicate direct reporting authority, while the dashed lines indicate that there are interactions between these groups. While the University has a compliance requirement for all institutional functions, this document addresses only those features dealing with research activities. The Graduate School provides an institutional infrastructure for research, which advocates both research and research integrity. It also has responsibility for sound financial and business systems, which are maintained by the Office of Research and Sponsored Programs (RSP). The integral relationship of responsibilities for various academic and research functions within the Graduate School are shown in the diagram labeled as **Appendix B**.

The goal of research policy and compliance activities is to reduce transactional risks and costs, and establish collaborative partnerships with all responsible institutional offices dealing with research issues. There is a need for the development of an institutional model(s) to deal with long range overall compliance. Given the acute risk for research compliance that the University currently faces, this document will deal primarily with the institution of policy and compliance needs in research and those that are of the most urgent nature.

It is not the intent of this document to provide an absolute strategic plan for all issues, but to initiate in the institution a plan that will begin to reduce risk. Since there is a need for new financial support for various aspects of research policy and compliance related matters, the document will raise questions as to how funding might be engaged, but this ought to be a matter for administrative discussion and planning. Certain immediate needs will be identified and proposed for funding consideration and they will include both personnel and programmatic needs.

¹ Dr. Karin Ellison contributed to the crafting of this document.

Given the magnitude of the task at hand and the limited resources currently available, this document will deal with only four aspects of research policy and compliance, as these are deemed either the most critical or will permit us to reduce immediately present risk. These areas will include the Office of Research Policy and Compliance and its function, the animal care and use program, the human research protection program and conflict of interest. The document will provide a short historical synopsis for each of these areas, current state of affairs, and future needs as applicable to research compliance and the need to reduce risk for the institution.

Office of Research Policy and Compliance
and
Research Policy Advisory Committee

The Office of Research Policy was established to support and interface with a variety of research activities including Associate Deans for Research of the schools/colleges, conflict of interest, research integrity, Research and Sponsored Programs, the animal care and use program, the human research protection program, the select agent program, bioethics advisory committee, embryonic stem cell research oversight (ESCRO) committee, and the research, safety and security programs (chemical safety, biological safety and radiation safety). Within the organization of the Office of Research Policy and Compliance, the Associate Dean for Research Policy and Compliance provides the leadership for a research policy committee, the Research Policy Advisory Committee (RPAC). RPAC was established (October 24, 2003) to provide guidance and advice to the Dean of the Graduate School/Vice Chancellor for Research on matters relating to research policy development and implementation. This committee is chaired by the Associate Dean for Research Policy and Compliance and is constituted with the Associate Deans for Research from the Medical School, Engineering, L&S, CALS, and two other schools/colleges on a rotating basis, with ex officio members including the Director of RSP and a senior University legal counsel, and the assistant dean for research policy serving as staff. The original organizational structure is attached in **Appendix C**. The RPAC develops a list of priority issues and creates work teams for each topic. The future vision is that, whenever the campus community identifies research policy issues, the RPAC would be charged to make a well-studied recommendation.

The RPAC has completed several projects including open/closed meeting guidelines, documents dealing with the advanced technology program, invention disclosure process, effort reporting, research openness policy, *and is involved currently with issues dealing with export control, institutional conflict of interest, facilities use policy, and fee for services policy*. Although, RPAC has enabled the finalization of several important recommendations, of immediate concern is that funding of these initiatives has not been fully addressed. There are a number of important agenda items, which have not been addressed due to staff limitations. Moreover, for the foreseeable future there remains a seemingly endless list of issues requiring policy development and analysis that are of critical importance.

The current staffing level for the Office of Research Policy and Compliance consists of the Associate Dean for Research Policy (75%), Assistant Dean (100%; Dr. Lois Brako) (vacant as of July 1, 2005) and a compliance specialist (100%; Dr. Karin Ellison). The breakdown of duties for the latter two positions is attached in **Appendix D**. Since the position of Associate Dean for Research Policy and Compliance was filled on an interim basis from January 1, 2005 to October 3, 2005, a replacement for Dr. Brako was not sought until the structure for the Office of Research Policy and Compliance could be re-assessed. Therefore, as of July 1, 2005, Dr. Ellison assumed a broad range of responsibilities to fulfill critical elements of the assistant dean position due to the departure of Dr. Lois Brako. In addition, there are two additional positions in the Office of Research Policy and Compliance an accreditation specialist (100%) and an IT/business process specialist (100%), which support human subject protection. These two latter positions were created to assist in the process of accreditation of the UW's human research protection program through the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Support for these two positions comes from the NIH grant (entitled: Enhancements to UW's Human Subjects Protection Program) awarded to the University of Wisconsin-Madison with total direct costs of \$500,000 and will terminate in August 2006. However, even if we are successfully accredited, these two positions will become necessary in the future for continuous support functions within the realm of human research protection.

The future effectiveness of the Office of Research Policy and Compliance will depend on restructuring its activities and the addition of personnel. The parsing of previous responsibilities was sufficient to establish or assist a number of ongoing or new policy/compliance programs. However, in evaluating several areas it has become apparent that the level of activity needed in human research protection, animal care and use program oversight, conflict of interest, and projected activities in human embryonic stem cell oversight and export controls have already escalated to a point where the Office of Research Policy and Compliance cannot provide adequate support and direction. This is due to the necessary components of education and compliance/auditing oversight, which are presently minimal or non-existent. Thus even in cases where new policy has been generated we do not have the capacity to assure the desired outcome is being met. The function of RPAC is also limited with the small effort provided by current staffing. If RPAC is to make significant headway in research policy recommendations, a larger commitment will be needed from both policy development and staffing of the working committees as recommendations are crafted.

The following Office of Research Policy and Compliance staffing recommendations to insure efficient optimization of effort in research policy and compliance are presented. The flow diagram linking staff and function is shown in **Appendix E**. We believe the existing position of assistant dean should remain as such and become the director of the Office of Research Policy and Compliance. This individual will devote at least 50% effort to RPAC, with this growing to as much as 75% depending upon future needs of the institution. Other responsibilities will include oversight or interfacing with Research and Sponsored Programs, the animal care and use

program, human research protection program, conflict of interest, and various safety committees. An important aspect of the director's duties will be to keep abreast of changes in federal research regulations, assist in policy development regarding the federal regulations and inform appropriate groups on campus. Aside from policy development and implementation efforts, this individual will oversee the coordination of compliance through education and auditing functions. The overall programmatic efforts of this individual aims to be consistent with, and meet the Federal Sentencing Guidelines, which contain seven elements that must be met by an institution for compliance (see **Appendix F** for the Federal Sentencing Guidelines). One of these elements that we lack as an institution is the achievement of standards by utilizing monitoring and compliance/auditing systems for research. Thus, the increase in effort by RPAC will be necessary to permit development of not only the needed research policy and its coordination and implementation, but the establishment of standards through compliance monitoring across the campus.

The organization of Office of Research Policy and Compliance would be further divided to include three managerial positions. One position (*director for research compliance*) would be responsible for understanding the policy issues across the research areas and coordinate the overarching compliance/auditing functions. One might question whether this auditing function should be housed within the Office of Research Policy and Compliance and report to the Associate Dean for Research Policy and Compliance or to an independent official. However, at least in the inception of this program the direction and responsibility rest ultimately with the Associate Dean for Research Policy and Compliance and he/she needs to take responsibility for the outcome. Another approach would be to link to Campus auditing and perform co-sourced audits. To date, Campus auditing has limited resources to deal with research compliance issues in a time scale of review that the federal entities require. Thus, even with the addition of a compliance position it may be likely that an additional audit staff person should be hired. The vision for the scope of activities for this individual would be to conduct quality assurance review of research compliance programs and interface with Campus auditing where appropriate.

A second position (*manager for conflict of interest*) would have major responsibility for Conflict of Interest Committee support and oversight of all best practices for education of the University community for compliance related human research protection, conflict of interest, research integrity, human embryonic stem cell research, and various safety programs. Since education falls under the broad oversight of compliance this individual will also work closely with the compliance director to assure that the research compliance program's needs are being met through a sound educational mission. The third position (*director for human research protection program [HRPP]*) would have major responsibility for human research protection program, including interfacing with and supporting the campus IRBs (this individual brings an important aspect to the campus IRBs, that is an individual who can provide a measure of consistency and communication across the four campus IRBs) and in cooperation with the compliance director would assist in the oversight of all compliance initiatives through internal auditing to minimize the risk to the institution with regard to human subjects. Through the suggestion of the

Office of Legal Services, the duties of HIPAA Privacy Officer (currently under the auspices of the Provost) might be better served by delegating these responsibilities to the director for human research protection program. This would necessitate moving the current FTE and funding into the Office of Research Policy. However, an assessment of need for the duties of the current HIPAA Privacy Officer and for a HIPAA Security Officer should be determined and whether or not these duties are too great to be consolidated within one position or in fact if a single individual would have the skills to carry out these combined duties.

The director/manager positions would have the benefit of two staff persons assigned with the major responsibilities to support the functions of the three directors/managers. This will necessitate the development of one educational specialist position, whose primary function would be the development and implementation of educational initiatives for faculty, staff, and students involving the areas of compliance described above. This individual would have their duties assigned by the Director of the Office of Research Policy to assist in the various policy/compliance areas designated under Human Research Protection Program, Compliance and Conflict of Interest. In addition, the other individual would have a primary responsibility in assuring compliance through internal auditing across the various areas of compliance. These positions could also provide staff support to the committees carrying out conflict of interest and human research protection program. A draft of the tentative duties for positions within the Office of Research Policy and Compliance is presented in **Appendix G**. There will also be a need for a clerical assistant for the office positions listed above.

At the present time, four positions exist within the Graduate School fulfilling some of the functions listed above. The Graduate School presently funds two of these positions (assistant dean and compliance specialist) and two are funded by NIH grant money. The proposed plan would fund three additional positions, although a total of five will need new funding since the NIH grant expires in August 2006. However, should a decision be made that the HIPAA Privacy Officer position and duties be melded with the manager of human research protection program, then only four positions would be sought. Sources of funding will need to be discussed as to whether this needs new allocations or whether existing positions in the University can be reallocated, such as the movement of the HIPAA Privacy Officer. This may also require a phased-in approach to accommodate both financial and organizational constraints. However, the intent of crafting a new organizational structure is to minimize risk to the institution in these various research areas. Whether or not these positions will add to the base of support by federal indirect costs should be investigated.

Human Subjects Protection Program

The mainstays of human research protection at the University of Wisconsin-Madison are the individual Principal Investigators (PIs) and the oversight by the Institutional Review Boards (IRBs) that approve research protocols for human research. The organizational structure involves four IRBs: the Health Sciences-IRB, Health Sciences Minimal Risk-IRB, Social and Behavioral Sciences-IRB, and the Education Research-IRB. In comparison to other peer institutions the professional staffing of the IRBs tends to be understaffed, especially in the social and behavioral areas. In addition to the college/school-based IRBs, the All Campus-IRB (recently converted to the Human Research Protection Programs [HRPP] Advisory Board) is responsible for establishing the principles and coordinating the operations of the University's program to protect human research subjects and monitoring the consistency of applying the Common Rule by individual IRBs that review cases of non-compliance and unanticipated problems. It establishes IRB policies and is responsible for communicating these policies to the University community. At the request of any member of a campus IRB, a research subject, or a research investigator, the HRPP Advisory Board will review appeals of the actions and decisions from the four campus IRBs. Presently, the Associate Dean for Research Policy is the chair of the HRPP Advisory Board.

Since September 2002, the University has made substantial investments in an effective electronic database system to manage the business of campus IRBs. With our NIH grant (entitled: Enhancements to UW's Human Subjects Protection Program project), we have licensed Third Sky, Inc.'s IRBWebKit software and implemented its review tracking and management features. This project has allowed us to consolidate the records of all four of UW's IRBs that review protocols and improve business processes. Development of the ability for investigators to submit IRB protocols on-line is underway. In fact, as of February 2006 we have instituted electronic submission of protocols for two of the IRBs - Social and Behavioral and Education. Supporting this system will entail costs for staff to assure data integrity, to modify the database as office processes develop further, and to update on-line forms and automated email to investigators, as appropriate.

The task of having our human subjects protection program accredited through AAHRPP was requested by Chancellor Wiley and is being spearheaded by the Office of Research Policy and Compliance in conjunction with the staff directors of each of the IRBs. The target date for submitting the UW-Madison's documentation to AAHRPP for pre-review was early-December 2005 with an initial response due back by mid-February 2006. The nature of the response and feedback from AAHRPP has been such that our intention is to make changes in our domain documents and submit our final accreditation application in late spring 2006. A submission in this time frame will dictate an accreditation site visit in the late fall of 2006 and an accreditation determination by March 2007. In the meantime, we have several tasks ahead of us that will need implementation if UW-Madison is to receive full accreditation status.

The dissemination of the standards for human research protection as expected by AAHRPP will occur through two seminar series in the early fall of 2006. We will utilize funds from the NIH enhancement grant to cover the costs of programs referred to as IRB 101 (constructed by the Public Responsibility in Medicine and Research [PRIM&R] organization) intended to instruct PIs and IRB members on specific knowledge requirements that they will be expected to know during the site visit interviews. Two tracks are to be presented, the first dealing primarily with social, behavioral and education research and a second orientated towards biomedical research. In addition, a campus seminar program in the format of a “town meeting” is also proposed for informing faculty and staff of the impending accreditation requirements. We have also supported individuals from our IRBs (both faculty chairs and staff) through the NIH enhancement grant to attend PRIM&R annual meetings to enhance their effectiveness in addressing regulations and protocols in the human subjects protection program. Web site based educational materials will also need to be crafted; some of this cost will be covered by our NIH enhancement grant but obviously continuing costs will need new allocations of support. We already have initiated the assembly of a team, mainly from the Graduate School’s outreach program, to begin the task of coordinating the educational events to insure that the faculty and staff will be adequately trained prior to the site visit.

AAHRPP also requires that we conduct audits of the human research protection program, the IRB process, and the conduct of research to assess compliance with state and federal laws, regulations and guidance, and University policies and procedures. We presently do not carry out this function, although the Medical School is attempting to initiate portions of these requirements. Therefore, in the intervening time prior to our accreditation site visit we need to establish a working and operational mechanism to meet the auditing standard. This process again will require personnel to coordinate and develop a process and actually begin to carry out internal audits.

The continuing process of human subjects protection will require a number of supported functions including annual reports to AAHRPP, updating of documents, continual auditing and education activities (including the cost of meeting attendance for faculty chairs and staff of IRBs), oversight of re-accreditation every 3 years, and a management IT system to allow better control of document accrual and revision as well as recording of audits and the production of reports. The suggested structure of the Office of Research Policy and Compliance described above is meant to address the oversight and coordination of these functions in the long term. The immediate need for accreditation will require temporary hires and/or a reshuffling of present duties among current staff. The cost for an IT management system and Web site functions will require future analysis in collaboration with the Graduate School’s IT director and staff.

Conflict of Interest Initiative

Each spring semester, UW-Madison faculty and academic staff report outside activities and financial interests related to their field(s) of professional work at the UW-Madison to comply with federal, state, and University policy. Faculty and staff must submit reports even if the report only indicates no outside activities. Campus faculty and academic staff use a Web form to report. The report deadline, set by State law, is April 30 annually. Specifically by State Law (UWS.8) and University policy, the following individuals are required to report annually their outside activities:

- Faculty members
- Academic staff members and limited appointees whose campus appointments total 50% or greater
- Principal or co-investigators on federal grants or human subjects protocols
- Individuals with active management plans from the Conflict of Interest Committee

Faculty and academic staff are also responsible for updating their reports anytime there is a relevant change in their outside activities (e.g. new relationships with outside organizations or increased compensation for an on-going activity).

Colleges, schools, divisions, departments, and units share responsibility for obtaining annual reports from all faculty and staff who are required to submit them and for reviewing reports. Reviewers contact individuals to resolve any completeness issues with reports. They may also address conflict of interest or conflict of commitment issues with individuals. The target date for completion of reviews of Outside Activities Reports is May 31 annually.

The Graduate School is involved in coordinating the conflict of interest policy since it has responsibility for oversight of federal grants and human subjects research. Under its auspices, the Conflict of Interest Committee reviews outside activities reports of faculty and academic staff who engage in federally funded or human subjects research and works to eliminate, minimize, or manage any actual or potential conflicts of interest identified by the reporting process. In conflict of interest situations involving other kinds of research, the Conflict of Interest Committee provides advice to Deans and Directors.

Conflict of interest has seen significant and successful policy development in recent years. In the past five years, the committee has led the development of campus policies and practices for conflict of interest review for human subject researchers. Professor Brian Fox, chair of the Conflict of Interest Committee, selected faculty and staff members, and our conflict of interest specialist have spent considerable time during the last year to update the policy for both federally funded researchers and human subjects researchers and to develop a system for review that permits committee members to systematically evaluate potential conflicts and assign management plans to individuals.

The Graduate School provides the staff support for the Conflict of Interest Committee. The Research Policy and Compliance Office's compliance specialist presently devotes at least 75% time to support of the Conflict of Interest Committee and to assist the campus in compliance with state and federal regulations. The previous Assistant Dean also spent up to 25% time devoted to these activities. However, most of our peer-institutions utilize at least two FTEs for this function.

The Graduate School also provides substantial information technology support for both outside activity reporting and the Conflict of Interest Committee. Since 2002, the Office of Research Policy and compliance and the Graduate School IT group have collaborated to custom build the online outside activity reporting system for campus. The system includes multiple components. The online form simplifies reporting for faculty and staff. Web screens with searchable and sortable lists of campus personnel required to make reports and the date reports are submitted allow administrators to follow up on submission. A password-protected utility allows departments, colleges, schools, divisions, and other campus units to access and review reports. Informational Web pages provide instructions and other resources to the campus community. The Office of Research Policy and Compliance uses a Web database to manage Conflict of Interest Committee business. All of these systems will continue to require on-going support from both IT and Research Policy and Compliance Office staff.

While our conflict of interest process works extremely well, the recent and continuing site-visits by NIH to universities suggest that two aspects of our program will need attention. We will need to better define and systematize our follow-up procedures in cases where management plans have been issued. This will need coordination with School/College deans and chairs. Moreover, we will need to implement an on-going educational strategy that is standardized to insure full compliance. Development and implementation of an institutional conflict of interest policy is also an area of future effort for this program. Ongoing accreditation of our human research protection program will require such a policy. RPAC has initiated an assessment of the needs and challenges in this policy area. The proposed structure of the Office of Research Policy and Compliance, with full employment of personnel and continued collaboration with the Graduate School IT group, is designed to address these issues.

Animal Care and Use Program

Over the previous 2 years, the University has been engaged in revamping its animal care and use program. Much of this initiative was in response to the USDA's inspections, which pointed out a wide-ranging array of deficiencies and problems. Associate Vice Chancellor for Research Policy, Tim Mulcahy, secured approximately 1.2 million dollars as a base-budget increase and approximately \$700,000 in one-time costs (not recurring) to implement a variety of changes dealing with physical facilities, external auditing, PI training, and personnel hires. While these changes have been in various stages of implementation, we have continued to have some problems as noted by USDA

inspection reports in the spring and summer of 2005. These actions culminated in the University paying a fine of \$6,875 to the USDA in September 2005. While this fine is disconcerting, a disturbing audit report by the Office of the Inspector General of the USDA to the Animal and Plant Health Inspection Service (APHIS) finds fault with APHIS not being aggressive enough with violators and could mean that our fine of \$6,875, in the future for similar violations, could amount to a total \$240,000. This in itself creates the need for the campus to make sure that our animal use and care program minimizes violations and risk for the University.

Throughout this past year, we have continued to address these problems and begun a new initiative further refining the animal care and use program. With Dr. Christine Parks' retirement as of August 1, 2005, two individuals were appointed to fill interim positions. Dr. Eric Sandgren was appointed to fill a *newly created position* as Acting Director of the Animal Care and Use Program on July 1, 2005. He was charged with establishing an overall animal care and use program that was consistent with The Guide for the Care and Use of Laboratory Animals (i.e., The Guide) and insuring that the campus Animal Care and Use Committees (ACUCs) acted in a uniform manner. The responsibility for this position also includes oversight of the Research Animal and Resource Center (RARC) and all veterinary care of research animals. Dr. Janet Welter was appointed as the Interim Chief Campus Veterinarian for the University of Wisconsin-Madison with a starting date of July 1, 2005. The responsibilities of this position include oversight of the veterinary care of all research animals, and direct supervision of the campus veterinarians and the animal care staff. Dr. Welter reports to Dr. Sandgren since he has over-all responsibility for the animal care and use program.

Under Dr. Sandgren's leadership we have begun to make progress in several areas. The organization of RARC and the veterinary care component of our animal care and use program have been revised (**Appendices H and I**). There are clear responsibilities for the operational aspect of the program (RARC) and the veterinary care part and the further establishment of direct lines of communication between the veterinarians and care staff and RARC. Moreover, this is extended to the PIs and research staff who are conducting animal-based research. The conclusion at this time from eight months of experience in the newly evolving animal care and use program structure suggests that the position of Director should be maintained and new funds will be needed to continue this position. The Graduate School is funding Dr. Sandgren's interim position currently at 50% that includes a 10% salary adjustment to his faculty base salary. We believe that this position in the future will require in reality a new FTE establishing a Director of the Animal Care and Use Program and will require a national search to fill the position with a competitive salary structure. This position will have oversight of both the operational aspects and veterinary care program under RARC. In addition, RARC had approval for a business manager to assist in the overall management of the operational budget. It is imperative that the FTE for this position be filled. While an individual currently employed in RARC has the qualifications to carry out the duties, it would require an upgrade in classification. Furthermore, following this upgrade, an additional individual would need to be hired to fill the position of Department Secretary.

There is a clear need for additional personnel in this new model structure, although it is in its initial stages of implementation. The aim of this new structure is to enable the campus to provide service to the PIs and research staff during animal protocol development and throughout the process of conducting their research. In addition, as with other aspects of the University's research policy and compliance program, we are initiating a self-auditing process that will be coupled to training and facilities management, which will help to insure compliance. Thus, during auditing of animal research protocols, should a violation be found, we can immediately offer the researcher and staff re-training to prevent future non-compliance. Likewise, if a deficiency in an animal facility is noted during the inspection we can notify physical plant and have the deficiency corrected immediately. A portion of the previous new funds that were allocated to the animal care and use program in 2004 was utilized to hire trainers. The ongoing study of the animal care and use program has also identified the need for a new FTE classified as a training support technician. This individual would be responsible for maintaining, preparing, and cleaning the training room and assisting the trainers in other aspects of their work. With the new proposal of coupling auditing, compliance, and training/re-training of investigators it will be necessary to maximize the trainer's time for actual training and not on ancillary functions.

We estimate that three additional compliance specialists will need to be hired in RARC to provide these auditing and correcting services to the campus animal care and use program. These individuals would interface necessarily with the newly proposed compliance manager associated with the Office of Research Policy to insure consistency across campus of compliance programs. Two of these individuals will be responsible primarily in protocol compliance (new unfunded FTEs, the Research Animal Program Assessment Specialists). A third individual is tentatively attached either to Facilities Planning and Management (specifically associated with Physical Plant) or to RARC whose position would be defined as a full-time coordinator/advocate for animal facilities repair and maintenance (new unfunded FTE, not shown on the organization chart, since it may be associated with Physical Plant). We view these three positions as crucial to the compliance function of the animal care and use program. Finally, we need to support current efforts to reclassify and upgrade several positions that report to the IACUC Administrator, to more accurately reflect their actual duties.

The campus has undergone an animal care inspection by AAALAC during the fall 2005 for three programs including the Graduate School (Primate Center and Biotron), School of Veterinary Medicine, and the Medical School. Both the Graduate School and the School of Veterinary Medicine programs have done well, and received continued full accreditation. The Medical School program was noted to have several deficiencies including in the areas of veterinary care, husbandry, and protocol violations. We have since learned via communication from AAALAC that the Medical School will be placed on probationary accreditation for a period of twelve months. Based on the Medical School responses by written report and another site visit, AAALAC council will re-evaluate the program. The institution of the self-auditing procedure described above will more effectively deal with deficiencies and will place us in a better position of compliance.

The veterinary care issue has been the subject of intensive analysis by Dr. Sandgren and all of the current veterinarians. A detailed summary of needs together with the proposed organization chart is presented as **Appendix I**. This organizational plan also is strongly related to the future accreditation by AAALAC of the campus's remaining two animal programs in the College of Agriculture and Life Sciences and College of Letters and Sciences. Note that in **Appendix I**, we show a single attending veterinarian, the Chief Campus Vet; other veterinarians are classified as either senior program vets or program vets, since all laboratory animal veterinarians work directly in one or more ways with the Animal Care and Use Program.

Dr. Sandgren's working group has identified the need for at least 10.5 FTEs within the veterinary care unit of the animal care and use program. We require three new FTEs as veterinarians, and need to fill one approved but unfilled position. One veterinarian would provide necessary relief work when other veterinarians are on vacation, at professional meetings, or sick. One more (already approved) is needed to meet Medical School needs. The final two are needed to provide sufficient veterinary coverage to the small animal programs of Grad, L&S, SVM, and CALS. In addition, these latter individuals will have the responsibility of establishing a much needed residency program in the specialty of laboratory animal medicine. There is currently a shortage of veterinarians in this specialty and it behooves the campus to establish a strong training program. A position for a veterinary program research assistant also has been identified to support veterinary care. This position could be filled by a current employee in RARC who is qualified, but it would require an upgrade to the job description and salary support rather than crafting a new position. Finally, 3.5 additional veterinary technicians (new FTEs) will be required to work with the laboratory animal veterinarians to ensure that the campus veterinary needs are addressed (we anticipate that a ratio of one vet tech to one veterinarian gives us the appropriate mix of expertise and job expectations).

The UW-Madison Lab Animal Care Workgroup (chaired by Mark Walters) continues to meet in order to address the status of the animal research technician program within the classified staff group. A request emanating from a previous study of workforce needs and subsequent submission to the UW System by Chancellor Wiley for a change in pay grade and classification for technicians has been implemented. This initiative was (and continues to be absolutely critical) to the functioning of the animal care and use program. Initial assessments indicate that this has had a positive effect on units hiring entry-level animal research technicians. There are two immediate situations that the university will need to address that will require resources be allocated. A brief survey of the animal units indicates that greater than 50% of the applicant pool for animal research technicians are non-native English speakers. The UW-Madison Lab Animal Care Workgroup currently is assessing options including language training to improve communication and increasing the number of full-time interpreters working in the animal units. A second issue involves the training and certification of the animal research technicians. The AC-IACUC and the Lab Animal Care Workgroup have recommended that the animal research technicians undergo American Association for Laboratory

Animal Science (AALAS) training and certification. In fact in the current union contract (CONFIDENTIAL) certification of a worker at level one (there are currently three levels of certification with one being the most basic), results in remuneration of \$1.00 per hour. The recommendation also is being made that the campus funds this training at the basic level. The cost per worker, including cost of exam, book, and coverage time while the worker attends class amounts to an estimate of \$550 per worker. RARC estimates that 20 workers per semester could be trained. Thus at current capacity the annual cost would be \$22,000 per year. A sub-committee of the AC-IACUC has been formed to establish criteria for offering training to the workers such as how seniority will be handled, how to make training opportunities equitable across the various units, what is the obligation of the worker to the university with regards to employment once certification has been achieved, etc. We believe that this program adds to the professional aspects of these positions and could assist in the recruitment process for the future. It also demonstrates the University's commitment to the critical nature of these workers to the excellence of the animal care and use program.

The campus also has a contract with Priority One for the training and hiring of animal research technicians on a temporary need basis, although this has been only minimally effective. The Lab Animal Care Workgroup is also working on a strategy to partner with other local institutions to increase the numbers of individuals who would choose to become animal research technicians. Taken together we are hopeful that these initiatives will provide a well-qualified cadre of animal research technicians to provide support to our animal care and use program. Drs. Sandgren and Welter are working cooperatively to integrate these staff into the equation of additional supervisory needs for the animal care and use program in the area of veterinary care.

The initial proposal to Chancellor Wiley and Vice Chancellor for Research Cadwallader requested the development and implementation of an effective electronic database system that would support protocol submission, tracking, and monitoring. The original request was for the commitment of \$100,000 (part of the \$700,000 in non-recurring costs provided last year) towards the development of this component, which would be added to the human subjects database program being developed and supported by the NIH, Enhancements to UW's Human Subjects Protection Program. Upon further analysis by the Graduate School's IT staff, the human subjects database will not meet the broad needs of the animal care and use program. Therefore, a committee composed of Dr. Sandgren, several staff in RARC, Mr. Rick Lane, Dr. Welter, and Mr. Chip Quade (Graduate School) has spent several months assessing the needs for an animal care information system. The conclusion of this study makes a recommendation to purchase a commercially available system that will have several features including laboratory registration for PIs and researchers, electronic protocol submission, administrative protocol tracking capabilities and an on-line protocol review and approval feature (see **Appendix J**). The estimated cost is projected to be \$350,000 of which most, if not all, can be offset from the previous campus allocation. There will also be an annual maintenance fee of approximately \$18,000. The animal care and information system is flexible such that it will also permit future modules to be developed and added to

integrate a variety of safety protocols, grants and contract information linkage, personnel directors, etc.

Summary and Conclusions

This report attempts to define the most critical needs for the University of Wisconsin-Madison with respect to research policy and compliance. It identifies specific current needs for staffing in the Graduate School's Research Policy and Compliance Office, staffing in the University's animal care and use program, and infrastructure, particularly information technology infrastructure, across a variety of research compliance programs. Areas of probable future need are outline very briefly below. Given these current and future demands, it will be vital for the University to engage in a process of assessment of ways to support these areas in the long-term, as well as to address immediate issues.

There are clearly several other areas pertaining to embryonic stem cells, export controls and the bioethics advisory committee that will require new administrative, legal and technology support in the near future. The Graduate School supports the Embryonic Stem Cell Research Oversight (ESCRO) committee chair by supporting the salary (10%) of his departmental administrative assistant. The future obligations of the ESCRO committee will require a significant increase in support as it reviews protocols, enrolls investigators, and manages the human stem cell research on the campus. There will be the need for many of the same oversight functions delineated above and described for other research related matters.

The Research Policy Advisory Committee is studying the area of export control as indicated in the introduction of this report. The University currently supports a web site for campus investigators that provides minimal information on complying with export control legislation. Legal Services also has committed, in part, the time of one attorney to interface with faculty and staff on export control issues. However, the relative risk for the campus in this area could become significant given impending legislation, and an increased effort would be required to permit research to go forward on the campus should these likely changes come into effect. Other peer universities are already devoting at least one full-time individual to these activities and are anticipating increasing needs.

The reestablishment of the Bioethics Advisory Committee will also require some administrative support. The Graduate School has committed a one-third PA to the current committee chair to support the future operations. The future activity of the committee will need to be assessed and this in part will determine the needs for administrative support.

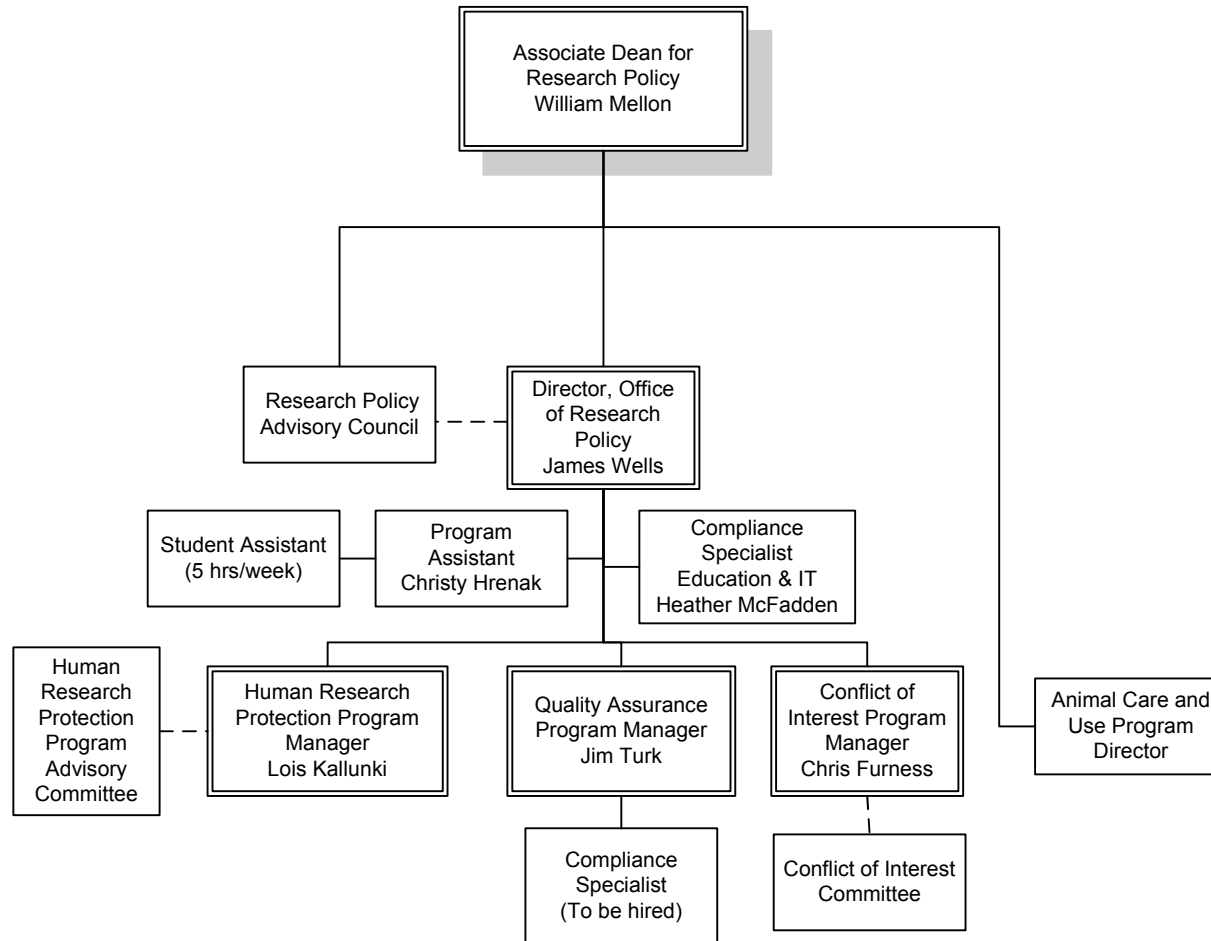
In the long-term, a critical issue for managing a policy and compliance program is the funding source(s) for initiatives. For example, how should the University fund the

necessary costs to maintain an animal care and use program that stresses total compliance, assures the welfare of research animals, and minimizes risk to the investigator and University? While such a program is not the direct responsibility of the Office of Research Policy and Compliance, there needs to be some formulaic approach to provide for future programmatic needs. At present, funding for the animal care and use program, in general, is divided among central, school/college, and animal per diem charges to the investigator. The appropriate contribution of each of these entities needs to be reviewed. A related concern is that per diem charges may vary between schools/colleges and even within a school or college. Another unresolved issue is how to fund capital equipment needs (e.g., cage washers, cages, racks, etc.) on a recurring basis and new facilities based on increasing animal use projections. One suggestion would be to commission a study on per diem charges, which are applied as costs to grants, to determine if there should be a campus rate or whether various units can make the case for variable rates. Dr. Sandgren has provided a summary document, which identifies the need for critical resources, justification of these resources and an assessment of risk for the Animal Care and Use Program that summarizes the previous discussion (**Appendix K**). Funding for other compliance areas raise similarly intricate issues. Unless the campus finds a mechanism to deal effectively with the various research policy and compliance facets the campus as a whole is at risk for losing research dollars under a variety of unmet federal mandates.

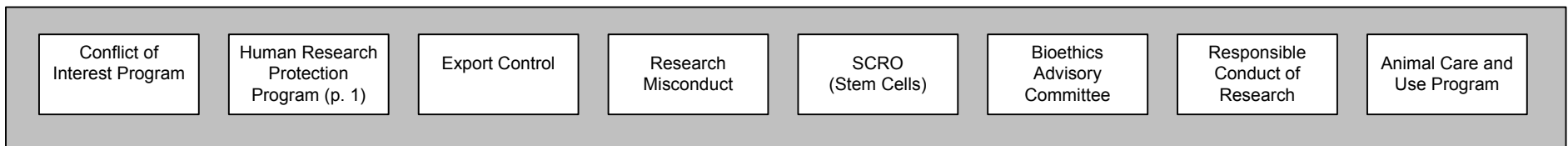
While this report is not comprehensive for all research-related policy and compliance issues for the University, it attempts to put a number of these issues into perspective with regard to the current status of support. There is a need to approach research compliance from a holistic view to better protect the University and its faculty, staff, and students. This will be an evolutionary process that will require continual diligence and oversight.

Office of Research Policy

August 2007

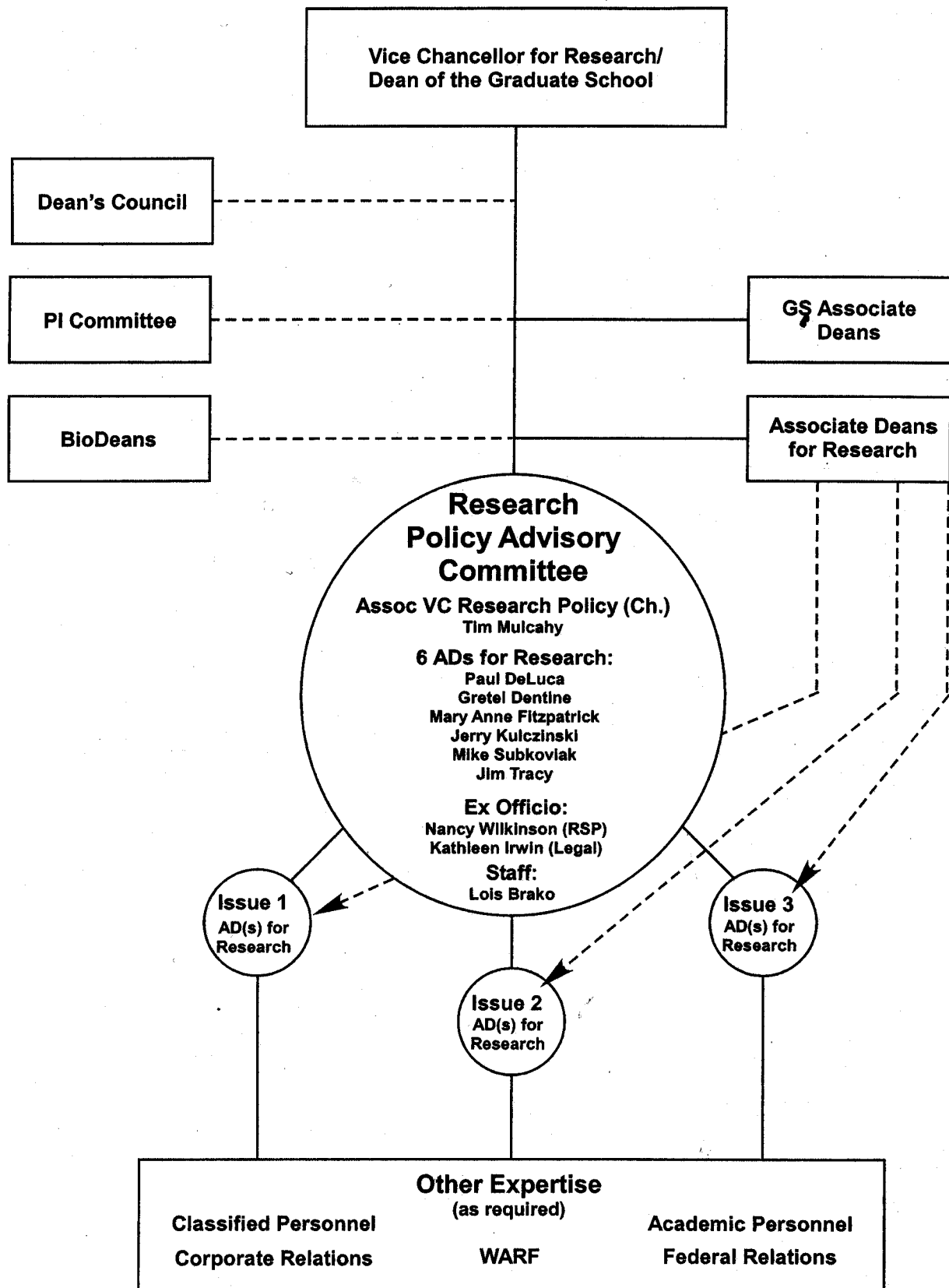


Compliance programs supported by the Office of Research Policy*



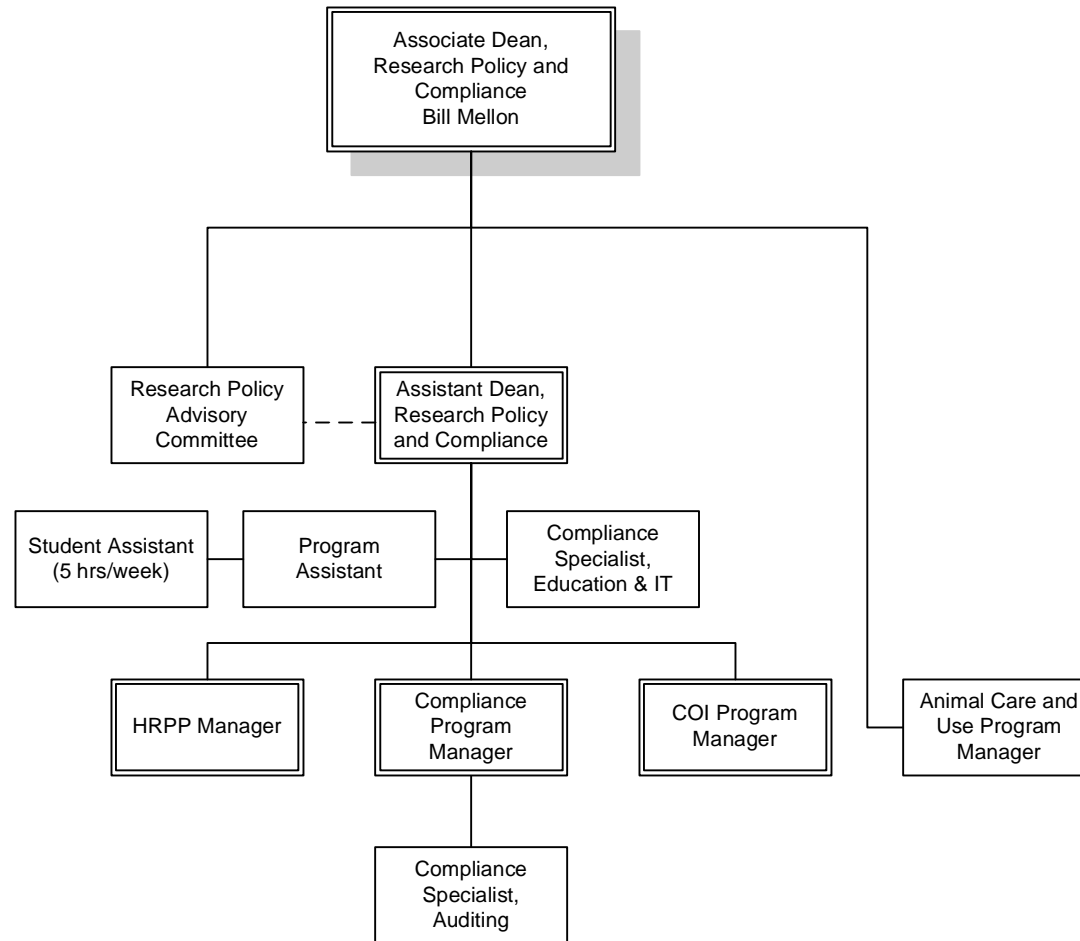
*The need for compliance programs in the areas of export controls and institutional conflict of interest is currently under review by RPAC.

Appendix C: Research Policy Advisory Committee Organization Chart, October 2003

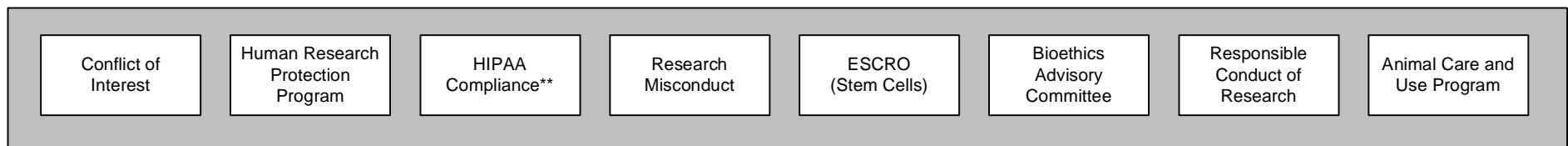


Appendix E: Research Policy and Compliance Office Proposed Structure

Tuesday, May 02, 2006



Compliance programs supported by the Research Policy Office*



*The need for compliance programs in the areas of export controls and institutional conflict of interest is currently under review by RPAC.

**Proposed pending discussion with Chancellor and Provost on appropriate location of this function.

Appendix G: Research Policy and Compliance Office, Proposed Staff, Duties Summary

Associate Dean, Research Policy and Compliance

- Coordinate research policy and compliance with colleges and schools
- Develop budget and obtain resources
- RPAC chair
- Institutional Official (IO) for protection of human and animal subjects and research misconduct
- Ensure non-financial research compliance
- Set priorities for the Research Policy and Compliance Office and develops and implements annual goals and objectives
- Campus auditing committee liaison

Assistant Dean, Research Policy and Compliance

- Staff RPAC
- Recommend policies and procedures relevant to non-financial compliance activities
- Act as a liaison between Research Policy and Compliance Office and other University research compliance programs
- Supervise Research Policy and Compliance Office staff
- Oversee the development of education programs for researchers and staff on non-financial compliance issues
- Oversee the development of electronic tools for non-financial compliance tracking and monitoring
- Oversee quality assurance programs
- Act as liaison to Internal Audit

Human Research Protection Program (HRPP) Manager

- Provide leadership and coordination for a decentralized HRPP & the Health Insurance Portability and Accountability Act (HIPAA) compliance program
- Develop recommendations for policies and procedures for the HRPP & HIPAA compliance
- Direct development of educational resources and communication strategies for the HRPP & HIPAA compliance
- Collaborate with Compliance Program Director to direct auditing for the HRPP & HIPAA compliance
- Provide leadership for Associate for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation process
- Staff the HRPP Advisory Committee

Compliance Program Manager

- Direct non-financial compliance risk assessment
- Direct quality assurance review of non-financial compliance programs
- Direct internal noncompliance reporting processes and procedures for campus
- Work with Assistant Dean to coordinate activities with Internal Audit

Appendix G: Research Policy and Compliance Office, Proposed Staff, Duties Summary

- Act as a liaison to other units with University research compliance responsibilities (e.g. Research and Sponsored Programs, Safety Department, and the Research Animal Program) concerning matters of risk assessment, quality assurance, and internal noncompliance reporting

Conflict of Interest (COI) Program Manager

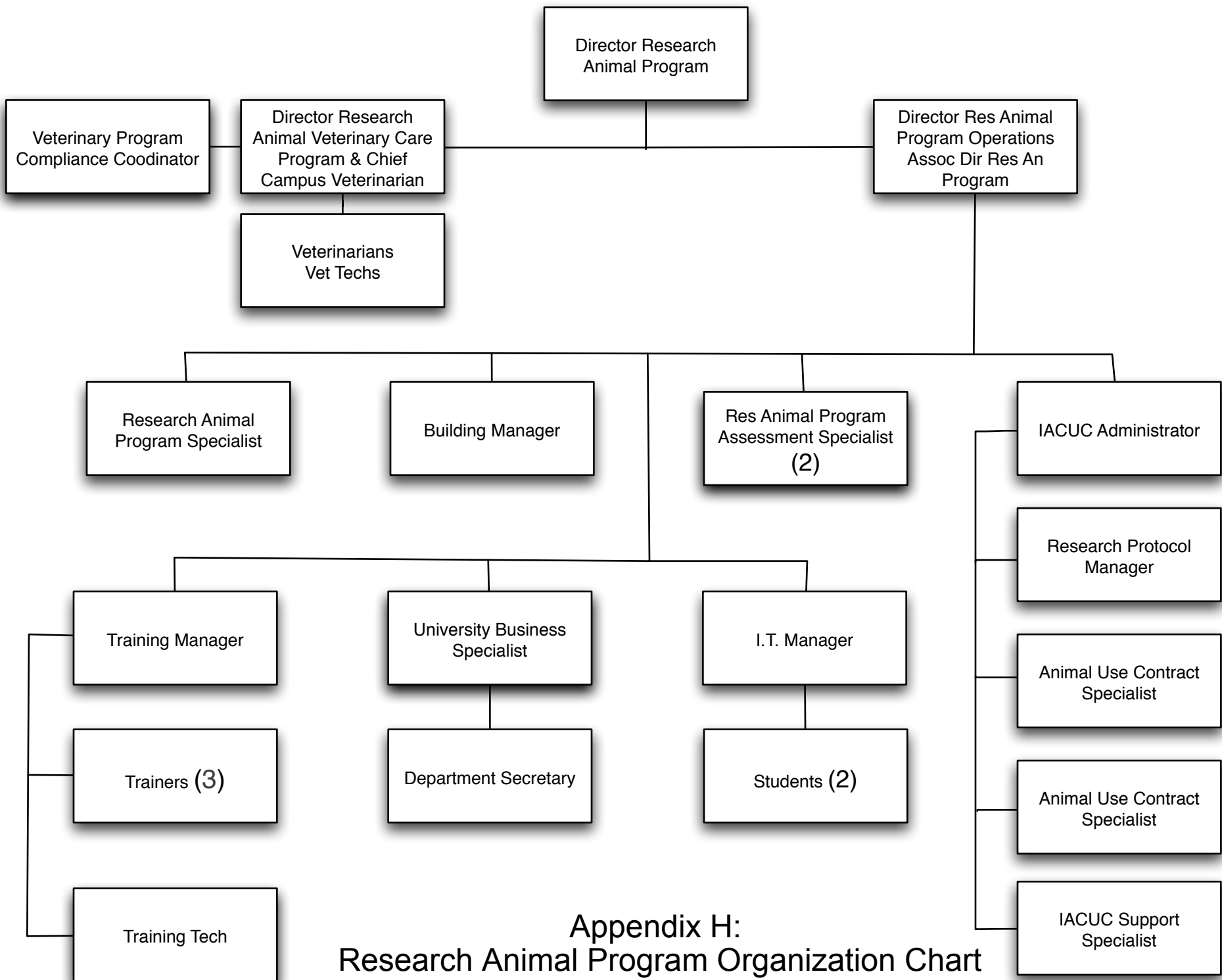
- Staff the COI Committee
- Direct preliminary evaluation of Outside Activities Reports
- Coordinate Outside Activities Reporting
- Develop recommendations for policies and procedures concerning personal financial COI
- Direct development of educational resources and communication strategies concerning personal financial COI
- Collaborate with Compliance Program Director to direct auditing concerning Outside Activity Reporting and personal financial COI

Compliance Specialist, Education & Information Technology

- Work with Research Policy and Compliance Office staff to develop educational materials, Web resources, and other electronic tools for all compliance areas that fall within the purview of the office

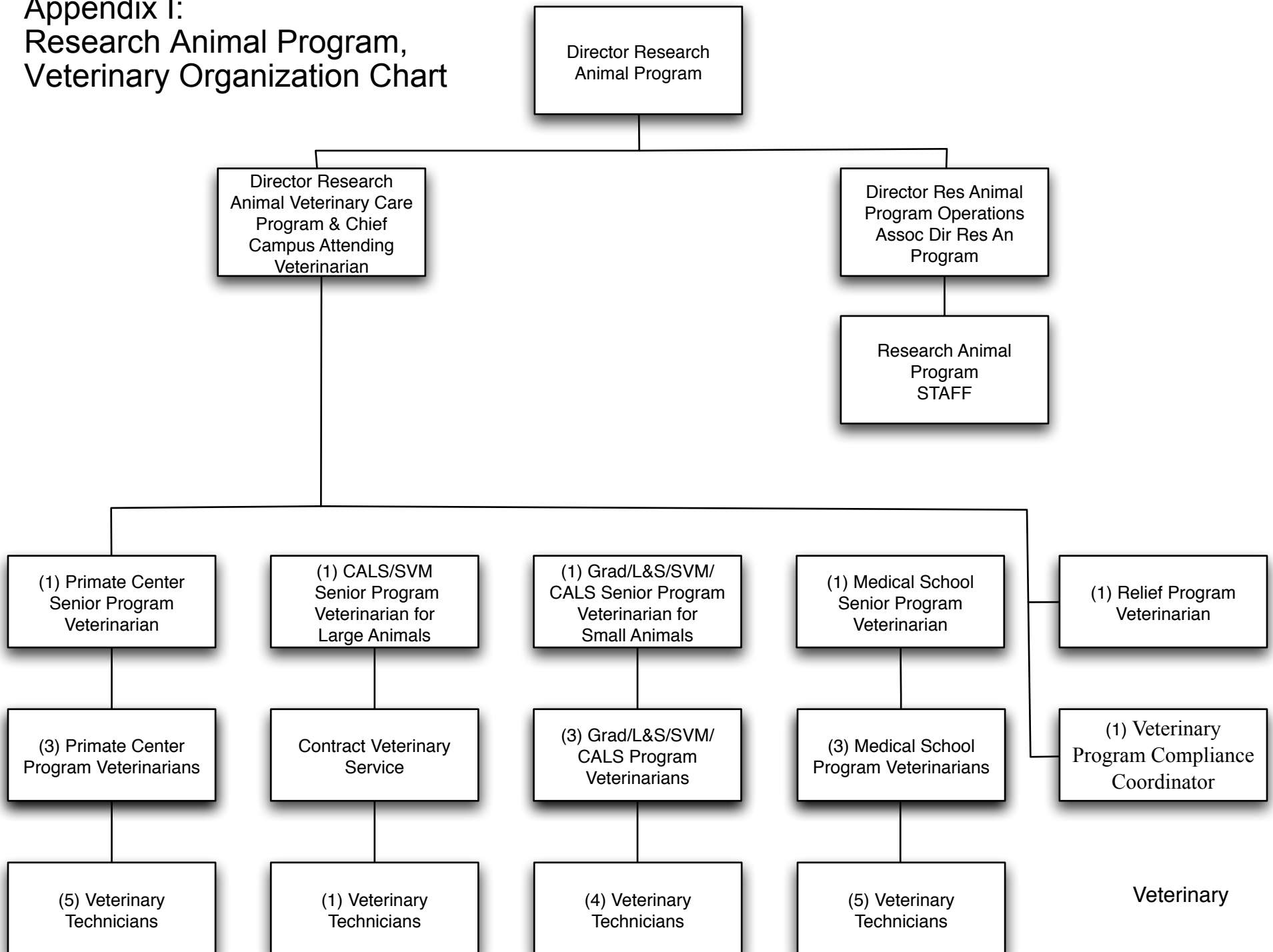
Compliance Specialist, Auditing

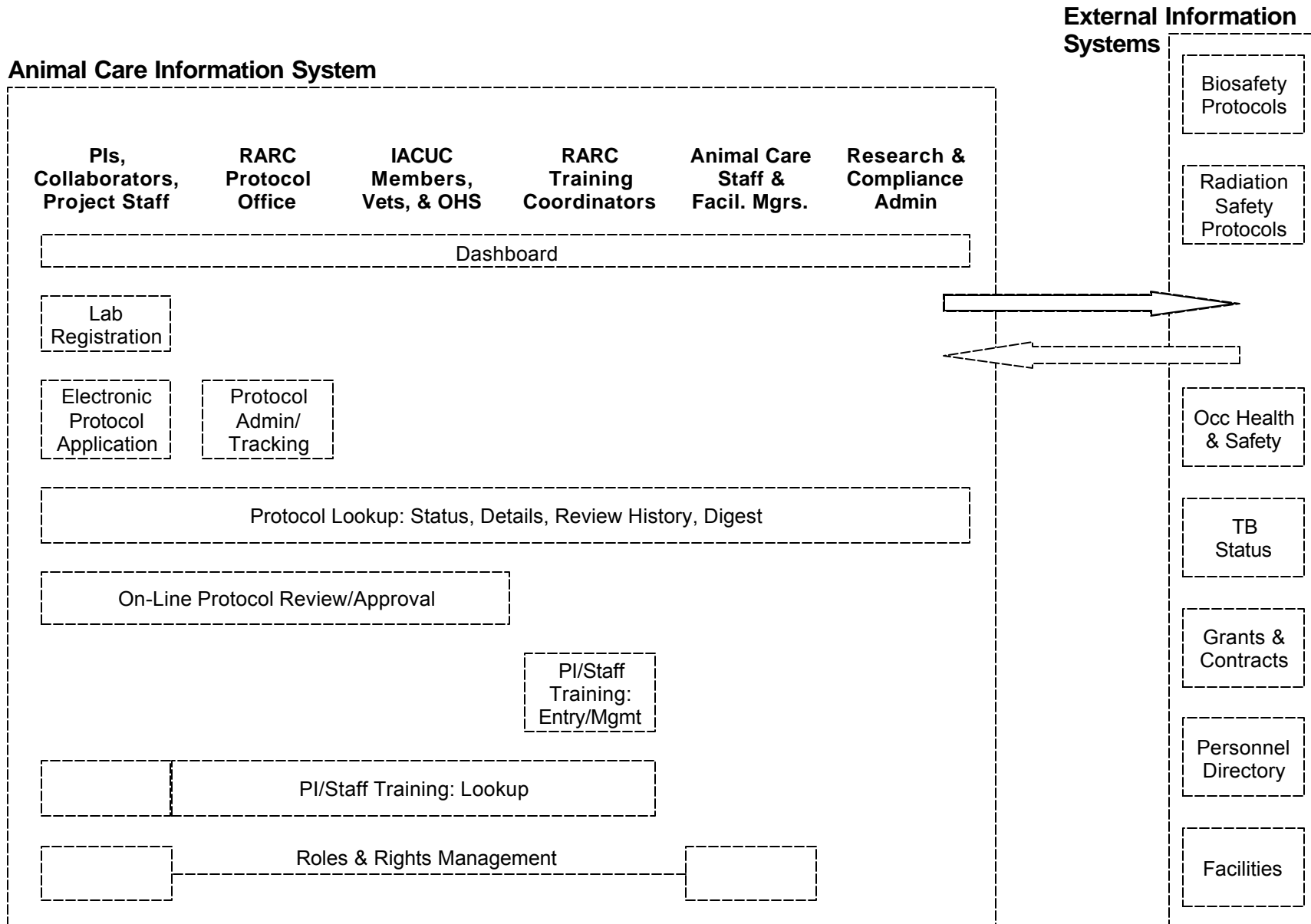
- Work with Research Policy and Compliance Office staff to develop auditing processes and procedures for all compliance areas that fall within the purview of the office
- Conduct non-financial compliance audits



Appendix H:
 Research Animal Program Organization Chart

Appendix I: Research Animal Program, Veterinary Organization Chart





APPENDIX K

UW-Madison Animal Care and Use Program Needs

Eric Sandgren, VMD, PhD

Associate Professor of Pathobiological Sciences

Acting Director, UW-Madison Animal Care and Use Program

The request for support of the UW-Madison Animal Program is outlined in detail in the document submitted by Dr. Bill Mellon. Key aspects of this request and my analysis of risk are summarized below.

Critical Resources...

1. Staff resources
 - Director, 1 new FTE
 - Veterinary Unit: 2 new FTEs for veterinarians; 3.5 new FTEs for veterinary technicians
 - Operations Unit: 1 new FTE for FPM liaison; 2 new FTEs for compliance assessment (Program Assessment Specialists); 1 new FTE for training technician
2. Budget resources
 - Resources for new FTEs
 - Resources to reclassify present staff to match their actual responsibilities
 - Resources to bring all campus animal facilities into compliance with regulations and guidelines, and to maintain them in that state
3. Policy resources
 - Comprehensive analysis of the sources and allocation of funding for the campus animal Program
 - Restructuring of support and funding to meet all campus animal care and use requirements
 - Comprehensive, ongoing analysis of current staffing strategies to ensure we can hire and retain appropriate personnel at all Program levels

Justification...

Historically our Animal Program has expanded by accretion, in response to a crisis (often identified by an outside agency) engendered by changing regulations, insufficient resources, or inadequate organization.

During the last 9 months we have developed a comprehensive definition of “Program”, established a mechanism to evaluate this Program at the Unit and All Campus levels, and proposed a restructuring of the Program tailored to the specific needs and character of this campus. The staff, budget, and policy analyses we request support implementation of this Program.

1. Staff
 - The USDA, AAALAC, and our own faculty oversight bodies, the Animal care and Use Committees (ACUCs), have identified deficiencies in veterinary resources that could directly threaten animal safety. We have established a structure for the Veterinary Unit within the Research Animal Resources Center (RARC) that meets national standards for resources and organization. This structure is based in part on an analysis of the veterinary support provided at other large research universities.
 - We have restructured the RARC Operations Unit, which encompasses ACUC support and administration, animal use protocol management, and campus-wide training. USDA, AAALAC, and our own ACUCs have identified a major deficiency in investigator compliance monitoring. The new organization proposes and requests support for 2 FTEs to correct this deficiency

- We have determined that the Veterinary unit within RARC requires a full-time director, who will serve as the Chief Campus Veterinarian. This requires the addition of a new position, Program Director, who will ensure that our program evolves in concert with changing external regulations and internal needs, coordinate activities of the Operations and Veterinary Units, and serve as advocate for both Units to the Institutional Official. My experience as acting director since July 2005 indicates that this is a full-time position.
2. Budget
- We require several new FTEs, but also must retain our current staff, who have been doing an outstanding job to support the Program under stressful conditions and without appropriate classification. Position descriptions have been submitted for these individuals, principally in Operations, that reflect their actual duties.
 - We are cited repeatedly by USDA (and have been fined) for facility maintenance problems that should be easy to fix. We have worked with FPM and established a preventative maintenance program to assess, repair, and maintain all campus animal facilities. This will require some central campus funding to avoid the risk that some of these facilities will have to be closed.
3. Policy
- We desperately need campus-wide analysis planning to clarify the financial support for animal research, including future expansion.

Risk analysis...

Should we fail to correct deficiencies that have been identified at the campus level, and that also have been identified by USDA, OLAW, and AAALAC, we risk additional USDA fines, an OLAW investigation, loss of AAALAC accreditation, and loss of PHS research funding. The bad publicity that accompanies Program failures is intense and nation-wide. We also have an ethical responsibility to establish and maintain a strong program.

Examples of failures are available from other institutions. The University of Connecticut had 43 USDA citations over 3 years, paid a \$129,500 fine, and had to commit \$20 million to upgrade its animal Program. They also agreed to pay \$25,000 for additional violations. Other institutions cited and fined from \$2000 to \$11,400 by the USDA include New York University, Columbia University, University of Nevada-Reno, Northwestern University, and UC-Davis. UCSF received a USDA warning in 1999, was fined \$2000 in 2000, then legally challenged the USDA's most recent citation and settled after much legal maneuvering by agreeing to pay a fine of \$92,500. Each incident was accompanied by extensive press coverage.

UW-Madison received a USDA warning in 2004, was fined \$6,875 for 24 violations of the Animal Welfare Act (AWA) in 2005. This reflected a discount of 75% applied to research institutions, currently allowed by USDA regulations. In September 2005, the Inspector general's office audited the branch of USDA responsible for enforcement of the AWA. The auditors concluded that the USDA has not been aggressive enough in enforcing actions against violations of the AWA. One recommendation of the IG is to increase fines to \$10,000 per violation for research institutions; another is to abolish the 75% discount. If the UW-Madison receives a similar fine in the future, it could total \$240,000. The cost in bad publicity will be far higher.

We are under close scrutiny by USDA, OLAW, and AAALAC. We must finish implementing our Animal Program reorganization so that we establish the means to prevent additional violations. We do not want to find ourselves in a position of being forced to do so from the outside.

§8B1.4. Order of Notice to Victims - Organizations

Apply §5F1.4 (Order of Notice to Victims).

Historical Note: Effective November 1, 1991 (see Appendix C, amendment 422).

2. EFFECTIVE COMPLIANCE AND ETHICS PROGRAM

Historical Note: Effective November 1, 2004 (see Appendix C, amendment 673).

§8B2.1. Effective Compliance and Ethics Program

- (a) To have an effective compliance and ethics program, for purposes of subsection (f) of §8C2.5 (Culpability Score) and subsection (c)(1) of §8D1.4 (Recommended Conditions of Probation - Organizations), an organization shall—

- (1) exercise due diligence to prevent and detect criminal conduct; and
- (2) otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.

Such compliance and ethics program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct. The failure to prevent or detect the instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct.

- (b) Due diligence and the promotion of an organizational culture that encourages ethical conduct and a commitment to compliance with the law within the meaning of subsection (a) minimally require the following:

- (1) The organization shall establish standards and procedures to prevent and detect criminal conduct.
- (2) (A) The organization's governing authority shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program.
- (B) High-level personnel of the organization shall ensure that the organization has an effective compliance and ethics program, as described in this guideline. Specific individual(s) within high-level personnel shall be assigned overall responsibility for the compliance and ethics program.
- (C) Specific individual(s) within the organization shall be delegated

day-to-day operational responsibility for the compliance and ethics program. Individual(s) with operational responsibility shall report periodically to high-level personnel and, as appropriate, to the governing authority, or an appropriate subgroup of the governing authority, on the effectiveness of the compliance and ethics program. To carry out such operational responsibility, such individual(s) shall be given adequate resources, appropriate authority, and direct access to the governing authority or an appropriate subgroup of the governing authority.

- (3) The organization shall use reasonable efforts not to include within the substantial authority personnel of the organization any individual whom the organization knew, or should have known through the exercise of due diligence, has engaged in illegal activities or other conduct inconsistent with an effective compliance and ethics program.
- (4)
 - (A) The organization shall take reasonable steps to communicate periodically and in a practical manner its standards and procedures, and other aspects of the compliance and ethics program, to the individuals referred to in subdivision (B) by conducting effective training programs and otherwise disseminating information appropriate to such individuals' respective roles and responsibilities.
 - (B) The individuals referred to in subdivision (A) are the members of the governing authority, high-level personnel, substantial authority personnel, the organization's employees, and, as appropriate, the organization's agents.
- (5) The organization shall take reasonable steps—
 - (A) to ensure that the organization's compliance and ethics program is followed, including monitoring and auditing to detect criminal conduct;
 - (B) to evaluate periodically the effectiveness of the organization's compliance and ethics program; and
 - (C) to have and publicize a system, which may include mechanisms that allow for anonymity or confidentiality, whereby the organization's employees and agents may report or seek guidance regarding potential or actual criminal conduct without fear of retaliation.
- (6) The organization's compliance and ethics program shall be promoted and enforced consistently throughout the organization through (A) appropriate incentives to perform in accordance with the compliance and ethics program; and (B) appropriate disciplinary measures for engaging in

criminal conduct and for failing to take reasonable steps to prevent or detect criminal conduct.

- (7) After criminal conduct has been detected, the organization shall take reasonable steps to respond appropriately to the criminal conduct and to prevent further similar criminal conduct, including making any necessary modifications to the organization's compliance and ethics program.
- (c) In implementing subsection (b), the organization shall periodically assess the risk of criminal conduct and shall take appropriate steps to design, implement, or modify each requirement set forth in subsection (b) to reduce the risk of criminal conduct identified through this process.

Commentary

Application Notes:

1. Definitions.—For purposes of this guideline:

"Compliance and ethics program" means a program designed to prevent and detect criminal conduct.

"Governing authority" means the (A) the Board of Directors; or (B) if the organization does not have a Board of Directors, the highest-level governing body of the organization.

"High-level personnel of the organization" and "substantial authority personnel" have the meaning given those terms in the Commentary to §8A1.2 (Application Instructions - Organizations).

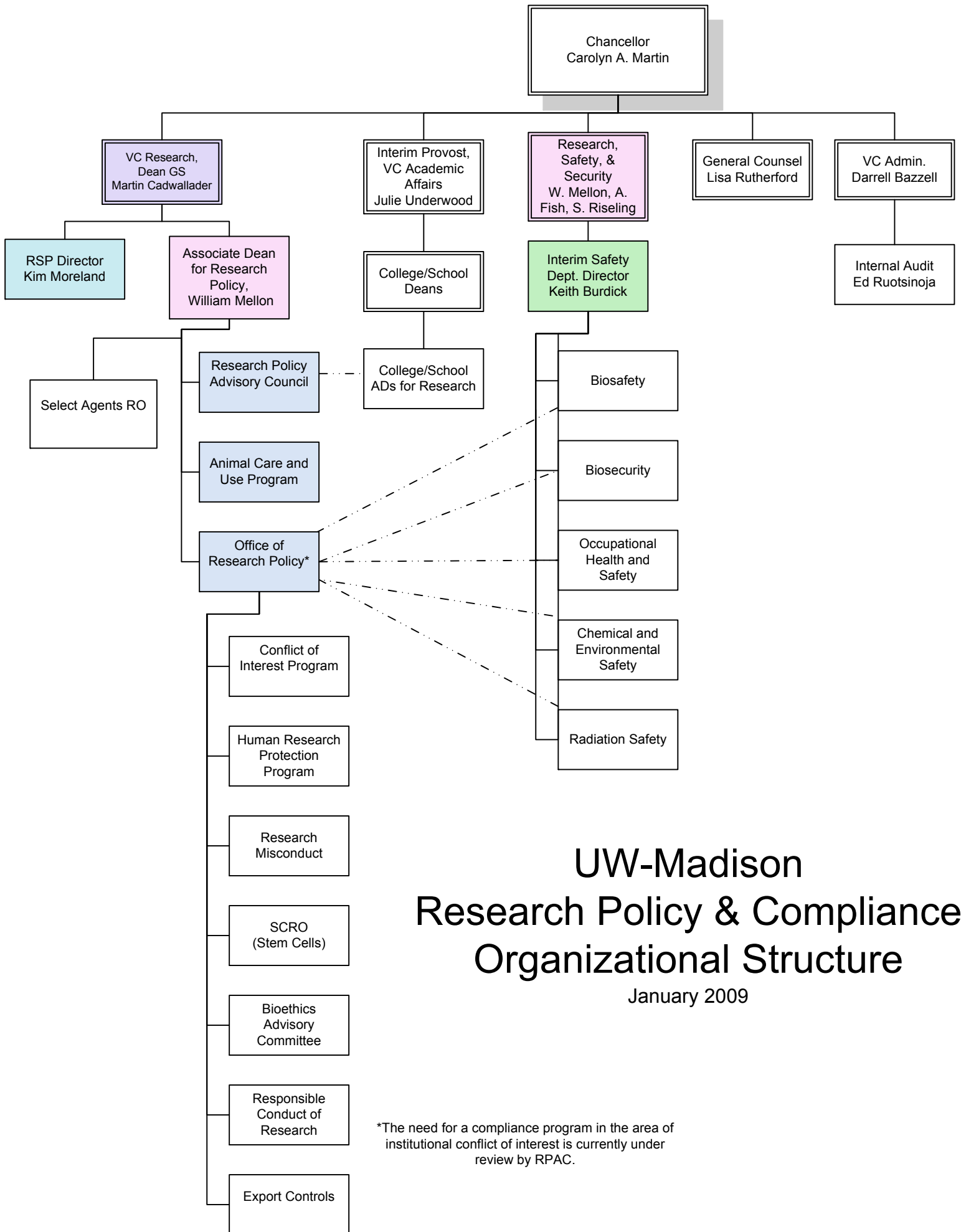
"Standards and procedures" means standards of conduct and internal controls that are reasonably capable of reducing the likelihood of criminal conduct.

2. Factors to Consider in Meeting Requirements of this Guideline.—

(A) In General.—Each of the requirements set forth in this guideline shall be met by an organization; however, in determining what specific actions are necessary to meet those requirements, factors that shall be considered include: (i) applicable industry practice or the standards called for by any applicable governmental regulation; (ii) the size of the organization; and (iii) similar misconduct.

(B) Applicable Governmental Regulation and Industry Practice.—An organization's failure to incorporate and follow applicable industry practice or the standards called for by any applicable governmental regulation weighs against a finding of an effective compliance and ethics program.

(C) The Size of the Organization.—



UW-Madison Research Policy & Compliance Organizational Structure

January 2009

*The need for a compliance program in the area of institutional conflict of interest is currently under review by RPAC.

11/16/09 Survey of UW-Madison Academic Staff

On November 16, 2009, the ASEC Ad Hoc Committee on the Research Enterprise sent an email to all UW academic staff, soliciting their comments regarding Chancellor Martin and Provost DeLuca's proposal to reorganize the Research Enterprise at UW-Madison.

Academic staff were asked to respond to the five questions below and to provide their opinions on which areas of the research enterprise they considered to be currently successful and which operational areas they considered to be limiting or currently ineffective. They were also asked to provide suggestions of alternative ideas or organizational structures that would better advance UW-Madison's graduate education and graduate research.

The Committee received 62 responses from academic staff, and these responses were reviewed individually by Committee members and discussed during the November 24, 2009 meeting. Overall, these responses echoed the themes presented in this report.

1. What role do you play on campus in relationship to Graduate Education and Graduate Research?
2. What works well with the current Graduate School structure?
3. What needs improvement (and why)?
4. What needs change (and why)?
5. Regarding the current proposal to restructure, how do you perceive that this will benefit graduate education and graduate research?



Inspection Report

UNIVERSITY OF WISCONSIN-MADISON

Customer ID: **616**

Certificate: **35-R-0001**

RESEARCH ANIMAL RESOURCES CTR.

Site: 001

DIRECTOR RESEARCH ANIMAL

ALL CAMPUS SITES

1710 UNIVERSITY AVENUE 396 ENZYME INST

Type: ROUTINE INSPECTION

MADISON, WI 53726

Date: Dec-09-2009

2.31 (c) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(3)(c) IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:.....

.....The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals.....

**IACUC facility inspections and program reviews did not contain reasonable and specific plans for correcting deficiencies. The IACUC must include plans for correcting deficiencies and should also consider methods in the plan to prevent re-occurrence of the non-compliance.

Correct by: from this date forward

2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(d) IACUC review of activities involving animals..... (1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing;.....

.....(ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources,....., used to determine that alternatives were not available;.....

**Protocols #A01195, #A00810, #00664, #G00510, #V1296 contain painful procedures. There is nothing to indicate that the principal investigators had considered alternatives to potentially painful procedures that may cause more than momentary or slight pain and/or distress to the animals in the written narratives of these protocols.

Prepared By:

DAWN E BARKSDALE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1062

Dec-10-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Dec-10-2009



Inspection Report

Correct by: from this date forward

2.31 (d) (1) (viii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(d) IACUC review of activities involving animals. (1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing:..... Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:

.....(viii) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures;.....

**In Protocol V846 there has been an unexpected high mortality rate in gerbils attributed to anesthesia. This has not been reported to the veterinary staff or to the IACUC. The research staff was not adequately trained to report incidents of this nature.

Correct by: From this date forward

2.31 (d) (1) (ix)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(d)(1)Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:.....

.....(ix) Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices.

**Protocol V1296: Under this protocol dogs undergo major survival surgeries after which they may be expected to develop acute, terminal renal failure, which did occur in at least two dogs on the study. The post-operative care for these dogs, as approved in the protocol, calls for the administration of subcutaneous fluids to the dogs post-operatively instead of intravenous fluid therapy. This post-operative treatment is not in accordance with established veterinary medical practices, and the protocol contains no scientific justification for such a departure.

Correction: from this date forward

2.31 (d) (7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(7) If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity;.....

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Dec-10-2009

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Dec-10-2009



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**Protocols L294, M1486, M1640 were suspended by the ACUC in February 2009, however, no notification was provided to APHIS by the Institutional Official regarding the reasons for suspension and the corrective actions that had been taken.

Correct by: January 10, 2010

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

.....(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:.....(3) A complete description of the proposed use of the animals.....

1. Review of Protocol #A01245: The protocol includes the administration of several substances by means of needle/syringe injection or with a novel medical device system. The description of the proposed use of the animals contains insufficient detail to follow exactly what procedures will be done to the animals from the beginning of the study until the study's conclusion.

2. Review of Protocol #A00810: The protocol studies cardiac electrical activity in Swine. The narrative of this protocol refers to the following:

- a. Performing ablation of liver, kidney and lung as part of the study but includes no specific details.
- b. A statement about external stimulation of brain tissues but includes no specific details.
- c. The surgical training portion of the protocol is mentioned, however, there is an insufficient description of the proposed use of the animals for the training portion.

A proposal for animal use must contain a complete description of the proposed use of the animals so the IACUC can determine that the proposed activities meet the requirements outlined under 2.31 (d) (1).

Correct by: From this date forward

2.32 (a)

PERSONNEL QUALIFICATIONS.

(a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel.....

**A technician was observed inadequately restraining a non-human primate in a squeeze cage requiring her to make several attempts to administer an anesthetic via syringe. It is the responsibility of the facility to ensure that animal care staff are properly trained and qualified to perform their duties.

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Received By:

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Date:

Title:

Dec-10-2009



Inspection Report

Correct by: From this date forward

2.33 (b) (1)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include: (1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter;

**In Building O-Rooms 3244A & 3244B are used for major operative survival surgical procedures. The following items were identified in these rooms after having been cleaned: 1.rusty base of IV stand and shelves/side bar of steel cart; 2.hair clippings on a table; 3. drips/splatter residue on wall; 4. excessive accumulation of dirt on air vents; 5. dark colored material on front drawers of anesthesia machine. These items can interfere with effective sanitation and may compromise aseptic procedures performed in this room

Correct by December 17, 2009

2.33 (b) (2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include: (2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;

1. Use of Chemical grade compounds

a. A bottle with a label stating saturated Potassium Chloride, (KCL) was noted in Building T- Rm142D. It was being used to euthanize swine under protocols #A00664, A00810, and A01195.

b. Protocol #A01245 calls for the administration of "Sodium Salicylate, USP grade from Sigma" to Swine as part of the proposal for animal use. The approved proposal does not contain any scientific justification for the use of a chemical grade compound when pharmaceutical grade sodium salicylate for injection is available. Non pharmaceutical grade chemical compounds must only be used when veterinary or human pharmaceutical grade products are not available or for scientific reasons with the approval of the IACUC.

2. The following outdated drugs or medical supplies were identified in various locations of the facility as noted:

- a. Building I-Room109: Acetaminophen liquid, 1 oz bottle, #1, exp 11/09.
- b. Building M: Triple antibiotic ophthalmic, tube #1, exp 5/09.

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- c. Building M Room 232: Chlorhexidine solution, gallon bottle, #1, exp 6/09.
- d. Building J Room 658: Betadine solution, gallon bottle, #1, exp 11/08; Betadine solution 32 oz bottle, #1 exp 11/06 and #1 exp 2/07; Ophthalmic lube, tube #2; exp 7/08; Lactated Ringers Solution bag 500 ml, #1, exp 4/09
- e. Building Room 575: Cyprofloxacin ophthalmic, tube #1, exp 9/02; Lubricant jelly tube, #1, exp 1/85
- f. Building F Room 142: Furosamide, 50 ml bottle, #1, exp 7/09; Lidocaine, 100 ml bottle, #1, exp 8/07; Propofol, 50 ml bottle, #4, exp 11/1/08; Ketamine, 10 ml bottle, #2, exp 4/08; Dexamethasone 4 mg/ml, 30 ml bottle, #1, exp 11/08.
- g. Building O Room 3244: Ophthalmic lube, tube #1, exp 3/08; Nexaband solution, #1, exp 12/01.
- h. Building O Room 3243: Plastic bottle containing brown liquid that was labeled "Povidone Iodine Solution" that did not include the exp date of the contents of the bottle.
- i. Building Room 243: 3.0 Maxon suture packets, #12, exp 5/09; Red top tubes, #75, exp 9/08; Sterile water for injection, 10 ml bottle, #1, exp 2/1/08,
- j. Building T Room 142D: Sterile water for injection, 20 ml bottle, #1, exp 3/07; Halothane 250 ml bottles, #1 exp 1/04, #1 exp 3/08, #1 exp 5/09; Isoflurane 250 ml bottles, #2, exp 7/08; Pentothal 1 gm bottles, #3, exp 9/1/06; Fentanyl, 50 ml bottle, #1, exp 9/1/06; Omnipaque contrast agent, 50 ml bottles, #1 exp 10/21/06, #1 exp 7/3/09; Lactated Ringers Solution bag 1000 ml, #8 exp 1/1/07, #3 exp 7/07; 0.9% Sodium Chloride bag 1000 ml, #2 exp 5/09

The use of outdated medications may not be safe or efficacious and is not considered an acceptable standard of veterinary practice. The IACUC and AVs need to address this issue.

Correct by: From this date forward.

2.33 (b) (3) DIRECT NCI
ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:..... (3) Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian.....

1. Gerbil #1 housed in Building P Room 310B: was thin, sunken flank, difficulty breathing, wobbly, weak, some open mouthed breathing unrecognized by facility personnel. Necropsy findings revealed that this animal had a body condition score of 1 out of 5, the subcutis had negligible body fat and that the thoracic cavity contains moderately abundant red watery pleural effusion.
2. Review of Medical records for Dog #BDW8, #SRS-6, and TJG-7 on Protocol #V01296: All of these dogs had a major operative procedure as described in the proposal. Post-operatively Dog #BDVW8's medical records contained notations that it had sub-mandibular, cervical and facial edema, #SRS-6's medical records stated this dog was not eating vomiting and very depressed with edema not producing urine, TJG-7's medical records stated this animal was very depressed, vomiting with no urine. There was no documentation in the animals medical records that the changes observed in the dogs condition were conveyed to the attending veterinarian for evaluation and assessment.

It is the responsibility of the research facility and research staff to have a mechanism of direct and frequent

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Dec-10-2009

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Dec-10-2009

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Inspection Report

communication to ensure that problems of animal health and/or behavior are conveyed in a timely manner to the attending veterinarian for evaluation and assessment to ensure the health and well-being of the animals.

Correct: From this day forward

3.2 (b)

INDOOR HOUSING FACILITIES.

(b) Ventilation. Indoor housing facilities for dogs and cats must be sufficiently ventilated at all times when dogs or cats are present to provide for their health and well-being, and to minimize odors, drafts, ammonia levels, and moisture condensation.....

1. Building O Room 2429: Two Dogs were being housed in this room at the time of the inspection. There was a strong odor of dog urine noted immediately upon entering the room. The enclosures did not contain urine or feces, the unoccupied enclosures in the room were clean, and there was no obvious source of the strong odor.

Indoor housing facilities must be sufficiently ventilated to minimize odors. The facility needs to assess the ventilation system servicing this room to provide for the health and well-being of the dogs.

Correct by December 17, 2009

3.11 (c)

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

(c) Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair to protect the animals from injury, to facilitate the husbandry practices required in this subpart,.....

****The air filters above the animal enclosures in Building A, Room K4/150 had an excessive accumulation of debris. No notation was found in the log to indicate the filters had been changed in the month of November. The filters should be cleaned and maintained in a manner to prevent the accumulation of debris in order to facilitate proper husbandry practices and promote the health and well being of the animals.

Correct by December 17, 2009

3.75 (a)

HOUSING FACILITIES, GENERAL.

....(a) Housing facilities for nonhuman primates must be designed and constructed so that they are structurally sound for the species of nonhuman primates housed in them. They must be kept in good repair.....

1. There were areas of flaking and peeling paint on the ceiling above occupied NHP enclosures in Building L, Room L-144 and Building K Rooms 428C, K-B11.

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Dec-10-2009



Inspection Report

2. Building M Room 251: The cover of a ceiling mounted light fixture above an occupied primary enclosure housing two NHP was hanging down as a result of a broken clip, and water had accumulated inside the light fixture cover.

Correct by January 15, 2010.

3.75 (e)

HOUSING FACILITIES, GENERAL.

(e) Storage. Supplies of food and bedding must be stored in a manner that protects the supplies from spoilage, contamination, and vermin infestation. The supplies must be stored off the floor and away from the walls, to allow cleaning underneath and around the supplies. Food requiring refrigeration must be stored accordingly, and all food must be stored in a manner that prevents contamination and deterioration of its nutritive value. Only the food and bedding currently being used may be kept in animal areas, and when not in actual use, open food and bedding supplies must be kept in leakproof containers with tightly fitting lids to prevent spoilage and contamination. Substances that are toxic to the nonhuman primates but that are required for normal husbandry practices must not be stored in food storage and preparation areas, but may be stored in cabinets in the animal areas.....

1. There were open supplies of NHP food not stored in a container with a tightly fitting lid to prevent spoilage and contamination in the SPF kitchen. There was a plastic bucket with a broken top containing marshmallows in the cabinet and an uncovered pan containing uncovered pieces of fruit inside the walk-in refrigerator.
2. Cooling vests were stored inside the walk-in refrigerators on a shelf in two different refrigerators in Building L.
3. Employees in Building L were observed cutting NHP diet with cleaning compound on the table where food was being prepared.
4. Building M Room 337: Primate chow in bags was stored on a table directly against the walls.
5. Building L-SPF Kitchen: Cartons of fruit were stored on the floor of the walk-in refrigerator

Supplies of food for NHP's should be stored in a manner to protect the food supplies from spoilage, contamination and vermin infestation. The facility needs to address this issue of food storage for the health and well-being of the primates.

Correct by December 17, 2009

3.75 (f)

HOUSING FACILITIES, GENERAL.

.....(f) Trash containers in housing facilities.....must have tightly fitted lids on them at all times.....

1. Building M: There were uncovered trash containers located in several NHP testing rooms that did not have a tightly fitted lid. Per this Section, there must be a tightly fitting lid present on trash containers in NHP housing facilities at all times to minimize odors and disease hazards.

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Dec-10-2009

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(b)(6), (b)(7)(c)

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Dec-10-2009



Inspection Report

Correct by December 17, 2009

3.80 (a) (2) (ii)

PRIMARY ENCLOSURES.

.....(a)(2) Primary enclosures must be constructed and maintained so that they:(ii) Protect the nonhuman primates from injury.....

1. Red rubber hoses are used to supply water to NHPs in Building M. One of the hoses on top of an enclosure housing 2 primates in Room 29 was missing pieces of the outermost layer of red rubber as a result of the NHPs picking at the hose. Primary enclosures should protect the NHPs from injury. Ingestion of foreign material can pose a hazard to the animals. This item was corrected by the facility during the inspection by replacing the damaged hose.

Corrected during the inspection

3.84 (c)

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

(c) Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair in order to protect the nonhuman primates from injury, to facilitate the husbandry practices required in this subpart,.....

1. Building L Room 109: Sides of the floor drain were dirty and had particulate debris and Betadine on its surface.
2. Building L Hallway outside Room 119: NHPs are transferred to rolling cages while their home cages are cleaned and sanitized. The rolling cages are placed temporarily in the hallway until being returned to their home cages. The textured ceiling tiles in the hallway were dirty, and the ceiling was within reach of the NHPs through the top of their temporary enclosures.
3. Building M Room 16: Dirty ceiling mounted air filter.
4. Building L Room 113: A leather restraint glove was on located on the top of an occupied primary enclosure and was accessible to the animals.
5. Building M Room 41: Housing room wall dirty and had dried dark colored spots/splashes on the upper wall in the back corner of room.

Primate housing areas must be kept clean and in good repair in order to protect the nonhuman primates from injury, and to facilitate the husbandry practices required in this subpart,

Correct by December 17, 2009

Prepared By:

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Dec-10-2009



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3.125 (a)

FACILITIES, GENERAL.

(a) Structural strength. The facility must be constructed of such material and of such strength as appropriate for the animals involved. The indoor and outdoor housing facilities shall be structurally sound and shall be maintained in good repair to protect the animals from injury and to contain the animals.....

1. Building D Holding Barn: Metal flashing on one of the corners of the holding barn had been damaged exposing jagged edges. The corner of the holding barn should be repaired in order to prevent injury to the animals housed in the area.
2. Building T Room 115: The floor of one pen housing a large adult male Pig was comprised of narrow slats/grate system. The animal's feet continually slid on the floor surface as it walked around the enclosure and the animal's feet slipped out from under the animal and it fell down several times. Other animals in the room were also observed to slide on the portion of their pens that had a solid concrete surface. The facility should be constructed in a manner that is structurally sound and maintained in a manner to protect the animals from injury as set forth in this section.

Correct by December 17, 2009

3.131 (c)

SANITATION.

.....(c) Housekeeping. Premises (buildings and grounds) shall be kept clean and in good repair in order to protect the animals from injury and to facilitate the prescribed husbandry practices set forth in this subpart.....

1. The wooden shelves in the feed/bedding storage room of Building J were not sealed or impervious to moisture. The unsealed surfaces could interfere with effective cleaning and sanitation of the shelving. The facility needs to address this issue.
2. Building J Room 662: Facility personnel stated that investigator staff is responsible for cleaning the room after animals are moved out. Animals were housed in this room until 11/26/09 and had already been cleaned. Wooden shavings and animal waste were present on the shelves where the animal enclosures are placed, there was a thick layer of dust on various surfaces in the room, and the wall in the back corner of the room was dirty.
3. Building J Room 663: Assorted equipment and cleaning implements were stored on the same shelf adjacent to primary enclosures housing AWA covered species.
4. Building J Room 575: There was a thick layer of dust on the ceiling mounted air vent in the room that housed chinchillas and the ceiling surface next to the air vent was dirty.
5. Building O Room 3243: There was dried blood on the outside surface of the drawers and on the wall adjacent to the sharps container in the room.
6. Building T Room 115: Broken ceiling mounted light fixture cover above pen housing one pig.
7. Heifer area at Building G had not been adequately cleaned and cleared of hay manure and debris. Life stock panels enclosing the area were not secure and were leaning from their supports in several areas.

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Dec-10-2009

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Dec-10-2009



Inspection Report

Correct by December 17, 2009

3.131 (d)

SANITATION.

(d) Pest control. A safe and effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained.....

**There was an excessive accumulation of flies in Building T Room 115. It is the responsibility of the facility to ensure that a pest control program is in place in order to control insects and/or pests in order to promote the health and well-being of the animals.

Correct by December 17, 2009.

Note: This was a full facility inspection conducted 12/1/09 through 12/10/09 by Drs. Robert Willems, Paula Gladue, Michael Smith and Dawn Barksdale with the exit interview on 12/10/09.

Prepared By:

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Dec-10-2009

Received By:

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Dec-10-2009



December 7, 2009

Professor Hector DeLuca
Chair, Ad-Hoc Committee
Department of Biochemistry
College of Agricultural and Life Sciences

Noel Radomski
Chair, Ad-Hoc Committee
Academic Staff Executive Committee
317 Bascom Hall

Dear Hector and Noel:

I am writing on behalf of the College of Agricultural and Life Sciences in response to your requests for feedback regarding the recently proposed research reorganization plan advanced by the Provost. My letter is based on discussions with faculty, staff, students, and our governance groups including our Academic Planning Council and department chairs. I will also add some additional comments of my own based on my experience working in research administration for the past five years in our college and across the UW-Madison campus.

I would like to indicate at the outset that the conversations provoked by the proposal to reorganize our research enterprise have been some of the best conversations our community has engaged in during the past several years. This subject has elicited the creative input, strategic thinking, and imagination of our research community and has elevated the subject of research administration to a topic of daily conversation.

As a person who has long wished that such conversations would take place in those corners of our campus where the research is taking place, I am deeply gratified to see the subject elevated in this way, and I wish to thank the Provost for getting this issue on our docket. There is not a researcher in our college who does not have an anecdote about a grant proposal, protocol, or invoice that was delayed, mismanaged, or otherwise poorly handled on our campus. There is not a researcher in our college who has found it consistently easy to fund graduate students or fellows, or to react to changes in the vagaries of federal funding and in federal research policy. The opportunity to translate those experiences into useful and productive discussions about how we can do better has been an incredibly valuable process. If nothing else, the proposed research

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reorganization has raised the level of our discourse on managing the research enterprise and emphasized its immediacy to our community.

I would also like to indicate that in the comments below you will find strong evidence of support from the CALS community to enhance key research functions on this campus such as Research and Sponsored Programs, animal compliance, human subjects and IRB review, and bio-safety oversight. While the scientists within our college were not optimistic that the proposed organizational structure advanced by the Provost would produce the desired outcomes, there was unanimity with respect to the need for such enhancements to keep our research enterprise strong.

1. Our process and the summary of our findings

Our college held two meetings where the proposed research reorganization plan was discussed in detail. Our Academic Planning Council held a special meeting on November 18, 2009, where the entire agenda was focused on the proposal and its merits. Our Department Chairs met on November 23, 2009 and devoted 35 minutes to the topic of the proposal. At least five individual departments discussed the proposal at their department meetings, and two passed formal resolutions regarding the proposal. In addition to these formal meetings, we participated in dozens of individual conversations with interested parties during the past several months. In these sessions, there was considerable agreement among faculty and staff regarding issues central to the proposed reorganization and I have attempted to summarize these points of agreement below.

There is a strong sense among those in our college that substantial changes to research administration must take place for our campus to remain competitive in the future. However, there was equally strong skepticism that the proposal for research reorganization advanced by the Provost would produce the desired outcomes. Much, if not all, of the skepticism about the proposal focused on three major areas: (1) a lack of detail concerning the job duties, staffing, support resources, and portfolio for the Vice Chancellor for Research; (2) a persistent concern as to whether the creation of a new position for a high-level campus administrator could or would solve what many believe to be local, lower-level problems with research administration and compliance; and (3) a concern that the proposal did not have the benefit of faculty and staff input during its creation and, therefore, felt to some as contrary to the campus culture for shared solutions to complex problems. On a positive note, some felt that perhaps the lack of detail in the proposal was a strategy to encourage future participation of the community through shared governance processes while also recognizing the need to move forward.

2. The problems we are trying to solve

To address each of these areas in a bit more detail, I will provide some specific details here. Our discussions about the reorganization inevitably came back to a single question, which is essentially, "What are the problems we are trying to solve?" In attempting to answer that question, most felt that the campus could make much more progress toward an improved research infrastructure than to install a high-level campus administrator. For example, if the fundamental problems are centered in Research and Sponsored Programs (RSP) and various offices involved in research compliance, then it might be most prudent to simply put more

resources and staffing into those areas while emphasizing best practices and strong management skills. If the fundamental problems involve management of campus compliance offices, our faculty and staff urged campus leaders to consider making personnel changes in those offices or more closely managing their activities to ensure success. If the fundamental problems involve our lack of representation in Washington D.C. with respect to UW participation when key decisions on levels and targets of funding are made by federal agencies, there was a sense that deploying current campus human resources in strategic ways may allow better and more focused representation. In short, what we heard in our discussions was the perception that the proposed reorganization of campus research administration is misguided. As proposed, it cannot and will not resolve the problems occurring on a daily basis within research administration.

A number of commentators on the proposed reorganization have focused on asking the question “What makes the UW-Madison unique in terms of research success?” As expected, there was much sentiment in our discussions that the WARF-funded faculty-driven process of graduate education and research is key to the tremendous national reputation we have developed in these areas. While the proposed research reorganization does not explicitly dismantle this structure, the perception that WARF funds and faculty involvement in their distribution might be modified in some substantial way raised substantial concerns in the research community. The process of distributing WARF funds is one where it is critical for the campus leadership to make sure that whatever changes are made have the benefit of thorough discussion with the research community. There was a strong sense in our community that it is important to understand the relationship between the distribution of WARF funds and the activities that generate WARF funds.

3. The changes we wish to see

It is my sense that our campus culture is one where calls for significant change often invigorate the process of faculty governance. This can be a good thing, for it is one of the best ways to ensure participation and feedback from the community. However, it can also sway us and, in some cases, delay us from our focus on making changes that must be made for the good of the campus. To that end, our college community was strongly in favor of making changes to what they perceive as some of the primary challenged pieces of the Graduate School, including RSP, some offices involved in research compliance, aspects of graduate training including fellowships, tuition remission, and related funding concerns, and representation in key discussions with funding agencies. There is a strong concern that the continued growth in extramural support generated by faculty initiative has not been paralleled by a growth in the infrastructure needed for efficient pre- and post-award management. Efforts to repair these elements will almost certainly receive widespread support from our researchers. Solutions that focus on creation of additional levels of high-level administration will breed cynicism because of a fear that the “on the ground” problems will remain unsolved.

Our community is especially receptive to proposals that address the “on the ground” issues directly. Their sense of the lack of responsiveness of some Graduate School functions continues to raise doubts in their minds about the future of our research enterprise. Therefore, it would seem that approaching the problem from this vantage point might yield the best results. A successful structure will be one that reaches out and engages with our faculty and researchers to

ensure our campus leadership is properly informed and aware of the concerns facing our faculty and the impact that policy decisions have on our ability to remain among the nation's premier research university.

One of the “on the ground” issues that arose several times in our discussions was the awareness by Graduate School units of pressing issues facing our faculty. Training grants, tuition remission, and funding of graduate fellowships and traineeships were all cited as key areas where our faculty perceive a lack of assertiveness and understanding by the Graduate School. Faculty repeatedly commented that they felt the Graduate School was not able to advance key discussions on these issues at either the campus or national levels, and that continued failure to do so was tantamount to losing our competitive edge we've worked so hard to develop. This may be one of the most important sources of expertise to restore to the Graduate School in any reorganized research enterprise.

We also heard discussion of the merits of pursuing “big science” projects in parallel with our continued support for individual investigator driven projects. Increasingly, we are witnessing federal agencies calling for larger and more integrated research proposals to tackle some of our nation's most pressing issues. Our community felt that to remain competitive, it will be important that our campus research enterprise be structured in a way that fosters greater collaboration between divisions while also continuing to support and encourage the individual researcher who may be competing for the smaller or more traditional grant. In other words, not losing sight of individual-investigator driven grants was viewed as an important element of any restructuring designed with “big science” in mind.

4. The costs and the benefits

Substantial worry exists among our researchers about the cost of the proposed reorganization, with the cost of the salary for a Vice Chancellor as a very small element. Far more important is the return of Facilities and Administrative (F&A) costs to schools and colleges currently near 19% of the F&A generated, which is an historically low figure. Many perceive that the source of funds for staffing the office of a Vice Chancellor for Research would be F&A dollars such that we would realize even lower returns in the future to support our research infrastructure. Campus PI's are skeptical that the proposed reorganization will continue or even accelerate the decline in F&A returns that researchers already see as limiting. I understand that the inability of the state to provide for more of the essential campus infrastructure in a difficult economy is a part of the F&A dilemma, but the faculty believe their success at securing extramural funds leads to ever diminishing support.

While not discussed in much detail in our group meetings, several individual conversations focused on the benefits that an appointment such as a Vice Chancellor for Research might accrue because we would have an advocate whose primary job would be the oversight for key offices involved in research on our campus. Although this function is currently vested with the Dean of the Graduate School, there is a widespread perception that the Graduate School Dean has too large a portfolio to be effective in so many different arenas. To hire an administrator whose focus is on research has the potential to change the dynamics of the conversation on our campus. While a “squeaky wheel” for research administration might help our research community, this concern

cuts both ways because some see such an appointment as a way to build competing and possibly conflicting enterprises in research administration and graduate education. The combination of those functions on our campus is viewed as something of a sacred union, and their proposed separation is cause for concern among many.

In summarizing the comments from our research community in CALS, there is a strong sense that the campus leaders proposing reorganization have not yet made a case for this model of reorganization. There is some support among our researchers for proposals that deal with “on the ground” changes in research administration, compliance, funding models for graduate education, and representative participation in key funding and policy discussions at the national level. However, the proposed solution of constructing a new office for a Vice Chancellor continues to meet with skepticism that it can solve what faculty perceive to be the problem. The good news is that there is a deep and abiding interest in improving research administration and strengthening graduate education. Thus, the Chancellor and Provost need to build a case for why the proposed reorganization is ‘the’ solution for the current problems in RSP and elsewhere – at this time, the faculty perceive the ‘solution’ as a mismatch for the ‘problem.’ There is much sentiment that additional investments in our current structure could address these problems in a more straightforward fashion.

Thank you for this opportunity to provide feedback on this important topic. We would welcome further discussion and opportunities to engage with campus leaders on this topic as this subject moves forward through governance processes this year.

For the CALS community,



Irwin L. Goldman
Interim Dean and Director

cc: Chancellor Bidy Martin
Provost Paul DeLuca
CALS APC Members
CALS Chairs and Directors

December 11, 2009

Noel Radomski, Chair
Ad Hoc Committee on the Research Enterprise Chair
Academic Staff Executive Committee
Center for Advancement of Postsecondary Education
324 Lathrop Hall

Dear Mr. Radomski:

As elected faculty representatives to the Graduate Faculty Executive Committee, we write to express our concern about the implications of the proposed reorganization of university governance of graduate education and research. In particular, we request that any decision be based on an analysis that includes explicit recognition of the full set of relevant values and goals, a detailed specification of the proposed alternative to the existing arrangements, and a systematic comparison of the alternatives in terms of their relative effectiveness in furthering the values and goals.

We approach this issue with some skepticism about the desirability of separating the governance of graduate education and research. The nature of the relationship between graduate education and research varies greatly across disciplines, ranging from team production in some of the sciences in which faculty and graduate students co-produce research to mentorship in some of the humanities in which the graduate student produces fully independent work under faculty guidance. Any change in governance should recognize this diversity in the roles of graduate students in research. It should also recognize that the future creation of research depends on the appropriate training of graduate students today.

We hope that the analysis of alternative governance arrangements will include among the relevant goals the improvement of graduate student funding. Many departments at the university find themselves disadvantaged in terms of graduate student support when competing for top candidates. The problem is most severe in the social sciences and humanities where heavy reliance on teaching assistantships for graduate student support often forces new graduate students to begin teaching as they are just beginning their training. Even in the sciences, where faculty routinely fund graduate students out of their research grants, limited availability of first-year funding hinders many interdisciplinary programs that seek to involve students in training best done before students join research teams. Ideally, any reorganization should contribute to making the university more competitive in terms of graduate funding; it certainly should not make the problem worse by diverting resources from graduate support.

We also recognize that there are important issues with respect to research compliance that should be addressed. For example, the wholesale application of human subjects protections appropriate for clinical research to all forms of research imposes substantial costs on many types of research involving no or minimal risks to subjects. We hope that

any new governance arrangements take account of the diversity of the research endeavor and not favor any one type of research in the imposition of compliance measures.

Sincerely,

David L. Weiner

Palomares

Marc Sill

William F. Bleam

Jon Ruppert

Ja J Sh

Don. J. J. J.

Gary K. J. J.

John B. Sharpless

Ronald K. J.

JAN - 4 2010



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-2803

December 18, 2009

Re: Animal Welfare Assurance
A3368-01 [OLAW Case 1R]

Dr. William S. Mellon
Interim Associate Dean for Research Policy
University of Wisconsin-Madison
327 Bascom Hall
500 Lincoln Drive
Madison, WI 53706-1380

Dear Dr. Mellon,

On behalf of the Office of Laboratory Animal Welfare (OLAW) we wish to thank you and your staff for the hospitality shown to us during the site visit of the University of Wisconsin-Madison conducted by our Office and the US Department of Agriculture on December 1-2, 2009. We appreciate the time spent and information provided by you, Rick Lane, Dr. Eric Sandgren, Dr. Janet Welter, [REDACTED], Dr. Buddy Capuano, [REDACTED], Holly McEntee, [REDACTED] the Find-it/Fix-it (FiFi) staff, [REDACTED], the Institutional Animal Care and Use Committee (IACUC) members, and all other animal program staff. As discussed in our exit briefing we found all the animals examined to be in good condition and comprehensive environmental enrichment strategies for the [REDACTED] and the [REDACTED] including extensive social housing for the nonhuman primates. The animal study proposal forms appeared to be sufficiently detailed to solicit adequate information for the IACUC reviews which, based on minutes review, are very thorough.

As we also indicated, several issues were identified which need to be addressed and modified or corrected. In order for OLAW to monitor the plans and schedules for correction the University of Wisconsin-Madison is hereby placed on an enhanced reporting schedule. The specific items needing attention are as follows:

- 1) Each of the five IACUCs is to independently promptly report, through the Institutional Official, to OLAW any serious or continuing noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals, any serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals (Guide)*, or any suspension of an activity by the IACUC as required by the PHS Policy at IV.F.3. The IACUCs are to carefully review NOT-OD-05-034 Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals (enclosed) and are encouraged to contact the OLAW Division of Compliance Oversight regarding questions on prompt reporting.
- 2) The institution must operate in accordance with NOT-OD-07-044 NIH Policy on Allowable Costs for Grant Activities Involving Animals when Terms and Conditions are not Upheld (enclosed) and not allow charges to be made to grant awards for the conduct of animal activities during periods of time that the terms and conditions of the NIH Grants Policy Statement are not upheld. This includes the implementation of significant changes to protocols without prior IACUC approval.

Page 2 – Dr. Mellon
December 18, 2009

- 3) Significant changes must receive prior IACUC approval either by full committee review or designated member review. Significant changes cannot be approved by the veterinarian and/or IACUC chair unless all IACUC members have been given the opportunity to call for full committee review and no one requested such a review. OLAW has published examples of significant changes which include changes in anesthesia, analgesia, or euthanasia method. The IACUCs are to conduct continuing review of each previously approved, ongoing activity covered by the Policy at appropriate intervals as determined by the IACUC.
- 4) The role of the All Campus IACUC needs to be reevaluated. This committee is not to overrule the decisions made by any other IACUC or modify the semiannual review findings of any other IACUC. The All Campus IACUC must not usurp the authority of any other IACUC or the Institutional Official. Having a central committee such as the All Campus IACUC serve in an advisory role for development of institutional policies and harmonization of animal care and use practices is acceptable.
- 5) Measures must be taken to address animal rooms which do not have a centralized monitoring capacity for temperature ranges to ensure that procedures are in place to address fluctuations which could negatively impact the animals. See OLAW Frequently Asked Question at <http://grants.nih.gov/grants/olaw/faqs.htm#f6>. If there are animal rooms that cannot achieve air changes as recommended in the *Guide*, such as in the [REDACTED], there should be a consideration given for discontinuing their use as animal holding rooms.
- 6) Vehicles used to transport animals must have appropriate climate control.
- 7) OLAW strongly encourages the continuation of pair or group housing of primates wherever possible. OLAW supports the plan of placing animals not eligible for inclusion on active studies due to age or other condition as partners for single housed primates on Simian Immunodeficiency Virus studies.
- 8) The concept of the FiFi staff providing assistance to investigators to achieve protocol compliance is a good approach. Instances of noncompliance identified by FiFi staff must be reported to the appropriate IACUC which is to assess whether the item also needs to be reported to OLAW and whether corrective actions proposed are appropriate.
- 9) Oversight of the numbers of animals used on protocols must be enhanced especially in locations where investigators using rodents are under minimal restrictions regarding the numbers of animals ordered or bred.
- 10) The concept of reviewing the same protocols by more than one IACUC should be assessed to ensure that this practice does not lead to conflicting authorities.
- 11) The chickens housed in the [REDACTED] are to be maintained in accordance with the provisions outlined in the *Guide*, page 42-44, and this must be overseen by the IACUC and veterinarian. Having the bedding changed annually and the watering equipment sanitized once per year is not consistent with the provisions of the *Guide*.
- 12) OLAW recommends that overarching policies for the animal care and use program be developed for transportation, environmental enrichment, post-approval monitoring of ongoing animal activities, an inventory control system for pharmaceuticals, animal tracking, animal ordering, including common forms and cage cards, rather than having these policies emanate from the individual college or building.

Page 3 -- Dr. Mellon
December 18, 2009

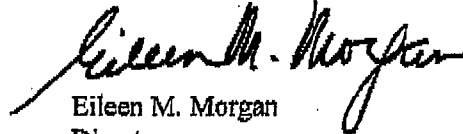
As noted above, OLAW is placing the University of Wisconsin- Madison on an enhanced reporting schedule to monitor progress regarding the implementation of corrective actions or modifications as described. Please provide an assessment of all items outlined by April 1, 2010 to the OLAW Division of Compliance Oversight (DCO), attention Dr. Axel Wolff. Provide a copy of the next complete semiannual program review and facility inspection report to DCO, ensuring that it is prepared in accordance with IV.B.1-3 of the PHS Policy. Upon review of these documents by this Office, additional guidance on further reporting will be provided. The Annual Report is to be submitted independent of these documents to the Division of Assurances. Feel free to contact us should you have any questions.

Sincerely,



Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

Sincerely,



Eileen M. Morgan
Director
Division of Assurances

cc: Elizabeth Goldentyer, D.V.M., Eastern Regional Director, USDA-APHIS-AC
Daniel Uhlrich, IACUC Chair School of Medicine and Public Health
Nancy Schultz-Darken, Ph.D., IACUC Chair Graduate School
Norlin Benevenga, Ph.D., IACUC Chair CALS
Hannah Carey, Ph.D., IACUC Chair School of Veterinary Medicine
Robert Streiffer, Ph.D., IACUC Chair College of Letters & Science

Enclosures

NIH Policy on Allowable Costs for Grant Activities Involving Animals when Terms and Conditions are not Upheld

Notice Number: NOT-OD-07-044

Key Dates

Release Date: January 26, 2007

Issued by

National Institutes of Health (NIH), (<http://www.nih.gov>)

The purpose of this Notice is to clarify that no costs for activities with live vertebrate animals may be charged to NIH if there is not a valid Animal Welfare Assurance and Institutional Animal Care and Use Committee (IACUC) approval. This notice is applicable to grants and cooperative agreements involving activities with live vertebrate animals.

Background

Terms and conditions applicable to all grant awards that involve live, vertebrate animals - including research, research training, experimentation, biological testing, custom antibody preparation, or related purposes - require a valid Animal Welfare Assurance (Domestic, Foreign, or Inter-institutional Assurance, as applicable) approved by the NIH Office of Laboratory Animal Welfare (OLAW), and valid IACUC approval. IACUC approval must be dated within the last three years in order to be valid. IACUCs are not authorized to administratively extend approval beyond three years. Foreign grantees receiving direct support are not required to provide IACUC approval, but must have a valid Foreign Assurance on file with OLAW (see <http://grants.nih.gov/grants/olaw/assurance/500index.htm> for list of foreign institutions with approved Assurances).

Policy

The Office of Management and Budget Cost Principles and the NIH Grants Policy Statement (NIHGPS) do not permit charges to grant awards for the conduct of animal activities during periods of time that the terms and conditions of the NIHGPS are not upheld. Specific situations under which charges are not allowable are:

1. The conduct of animal activities in the absence of a valid Assurance on file with OLAW.
2. The conduct of animal activities in the absence of valid IACUC approval of the activity. Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval. Suspension is described in the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) at section IV.C.6. (<http://grants.nih.gov/grants/olaw/references/phspol.htm>)

Institutions are required to report such situations to the Institute/Center (IC) supporting the award. NIH expects grantees to continue to maintain and care for animals during the periods described above. Funding components may allow expenditure of NIH grant funds for maintenance and care of animals on a case-by-case basis.

Additionally, these situations constitute serious noncompliance with section IV.F.3. of the PHS Policy and as such must be promptly reported to OLAW in accord with the PHS Policy. See NOT OD-05-034, Guidance on Prompt Reporting to OLAW (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>)

Grantees are reminded that under consortium (subaward) agreements in which the grantee collaborates with one or more other organizations, the grantee, as the direct and primary recipient of NIH grant funds, is accountable for the performance of the project, the appropriate expenditure of grants funds by all parties, and all other obligations of the grantee as specified in the NIHGPS. The animal welfare requirements that apply to grantees also apply to consortium participants and subprojects. The prime grantee is responsible for including these requirements in its agreements with collaborating organizations, and for ensuring that all sites engaged in research involving the use of live vertebrate animals have an appropriate Animal Welfare Assurance and that the activity has a valid IACUC approval. (see <http://grants.nih.gov/grants/olaw/assurance/300index.htm> for a list of domestic institutions with Assurances). If the prime grantee does not

NOT-OD-07-044: NIH Policy on Allowable Costs for Grant Activities Involving Animals when Terms a... Page 2 of 2

have an Animal Welfare Assurance and the animal work will be conducted at an institution with an Assurance, the grantee must obtain an inter-institutional Assurance from OLAW. When the grantee is a domestic institution and there is a foreign performance site using animals, the grantee must ensure that the performance site has an appropriate Foreign Assurance and must provide verification of IACUC approval by the domestic grantee's IACUC, certifying to NIH that the activity as conducted at the foreign performance site is acceptable to the grantee. (See NIH GPS, Part II, Terms and Conditions of NIH Grant Awards, Consortium Agreements, http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600251).

Inquiries

Questions concerning this Notice should be directed to:

Office of Policy for Extramural Research Administration
National Institutes of Health
Telephone: 301-435-0938
Email: grantspolicy@od.nih.gov

Questions about Assurances or IACUC approval of animal activities should be directed to:

Office of Laboratory Animal Welfare
Division of Assurances
National Institutes of Health
Telephone: 301-496-7163
Email: olawdoa@mail.nih.gov

[Weekly TOC for this Announcement](#)
[NIH Funding Opportunities and Notices](#)



Office of
Extramural
Research (OER)



National Institutes of
Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892



Department of Health
and Human Services
(HHS)



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Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals

Notice Number: NOT-OD-05-034

Key Dates

Release Date: February, 24, 2005

Issued by

Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research (<http://grants.nih.gov/grants/olaw/olaw.htm>)

This Notice provides guidance to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs) on the prompt reporting requirements of the PHS Policy on Humane Care and Use of Laboratory Animals (Policy) (<http://grants.nih.gov/grants/olaw/references/phspol.htm>). This guidance is intended to assist IACUCs and Institutional Officials in determining what, when, and how situations should be reported under IV.F.3 of the Policy, and to promote greater uniformity in reporting. This Notice supersedes the January 12, 1994 Dear Colleague letter from the former Division of Animal Welfare, Office for Protection from Research Risks (now the Office of Laboratory Animal Welfare, or OLAW).

Background

PHS Policy, IV.F.3, requires that:

"The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- a) any serious or continuing noncompliance with this Policy;
- b) any serious deviation from the provisions of the *Guide [for the Care and Use of Laboratory Animals]*; or
- c) any suspension of an activity by the IACUC."

IACUC suspensions of activities are cited at IV.C.6 and 7 of the Policy, and require a convened meeting of a quorum of the IACUC and the vote of a majority of the quorum present. The Institutional Official must review the reasons for suspension in consultation with the IACUC, take appropriate corrective action and report that action with full explanation to OLAW.

All institutions with Animal Welfare Assurances are required to comply with the provisions of IV.F.3. The Institutional Official signing the Assurance, in concert with the IACUC, is responsible for this reporting.

Reporting promptly to OLAW under IV.F.3 serves dual purposes. Foremost, it ensures that institutions deliberately address and correct situations that affect animal welfare, PHS-supported research, and compliance with the Policy. In addition, it enables OLAW to monitor the institution's animal care and use program oversight under the Policy, evaluate allegations of noncompliance, and assess the effectiveness of PHS policies and procedures.

The underlying foundation of the PHS Policy is one of institutional self-evaluation, self-monitoring and self-reporting. Public Law 99-15 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>) requires that institutions be provided a reasonable opportunity to take corrective action before a grant or contract is suspended or terminated, and it is OLAW's role to assess whether the corrective actions reported by institutions under IV.F.3 are adequate. OLAW will assist the reporting institution in developing definitive corrective plans and schedules if necessary. Compliance actions affecting an award are rare because institutions are usually able to address incidents successfully and take appropriate actions to prevent recurrence.

Guidance on Prompt Reporting

A comprehensive list of definitive examples of reportable situations is impractical. Therefore, the examples below do not cover all instances but demonstrate the threshold at which OLAW expects to receive a report. Institutions should use rational judgment in determining what situations meet the provisions of IV.F.3 and fall within the scope of the examples below, and consult with OLAW if in doubt. OLAW welcomes inquiries and discussion and will provide guidance with regard to specific situations. Situations that meet the provisions of IV.F.3 and are identified by external entities such as the United States Department of Agriculture or the Association for

Assessment and Accreditation of Laboratory Animal Care International, or by individuals outside the IACUC or outside the institution, are not exempt from reporting under IV.F.3.

Examples of reportable situations:

- conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
 - conduct of animal-related activities without appropriate IACUC review and approval;
 - failure to adhere to IACUC-approved protocols;
 - implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;
 - conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);
 - conduct of official IACUC business requiring a quorum (full Committee review of an activity in accord with IV.C.2 or suspension in accord with IV.C.6) in the absence of a quorum;
 - conduct of official IACUC business during a period of time that the Committee is improperly constituted;
 - failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
 - chronic failure to provide space for animals in accordance with recommendations of the *Guide* unless the IACUC has approved a protocol-specific deviation from the *Guide* based on written scientific justification;
 - participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;
-
- failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);
 - failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
 - failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO₂);
 - failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or
 - IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Animal Welfare Assurance.

OLAW recognizes that there may be levels of morbidity and mortality in virtually any animal-related activity, including those associated with the care and use of animals in research, testing, and teaching that are not the result of violations of either the Policy or the *Guide*. OLAW offers the following examples of situations which may *not* meet the threshold for reporting, based on consideration of the circumstances by the IACUC.

Examples of situations *not* normally required to be reported:

- death of animals that have reached the end of their natural life spans;
- death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;

NOT-OD-05-034: Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and... Page 4 of 4

For questions or further information, contact:

Director, Office of Laboratory Animal Welfare
Office of Extramural Research,
Office of the Director, National Institutes of Health
RKL 1, Suite 360
6705 Rockledge Dr.
Bethesda, MD 20892-7982
(For express or hand-delivered mail use zip code 20817)
Telephone (301) 498-7163
olaw@od.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices



Office of
Extramural
Research (OER)



National Institutes of
Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892



Department of Health
and Human Services
(HHS)



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MEMORANDUM

To: Heather Daniels, Chair, ASEC
Hector Deluca, Chair, UC ad hoc committee
David Musolf, Secretary of the Faculty
Noel Radomski, Chair ASEC ad hoc committee
Donna Silver, Secretary of the Academic Staff
William Tracy, Chair, University Committee

From: Lori M. Berquam, Dean of Students
Gilles Bousquet, Dean, Division of International Studies & Director, International Institute
Daryl D. Buss, Dean, School of Veterinary Medicine
Kenneth B. Davis, Jr., Dean, Law School
Robin A. Douthitt, Dean, School of Human Ecology
Robert N. Golden, Dean, School of Medicine & Public Health & Vice Chancellor, Medical Affairs
Michael M. Knetter, Dean, Wisconsin School of Business
Katharyn A. May, Dean, School of Nursing
Paul S. Peercy, Dean, College of Engineering
Jeanette Roberts, Dean, School of Pharmacy
Marv Van Kekerix, Dean, Division of Continuing Studies & Vice Provost for Lifelong Learning

Subject: Organization of Research and Graduate Education at the UW-Madison

Since the beginning of this semester, a proposal to modify the campus administrative structure that supports research and graduate education has been discussed in multiple Town Hall Meetings and other venues. Prior to that, the campus Leadership Council had discussed on multiple occasions the problems of our current research infrastructure, the significant and rapid changes in our national research environment, and the importance of our taking action to position the UW-Madison to compete and thrive in that changing research environment.

The deans represent a significant element of shared governance at UW-Madison, with roles, responsibilities and perspectives to contribute to the campus-wide dialogue. In that spirit, we take this opportunity to share our perspective and views within the framework of shared governance. We welcome the opportunity to engage in discussion with the committees of the UC and ASEC now considering this question.

In our rapidly changing environment, it is ever more critical that the UW-Madison be able to effectively and proactively support and provide advocacy for graduate education and for research and creative activities for all elements of our institution. The administrative structure that supports graduate education and research must be able to accommodate current and anticipated future needs if it is to effectively serve our faculty, staff, and graduate programs. Those needs are very different from those of years past and

will continue to evolve and increase in complexity. Consequently, our systems must have the capacity and organizational structure to let us meet the needs of tomorrow as well as of today.

In addition to developing an administrative structure that can adequately support research and graduate education, we must:

- continue to deploy scarce resources (e.g., WARF funds) in a manner that supports the diverse and highly varying needs of all elements of the campus, recognizing the critical role that these resources play in the arts, humanities, and social sciences as well as in the biological and physical sciences.
- provide advocacy and oversight for graduate education as well as for research and creative activities. In that process, maintaining the many and necessary connections and communication between graduate education and research is essential.
- facilitate an agile, timely response to extraordinary opportunities (e.g., Bioenergy Center) and to non-federal funding opportunities, such as foundations that are major supporters of the arts, humanities, and social sciences, private sector contracts and grants, private philanthropists, etc.
- allow UW-Madison to provide leadership on the national scene regarding research/creative activities and graduate education; e.g., promoting federal funding for physical, biological, and social science and the arts and humanities, helping develop national priorities for research within federal agencies, developing realistic, achievable accountability and reporting standards, providing better mechanisms for entry of international students and foreign visiting scientists into our graduate programs, and participating in many other initiatives.

Our current organizational structure began a century ago as the Graduate School. The many subsequent additions have been progressive and opportunistic, rather than a reflection of a prospective and intentional administrative plan. Examples of the changes in dimensions and responsibilities include:

- Research functions developed and evolved as the research enterprise expanded dramatically in scale, especially with the advent and growth of federal funding of research following World War II;
- The Graduate School began its open “*fall competition*” which expanded to include the arts, humanities, and social sciences in the early 1960s.
- Research administration and compliance became far more complex, most notably with compliance requirements post-9/11;
- RSP was added in the mid 1990s;
- The “Vice Chancellor for Research” title was added in the mid 1990s.
- Research Policy and Compliance was added in 2002;
- The importance of industry contracts and research relationships, combined with the significance of economic development in Wisconsin and beyond, has expanded significantly;
- Graduate School-based centers/institutes/programs grew from zero to 17 today. There are another 107 centers/institutes/programs which currently fall outside of the Graduate School.

These examples illustrate the growth in scale and complexity of research and of graduate education that has made the current system increasingly complex and unwieldy.

As deans, we believe we need to provide additional resources to the research enterprise, but also support the exploration of administrative realignment. We appreciate and support the initiative of the Chancellor and Provost in considering such an administrative alignment. Our support reflects our experience in working within our current organizational framework, an experience that has led us to conclude that our current structure, even with additional resources, is inadequate to meet our needs, now and in the future:

- Today’s world demands an enormously higher level of accountability and compliance than that of a decade ago. The consequences of infrastructure failure are far more severe, and potentially catastrophic, today. With our current structure, we cannot provide adequate oversight of these functions with so many other competing administrative needs. Failure of our administrative

structure and the processes it must manage imperil the entire university, including the arts and humanities.

- Due to the time demands created by today's unwieldy structure, we lack the time to have an effective presence on the national scene in such areas as helping establish future priorities for appropriated federal funding for research and scholarship in the sciences and humanities, the development and implementation of effective but achievable compliance requirements, etc.
- The tremendous increase of scale and complexity of the research enterprise necessarily limits the time available for oversight and advocacy for graduate education.

Clearly additional resources are needed to handle the many and diverse responsibilities in the support and oversight of research and graduate education. However, we believe that the addition of new resources alone will be insufficient to effectively improve and support these enterprises going into the future. Time is of the essence. Failure to move forward expeditiously with resources and an organizational structure that will meet our present and future needs will increasingly threaten the viability of our current programs and impede their further growth and development. We will not continue to be successful in the 21st century with a 20th century infrastructure.

cc: Chancellor C. Martin
Provost P. Deluca

To: Heather Daniels, Chair, ASEC
Hector Deluca, Chair, UC ad hoc committee
David Musolf, Secretary of the Faculty
Noel Radomski, Chair ASEC ad hoc committee
Donna Silver, Secretary of the Academic Staff
William Tracy, Chair, University Committee

From: Gary Sandefur, Dean, College of Letters and Science

Date: November 13, 2009

Re: Proposed Reorganization of the Graduate School

Cc: Chancellor Martin, Provost DeLuca, Vice Chancellor Cadwallader, Vice
Chancellor Bazzell, Vice Chancellor Sweeney, Letters and Science Faculty, Staff,
and Graduate Students

I write in regard to the proposed reorganization of the Graduate School into two separate entities and the creation of a new position of Vice Chancellor for Research that is distinct from the Dean of the Graduate School. My statement reflects what I have heard from my faculty, staff, and graduate students, and my own views about how to move forward.

I hosted one Town Hall meeting in Science Hall and co-hosted another in the Humanities Building. I also discussed these issues with my Associate Deans, with the L&S Academic Planning Council, with the L&S Council on Academic Staff Issues, and with the L&S Faculty Senate. In addition I have participated in discussions of these issues at the Chancellor's Cabinet and in the Deans' Council. I thank Provost DeLuca and Chancellor Martin for encouraging open discussion of these issues by the Deans and for providing us with several opportunities to do so. I have also had a number of one-on-one conversations with faculty and staff.

Almost everyone with whom I talked in the College was concerned that the creation of a new position seemed to be on a very fast track. Most of the people with whom I talked expressed a preference for the track we are now on, where there is extensive campus discussion culminating in reports from the Faculty and Academic Staff Ad Hoc Committees to the Chancellor and the Provost. I express my thanks to our Chancellor and Provost for their responsiveness to concerns voiced by many faculty and staff.

An issue of general agreement is that the world of research has become increasingly complicated. Part of this has to do with regulations. New regulations involving conflict of interest, effort reporting, institutional review boards, compliance, and allowable expenditures with federal grant money have created headaches for researchers and research administrative staff. Another major change is the growth in multi-investigator and sometimes multi-institutional awards and the opportunities for pursuing these awards. These new sorts of opportunities require a different sort of approach than grants involving one or two principal investigators. I also heard general support for more resources in research and sponsored programs and compliance, including laboratory safety.

As one would expect there is no one view from within the College of Letters and Science on how to address these issues and whether the proposed reorganization is the way to go. The current discussion has provided an opportunity for people to reflect on how the University might address these issues. Some people have expressed support for the proposed reorganization, pointing to the fact that most of our peer institutions have separate research and graduate education entities. Others expressed openness to the idea but wanted to hear more information about 1) what would remain in the Graduate School and what would be part of the new office; 2) how would this address the issues that have been previously identified with Research and Sponsored Programs, contracts with private industry, laboratory safety, and other compliance issues; 3) how much would this cost; and, 4) how would the costs be paid? Still others expressed the view that we have not had to pay any major fines, as have some institutions with a separate graduate school and research enterprise, and we are among the leaders in research and development spending, so why do we need to contemplate a major change? Should we not be focusing just on reorganizing problematic areas and putting resources and personnel into under-funded parts of our research administrative infrastructure?

A concern that I heard frequently was the fear that the reorganization of the Graduate School and the research enterprise was being driven by needs and concerns in the biomedical research community. This concern was expressed not only by members of the arts, humanities, and social sciences but also by faculty and staff in the biological and physical sciences. The fear is that focusing exclusively on the needs of the biomedical research community in any reorganization may unintentionally disadvantage researchers in other fields.

Another concern was that the current organization allows for a major role of shared governance in the research enterprise, and that moving the research enterprise to a Vice Chancellor position would not be conducive to this. Still another concern was that much of the discussion focused on research, and only passing attention was given to graduate education.

My own views about all of this are as follows. I think it is good to ask ourselves why most of our peers now have a structure that differs from ours. Most of them have separate graduate school and research enterprises. Perhaps we have a good deal to gain from doing this. On the other hand, it could be that our situation is such that our system works better for us than what most of our peers do. To resolve this question would seem to require some conversations with our peers about the costs and benefits of their system relative to ours.

I do think it is time to reexamine our graduate education and research enterprises and ask ourselves how we can best position ourselves for future success. Both research and graduate education have changed significantly in recent times. I do not claim to know what the best structure is. However, we should examine the changes that have occurred and develop some proposals for adapting to these changes.

One could imagine a separate Vice Chancellor for Research, or a Vice Provost for Research, or a position for research that reported to the Dean of the Graduate School. I do not think it is a good idea to create such a position and then charge that person with the task of reorganizing our research enterprise with no budget, no staff with whom to work, and no well-defined process for moving forward with reorganization. I think that is too much to ask. Instead I think a committee or task force appointed by the Chancellor, the University Committee, and ASEC should examine our problems and our opportunities and suggest a set of alternatives from which the Chancellor and Provost can choose.

Thank you for the opportunity to provide my input into the discussion.