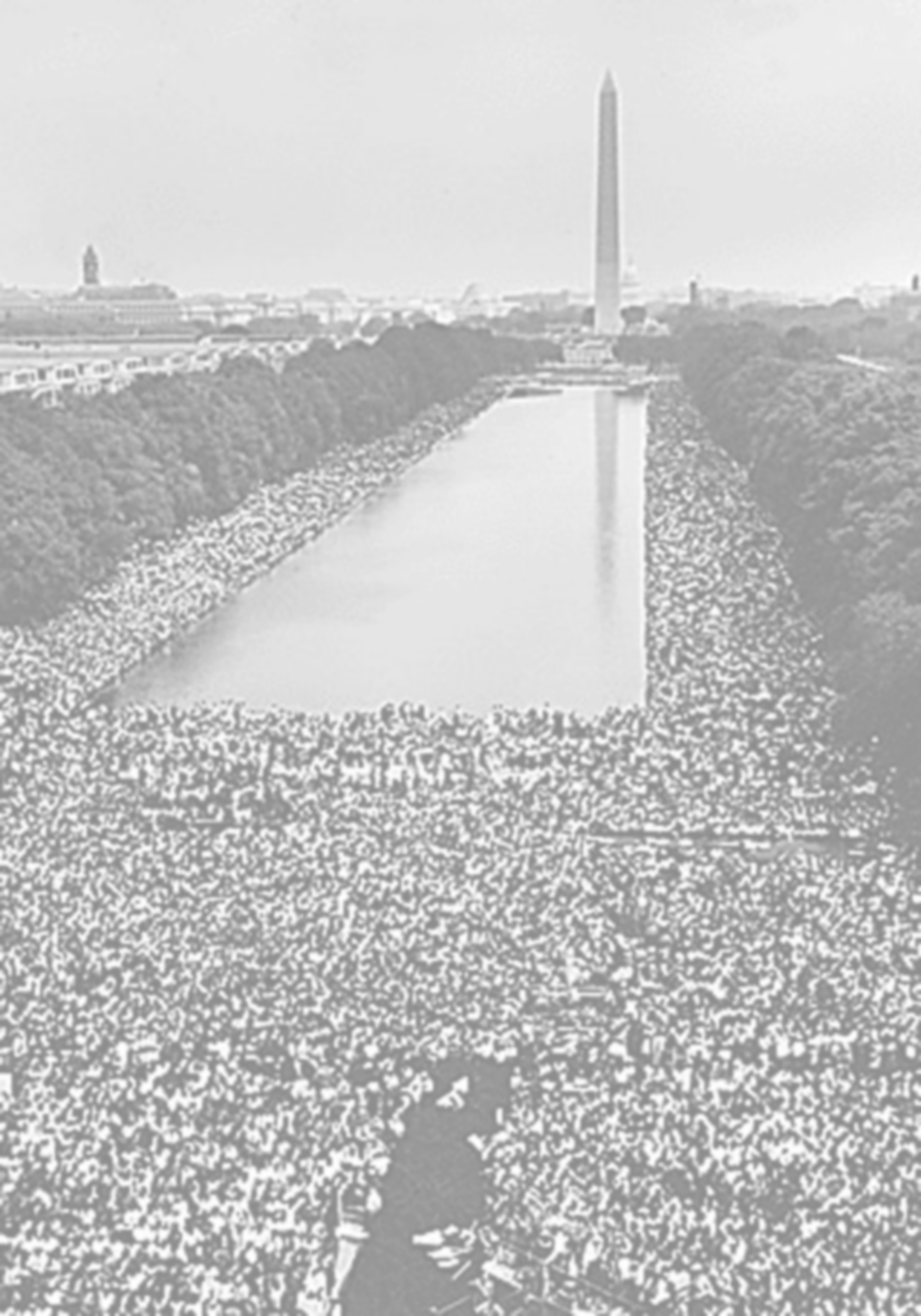
Volume XXXIX, Number 2 Fall 2008

The Journal of Research Administration

Published by
SRAInternational
Society of Research Administrators International



2008 PUBLICATIONS AWARD
NATIONAL GRANTS MANAGEMENT ASSOCIATION

Journal of Research Administration

Prepared by Graphic Arts and Publishing Services
at The Henry M. Jackson Foundation
for the Advancement of Military Medicine, Inc.

1401 Rockville Pike, Suite 600
Rockville, Maryland 20852
Rick Crites, Art Director
301-294-1218

Journal Editorial Staff

Correspondence

Manuscripts or Letters to the Editor are to be submitted to the Editor. Submission of a manuscript is considered to be a representation that it is not copyrighted, previously published, or concurrently under consideration for publishing in print or electronic form. Consult the Journal web page (www.srainternational.org/journal) for specific information for authors, templates, and new material. The preferred communication route is through email at info@srainternational.org, Attention: Editor.

Subscriptions

Subscriptions: $100 per year in the United States, Canada, and Mexico; $125 per year international. Make checks payable to *The Journal of Research Administration.* Subscriptions for SRA Members are included as part of an individual's annual dues. All subscriptions include electronic access to the two yearly print-editions mailed separately via USPS. Send change-of-address notices (together with your address label) and all other correspondence regarding subscriptions and purchase of back issues to Society of Research Administrators International, Executive Office, 1901 North Moore Street, Suite 1004, Arlington, VA 22209 USA. Phone: +1-703-741-0140. Periodicals are postage paid at Arlington, VA and at an additional mailing office.

Copyright © 2008 by the Society of Research Administrators International.

Officers of The Society Of Research Administrators International

The Journal of Research Administration is published by the Society of Research Administrators International, Arlington, Virginia 22209 USA. Founded in 1967, the Society of Research Administrators International is dedicated to the education and the professional development of research administrators and to enhance public understanding of research and its administration. Representing all disciplines and sectors in research administration, it serves as the international society to promote quality and innovation in research administration. USPS No. 008245. ISSN No. 1539-1590.

Table of Contents


UAW

Contributing Authors

Dr. Ibrahim Adib Abdel-Messih is a Medical Research Scientist for the Clinical Trials Program, U.S Naval Medical Research Unit 3, Cairo, Egypt (NAMRU-3). He was formerly an infectious Diseases Pediatrician at Embaba Fever Hospital, the major infectious diseases hospital in Egypt. He started his career in medical research in 1995 after obtaining a Masters in Epidemiology at the Institute of Child Health, University of London. He is a member of NAMRU-3 Institutional Review Board.

Lynne Chronister, MPA, is Assistant Vice Provost for Research at the University of Washington. She is a Past-President of the Society of Research Administrators International and has served in various leadership capacities for the Society over the years. She has been at the forefront of the Society's international outreach program overseas. She is co-editor of the recent work, Research Administration and Management (Jones/Bartlett).

Philip Cola, MA, is Vice President for Research and Technology Management at University Hospitals Case Medical Center in Cleveland. He has overall responsibility for Hospital-based research administration including oversight of the Institutional Review Board, research compliance, grants and contracts, Clinical Research Education, and technology management. He holds a master's degree in Experimental Psychology. He has published and presented widely, most recently serving as an Editor and contributor for Responsible Research: A Guide for Coordinators (Remedica).

Dr. Michael Crouch has spent most of his career in academic research administration and management. He previously held positions at Ferris State University, Northwestern University, the University of Pittsburgh, and MedStar Health. He is presently Executive Director, Office for Sponsored Programs and Assistant Vice Provost for Research at the University of Connecticut. His scholarly interests include the Responsible Conduct of Research and higher education organizational policy and practice.

Dr. Kenneth C. Earhart is an Infectious Diseases physician in the United States Navy. He has served previously as the Chairman of the Institutional Review Boards at U.S. Naval Medical Research Unit No. 3 and Naval Medical Center San Diego. He holds the rank of Captain and is currently Commanding Officer of U.S. Naval Medical Research Unit No. 3 in Cairo, Arab Republic of Egypt.

Dr. Maged El-Setouhy is Professor of Public Health and Vice-Chair of the REC at the Faculty of Medicine, Ain Shams University. Cairo. Egypt. He is also the Program Co-Director of the Health Research Ethics Training Initiative in Egypt (http://medschool.umaryland.edu/hretie/). Dr. El-Setouhy is also the elected chairman for the EMRO Regional Program Reviewing Group for the Program of Elimination of Lymphatic Filariasis. He worked for a long time on epidemiology and bioethics.

In This Edition

Dr. Carol Fedor is the Clinical Research Manager for The Center for Clinical Research and Technology at University Hospitals Case Medical Center in Cleveland. She directs the Office of Research Compliance together with the research monitoring and education programs and has presented and published on the topic of prospective compliance monitoring and the professional development of Clinical Research Coordinators. She also served as Senior Editor and contributor for Responsible Research: A Guide for Coordinators (Remedica).

Cristina Ferrazzano Yaussy, MPH, is Research Compliance Specialist at University Hospitals Case Medical Center with 12 years of research experience in both academia and industry. She is primarily responsible for leading the research monitoring program. She has given numerous presentations regarding research compliance monitoring and the responsible conduct of research. She was awarded first place 2006 SRA Symposium honors for Best Poster, Quantitative Analysis: Executing a Research Monitoring Program.

Dr. John Galland is Director of the UC Davis Laboratory Management Institute and creates educational programs that help researchers acquire managerial skills using a pedagogy, described in Nature, Science, and other journals, that includes assistance by theatre professionals. Dr. Galland also teaches a graduate course in Philosophy and Ethics for the Biological Scientist. Previously, as Professor of Veterinary Medicine at Kansas State University, he taught public health and conducted research on foodborne pathogens.

Dr. Rachel Ginham graduated from the University of Oxford with a doctorate in biochemistry and joined the University of Bristol in 2004 to work as a research scientist. Presently she is the Research and Human Tissue Specialist within the Research and Enterprise Department. Her role is specifically involved in the facilitation and advancement of research that involves the use of human tissue. In this role, she provides advice on and ensures compliance with the UK Human Tissue Act.

Dr. Elliott Kulakowski is President of the Research Administration and Management Strategy Group, Inc. He has served as a Past-President of the Society of Research Administrators International. He has been an executive in research management in federal, university, academic medical center, and corporate environments. A proponent of the SRA educational mission overseas, he is co-editor of the recent work, Research Administration and Management (Jones/ Bartlett).

Dr. David Langley is Director of Research and Enterprise Development at the University of Bristol. He has extensive experience of research administration, particularly the management of clinical and biomedical research, including trials and research integrity. His doctorate is in neuropharmacology and he undertook research at the NIH as a Fulbright Scholar. Dr. Langley is Deputy Chair of the Association of Research Managers and Administrators (UK) and an Associate Editor of the Journal of Research Administration.

Elizabeth M. Lintz, MA, CRA, is Director of Grant Development and Sponsored Research, College of Education, University of Maryland, College Park. Her interests include research integrity and compliance issues in academic settings and graduate student development. She frequently presents workshops for graduate students and faculty on grant development and post-award management.

Dr. Jade Rosina McCutcheon is Assistant Professor in the Department of Theatre and Dance, University of California. A Visiting Scholar at the Tisch School of the Arts in 1996, she is currently Co-Convener of the Performance and Consciousness working group for the International Federation of Theatre Research. McCutcheon has been working with Dr. John Galland to develop the system of LabAct. Her book, Awakening the Performing Body, has just been released by Rodopi Press.

Dr. Victoria J. Molfese is the Ashland/Nystrand Chair in the Department of Teaching and Learning at the University of Louisville and is the Director of the Center for Research in Early Childhood. She has published, lectured, and received various research grants in areas related to cognitive development in infants, children and adults. She is a Past-President and Past-Secretary of the Society of Research Administrators International.

Dr. Phillip E. Myers, is Director of the Office of Sponsored Programs and of Administration of the Western Kentucky University Research Foundation. For SRA International, Dr. Myers is a frequent presenter, serves as an Associate Editor of the JRA, is Co-Chair of the Body of Knowledge Project, serves on the Board of Directors/Executive Committee, and is SRA Historian/Archivist. He recently published Caution and Cooperation: The American Civil War in British-American Relations (Kent State University Press).

Mary Perkins, DHealth (cand), is Research and Development Manager at the University Hospitals Bristol NHS Trust, a large regional clinical centre in the southwest of the United Kingdom. Within her doctoral studies that are presently in progress, she is investigating partnerships and interactions between universities and hospitals and how these impact the management of clinical research.

Debra Schaller-Demers, MSOM, is the Research Education and Communication Manager at Memorial Sloan-Kettering Cancer Center. As such she is responsible for developing and implementing programs to educate researchers about the responsible conduct of research and other institutional policies and procedures, and designing mechanisms to communicate more effectively with the research community. She has been an active member of the Society of Research Administrators International since 2002.

J. Michael Slocum, JD is a senior member of the law firm of Slocum & Boddie, P.C. He has more than thirty years of experience in grant and contract law. He is a Distinguished Faculty member of the Society of Research Administrators. He is a member of the Virginia State Bar, and is President of Slocum & Boddie, PC in Springfield, Virginia.

In This Edition

Marie F. Smith, CRA is Grants Administrator/Compliance Officer at the Cary Institute of Ecosystem Studies in Millbrook, New York. Her duties include pre and post award administration, contract negotiation, subaward management, grant accounting, A-133 audits and researchcompliance issues. She has an Associates Degree and a Bachelors Degree in Accounting and Management from the State University of NY. Ms. Smith is a board member of RACC and is a member of SRA, NACUBO and NCURA.

Dr. Cliff Studman is a private consultant in Research Management, Funding and Practice, currently developing and monitoring research projects for the New Zealand Accident Compensation Corporation. His past roles have included Advisor on Government Research Allocations with the NZ Tertiary Education Commission; Director of Research at the University of Botswana; and consultancy work including FAO and UNDP. He holds a doctorate in physics (Cambridge, UK) and a post-graduate Diploma in Education (Massey, New Zealand).

Lori Walker is the Research Ethics Officer at Brock University, St. Catharine's, Ontario. Beforehand, she was engaged in a national research project examining community factors that impact early child development and school readiness. As a teacher, Lori worked in Scotland for seven years. Lori has a Bachelor of Arts in Psychology and a Bachelor of Education degree. She is currently in the process of completing her Master's of Education degree focusing on research ethics administration.

Paul Waugaman, MPA, is Principal and Co-Founder of the Technology Commercialization Group. He has served in diverse leadership positions within the Society of Research Administrators International, and has led various research administration initiatives at the executive level for diverse institutions of high renown. He has been instrumental in expanding the SRA mission to the global community and has expanded greatly the awareness of indigenization as an important goal for research management and administration practices.

Dr. Birgit Whitman leads the Research Governance Team at the University of Bristol. Her role and responsibilities encompass ethics, clinical trials and human tissue research. Previously she worked for 20 years as a Surgery Research Assistant and then Research Manager at one of the largest hospitals in the United Kingdom. Dr. Whitman holds a doctorate from the History of Medicine Unit, Glasgow University. In her doctoral research, she explored breast cancer treatment and patient narratives.

Dr. Lorenzo York, is a Captain in the Chaplain Corps of the United States Navy. CAPT York is Command Chaplain and Special Assistant for Pastoral Care at the National Naval Medical Center, "The President's Hospital," in Bethesda, Maryland. He is a Board Certified-Eligible Chaplain with the Association of Professional Chaplains, and a Doctor of Ministry candidate at Ashland Theological Seminary in Ashland, Ohio.

From the Editor's Desk

Dr. Edward Gabriele

What happens to a dream come real?
Does it swell up
like a wheat shaft in the sun?
Or does it implode
into every living thing?

Langston Hughes, the famous African-American poet, would have preferred living in a social climate where he could have written the above rather than his starker, bitter words in *A Dream Deferred*. Hughes' original work was a deservedly harsh and stinging criticism of an American people whose founders fought for Freedom, but then over the centuries have denied that same gift to others by the atrocities of slavery and discrimination of every form.

This year, the yearned-for dream that pulsed beneath the hardened callous of Hughes' poetry has come real. America has elected an African American as president. Beyond any form of politics and partisanship, this is clearly the dream-come-real indeed. From the raucous debates of the past months, something entirely new has taken place. A people's hope has given a wakening realism to images and visions once thought to be so much the stuff of which dreams are made. This is a year in which all people of good will can celebrate that elusive but compelling dream, Freedom.

This coming near of Freedom's Dream is wonderfully reminiscent of the stirring figure of Dr. Martin Luther King, Jr. This year, we remembered somberly the 40th anniversary of his assassination. We also remembered with pride the 45th anniversary of his famous speech, *I Have A Dream*, given on the steps of the Lincoln Memorial in Washington, DC. In a very deep and powerful way America's electoral events this year are both a fulfillment of King's vision, and a call to make his dream continually come real over and over again, deeper each time.

Within this swirl of memories and challenges, our dreamings and our wakings, this edition of the Journal is dedicated to Dr. King in a year of incalculable cultural change. It is dedicated to a renewed vision of Justice and Freedom. This edition opens and closes with special essays on King's Dream. These special texts remind us that research itself is one critical means by which humans claim their inalienable right to a Freedom marked by quality of life and humane progress. The articles in this edition prompt us to take stock of the new roads of research administration that are before us. This edition stings our conscience…..to remember that ours is not a "trade"…..but a profession…..a public service…..not just for researchers or institutions…..but for the poor, the dispossessed, the still-enslaved, the despairing……and all those who look to research for Life, for Justice, for Freedom…..for Dreams Deferred to come Real.

Martin Luther King, Jr.
Reflections on Ethical and Moral Research Administration

Lorenzo York, MDiv, DMin
Director, Pastoral Care Department
National Naval Medical Center
Bethesda, Maryland
Email: Lorenzo.York@med.navy.mil

Forty-five years ago, Dr. Martin Luther King, Jr. delivered a riveting, inspiring, and chastening message to the nation in his "I Have a Dream" speech. He stood in the shadows of the Lincoln Memorial on the mall of the capital of the United States of America while a multitude gathered to hear a message of hope, challenge, prophecy, and -- yes -- condemnation. King raised concerns about our rich nation being pregnant with promise and possibilities and yet miscarrying on fulfillment of the same.

King charged that "….. even though we face the difficulties of today and tomorrow, I still have a dream. It is a dream deeply rooted in the American dream. I have a dream that one day this nation will rise up and live out the true meaning of its creed—`We hold these truths to be self-evident, that all men are created equal'" (Speech in Washington, August 28, 1963). His resonant voice rose in a rhythmic cadence, charging that America had issued a "bad check" against its Constitution and the Declaration of Independence. He observed that the check had come back marked "insufficient funds" for its citizens of color. The impact of this powerful speech culminated in the Civil Rights Act of 1964, a landmark piece of legislation that outlawed segregation in schools, public places, and employment. This eloquent speech was also a watershed event that ultimately contributed to the passage of the Voting Rights Act of 1965, which ensured voting rights of African Americans.

Five years after his famous speech Martin Luther King, Jr. was assassinated in Memphis, Tennessee. His resonant voice was silenced by an assassin's rifle bullet in a city that was not on his original itinerary. So why did Dr. King feel compelled to visit Memphis on that day? This diversion from his planned visit to Washington, D.C. was not supported by his aides, yet he felt duty bound to take part in a protest staged by sanitation workers who were striking for better wages. Instead of attending the Poor People's Campaign in Washington, he felt his presence was needed in Memphis.

What prompted King to make this trip to Memphis is known only to him, but as a pastoral care leader in a major medical center, I have tried to answer this question by relying on my background as a minister and an academic. Indeed, theologically speaking, Dr. King heard the *Macedonian call* (Holy Bible, Acts 16: 9) for help, and he dropped his own perceived priority to take on a morally emergent one, practicing what he preached in a speech he gave in June 1963 in Detroit. "I submit to you," he said "that if a man hasn't discovered something he will die for, he isn't fit to live."

Prelude

Forty years after the death of Dr. King there is opportunity to reflect on needs, hopes, and resources of a global community through the prism of the Kingian message of hope. This message focuses on his concept of living in "the beloved community" as elaborated in his book, *Stride Toward Freedom* (1958). This term was first coined by Josiah Royce, a 20th century American philosopher and founder of the Fellowship of Reconciliation, but Dr. King popularized the term. To him the "beloved community" was one that encapsulated a global yearning for peace and reconciliation wrapped in justice and dignity for all. His understanding resonates with this Baptist pastor, and many others in the world, who have been influenced by his yearning for justice and belief in Mahatma Ghandi's concept of civil disobedience through nonviolence resistance.

All these years later, we are now in a unique position to consider questions about how the Kingian message of hope might impact on the work that is undertaken by researchers in 2008. Reflecting on Dr. King's message, we might pay more attention to how we undertake our research in relation to our environment and the betterment of humankind. For example, we might choose to discover how our interdependent world can become a better place by undertaking research that addresses significant human problems of hunger, disease, strife, and war. We might focus our attention on stewardship related to our dwindling natural resources and fragile ecosystems. We might also be more vigilant in our adherence to policies and procedures that are stipulated by our Institutional Review Board as it strives to ensure research is conducted with integrity and for the betterment of humankind.

In his book, *Strength to Love* (1963), King observed, "Our scientific power has overrun our spiritual power. We have guided missiles and misguided men." Researchers need to reflect on his words to determine if they still hold true for our present generation. We should be asking ourselves: Are we abusing our scientific prowess at the expense of spiritual realities? What are our spiritual realities as we go about doing research? Are guided missiles or other technological advantages more influential today in balancing global political power? Do we have more misguided men and women who are more inclined to do the expedient? Where are the present day morally courageous and ethically sensitive men and women who are poised to develop what Martin Luther King passionately spoke of as the "beloved community?"

In 2008 opportunity abounds for the research community to create an innovative path that points the way for all of humanity to tap into scientific advances leading to a higher quality of life for everyone, including the poor, dispossessed, and disenfranchised members of society. By including King's concept of the beloved community in the design and execution of our research, we will be better able to respond to the needs of those members who may not have access to the kinds of resources available to those of us who are more fortunate. We have a moral obligation to ensure that our research is conducted with respect, integrity, and ethics, and to consider the impact it might have on others during the research process and at the dissemination phase.

How can we in our roles as leaders, research administrators, and researchers capitalize on moral imperatives that reflect Kingian thought? Gary Yukl and Richard Lepsinger (2004) in their book, *Flexible Leadership: Creating Value by Balancing Multiple Challenges and Choices*, suggest

that leaders are pivotal influencers at all levels of research and research management. As research administrators we can assume a leadership role when we create ethical guidelines and codes of conduct that reflect the teachings of Martin Luther King, Jr.

We can also influence the integrity of research that is being conducted and the impact that this cutting edge research can have on our own lives and those of others. We can think of ourselves as leaders who exercise sound judgment and provide congruent leadership that is reflective of a Kingian perspective through moral decision-making in our personal and professional lives.

Finally, 40 years later, we can continue to accept the challenge made by Dr. King to his generation when he asked, "What are you doing for others?" By taking a leadership role in our "beloved community," we can ensure that the kind of research we undertake and oversee is for the betterment of humankind, the environment, and future generations.

Research Administration in History: The Development of OMB Circular A-110 Through Joseph Warner's COGR Subcommittee, 1976-1979

Phillip E. Myers, PhD
Director, Office of Sponsored Programs and Director of Administration
Western Kentucky University Research Foundation, Inc.
Western Kentucky University
1906 College Heights Blvd. #11026
Bowling Green, KY 42101-1026
Tel: (270) 745-4652
Email: Phillip.Myers@wku.edu

Marie F. Smith, CRA
Grant Administrator and Compliance Officer
Cary Institute of Ecosystem Studies
PO Box AB, 2801 Sharon Turnpike
Millbrook, NY 12545
Tel: (845) 677-7600 x202
Email: smithm@ecostudies.org

Authors' Note

Joseph S. Warner was the Assistant and Associate Director of Grants and Contracts at Yale University from 1966 to 1970, and Director from 1970 to 1983. His tenure occurred during the spurt in research and research administration in the 1960s and 1970s. He served two terms on the Committee on Governmental Relations, subsequently known as the Council on Governmental Relations (COGR), an association of research-intensive universities, and he chaired COGR from 1980-81. Yale was a leading research university, and Warner chaired the Committee of Government Relations Subcommittee on Grants and Contracts Provisions to revise certain principles of A-110 prior to his becoming COGR chair. Upon his retirement from the Cary Institute of Ecosystem Studies in Millbrook, New York, where he worked in research administration and other significant capacities from 1983-2006, Mr. Warner reposited the part of his papers about developing Office of Management and Budget (OMB) A-110 with Marie F. Smith, CRA, Grants Administrator and Compliance Officer at the Cary Institute. Mr. Warner gave Ms. Smith control over the papers, and she opted to have the Society of Research Administrators International become the archive for the collection. With SRA's approval, the originals were mailed to Dr. Phillip E. Myers, SRA's Historian/Archivist, for research, writing and cataloging. Ms. Smith joins Dr. Myers in co-authoring this article about the contributions of Mr. Warner and his colleagues. The authors are especially indebted to Mr. Warner for his assistance and perceptions during the research and writing of this article. Upon the completion of this research, the Warner Papers will be reposited in the SRA Archives. This article is based on evidence from the Warner Papers. In most cases the authors have cited the correspondents in the narrative.

Abstract

Research administrators can be assisted in resolving issues with awareness of the critical period of policy formation divulged in the Joseph Warner Papers. He and his colleagues on the Subcommittee on Grants and Contracts Provisions of COGR adopted the philosophy that research administrators needed flexibility and reduced paperwork and costs. Federal principles needed standardization without stifling the diversity that is the strength of American higher education. Of note were attempts to reduce the burdens associated with property and procurement matters. In this and other matters, the subcommittee's federal counterparts respected and cooperated with the erudition of the subcommittee's members about issues that curtailed research administrators from their duties and threatened to raise costs of accounting for federal awards. The subcommittee's goal was to ensure revision of the OMB Circular A-110 after it was first published on July 1, 1976. The COGR subcommittee's successes are causes for celebration and recognition that research administrators' common sense and experience count in shaping federal principles. Thus, this article uses a critical era in the history of research administration to retrieve a new and deeper understanding of A-110 and why the experiences of research administrators and their networks are critical in shaping continual evolution. This knowledge presents a deeper appreciation for principles. All parties in the research effort--scientists, researchers of every discipline, executives, and controllers--need to get this message to continue the necessary work of transforming the vision for the public good.

Keywords: Research administration, professional development, responsible conduct of research, research regulations.

The Warner Subcommittee

Administrators seldom ponder the origins of the documents they use to interpret principles. Research administration developed rapidly beginning in 1948 with the federal government's transition from purely military procurement to investment in academic research. The inauguration of COGR in 1960, along with the proliferation of research administration offices in the 1960s, the growth of federal funding in the era of the Cold War and Sputnik from $405 million in 1960 to $1.7 billion in 1970, made it imperative for research administrators to have a voice in the revision of A-110, the first codification of federal standards to federal granting agencies (Norris & Youngers, 2000). When Joseph Warner's subcommittee arrived on the scene, university central sponsored programs offices were proliferating, and feeling their way with a fierce desire for independence from the federal oversight that had been the norm in the 1960s (Warner, 2008; Norris & Youngers, 2000). They were swept into the issue of federal principles guiding federal agencies, which concerned A-110. This issue characterized the period from the mid-1970s to the late 1980s, which, as Norris and Youngers (2000) explain, "saw the greatest growth of regulation and compliance activity in the research enterprise." In this period the federal government began to play a direct role in assuring that universities fulfilled their responsibilities for handling federal funds, especially because of the phenomenal rate of growth from $2.5 billion in 1976 to $9 billion in 1989 (Norris & Youngers, 2000).

During this surge, the Warner subcommittee worked to assure that the federal principles governing the grants and contracts actions of federal sponsoring agencies were not intrusive and impractical compared to the needs of university research and research administration.

The subcommittee endeavored on behalf of 100 research universities to secure and maintain a positive relationship with the Office of Management and Budget (OMB), which was the link between the universities and the federal sponsors. The OMB knew that COGR was the primary communication link for revisions. COGR's role, then, was to develop a university consensus on the principles for revision and to suggest alternatives for resolutions. COGR's views prevailed most of the time (Warner, 2008).

This activity spanned the initial concern with financial research administration for policy design and proposal preparation. Mr. Warner, as Chair of the Subcommittee on Grant and Contract Provisions, often performed the initial analysis of the A-110 principles under revision. He then transmitted his draft to the subcommittee members. After they responded, Mr. Warner created a summary statement for Reagan Scurlock, the Executive Director of COGR. In this process, Mr. Warner observes that the subcommittee members from research universities brought a "keen understanding and empathy" to faculty research and a desire to protect academic freedom (Warner, 2008).

The pursuits of the Warner subcommittee confirm that research administration has developed quickly over the past 50 years, in response to the rapid development of research and supportive technology. Knowledge of the origins and revisions of federal principles that govern university-sponsor relationships helps with interpretation and confidence in doing business and in reorganizing research administration offices to better facilitate the needs of researchers (Norris & Youngers, 2000). The subcommittee's pursuits manifest the goal that COGR's mediating function has always been the education of federal sponsors about academic operations and unnecessary burdens (COGR, 2001).

For these reasons, it is instructive to show how Mr. Warner and his colleagues shaped many of the key principles in the 1970s and 1980s, when compliance became a large issue and experienced its greatest growth in the relations among research administration offices, campus structures and the federal government, which was composed of 18 grant-awarding departments. The tipoff came on July 1, 1976, when these departments fell under the initial version of OMB Circular A-110, which Norris (2008) writes was issued "to provide standardized administration of research programs funded by grants and cooperative agreements," with the intent of reducing the burdens of research administrators and the federal sponsors. Implicit in this directive was the idea that more responsibilities were placed upon faculty and research administrators to handle federal awards. This change was prominent compared to the 1960s, when the government took a stronger hand in the administration of research.

The advent of A-110 to explain the maximum requirements that federal granting agencies could put on universities was timely. The mid-1970s witnessed the increased role of research administrators from identifying funding sources and helping with proposals to including negotiations with potential sponsors based on the terms and conditions of awards; and then officially accepting the awards and ensuring compliance with procurement and financial accountability. The question concerned the responsible relationship among the OMB; federal granting agencies for approval authority for purchasing equipment, filing reports, and maintaining auditable financial records; and the universities, which were on the line for compliance. In this mix, university research administrators monitored projects through

closeout to watch for abuses in individual rights and responsibilities; protection of living organisms; and fraud, waste, and abuse. Beyond these new tasks, Norris (2008) explains that research administrators had to begin providing "certification or assurance of compliance with the principles in A-110 and to have institutional policies and procedures in place to ensure compliance." In most research institutions, Norris continues, the sponsored programs director was made the official responsible "for coordinating and ensuring" that the requirements were understood and met.

Therefore, the work of the Warner subcommittee occurred during this rapid professionalization of research administration; and it increased the body of knowledge requirements. To serve these developments, the subcommittee identified the purpose of compliance as not to restrict or obstruct science, humanities, and research for the public good. Its work illustrated that the principles ensured progress through shared responsibility of institutions, COGR and OMB without incurring needless burdens on each group.

Table 1

Members of the COGR Grant and Contract Provisions Subcommittee

Mr. Joseph S. Warner, Chairman, Director of Grant and Contract Administration, Yale University
Mr. Reagan Scurlock, Executive Director, COGR
Mr. Cedric L. Chernick, Associate Vice President and Director, Office of Sponsored Programs, The University of Chicago
Mr. G. A. Frick, Director, Office of Contract and Grant Business Affairs, Purdue University
Dr. G. R. Holcomb, University of North Carolina
Mrs. Margery E. Hoppin, Director, Division of Sponsored Programs, University of Iowa
S. A. Kimble, Administrator of Sponsored Programs, Georgetown University

Politically, Warner's subcommittee constitutes part of the roadmap to freedom in a democratic society. Freedom does not equal license. Too often people interpret, approach, and think of the principles as being obstructive. This was a critical period because with more decision-making handed over to research administrators they had to become more professional in their work with both sponsors and researchers. Research administration practices were formed by these dedicated professionals and federal officials and their cooperation and understanding.

The Subcommittee's Arguments

The subcommittee's philosophy was minted on behalf of research administrators to make "uniform standards make sense to the institutions affected." Its goal was for "one set of

requirements in lieu of a multiplicity of sometimes very different rules . . .” The standards had to “1) advance the public interest,” and 2) be acceptable to the institutions to which the rules applied. Moreover, they must be “reasonable and able to be implemented and complied with without major disruption or cost.” With this view, Joseph Warner and his colleagues counseled the government that the time had arrived to remove outdated administrative principles and to “refine, clarify or streamline those which are necessary but cumbersome . . . and to simplify and consolidate whenever possible.” To ensure uniform standards, Warner’s subcommittee wanted to ensure that universities would not have to separately negotiate provisions that were satisfactory to them (Warner, 1975, March 10).

Yale University’s comments on the proposed A-110 reflected the goal of standardization and streamlining, and typified the subcommittee’s concerns. Mr. Warner was concerned about the definition of “subrecipient” and “substantive work.” His comments questioned why separate bank accounts had to be used to reduce administrative burdens and costs. The comments questioned why nonexpendable property records, which were not being maintained for items acquired under grants, had to be maintained because of the cost. Why was there “such a long retention requirement for property records,” and what is meant by “three years after its [a piece of property] final disposition,” while the cut-off for other records was three years? Yale’s comments held that “The rights granted the government are too broad” concerning subrecipients. They should not be vendors or suppliers but only public or private institutions receiving federal funds through a recipient as payment for a cooperative project. Moreover, access to books, documents, papers and records was too broad and should focus on material per specific program. Also, Mr. Warner questioned why technical and financial reports had to be sent together. His argument was that the financials were prepared and certified by university financial affairs staff while the technical reports were written by the principal investigators and read by program officers rather than program financial staff, who were not interested in the technical reports. If needed, he continued, program officers could obtain financial data from counterparts (Warner, 1975, March 10).

The exchange on this point continued until on November 12, 1976, John J. Lordan, Chief, Financial Management Branch, Budget Review Division, OMB, wrote to Warner about the reporting requirements for closeout in A-110. Lordan detected that campuses did not always use the same offices to send out the program and financial reports, as specified by paragraph 4 of A-110. The subcommittee wanted this changed. Lordan clarified that the interagency study team did not intend to have the award recipient submit both reports at the same time. This decision was helpful. Sponsored programs offices often were responsible only for the final project report, while grants and contracts accounting offices were responsible for the final financial reports. Neither office should have been expected to synchronize its efforts. Especially in larger research universities, such coordination was difficult. The subcommittee believed that the best solution was to remove the simultaneous reporting principle in A-110 (Warner, 1976, March 8).

By the end of 1976, Joseph Warner’s Subcommittee worked on other “serious wrinkles” in A-110 (Warner, 1976, November 8). Attachment N (Property Management Standards) aimed at helping research administrators be compliant. Mr. Warner noted that the numbered paragraphs dealing with different kinds of property were not “segregated and identified clearly enough.” To alleviate this problem he took the advice of his colleagues on the subcommittee that major headings be centered and capitalized, and that the “most troublesome portion of the Attachment was non-

expendable personal property," which needed clearer language. He stated that property purchased under a federal grant remained with the grantee. (Here is the origin of our present day policy of keeping the equipment on the campus to foster research after the funded project is completed.) If the campus no longer needed the equipment, or it was outdated, the campus could dispose of it without the approval of the Federal agency if the property had a unit cost of under $5,000. Mr. Warner did, however, agree with the OMB that federal agency approval was still needed to dispose of property of over $5,000. He also suggested that A-110 be changed to read that any "residual inventory" from grants could be used without reimbursing the government. To reduce paperwork, the Warner Subcommittee recommended that the definition of non-expendable personal property be raised to $500 and a useful life of two years instead of $300 and one year. OMB approved the subcommittee's recommendations, and A-110 was amended. This action was the beginning of the movement toward the present definition of equipment, which is $5,000. The subcommittee's work underlined today's principle that federally funded equipment vests with grant recipients (OMB, 1999).

COGR, the NSF and the Human Factor

In December 1976, Reagan Scurlock, Executive Director of COGR, sent a memo to the subcommittee about the NSF Grants Policy Manual (GPM), which was then about to be published. The subcommittee's task was to isolate deviations from A-110 prior to the GPM's publication in the Federal Register. Mr. Warner noted that some of the subcommittee's recommendations had not been entered into the draft GPM, specifically, the recommendations concerning use of consultants and on- and off-campus indirect cost rates policy. The NSF assured Mr. Warner about the inclusion of these amendments in the final draft. Other subcommittee comments concerned preventing commingling personal and grant funds. Moreover, the NSF's cash transactions report needed more justification in lieu of the SF 269 and 272 being the standard set by A-110. The timing of performance and fiscal reports was thought by the subcommittee to need more justification before the A-110 requirement that they be submitted simultaneously could be waived. The subcommittee supported the three-year records retention provision of the NSF. The NSF adopted the subcommittee's recommendations, as seen by the use of SF 269 and 272 today. This action was a compromise between COGR and OMB because A-110 continues to instruct federal agencies that they may use the "Remarks" section of SF 269 if they deem that more information is needed (OMB, 1999, Subpart .52 (1)(iv) and .52(b)(1)).

These subcommittee and COGR successes demonstrated that there was mutual understanding that the university leaders should write the revisions of A-110 in simple and clear language for research administrators. Work on the revision of A-110, issued on July 30, 1976, began with a closed meeting of Joseph Warner's subcommittee and Palmer Marcantonio of OMB on October 21, 1976, to discuss the final (July 30, 1976) version of A-110, about which research administrators had already raised issue to COGR. In the spirit of cooperation and producing acceptable outcomes evidenced with the NSF GPM, Mr. Marcantonio said that any further revisions would be first referred to COGR before exceptions were granted. Since "unit cost" provisions of A-110 were burdensome, OMB wanted the subcommittee to suggest revisions. The subcommittee lost no time in explaining to Mr. Marcantonio that it needed to revisit the section (5.b of Attachment G) that allowed OMB to approve additional financial reporting forms from those sent beyond A-110's standard. Mr. Marcantonio said that COGR would be contacted to

provide advance comments about exceptions. He further stated that OMB did not intend that technical and financial reports be submitted together. Mr. Marcantonio thereby clarified the NSF Important Notice No. 62 that required these reports be transmitted together as of October 1, 1976. Furthermore, the subcommittee objected to the government trying to standardize the definition of property acquired under grants and contracts because the provision was difficult for research administrators to administer. Mr. Marcantonio asked that the subcommittee's suggestions to improve A-110 be sent to OMB for incorporation in future revisions (Warner, 1976, October 21-22).

Joseph Warner contacted the subcommittee to write the revisions. He explained to his colleague at Georgetown, Sam Kimble, that "Recognizing the futility of assigning this task to a federal employee," Palmer Marcantonio at OMB had suggested that COGR write the first draft of "a re-write" for subcommittee consideration. Mr. Warner supplied direction to Kimble by asking that vague words like "exempt" and non-exempt" property be removed "in favor of words which have meaning." Furthermore, the draft should be concerned only with government property instead of all property purchased with federal funds under a grant or contract, to remove some of the burden from universities for property accountability. The definition of a piece of property, Mr. Warner advised, should be increased from the threshold of $300 to $500 to further reduce work and expense. He believed that the property threshold was "the most troublesome of all the standards, . . ." Thinking of the coming holidays, Mr. Warner gave Mr. Kimble a deadline with "If possible, I'd like to enclose our suggestion in a Christmas card to Palmer [Marcantonio at OMB]" (Warner, 1976, November 3).

Mr. Warner's assignment to Kimble stimulated the work of others on the subcommittee. In early March 1977, Mr. G. A. Frick, Director of the Office of Contract and Grant Business Affairs at Purdue, sent his review of the proposed implementing instructions for A-110 that the NSF had published in the Federal Register in January. Frick's comments were part of a subcommittee report for Reagan Scurlock at COGR. Several of his points stand out. First, he was concerned with the use of the phrase "Federal financial assistance for the performance of research or other science projects," which he thought might give the impression that federal agencies were making gifts to universities for research projects. Second, Mr. Frick noticed that federal agencies "used different terms to identify the same thing." The NSF used "grantee, awardee, and performing organization," and "standard and continuing grant;" the Energy, Research and Development Administration (ERDA) used "grantee" and "discrete and continuing grants"; A-110 used "recipient" of funds. A-110 did not require standard terminology, but Frick recommended standard terms. Third, the NSF wanted to approve use of grant funds for consultants, which exceeded A-110 and A-21 requirements. Fourth, Frick commented that sponsor budget approval that contained consultants was enough approval. Fifth, he noted that A-110 did not require equipment certification for nonexpendable property such as the NSF required. Sixth, Frick believed sponsor approval on revised budgets was too high at the $10,000 or 10 percent marks. He wanted a revision to 10 percent or $3,000, whichever was higher. He also wanted a revision to permit allowable post-award costs obligated prior to the 90-day post-award technical report deadline. Seventh, Frick pointed out the discrepancy that A-110 required financial reports quarterly but that the NSF required the reports within fifteen days after the recipient received the Federal Cash Transaction Report. He suggested that the reconciliation be the NSF deadline of 15 days. Eighth, he recommended that equipment with a useful life of over a year be defined as

being $500 or more per unit per Cost Accounting Standards Board guidelines. For the university researcher, Frick also made the point that researchers should be able to purchase items according to new needs discovered during a project, to better accomplish objectives (Warner Papers, Frick, 1977, March 4).

Sam Kimble's report about A-110 property management was sent to Mr. Warner on January 18, 1977, with his remark that: "I may have been too cautious in the proposed revision to suit some subcommittee members. What I tried to do, however, was suggest some things that [Palmer] Marcantonio might be able to accept and sell within OMB and to Federal Agencies." His comments on Attachment N to A-110, Property Management Standards, called for segregating and identifying clearly by centering headings such as Definitions, Real Property, Non-Expendable Property, Expendable Personal Property and Intangible Property. He found Non-Expendable Property the most onerous; and he suggested that this property type be identified as property "furnished" to the recipient by the government rather than being paid for by the recipient and title remained with the government. He wanted to delete the term "Exempt Property," which was acquired at least partly with federal money to enable recipients of federal funds to keep this property as long as it was useful. At that point, the property could be used for other research or instruction. His revisions aimed at reducing costs for maintaining inventories when research universities had hundreds of federal grants active. Moreover, Mr. Kimble noted the difficulty in defining the amount of residual inventory of expendable personal property at closeout. He recommended that, unless a federal audit showed that the recipient stockpiled this property, any residual property could be used free of government controls or reimbursements. Finally, he continued the subcommittee's position to reduce burdens that the definition of non-expendable property be revised at the threshold of $500 instead of $300 and a useful life of two years instead of one year. This change conformed to Cost Accounting Standards Board (CASB) standards, "which are widely applicable to such a variety of organizations" that research administrators could safely use (Warner Papers, Kimble, 1977, January 18).

In addition to the concerns of Kimble and others about Attachment N on property management, another area that concerned the subcommittee was Attachment O on procurement standards. Mr. Warner wrote to Mr. Neil Markee, Executive Vice-President of the National Association of Educational Buyers (NAEB), to comment on the attachment. Mr. Warner identified this as an area that was still "troublesome" since the initial issuance of A-110 in July 1976 because some "university people (not procurement types)" found parts of the attachment "objectionable, while others have no trouble at all." Mr. Warner explained to Mr. Markee that his "goal was to remove as many of the difficult areas as possible." He requested that Mr. Markee poll the procurement community on behalf of the subcommittee, where issues had been raised. Specifically, Mr. Warner identified areas for comments. First, university fund raising "should not be precluded." Second, there needed to be clearer language about whether preparers of procurements were excluded. Third, he asked about the feasibility of requiring price or cost analysis for procurement. He explained that once NAEB's comments were received, they would be sent to OMB. Mr. Warner sent this same request to Mr. Eric Bergmann at the National Association of Purchasing Management for comments. Mr. Warner justified these requests even though A-110 was published in final form because Palmer Marcantonio of OMB had agreed to consider changes from the university community. Mr. Markee's request for comments from his organization went out immediately, on February 17. He stated: "we may have one more chance to get changes . . .

according to Joseph Warner," and he requested that the NAEB's membership comment directly to Mr. Warner (Warner Papers, Warner, 1977, February 14; Markee, 1977, February 17).

W. E. Donaldson, Director of Purchasing at Texas A & M, received Mr. Markee's request for comments and responded four days later to Mr. Warner. He believed that Section 3 of A-110 was trying to establish "an ethical standard" for grantees to prevent institutions from using "economic leverage provided by purchases from federal grants to extort contributions from suppliers." Mr. Donaldson believed that this objective could be accomplished without federal interference with "legitimate university fund raising activities." He suggested that the language be modified to state that grantees should not "solicit or accept gratuities, favors or anything of monetary value from contractors . . . for . . . personal use . . ." Second, Mr. Donaldson requested the deletion of Section 3b and substituting the mechanism of a conference call between purchaser and potential contractors to review specifications that might restrict competition. Third, he believed that granting agencies could require justifications for procurements for sole source equipment, which was already being done at many institutions. Fourth, since A-110's requirement for cost analysis took expertise and consumed time, only equipment over $10,000 should require this scrutiny, especially since the competitive bidding system satisfied the price analysis requirement in A-110. Fifth, Mr. Donaldson pointed out that the regulation was impractical in that it was difficult and time consuming to demonstrate that traditional research items such as centrifuges be fully used before additional items could be purchased from a grant. Donaldson's points were reinforced in a letter to Mr. Warner from Robert S. Mullen, Director of Purchases and Insurance, at Harvard. Mr. Mullen explicitly stated today's procedure, that under no circumstances should contractors be allowed to write their own contract for bid in lieu of purchasing departments (Warner Papers, Donaldson, 1977, February 21; Mullen, 1977, February 28).

Purchasing directors at several other research institutions also argued for flexibility in the bidding process. They objected to prior federal approval for sole source contracts with an aggregate expected expenditure in excess of $5,000, and they objected to procurement records for purchases in excess of $10,000 being required to document the basis for contractor selection, justification for the lack of competition, and the basis for the price or award from the contractor. The directors of purchasing made a further point about favoritism. Their approach was not the motivation for communicating with contractors prior to purchase. Many times, as equipment specifications became more technical, institutions needed to obtain specifications from contractors to help write a cogent bid. This action, the purchasing agents argued, did not amount to favoritism (Warner Papers, Morrell, 1977, February 25).

Several changes to the NSF's approval procedures were suggested about a month later by Mr. F. H. Taylor, the Deputy Controller at the California Institute of Technology. He noted to the NSF Division of Grants and Contracts, with copies to Mr. Warner and Mr. Scurlock, that the new NSF GPG of January 31, 1977, needed revisions in areas of "various approval requirements" that were not in A-110. First, consultants should not have to be reported until the post-award stage. Second, since A-110 did not have the principle for federal agencies to keep detailed records for exempt property, the NSF should not do so either; and CASB standards should be used by awardees to "avoid a double set of books." Third, Mr. Taylor requested further scrutiny on a number of provisions in the GPG to alleviate the creation of "internal papermills which will serve no useful purpose in the practical purpose" (Warner Papers, Taylor, 1977, March 11).

Mr. William A Stolfus, Assistant Vice President for Finance at Colorado State University, at the same time reminded the NSF that flexibility in exercising basic research grants was essential. In that regard, the NSF plan to have financial reports at each time period should be deleted in favor of only a final project financial report. He stressed that basic research was an estimated endeavor, and that the original approved expenditures might change based on changes that principal investigators frequently had to make to the research plan as they discovered ways to improve the original scope of the project. Thus, the principal investigator could over- or under-spend during the time periods, but a balance would be struck in the budget by the end of the project. "If one aspect of the research proved non-productive he/she could stop pursuing it and use the balance of these funds to pursue further an aspect that was proving productive." Mr. Stolfus reiterated the concerns of his counterparts at other institutions that requiring 15 days to complete and return reports was unreasonable. He was more conservative than others in requesting not more days, but 15 days after receipt of the notice for a report. Not as conservative was his comment on overbudgeted expenditures. He objected to the planned NSF requirement to give early warning about expected underexpenditures as "self-defeating from the standpoint of the government." He believed that this requirement "will encourage search for expenses to use up funds" to avoid having to give this notice. Moreover, Mr. Stolfus asked the NSF to rethink its cost sharing line on its financial report to allow for an "institutional or aggregate cost sharing arrangement." He noted that other federal agencies agreed. Nor should institutional cost sharing reports require a paperwork burden, which also could overburden the NSF. In sum, the NSF should not require a ratio of cost sharing to project amount in proposal documents, the award document, the university grant administration documents, and the final financial report of projects. "Multiply this by hundreds of NSF projects and the cost is astounding as compared to the benefits." Finally, Mr. Stolfus wondered whether institutions could refuse to turn over records to a granting agency. If this were done, who would pay for assembling and transferring these records (Warner Papers, Stolfus, 1977, March 8)?

As these comments show, there was close cooperation between the NSF and Joseph Warner's subcommittee after A-110 was implemented in regard to the GPG. COGR's position had been to oppose deviations from A-110 principles. The NSF cooperated in approving COGR's changes to the GPG to conform to the A-110 principle that Federal agencies could not require financial report more often than quarterly or less frequently than annually, with a final reports at the end of the project (OMB A-110, 1999). Then the NSF asked to deviate from A-110 to obtain projected financial data from awardees. Subcommittee members believed that the NSF was not requesting a deviation, since Attachment G permitted such a request; the subcommittee believed that the data could be reported without a burden, and OMB was informed. In this matter, one subcommittee member, Allen J. Sinisgalli at Princeton, explained his view that the NSF was trying to keep things simple. "What a relief" he wrote, "We should sometimes help our friends." (Warner Papers, Frick, 1977, December 12; Scurlock, 1977, December 12; Sinisgalli, 1977, December 12).

United States Department of Agriculture (USDA) Issues

In comparison, proceedings were not so smooth with the USDA, which threatened not to use A-110 for some of its agencies. Subcommittee member G. A. Frick at Purdue pointed out to Mr. Scurlock that USDA had requested that its State Extension Service programs be granted an

exception from the fiscal reporting requirements of A-110. This was an issue that could spread to other divisions in the USDA that funded grants and cooperative agreements. Mr. Frick informed Mr. Scurlock that the good news was that the Agriculture Research Service (ARS) and the Cooperative Science and Research Services (CSRS) within USDA had agreed to comply with A-110 because these two divisions had "always attempted to operate within their own guidelines and to ignore standard University practices and procedures . . . for the administration of grant and contract programs." Frick remarked that if the exception applied only to State Extension Services it could be made, but an exception should not be made for the other USDA divisions because "an approved deviation for formula type funds [to the state governments] should not provide the wedge that opens the door for additional deviations throughout the USDA, particularly for CSRS and ARS contracts, grants, and cooperative agreements (Warner Papers, Frick, 1977, March 10)."

While these matters remained unresolved, in 1978, the USDA was granted a deviation from the cost sharing and matching requirements of A-110. This deviation meant that it was not required to use the indirect cost provisions of A-21, which continues today (Warner Papers, Lordan, 1977, March 13).

Issues with Department of Health Education and Welfare (DHEW)

At the same time the deviation issue arose with the DHEW and other federal agencies issuing individual regulations drawn from A-110. COGR's view was that there should be one standard set of principles because federal agencies could not supersede A-110 without its consideration and that of the grant community. This recommendation was important because the university community seemed happy with A-110 after nearly a year of implementation. Thus, DHEW's desire to issue its own regulations kit based on A-110 brought a cooperative response from the subcommittee. Margery Hoppin of the University of Iowa, for example, wrote Scurlock in response to questions raised by Sam Kimble and Cedric Chernick: "I think we could live with the document as it is now without raising too much fuss about those clarifications that still have not been written in." Ms. Hoppin referred to several issues. First were records subject to audit. For example, A-110 was "silent," she wrote, on human subjects records and the Buckley Amendment of 1974 to protect students' privacy. She did not believe that such records would be called for; and certainly, if they were, the personal medical records of human research subjects could not be released without their consent. She thought that the government position of replacing equipment with "needed" equipment as research unfolded was "rigid," but "in certain circumstances was understandable to prevent flagrant abuses." Nor did she think that the A-110 principle that DHEW was allowed to transfer equipment to another institution within 120 days after a project closed was worth revision because over the "long haul" these matters between universities balanced each other out, and "it is quite essential that researchers going to new institutions have the right to take the equipment that they need to continue their research (Warner Papers, Hoppin, 1977, November 30)."

Writing from Georgetown, Sam Kimble was more wary than Ms. Hoppin. He was "disappointed" about DHEW's desire to revise A-110. He wrote Mr. Scurlock that he "despaired" that DHEW had not made the principles mandatory for all of the federal departments whose "operating agencies" and "individual granting programs" could "issue their own regulations,

manuals, and policy interpretations," which, he observed, could vary from DHEW in significant respects. (The DHEW contained the NIH and other agencies, and it was the largest grantor of federal dollars.) Kimble commented, "We are right back almost where we started with non-uniform requirements even within a single [federal] department." Moreover, he pointed out that the operating requirement by individual DHEW units such as the NIH and the Office of Education would not be subject to public comment prior to implementation. He worried that research administrators and researchers might be in for surprises. To resolve this issue, Kimble suggested that some regulations from unit to unit might be indicated because of "legal requirements; and the DHEW should create a system to incorporate the variations as addenda to A-110 to maintain one set of regulations in one document. This incorporation, by law, would enable public comments; and COGR should make strong efforts to get this problem resolved." In addition, Mr. Kimble pointed out that the DHEW had not dealt with disposal of program income from grants. Steps had to be taken to streamline this issue to prevent a negotiation each time the DHEW awarded a grant. The DHEW was also unique, he observed, in being the only federal agency to require grantees to submit audit reports at closeout; he suggested that COGR should urge deletion of this requirement. Joseph Warner, Cedric Chernick and Margery Hoppin also were copied on this analysis, and read that Kimble found it objectionable under 74.164(g) that allowed granting agencies to require universities to obtain prior federal agency approval for all sole source and single bidder contracts of over $5,000. This rule threatened to delay awards and paperwork for no good reason (Warner Papers, Kimble, 1977, November 30).

MIT's Vice-President for Financial Operations, Stuart H. Cowen, embellished Mr. Kimble's outlook. He wrote Joseph Warner that OMB had not approved NASA's deviation from A-110 by continuing to require monthly financial forecasts, which would be "quite burdensome." Mr. Cowen referred to a circular to all NASA grant recipients of December 2, 1977 that recipients had to put a "detailed listing" of "estimated cash requirements by grant or contract for each of the four months" in the remarks section of the SF 272 to keep monthly records of cash accruals to ensure the issuance of checks through the Treasury. Mr. Warner noted in the margin that he was contacting George Northway to draft a COGR letter on this issue (Warner Papers, Cowen, 1977, December 21; O'Brien, 1977, December 2).

With the NASA issue unsettled, Margery Hoppin, acting on behalf of the subcommittee, wrote to Reagan Scurlock at COGR, a summary memorandum about the DHEW's proposed revisions to A-110, particularly in the area of property purchased by grantees. While she believed that DHEW should be "complimented for the thoroughness of the proposed regulations, for exercising liberal options, and for its position on the replacement of property," which helped clarify the circular, she evinced reservations about the wording on property. First, DHEW officials could decide on deviations, but that should not be done without OMB's final approval and public comment through the Federal Register. As a research administrator, Ms. Hoppin saw the difficulties in the property subpart of A-110 as the DHEW had stated the requirement. She remarked: "There are hundreds of individuals [research administrators] in colleges and universities who initiate, approve, or review transactions of this kind that should know what the rules are, but who cannot possibly be adequately informed or trained for that purpose. There is something wrong with a Federal policy relating to property that requires almost three and a half pages of fine print to prescribe!" She continued with the contradictions in the subpart: agencies "tightly control" property purchases from grant funds, universities use this property for

the public good rather than "private gain," and the federal agencies rarely ask for property to be returned. These contradictions heightened concern. She further commented that the DHEW revision contained regulations that went beyond A-110: patients' medical records should not be made available without their consent; potential expenditures from program income should not be negotiated between the grantor and the grantee, and the three-year rule of charging program income to grants should be deleted; federal collection of unit cost data from grantees served no useful purpose and required institutions to erect elaborate systems to keep these records by function rather than expense class; audit reports sent to the federal granting agency at the close of each grant served no purpose and should be maintained in the institution's grant files with, Joseph Warner penned in the margin, a copy to the audit agency. Moreover, Ms. Hoppin pointed out that institutions should be able to have flexibility to trade property for a needed item. What she meant is that when one company makes infrared spectrometers and mass-spectrometers, and will value the old item in trade toward the cost of the new model, that transaction should be allowed. Nor did she believe that the DHEW revision to put a "blanket reservation" over the authority to recover or transfer equipment was in line with the intent of A-110. Ms. Hoppin recommended simplification of property standards by the DHEW, revising its proposal to "prescribe that this option will not be exercised by any granting agency except with the concurrence of the grantee, and permit a deviation from this policy only on a case by case basis" after OMB approval (Warner Papers, Hoppin, 1977, March 3; Scurlock, 1977, November 16).

The issue between the government and the university research administrators was one of mutual understanding. That was a challenge because the latter group wanted streamlining and a reduced work burden as external awards increased and it became more difficult and more expensive in human and material resources to monitor all of the awards (Warner Papers, Hoppin, 1976, December 28).

Mr. Warner summarized the criticisms of DHEW in a letter to the agency. First, he urged deletion of the requirement in DHEW's attempt to amend A-110 that program income be spent in three years from the end of the grant. Second, he wrote that it was "inappropriate" for DHEW to require copies of internal audit reports because this action went beyond A-110 requirements. "Such reports are for internal management purposes," Mr. Warner wrote. He not only mounted the criticism, but he suggested a remedy, which is in practice today. That is, he anticipated the paperwork reduction act (GPRA) when he suggested federal agencies could request audit reports if the need arose. Mr. Warner urged that the 15-day turnaround time for the report of Federal Cash Transactions needed to be increased to 30 days. Moreover, the Yale research administration director requested of DHEW that federal agencies be specific in their reasons for requiring such data with the increased workload this measure put on institutional accounting. More thought needed to be given to the benefits and weighed against the costs. Concerning the disposition of property after a grant, Mr. Warner wrote: "Subpart N [of DHEW's planned amendments] outlining property standards is virtually incomprehensible, a fault inherited from the A-110 attachment after which it is fashioned." COGR, Mr. Warner continued, "strongly" supported the provision of A-110, making it possible to trade old equipment for replacement items. He also raised the question about whether the public interest was best served by requiring grantees to repay the government for depreciated value of property. Under this amendment, institutions could end up paying back more than the original price of the property, especially when it came to equipment. He emphasized that institutions were non-profits in most cases, without the

money to pay the government for the continued use of the equipment for the public good. If DHEW agreed, Mr. Warner requested that the agency inform OMB and delete its requirement of charging the federal share for maintaining property records. He further said it was normal for institutions to solicit and accept gifts from contractors as part of fund-raising, and that the DHEW-proposed regulation should allow the activity. Mr. Warner applied the same reasoning to institutions being able to acquire specifications from potential contractors to inform bid writing by institutional purchasing agents. With precise logic he wrote: "It may be impossible to attract essential contractors to contribute their expertise during developmental stages [of a bid] if they know that such work will rule them out for follow-on work." Finally, many equipment items were ordered from catalogs or off the shelf and did not require negotiation with vendors. This clause needed to be clarified to that effect (Warner Papers, Warner, 1977, March 7; Ryan, 1977, March 9).

The work of Warner's subcommittee succeeded in the procurement arena. DHEW was granted a deviation from the procurement attachment in A-110 to approve requests from grantees to permit contractors who helped development specifications for institutional bids to compete for the contracts (Warner Papers, Lordan, 1978, March 13). Moreover, DHEW's request for a deviation from financial reporting in A-110 was denied. Grantees did not have to report expenditures by object class. In sum, the OMB granted the only DHEW deviation to the Office of Education (then known as OE) on a matter that COGR had argued was outside the realm of research administration, as it is today. The OE was permitted to use a new combined fiscal operations/application form for its College Work Study and Supplemental Educational Opportunity grants (Warner Papers, Lordan, 1978, October 17).

Warner's "Touch" and the Successes of His Subcommittee

As disclosed, by the fall of 1978, property standards required in A-110 were the remaining point of contention between COGR and OMB. The issues discussed earlier in this article had been taken care of in favor of COGR, reducing much frustration (and paperwork) for research administrators. The property accountability difference had to do with A-110's continuing to hold grantees accountable for equipment after grants end and the equipment became outdated and was being used, for instance, for instruction. The subcommittee recommended a further revision of A-110 to delete such reporting, which was a burden on grantee accounting practices. Once a grant was over, grantees should have no responsibility for reporting on where equipment purchased under a grant was located or what it was being used for. Mr. Warner prompted Reagan Scurlock to contact John Lordan at OMB with this suggestion. In obliging Mr. Warner, Mr. Scurlock wrote: "The central point we wish to make now is that as agencies implement these standards universities have to decide what to do. One is to ignore the requirements and hope that no questions are asked. The other is to spend the money needed to come close to compliance, and watch the overhead rate climb as the faculty's faith in rational judgment declines yet further." Thus, Mr. Scurlock recommended that A-110 be revised (Warner Papers, Warner, 1978, September 22; Scurlock, 1978, September n.d.).

On October 5, 1978, Mr. Scurlock's letter from COGR was sent to Mr. Lordan at OMB with several requests for revision. The COGR leader remarked: "I would observe that A-110 is a helpful and beneficial tool which has simplified and standardized many aspects of the

government-university relationship. Also, it is slowly reducing the variety of agency solutions to the same problem." He complimented George Northway for coordinating the waiver requests because waiver approvals had been limited to "two instances where unique and compelling situations were shown to exist." The differences that remained, according to Mr. Scurlock, had to do first with property. He requested revision of A-110's Attachment N "Property Management Standards" to delete $300 as the minimum cost of the definition of property and an increase of that definition to $1,000. Moreover, he wanted simplification of the subsequent use of real property purchased under federal grants in 3b and 3c. On this issue, Mr. Scurlock remarked that COGR had been "strongly opposed from the start" to the concept of university payback to the government for equipment purchased with federal money. He observed that after the equipment was outdated for cutting edge research it was often used for instruction. There was no sense in paying the government for a "continuing public purpose," and he recommended that this item be eliminated. Finally, Mr. Scurlock pointed out that property records were difficult to split between federal and non-federal funds invested in an overall institutional program; the burden of adjusting records when the grant expires served no use.

In 1977 and 1978, Joseph Warner continued to press Milton Goldberg, the Assistant Executive Director of COGR, to obtain revision of a requirement on which A-110 was silent. This requirement concerned federal agencies taking advantage of the silent provision in Subpart H that the DHEW requirement for internal audit reports exceeded the requirements of A-110. Ms. Hoppin of Iowa had prepared an unsuccessful revision for COGR in March 1977 that requested deletion of the provision; and currently "HEW does not interpret the circulars as prohibiting this requirement; OMB agrees." Mr. Warner commented that agencies should not introduce requirements about which A-110 was silent. The public debate on this issue should continue. Mr. Warner illustrated his point: "Using DHEW's reasoning, the fact that A-110 does not prohibit the provision of free coffee and sauna privileges for federal auditors on our campuses can be cited as justification for requiring us to provide them. I cite this analogy simply to illustrate the lack of substance to the argument." Mr. Warner suggested that internal audit reports should not be automatically posted unless the DHEW got a waiver from OMB (Warner, 1978, November 29). Today's A-110 reflects Mr. Warner's resolution. Internal audit reports are only submitted to a federal agency upon request (OMB, A-110).

As regarding research administration, Joseph Warner's philosophy was that the federal government and the funding recipients should have the same basic goal – the judicious use of public funds to prevent fraud and misuse. With this philosophy, Mr. Warner and his colleagues worked with the federal government to structure regulations that attained this goal in a reasonable, common sense and uncomplicated manner. He agreed with Raymond J. Woodrow (1978) that "Research Administration should be the management for research, not of research," and that not only research administrators need to be mindful of this premise but federal regulations should be structured keeping this basic premise in mind.

Joseph Warner had a reputation of holding a firm line against regulatory encroachments. Because of his tough attitude, Yale was known as a place that would draw clear lines. Much of this crept into COGR positions prepared during the public comment period for new principles because, as

chair of the Grant and Contract Provisions Committee, he drafted the COGR letters. Although the wording changed a bit during the internal review process, readers could generally recognize Mr. Warner's prose regardless of the signatures that ended up on the letters.

Consequences of the A-110 Transformation

In reading the correspondence about A-110, one is impressed by the depth of thought and insight. Mr. Warner's subcommittee worked hard to develop a timeless document to guide research administration. Often research administrators complain that regulations like A-110 are vague and do not provide specific guidance on topics such as effort reporting. However, the committee worked to structure guidelines, not instruction manuals, which were flexible enough to provide guidance to all types of institutions while encompassing a compliance framework that would be broad enough to effect change.

Like professionals in many careers, research administrators have demonstrated the ability to live between the eternity of change and the daily duties of approximation. Like the subcommittee, they realize that they must be mindful of the future while they deal with daily functions. They must tend to both dimensions of these time-sensitive activities (Smith, 2003).

Dealing with this dichotomy was the key learning experience that the subcommittee realized over the years of its coordination with the federal government. Mr. Warner's evidence discloses that research administrators have been empowered to live with change as a positive ingredient. A-110 is an early symbol of the transformation. Almost from its official inception in July 1976, A-110 began undergoing revisions because research administrators refused to accept vague and poorly presented language concerning property, procurement, and financial reports. The subcommittee succeeded in creating a national network to inject flexibility and facility for usability. The work of the subcommittee advanced from experiences not to accept the permanency of federal standards. The members were a lively group. Each believed that revisions were necessary and that they had to be implemented, even if it meant changing a primary standard that had just been published.

The respect that the research administrators responsible for helping pen the circulars had for each other is evident from the correspondence that passed between them. They valued each other's ideas, opinions and knowledge. Their understanding of the issues that were and would become relevant to research administration showed great insight and forethought. As research administrators, we must look to and follow the leadership of our predecessors not only in their approach to research administration but to the teamwork they displayed in laying the groundwork that governs us to this day. As research administrators we owe them our gratitude.

Federal officials at OMB and the agencies should also be commended for their open mindedness and cooperation. They appeared unembarrassed that their primary principles could be revised soon after publication. They agreed with the subcommittee that research administration was a human endeavor governed by human principles. With the subcommittee, these leaders recognized that principles are living documents, and that some subparts will stand while others need to be stated more clearly and functionally. There was a "spiritual sense" in this work, but not of the type that was dogmatic. The spirit at work was one of transformation to a more

professional interworking among all parties, and a growth of understanding of professional needs from both the federal government and the research universities. This merger evolves as experience and technology move the profession to best serve the public good.

References

Beasley, K. L. (2006). The history of research administration. In E. C. Kulakowski and L. U. Chronister (eds.), *Research administration and management* (pp. 9-29). Sudbury, MA: Jones and Bartlett Publishers.

Council on Governmental Relations. (1991). *COGR: Council on Governmental Relations.* [Brochure]. New York: Council on Government Relations.

Norris, Julie. (2008). Overview of Sponsored Research Administration. In Darla Fera and Richard P. Seligman, *Sponsored research administration: A guide to effective strategies and recommended practices.* (pp. 105: 1-3). Washington, D.C.: Atlantic Information Services and the National Council of Research Administrators.

Norris, Julie T., & Youngers, Jane A. (2000). Sponsored programs offices in higher education: A continuing Evolution responding to federal requirements. Washington, DC: Council on Governmental Relations.

Office of Management and Budget. (1976, July 30). *Uniform administrative requirements for grants and other agreements with institutions of higher education, hospitals, and other non-profit organizations.* Washington: Government Printing Office.

Office of Management and Budget. (1993, Revised; 1999, Further Amended). *Uniform administrative requirements for grants and other agreements with institutions of higher education, hospitals, and other non-profit organizations.* Washington: Government Printing Office.

Smith, Marie F. (2003). Embracing the body: A case study of research administration in a small institute. Annual Meeting of the Society of Research Administrators International Symposium, 2003 October 18 - 22; Pittsburgh, Pennsylvania, Proceedings, pp. 216-220.

Warner, Joseph. (1973-83). Papers. Arlington, VA: Society of Research Administrators International Archives.
Warner, Joseph. (1975, March 10). To General Services Administration.
Frick, G. A. (1977, March 4). To Sam Kimble, NSF Implementation of A-110.
Kimble, Sam. (1977, January 18). To Joseph Warner.
Warner, Joseph. (1977, February 14). To Neil Markee.
Markee, Neil. (1977, February 17). To A-110 Mailing List. Possible Modification to Circular A-110, Attachment O.
Donaldson, W. E. (1977, February 21). To Joseph Warner.
Mullen, Robert S. (1977, February 28). To Warner.
Taylor, F. H. (1977, March 11)). To the NSF.
Stolfus, William A. (1977, March 8). To the NSF.

Frick, G. A. (1977, December 12). To Milton Goldberg. NSF Request for Deviation from A-110.
Scurlock, Reagan. (1977, December 12). To George Northway (Financial Management Branch, Budget Review Division.
Sinisgalli, Allen J. (1977, December 12). To Milton Goldberg.
Frick, G. A. (1977, March 10). To Reagan Scurlock, with copies to the subcommittee.
Lordan, John J. (1977, March 13). To Joseph Warner.Taylor, F. H. (1977, March 11). To the NSF.
Hoppin, Margery E. (1977, November 30). To Reagan Scurlock.
Kimble, Sam. (1977, November 30). To Reagan Scurlock.
Cowen, Stuart H. (1977, December 21). To Joseph Warner.
O'Brien, Patrick F. (1977, December 2). To "All NASA Grant Recipients."
Hoppin, Margery E. (1977, March 3). To Reagan Scurlock.
Scurlock, Reagan. (1977, November 16). To Warner, Chernick, Kimble and Hoppin.
Hoppin, Margery E. (1976, December 28). To Reagan Scurlock.
Warner, Joseph. (1977, March 7). To Deputy Assistant Secretary for Grants and Procurement Management at DHEW.
Ryan, J. F. (1977, March 9). To DHEW.
Lordan, John J. (1978, March 13). To Joseph Warner and Subcommittee.
Lordan, John J. (1978, October 17). To Joseph Warner. Mr. Warner copied this memo to his subcommittee
Warner, Joseph. (1978, September 22). To Reagan Scurlock.
Scurlock, Reagan. (1977, September n.d.). To John J. Lordan.
Warner, Joseph. (1978, November 29). To Milton Goldberg.

Warner, Joseph. (2008, June 4). Interview with Phillip E. Myers.

Woodrow, Raymond J. (1978). *Management for research in U.S. universities*. Washington D.C.**:** NACUBO.

Developing Cultural Competence and Overcoming Ethical Challenges in the Informed Consent Process: An Experience from Egypt

Ibrahim Adib Abdel-Messih, MD, MPH, DrPH (cand)
U.S Naval Medical Research Unit#3
Cairo, Egypt
Email: Ibrahim.Adib.eg@med.navy.mil

Maged El-Setouhy, MD
Ain Shams University
Cairo, Egypt
Email: maged.elsetouhy@gmail.com

Michael M. Crouch, EdD, MBA
Executive Director, Office for Sponsored Programs
Assistant Vice Provost for Research
University of Connecticut
Tel: (860) 486-8704
Email: michael.crouch@uconn.edu

Kenneth C. Earhart, MD
U.S Naval Medical Research Unit#3
Cairo, Egypt
Email: Kenneth.Earhart@med.navy.mil

Authors' Note

The authors thank the members of the Institutional Review Board at the U.S Naval Medical Research Unit #3 (NAMRU-3), Cairo, Egypt for their continuous hard work in maintaining the ethical standards of research studies at NAMRU-3. The opinions expressed in this paper are those of the authors and do not reflect the official policy of the U.S. Department of Defense or the U.S. Department of the Navy. Address correspondence to**:** Ibrahim A. Abdel-Messih**,** Clinical Trials Program, U.S Naval Medical Research Unit#3, Box 5000, PSC 452. FPO, AE 09835. Email: ibrahim.adib.eg@med.navy.mil

Abstract

Research is conducted in a variety of cultural settings. Ethical standards developed in Europe and the Americas are increasingly applied in these settings, many of which are culturally different from the countries in which these standards originated. To overcome these cultural differences, investigators may be tempted to deviate from ethical standards. To suggest that, without such deviations, the contribution of these countries to medical science would be limited, is misguided.

The argument that research would be impossible without these deviations, which limit the contribution these countries make to medical sciences, is not accepted. To overcome these challenges, it is important for research administrators, managers and investigators to develop the cultural competence that enables them to establish recruitment and consent procedures consistent with cultural, political, and social practices. This paper presents some of the issues and challenges encountered in conducting research in Egypt. It is hoped that, by sharing these experiences, researchers and research administrators will gain insight into the design, implementation, and management of research in different cultural settings.

Keywords: Research ethics, ethical challenges, informed consent, developing countries, Egypt.

Introduction

Research activities are increasing in size, complexity, regulatory oversight, and cost, creating challenges and pressures on the research system. The ethical conduct of research related to health care in developing countries has been the subject of much recent discussion (Benatar & Singer, 2000; Lansang & Crawley, 2000; Bhutta, 2002; Caballero, 2002), particularly with the increase of research in these countries and the need to address their high burden of disease. Special challenges affect the conditions under which this research is conducted, such as sanitation, standards of care, and specific political, legal, and social contexts.

Wherever research is conducted, it must honor the autonomy and dignity of all persons, and fulfill the principles of respect for persons, beneficence, and justice -- the three basic ethical tenets of the Belmont Report. Although these principles were developed in Western societies, they have been widely adopted and play a significant role in research ethics worldwide. Application of these principles to the conduct of research leads to consideration of informed consent, risk/benefit assessment, and the equitable selection of human subjects.

The principle of respect for persons is embodied in the informed consent process, through which subjects, to the degree they are capable, are given the opportunity to choose what shall or shall not happen to them. This principle is honored when the consent process is informed, understood, and voluntary.

When research is justified on the basis of a favorable risk/benefit assessment, the principle of beneficence is honored. Such an assessment addresses the probability and magnitude of possible harm and anticipated benefits. Possible harms, and their corresponding benefits, may be psychological, physical, legal, social, and economic.

The principle of justice is embodied in the equitable selection of subjects, and seeks to ensure that participants neither suffer undue burden nor benefit disproportionately from their role in research.

To apply these principles globally in a way that protects the rights and welfare of subjects, it is essential that researchers have sufficient knowledge of socioeconomic, political and cultural aspects of the local research context. An effective child assent process, for example, requires an understanding of how different cultures define relationships between parents and their children.

Questions that may be considered innocuous in the United States and Western Europe could be offensive elsewhere. Different cultures have different authority structures that influence how researchers address potential coercion.

In this paper, issues and challenges encountered in conducting research in Egypt will be presented to provide researchers and research administrators with insight in the design, implementation and management of research in different cultural settings.

The Egyptian Context

Egypt is a country of about 75 million people, with diverse cultural beliefs and practices. Egyptians are very religious, and religious principles are noticeable in their daily lives. The population consists primarily of Sunni Muslims (about 90%) and Coptic Christians (about 10%).

As an Islamic country bordering the Middle East, Egypt is an Arabic republic. At the same time, as a country of North Africa with a 5,000-year heritage, it is altogether unique. In every major Egyptian city there are traditions carried over from the time of the Pharaohs; other areas retain the tribal customs originated by the many invaders throughout the centuries.

Family ties are strong in Egypt. Egyptian society consists of a mixture of Middle Eastern family values, taken from different religious rules, whether Islamic or Christian. This mixture of values colours Egyptian decision-making in a way that may be difficult for many people in the west to understand. In Egypt, clan obligations unite extended families – grandparents, aunts, uncles, and cousins -- in good times and bad. Clan elders arbitrate disagreements, even those between husbands and wives, and give opinions on topics ranging from farming techniques to religious obligations.

Issues and Challenges

Informed Consent Document Signatures

Populations with limited resources are particularly vulnerable, and the high-risk health conditions under which they live can affect both the researchers' and study subjects' assessment of the risk-benefit ratio (Nuffield Council on Bioethics, 2003). Complex documents and legalistic language make it increasingly difficult for prospective subjects to decide about their participation. Truly independent consent may be limited by cultural context and distorted when populations of limited economic means are offered incentives to participate.

The requirement to document consent through a signature or thumbprint may be difficult for investigators working with culturally diverse populations or with individuals who are socially marginalized or involved in illegal activities. In some areas of the world, both individuals and communities have suffered politically, socially, or economically because they signed "legal" forms that resulted in sanctions against them. Signing a document in some communities is always associated with a major life event, and asking research participants to sign a consent form can imply lack of trust.

Readability and Literacy

Comprehension of information during consent discussions is often influenced by misunderstandings about research. There are often negative connotations associated with the words "investigation" and "study," and a suspicion of "experimenting" or "practicing on my child." In many African languages, there is no word for research or science; the word used is generally the same as the word for medicine. The concepts of randomization and placebos used in clinical trials can be especially hard to explain, particularly when international researchers are working with communities and individuals who may be illiterate.

Influence of Medical Tradition on Consent

In many developing countries, medical doctors enjoy a high status and regard as a particularly knowledgeable group. Patients expect health professionals to make decisions for them and are reluctant to choose when given options about their treatment, as they do not question the medical competence in decision-making about their own care. This attitude is routinely applied to health care research, and can result in reduced participant autonomy. Individuals have limited familiarity with the notion of research and research design and find it unacceptable for doctors to express uncertainty regarding the best option available. This places the principal investigator/clinician at great risk of conflict of interest. In Egypt, it is important to take this medical tradition into consideration.

Influence of Social Structure on Consent

A critical element of conducting research is the process of obtaining informed consent. Sometimes, in non-U.S. communities, people other than the individual taking part in the research may be required to give permission before the potential subject can be asked to participate. These individuals may include a spouse, a head of household, or a group leader. The investigator must design a consent process that honors local custom. However, another individual's permission should not substitute for a subject's voluntary informed consent, unless that consent process has been waived by an Institutional Review Board (IRB) or equivalent local review committee. Unique cultural, religious, and socio-economic factors in Egypt pose many challenges for researchers obtaining informed consent.

Post- Study Communication

Another particularly difficult challenge for researchers in developing countries is what happens when the research is concluded. The Declaration of Helsinki (Principle 30) states, "At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic, and therapeutic methods identified by the study." However, in practice, results are neither communicated to nor discussed with the public. Progress to rectify this issue is desperately needed to ensure concise, accurate IRB study completion standards. In fact, IRBs cannot usually follow up the successive phases of the research and ensure that the succeeding study was properly managed.

Overcoming the Challenges

Understanding and Sensitivity

Research managers, administrators, and investigators involved in international research should have some understanding of, and be sensitive to, the social, economic, and political milieu that affects the context in which their research is taking place. This cultural competence would enable them to establish recruitment procedures consistent with cultural, political, and social practices, while developing sensitivity to the individuality of different cultural groups. Lessons learned from genuinely collaborative efforts in multi-center research could be applied in this context.

Disclosure of information should be sensitive to the local context during the informed consent process, and conducted in the local language, employing culturally appropriate idioms and analogies understandable to prospective participants. This obviously entails a need for collaborative partnership between investigators conducting research and local communities.

Novel Consenting Strategies and Maintaining Voluntary Participation

An experience from Mali (Doumbo & Ogobara, 2005) clearly illustrates the importance of cultural competence. A dynamic approach to obtaining informed consent and to maintaining it over time was developed through a stepwise process. First, permission from the community was sought by a discussion with the group of village elders, who determined that a particular study could proceed. Then focus group discussions were convened with the heads of extended families. Similar discussions were initiated with mothers whose children might become part of the study. Finally, consent of the individual families involved in the research study was obtained. "The consent process was open and better suited to the needs of the population than were more conventional approaches. It generated more confidence by the villagers in the research project and a better understanding for us of the village culture and behavior." the author reported in page 2, second column.

Ethical guidelines for international research offer limited advice on the issue of trust and the need for documentation of consent. However, a number of international guidelines suggest that verbal consent is acceptable when written consent is not feasible, but only when it is properly documented (CIOMS 2002; Council of Europe, 2004; Nuffield Council on Bioethics, 2002, 2005; World Medical Association, 2000; Sims, J. & Kuhnlein, H. V, WHO-CINE Indigenous Peoples and participatory health research, 2003). Audio-taping the consent process or ensuring an independent witness for verbal consent are other options for documentation. When audio-taping is inappropriate or an independent witness is not available, researchers should document in field notes that consent was obtained (Marshal, 2006).

Once subjects have been enrolled, strategies to maintain their voluntary participation need to be considered and reviewed by the IRB. Helpful strategies include additional home visits and educational and social activities. Special consideration and monitoring to avoid coercion is needed in certain circumstances, such as pressure to enroll within a defined period of time, competitive enrollment rates between sites, or payment to the research team for the number of subjects enrolled.

Sharing Information

Local knowledge and the reputation of the research institution influence the decision to participate in the study. Sharing information about the study with credible local organizations – government health services, for example – is important, because the population will check with these sources about the research projects. One way to earn the confidence of the community is to provide medical care while the study is being conducted. In rural regions of developing countries where medical care is limited or nonexistent, the research team must often set up its own clinic. Providing standard care for both study participants and others in the community during a research project where the team is the sole source of medical care can be a form of community compensation. Studies in developing countries should generally guarantee care for volunteers who experience serious adverse events – not only during the study, but after it has been completed. Care must be taken to ensure that the provision of these services does not induce participation in a study that may not be in the community's best interest. This ethical dilemma remains unresolved, and a source for concern. It is often difficult for potential participants to evaluate the risk/benefit ratio of a study. Perceived benefits, frequently including access to good health care, may exert the strongest influence.

Strengthening and Promoting Ethical Committees

The role of IRBs in developing countries should be strengthened and promoted by international institutions to help them resist political, economic, or institutional pressures. This role is strengthened with proper structure and when members' profiles, their independent finance, and their relationships with public institutions are defined.

Adequacy of the Administrative Support for Institutional Review Board/ Informed Consent

It is incumbent upon local investigators to have performed an audit of the resources available for study support. This includes staffing, communications, transport and general access to dispersed study populations. Sufficient resources to address recordkeeping, whether manual or electronic, need to be assured. For example, tailored software is now available for records management of IRB documents. However, the relative adequacy of local financial resources needs to take this into account, and satisfactory alternative means of recordkeeping (and record retrieval) need to be in place.

Focused Training of Research teams

In both wealthy and poor countries, training in research ethics must be enhanced for investigators in all settings, particularly when studies involve participants challenged by poverty or low literacy. Minimally, research team members should be trained to obtain informed consent in a manner that is both culturally and linguistically appropriate. Moreover, capacity building is necessary to insure that IRBs in developing and industrialized nations understand the need for culturally appropriate strategies for obtaining consent to research in international settings.

Studies to Assess Research Understanding

There is an increased need for studies to evaluate subjects' levels of understanding of research components, as well as more systematic investigations on informed consent practices for research conducted in international contexts. Such studies can also evaluate the characteristics of participants and their circumstances that are thought to have a critical influence on informed consent. They will improve our understanding of the process, written information, the experience of subjects and strategies that work best. Comparing data from similar studies in developed and developing countries could also illuminate any differences or similarities in the quality of informed consent in the two settings. Greater attention should be given to the development of approaches and analytical tools for assessing social and ethical challenges to informed consent.

These data will not only give researchers an understanding of how they are doing now, but will also be useful to identify differences in the consent process as it relates to different study populations, study designs, and other factors. It is hoped that through this process, continual changes to improve the consent process by researchers throughout the world will result in better informed prospective study subjects and continued excellence in research. The international research community has to share information and debate questions relevant to ethics of research in developing countries and to foster dialogue on ethical issues among actors in the scientific and decision-making communities involved in medical research, with regard to ethical considerations.

Conclusion

Ethical issues apply globally. The Eastern Mediterranean Region, World Health Organization (WHO) has established basic guidelines for exercising research ethics in the Middle East *(http://www.emro.who.int/his/medicalethics.htm)*. Basic ethical principles are consistent with the rich cultural environment of Egypt. How these principles are applied to research in Egypt must take into consideration the cultural context. Egypt's unique cultural context leads to many challenges that require innovative and creative approaches, some of which are described in this manuscript. Egyptian scientists are eager to adapt and apply the latest scientific advances to their country. Egypt is forming IRBs to support a growing interest in research, and beginning to address its related ethical issues. Egyptian scientists must apply their cultural experiences, must bring in community and non-scientific leaders, and conduct and document healthy ethical discussions about research to find the best methods to adapt global ethical principles into their unique local context. Lastly, these practical experiences and challenges must be shared with other researchers to develop cultural sensitivities among the research community and ensure that the rights of human subjects are protected. Studies to evaluate and assess the level of understanding of research subjects to the research elements can serve as a good monitoring tool.

References

Benatar, S. & Singer, P. (2000). A new look at international research ethics. *British Medical Journal*. 321:824-826.

Bhutta, Z. A. (2002). *Ethics in international health research: a perspective from the developing world.* Bulletin of the World Health Organization. 80(2):114-120.

Caballero, B. (2002). Ethical issues for collaborative research in developing countries. *The American Journal Of Clinical Nutrition*. 76:717-720.

Council for International Organizations of Medical Sciences (CIOMS)/World Health Organization (2002). *International Ethical Guidelines for Biomedical Research involving Human Subjects.* World Health Organization Geneva, Switzerland.

Doumbo, K. Ogobara (2005). *It Takes a Village: Medical Research and Ethics in Mali.* Science: Vol. 307, 679-681.

Lansang, M. A. & Crawley, F. P. (2000). The ethics of international biomedical research. *British Medical Journal*. 321:777-778.

Marshal, P. (2006). *Informed Consent in International Health Research.* Journal ofEmpirical Research on Human Research Ethics: 2006; 1(1):25-42. 30.

Nuffield Council on Bioethics (2003). *The Ethics of Research related to Healthcare in Developing Countries.* Nuffield Council on Bioethics London, UK.

Nuffield Council on Bioethics (2002, 2005). London, UK.

Sims, J. & Kuhnlein, H. V. (2003). *Indigenous Peoples and Participatory Health Research: Planning and Management / Preparing Research Agreements.* Centre for Indigenous Peoples' Nutrition and Environment (CINE) and World Health Organization 2003 World Health Organization Geneva, Switzerland.

Development and Progression of a Model: Prospective Research Compliance Monitoring

Carol Fedor, RN, ND, CCRC
Clinical Research Manager
Center for Clinical Research and Technology
University Hospitals Case Medical Center
11100 Euclid Avenue
Cleveland, Ohio 44106, USA
Tel: (216) 844-5524
Email: carol.fedor@uhhospitals.org

Cristina Ferrazzano Yaussy, MPH
Research Compliance Specialist
Center for Clinical Research and Technology
University Hospitals Case Medical Center
Email: cristina.ferrazzanoyaussy@uhhospitals.org

Philip A. Cola, M.A.
Vice President for Research and Technology
Center for Clinical Research and Technology
University Hospitals Case Medical Center
Email: philip.cola@uhhospitals.org

Authors' Note

The opinions in this paper are those of the authors and do not reflect the official policy of the Center for Clinical Research and Technology, University Hospitals Case Medical Center. Dr. Carol Fedor is the corresponding author. The evolution of the program described in this paper has been an ongoing process, including paper and poster presentations at previous SRA International Symposia. Finally, the authors acknowledge our Research Interns, Stephanie Polites and Lauren Seeds, for their contributions in data entry and assistance with compilation of information.

Abstract

Recent trends in Human Research Protection Programs (HRPPs) have contributed to the rising emphasis on prospective monitoring of clinical research and education programs. Therefore, internal efforts and resources to monitor investigator compliance and site performance have become an important focus in the conduct of clinical research. Once the science and ethics of the research is approved by the Institutional Review Board (IRB), the investigator has the overall responsibility for conducting the research, protecting human subjects, and providing periodic reports and updates related to the research to the IRB. Any potential non-compliance issues that arise during the conduct of the study will be reported to the IRB and potentially prompt decisions about the continuation of the study. Nevertheless, institutions should recognize that

IRB review processes, investigations of noncompliance and prospective monitoring are distinct components within an HRPP. The Center for Clinical Research and Technology (CCRT) at University Hospitals Case Medical Center (UHCMC) recently implemented a prospective monitoring and education program and collected data to evaluate the program's development. Trends associated with resource utilization, monitoring procedures and educational activities of the program will be presented, as well as an analysis of the impact of the program.

Keywords: prospective monitoring, research compliance, responsible conduct of research, research administration

Introduction

More than a decade ago, Weijer (Weijer et al., 1995) called for institutional research compliance monitoring programs for several purposes: education of researchers; prevention of problems; and avoidance of financial loss due to fraudulent research. In 2001, the FDA monitoring program revealed that 70% of human subject protection deficiencies are the result of investigator noncompliance (Wolfe & O'Rourke, 2002). Following the 1999 death of a healthy volunteer, the University of Pennsylvania developed the Office for Human Research (OHR) to assume internal compliance monitoring responsibilities. The focus of OHR was on investigator-initiated studies and moderate- to high-risk research whose mission was "not only to discover possible noncompliance but also to provide the education, tools, and resources to correct noncompliance" (Sherwin & Fromell, 2002). The UHCMC CCRT implemented a comparable approach, emphasizing post-IRB approval monitoring in unison with research education to promote research integrity.

Prior to the development of a prospective compliance monitoring program, investigation of allegations of noncompliance was a burdensome task requiring extensive resources by the UHCMC IRB office. Rather than compromising the effectiveness of the IRB and compliance program by exhausting shared personnel, the CCRT recognized that separate staff with compliance expertise would ensure efficiency of the monitoring program. The CCRT's prior experience also demonstrated that directed monitoring, or monitoring required by the IRB in response to a noncompliance issue, was not an effective or proactive means by which to manage noncompliance. As a result, the Office of Research Compliance (ORC) was created under the quality improvement initiatives for the Human Research Protection Program (HRPP), and was introduced to the research community as research-support services. The ORC applied the Association for the Accreditation of Human Research Protection Programs (AAHRPP) requirements as the foundation for the ORC's Standard Operating Procedures (SOPs). The initial SOP manual summarized the monitoring process, including the categories listed in Table 1.

Table 1
Components of Monitoring Process

Pre-Monitoring	**Monitoring**	**Post-Monitoring**
Protocol selection	Monitoring Visit	Grant and Contract Review and Research Billing
Notification letter to Investigator	Informed Consent Observation	Investigational Pharmacy Evaluation
Scheduling visit, review of monitoring visit requirements		Certification Verification
IRB File Review		Conflict of Interest Assessment
Preparation for Monitoring		Post-Monitoring Letter
Informed Consent Document Review		Follow-up assistance
Pre-Monitoring Interview		

The following factors are considered when identifying priorities for monitoring of clinical research protocols: risk level; study population; whether the study involves treatment or intervention; and whether the study is investigator-initiated, industry or foundation originated, or federally funded. These categories represent factors to classify research conduct that poses greater than minimal risk to participants and may have a lesser amount of oversight by external regulatory monitors.

Congruently, with the development of the prospective compliance monitoring program, research education resources were being dedicated to establish a consistent offering of individualized and interactive education sessions. Beginning in September 2000, institutional programs were developed in preparation for the NIH mandate for investigator certification requirements in Human Subject Protections. Along with the initial core training utilizing the text "Protecting Human Subjects in Research" (Dunn & Chadwick, 1999) and subsequent adoption of the Collaborative Institutional Training Initiative (CITI) core curriculum, institutional seminar series, panel discussions, and workshops were developed, marketed and conducted monthly. The following categories of individuals from the research community were targeted for the research education and training (Table 2).

Table 2
Populations Targeted for Research Education

Principal/Responsible Investigators	Co-investigators
Residents/fellows/graduate students	Research Coordinators/staff
Research Administrators	IRB members

These extensive efforts have successfully culminated in improving the conduct and oversight of research and establishing a program that transformed compliance monitoring into research integrity through principles of research conduct.

Background

The diverse roles of research administrators have become progressively more comprehensive as this discipline moves toward continued professionalization and the conceptualization of research expands to an all-encompassing Human Research Protection Program (HRPP) (Cola, Fedor, & Haffke, 2005). Research administrators are responsible for the legal, fiscal, ethical, and scientific and compliance reviews of protocols from their initiation through completion. In the past, research administrators were regarded primarily as grant or IRB administrators (Cola, Fedor, & Haffke, 2005). In response to recent trends in clinical research and growth of regulatory oversight requirements, the profession has become more encompassing, and research administrators have assumed the roles of grant writers, clinical research coordinators, human subject protection and compliance specialists, and research billing professionals. This professional evolution has lead to increased awareness and understanding of the vital roles that research administrators serve in the conduct of both basic science and clinical research.

A distinct area that has recently gained considerable momentum has been the role of the clinical research compliance monitor. Similar to other academic or business specialties, the process of conducting clinical research is closely monitored. Historically, this monitoring has been performed by external sources (i.e., the sponsor, contract research organization(s), or federal agencies). During the past decade, given the remarkable growth in clinical research, it has become evident that relying solely on external monitoring is inadequate to preserve the responsible conduct of research. Slater (2002) noted that, not only has federal funding for research doubled in the past decade, but from 1997 to 2000, the estimated number of participants in federally funded research increased from 7 million to 12 million. Non-federally sponsored research has grown at a similar pace (Slater).

These trends have driven the desire and need to create internal research compliance monitoring functions in an effort to improve research programs and to provide supportive services to investigators that allow them to conduct clinical research effectively. Some institutions have developed these programs in response to specific compliance findings discovered by external monitoring activities (Steinbrook, 2002). Such shortcomings in human subject protection programs at major institutions should serve as a catalyst for all institutions, researchers and IRBs that are charged not only with promoting clinical advances, but first and foremost, protecting the human subjects involved in the process (Shalala, 2000).

Additionally, the continuing education of research administrators and institutional officials makes it apparent that internal compliance monitoring programs that proactively review the conduct of clinical research at the institution are essential. Research institutions must commit to regular and routine internal monitoring of all research activities. Critical self-examination can bring to light weaknesses and other issues before significant errors occur (Icenogle, 2003).

It is believed that, to be effectively connected to the other critical components areas of an HRPP (i.e., the administrative functions of an IRB and grant accounting), compliance monitoring programs should be established within Offices of Sponsored Projects at Universities and Research

Administration of hospitals based in Academic Medical Centers (AMCs) (Speers & Cooper, 2003, Institute of Medicine, 2001). Research compliance monitoring and education programs are not only a routine function of these types of institutions, but rather specialized functions that enhance the overall research administration effort.

In June 1998, the Office of Inspector General of the Department of Health and Human Services issued four investigative reports, which indicated that IRBs have excessive workloads and inadequate resources (Shalala, 2000). The inadequate resources included insufficient staff, expertise, space, and equipment such as databases.

It is difficult to absolutely ascertain the accuracy and impact of these reports on the behavior of AMCs, however, the information provided has prompted research institutions to define the role of the IRB in greater detail and to expand the scope of programs better designed to ensure the protection of human subjects in research. These programs have been developed by institutions through research administrative offices to provide assurances of their compliance with regulations (Sherwin & Fromell, 2002). Out of these developments, the focus has shifted from traditional research administration toward a prospective compliance and education focused approach.

The fusion of internal monitoring programs and research administration activities into central research offices has also led to the creation of external accrediting bodies for Human Research Protection Programs (HRPPs) (Cola, Fedor, & Haffke, 2005). This may be attributed to the concept that preparation for voluntary accreditation includes a self-assessment of the overall research protection programs, including compliance and safety (Burke, 2005). These programs are often construed as being synonymous with IRB accreditation, however the scope and purpose of such programs goes beyond the operational matters of an IRB and its corresponding administrative office and assesses many more components (i.e., institutional support and understanding; congruence with grant administration; research educational programs for investigators, clinical research coordinators, research administrators, research participants; and research compliance programs). Accreditation must approach the HRPPs broadly from an organizational perspective that is beyond a focus of IRB operations to examine whether policies and procedures of the organization as a whole result in a coherent, effective scheme for the protection of human research participants (Speers & Cooper, 2003).

Efforts aimed at improving HRPPs would be remiss if comprehensive education was not an integral component of the approach. As Shalala (2000) notes, "The never-ending challenge for academic institutions and other organizations participating in research is to make sure that researchers and other personnel have up-to-date training and a thorough knowledge of their responsibilities. Those responsibilities include communicating with IRBs, ensuring that procedures for informed consent are followed, monitoring compliance with protocols, and reporting on safety issues." Comprehensive education efforts for the entire research program at AMCs should be focused not only on facilitating the understanding of federal regulations and institutional policies and procedures, but also on the results of their own compliance activities.

Through compliance activities, AMCs are able to scrutinize the clinical research conducted at their institution, monitor for common non-compliance trends, and identify areas of needed continuing research education. Furthermore, improved educational efforts and compliance activities in conjunction with all components of research administration serve to improve the overall quality of the research, increase the quality of human subject protections, and enhance the efficiency of the IRB (Sugarman, 2000).

This paper aims to describe the development and implementation of a research compliance monitoring program along with the specific research educational support at an AMC. This combination allows for a focus on the role of research administration functions in the responsible conduct of clinical research. The combination of compliance monitoring and education advances research integrity and as a consequence and research administrators are better able to account for and incorporate these activities into their institutional responsibilities.

Methodology

An essential strategy for the ORC was to identify each of the activities involved in research compliance monitoring that would be captured for future benchmarking. Therefore, a database was created to accurately document the time and resource requirements for the entire monitoring process. A monitoring activity worksheet documented the date of the activity, the IRB protocol number, the principal investigator, the times the activity began and ended, and the specific activity that occurred. A Research Compliance Specialist (RCS) recorded and maintained the monitoring activity worksheet and database.

A summary of UHCMC ORC monitoring activities (n=14) is summarized in Table 3. In general, the activities are completed in the order that they are listed, although informed consent observations can occur at any time due to the random nature of participant enrollment. From February 2006 to August 2007, 55 protocols were monitored. For the purpose of this presentation, 49 monitored protocols are included in the summary; 6 were excluded because not all of the intended activities were completed at the time of analysis (August 2007). The sample of monitored protocols included 26 investigator-initiated protocols (23 prospective, 3 directed) and 23 sponsored (federal and industry) protocols (12 prospective, 11 directed). Prospective monitoring refers to a routine, random selection of protocols that have been approved by the IRB. Directed monitoring refers to a review requested by the IRB in response to a protocol deviation/unanticipated problem or compliance issue that is identified.

Table 3
Summary of ORC Monitoring Activities

Monitoring Activity	Examples of the Activity
Administrative	Composing and mailing of initial contact letter to principal investigator; creating compliance monitoring files
Scheduling	Explanation of the monitoring program; scheduling monitoring visit (s)
IRB File Review	Review all protocol submissions (New, Continuing Review, Amendments, Adverse Events, etc.)
Preparation for Monitoring	Review of protocol; copy of informed consent; creating inclusion and exclusion criteria checklist
Informed Consent Document Review	Thorough review of consent document for required and suggested elements
Pre-Monitoring Interview	Interview to discuss the study roles and responsibilities, location where protocol and consent process is conducted, and how and by whom the consent process is implemented
Monitoring Visit	Review of the subject source documents; subject recruitment; informed consent and Health Insurance Portability & AccountabilityAct documents; confirmation of eligibility; adherence to protocol; Adverse Event reporting; data collection; lab tests; research and medical records; all related study correspondence
Informed Consent Observation	In-person observation of the informed consent process
Grant and Contract Review	Review budget; contract status; patient billing; and other study expenditures
Investigational Pharmacy Evaluation	Test article accountability; site of storage; inventory and transaction records
Certification Verification	Review protection of Human Subjects Certification
Conflict of Interest Assessment	Verification of appropriate Conflict of Interest disclosure (if applicable)
Post-Monitoring Letter	Composition of summary of findings for principal investigator
Follow-up	Assist investigators with response, and addressing any findings

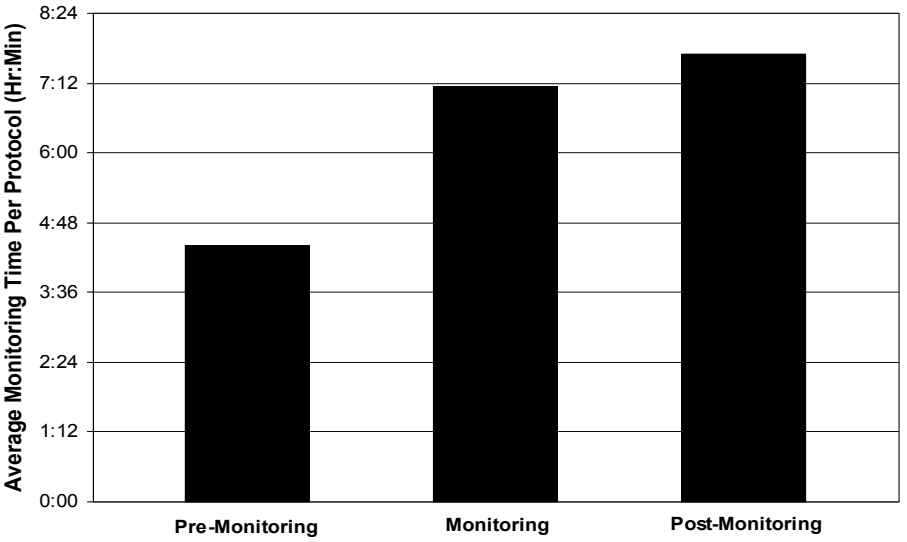
Results

To estimate the required resources for the monitoring program, a projected monitoring time was calculated, including each of the monitoring activities listed above. It is important to note that while a protocol may not utilize investigational pharmacy, monitoring would still encompass review of proper drug or device accountability. The resulting projected monitoring time was a total of 19 hours and 17 minutes. Actual monitoring time was analyzed by determining the average time required to monitor a protocol, which was found to be 17 hours and 15 minutes per protocol (Range: 5 hours 19 minutes to 40 hours 57 minutes). An average of 9 monitoring activities was completed per study.

The monitoring activities were pooled based on the following categories as listed in Table 1: pre-monitoring, monitoring, and post-monitoring. On average, the pre-monitoring phase required 4 hours and 25 minutes, the monitoring visit required 7 hours 9 minutes, and the post-monitoring phase required 7 hours and 42 minutes (Figure 1). The pre-monitoring phase required less than one-fourth of the total monitoring time, while both the monitoring and post-monitoring phases required approximately 40% of the total monitoring time. Of note, the post monitoring letter

that is completed during the post-monitoring phase requires 3 hours and 42 minutes (46.1%) of the total 7 hours and 42 minutes needed to complete this entire phase.

Figure 1
Average time per monitoring phase.



In addition, the time requirements for monitoring were categorized by how the study was chosen: directed versus prospectively selected protocols. On average, prospective protocols required approximately 15 hours and 25 minutes, and directed protocols required 18 hours and 54 minutes to monitor. Further analysis was done using the Fishers exact test to calculate the differences in types of studies and how the studies were selected (i.e., investigator-initiated / sponsored and prospective/directed). The result of this analysis ($p = 0.01$ two-tail) indicated that there was a significant difference in the types of protocols and method of selection.

As a result of the trends and common findings observed during the monitoring program, the ORC developed a series of education seminars for the research community that encompassed regulatory requirements, institution specific policies, and incorporated existing research coordinator training. The seminars addressed topics such as adverse event reporting, informed consent, IRB submissions (including chart reviews and research with discarded tissue), and exempt research. Continuing research education credits were offered for each of the sessions. A total of 437 individuals attended 23 one-hour sessions that were held from February 2006 through August 2007.

In addition, education sessions were developed in response to specific non-compliance matters reviewed by the IRB. These were mandatory education sessions that included topics such as adverse event reporting, informed consent, investigator responsibilities and an overview of responsible conduct of research. A total of 139 individuals attended 19 two-hour sessions that were held from February 2006 though August 2007.

While the total number of attendees was greater for the continuing research education sessions, the time investment per person for the mandatory education sessions was more intensive. The continuing research education sessions required 3 minutes per person compared to 16 minutes per person for the mandatory education sessions; a five-fold increase in the time and resources invested.

Conclusions

The CCRT prospective monitoring and education program has increased awareness in the research community amongst Principal Investigators, Clinical Research Coordinators and IRBs of the need for continual re-assessment of how research should be conducted. While the initial impression of a monitoring visit may be met with anxiety and a multitude of questions, the outcome has resulted in the perception of support and education. Deficiencies are noted, corrective actions are implemented and, most importantly, a relationship is established for improving ongoing communication. The ORC staff are the key individuals, in this setting, providing infrastructure for educational training sessions for principal investigators and research staff. The response to these training sessions and attendance has been very positive, bestowing credence to the ORC's role in education.

Furthermore, prospective compliance monitoring and education may ultimately reduce research staff workload and administrative burdens on the IRB office, as ongoing prospective monitoring and education will allow for earlier identification and correction of discrepancies. In other words, prospective monitoring in combination with continuing research education requires significantly less time and resources than directed monitoring and mandatory education. This allows for more efficient research administration, encourages the responsible conduct of research, and promotes the protection of human subjects.

For a research compliance and education program to be effective, continual assessment and quality improvement of the program are essential. The data collection and results of the monitoring program enabled the UHCMC CCRT to target the essential areas in the educational sessions. Research Monitoring and Education programs should be designed to support the needs of all members of the research community and emphasis placed on the responsible conduct of research. Effective approaches to research administration of an HRPP should include prospective compliance monitoring and continuing research education in order to more efficiently utilize resources and successfully educate a greater number of research community members.

References

Bigby, B. (2002). A continuous quality improvement plan for monitoring clinical trials. *Clinical Researcher*, *2*(8): 20-22.

Burke, G.S. (2005). Looking into the institutional review board: Observations from both sides of the table. *Journal of Nutrition*, *135*, 921-4.

CITI Collaborative Institutional Training Initiative. *CITI login and registration page.* Retrieved August 20, 2007, from https://www.citiprogram.org/default.asp

Cola, P., Fedor, C. & Haffke, L. (2005) The development, implementation and evaluation of a prospective research monitoring program, 2005 Symposium Proceedings, Annual Meeting of the Society of Research Administrators International. October, 2005. Milwaukee, Wisconsin.

Dunn, C.G., & Chadwick, G.L. (1999). *Protecting study volunteers in research: A manual for investigative sites.* Boston, MA: Thomson Centerwatch.

Ellis, G.B. (1999). Keeping research subjects out of harm's way. *Journal of the American Medical Association*, *282*, 1963-5.

Icenogle, D.L. (2003). IRBs, conflict and liability: Will we see IRBs in court? Or it is when? *Clinical Medicine & Research*, *1*, 63-68.

Institute of Medicine. Committee on Assessing the System for Protecting Human Research Subjects. (2001). Preserving public trust: accreditation and human research participants protection programs. Research Practitioner, 2(3), 110-114.

Office of Research Integrity Annual Report (ORI). (2006). Retrieved August 19, 2007, from http://ori.dhhs.gov/documents/annual_reports/ori_annual_report_2006.pdf

Shalala, D. (2000). Protecting research subjects -- What must be done. *The New England Journal of Medicine*, *343*, 808-810.

Sherwin, J.R., & Fromell, G.J. (2002). Post-IRB-approval monitoring of clinical trials: Assessment of investigator compliance documentation and training. *Research Practitioner*, *3*, 73-80.

Slater, E.E. (2002). IRB reform. *New England Journal of Medicine*, *346*, 1402-1404.

Speers, M. & Cooper, J. (2003). Accreditation comes of age. *Research Practitioner*, *4*, 24-27.

Steinbrook, R. (2002). Improving protection for research subjects. *The New England Journal of Medicine*, *346*, 1425-1430.

Sugarman, J. (2000). The role of institutional support in protecting human research subjects. *Academic Medicine*, *75*, 687-692.

Weijer, C. et al. (1995). Monitoring clinical research: An obligation unfulfilled. *Canada Medical Association Journal, 152*(12):1973-1980.

Wolf, D.Y., & O'Rourke, P. (2002). Improving the quality of clinical research: Recognizing common areas of noncompliance and providing quality-assurance and quality-improvement tips for investigators. *Clinical Researcher*, *2*(10): 15-19.

Laboratory Management Institute: A Model for the Professional Development of Scientists

John C. Galland, PhD
Director, Laboratory Management Institute
University of California, Davis
1850 Research Park Drive, Suite 300
Davis, CA 95618 USA
Tel: (530) 747-3822
Fax: (530) 747-3904
Email: jcgalland@ucdavis.edu

Jade R. McCutcheon, Doctor of Creative Arts
Assistant Professor, Department of Theatre and Dance
University of California
One Shields Avenue
Davis, CA 95616 USA
Tel: (530) 752-0891
Fax: (530) 752-8818
Email: jrmccutcheon@ucdavis.edu

Lynne U. Chronister, Assistant Vice Provost for Research
University of Washington
4333 Brooklyn Ave. Mail Stop 4333
Seattle, WA 98185
Tel: (206) 685-7065
Fax: (206) 685-1732
Email: lchronis@u.washington.edu

Authors' Note

Arthur Grueneberger and Matthew Tabora-Roberts are acknowledged for their contribution to the education program. Donna Davies and Erin Houston are acknowledged for editorial assistance. Portions of this article are used with permission from the Society of Research Administrators International (SRA), from a contributed paper entitled, "Mentoring through Practice: A Case Study," in the 2006 SRA Symposium Proceedings "Enriching the Art and Science of Research Administration through Scholarship and Professional Inquiry," Quebec City, Canada, October 14-18, 2006.

Abstract

The Laboratory Management Institute (LMI) at the University of California, Davis (UC Davis) was an experiment designed to enhance the leadership and management skills of researchers and thereby enhance the overall quality of the academic research enterprise. The educational

programs that resulted provide examples of how research administrators can help academic research teams become more productive, quality-vigilant, compliant, and safe; make a more satisfying research workplace; mitigate institutional risk; and advance science and careers. The LMI delivered educational programs for researchers that were novel in pedagogy, including *LabAct* learning, which used actors to help researchers practice skills such as communication, innovation, leading teams, and managing resources; *LabScripts*, which were sample dialogs researchers used to practice communicating authentically and to build their confidence before initiating important discussions (courageous conversations) with others; *LabTrek*, team building exercises for practicing research management skills; and *LabCheck,* a novel learning assessment tool. One of the LMI educational programs developed for postdoctoral scholars and some of the curricula and pedagogies developed through the LMI are described, as well as the rationale and significance for providing professional development for researchers at the institutional level.

Keywords: Laboratory management, responsible conduct of research, education, leadership, actors, theatre, postdoctoral scholars, pedagogy, career development, ethics, research integrity, compliance, *LabAct* learning, scientific method

Introduction

While announcements of new scientific discoveries appear almost daily, there also are reminders that some discoveries, such as the cloning of human cells by Dr. Hwang Woo-Suk from South Korea, are fabricated (Wade & Sang-Hun, 2006). Accusations of research misconduct are costly to an institution's recruitment, enrollment, funding and reputation. Increasingly, multiple million-dollar fines are levied by the federal government against universities for misuse of grant monies. Of the more than $200 billion invested in research annually in the United States (U.S.), the collective and less egregious errors and inefficiencies of scientists cost millions of dollars (Pascal, 1998). Excuses for research misconduct and inefficiencies include pressures to succeed, carelessness, poor recordkeeping, a breakdown of the peer-review system, lack of oversight of laboratory personnel, and the confusion and misunderstandings that sometimes can occur among personnel with diverse backgrounds or value systems. These rationalizations aside, misconduct and inefficiencies lie ultimately in the character and abilities of the individual researcher. Fortunately, leadership and management skills and, to an extent, integrity can be learned, but do researchers seek out and have time for this education, and do institutions have the necessary educational resources available for this learning to occur? The Laboratory Management Institute (LMI) was created to develop and use new educational resources to motivate researchers to acquire greater knowledge, abilities, and skills for establishing and managing their programs responsibly and efficiently.

1. Rationale

Research administrators have a broadly defined responsibility to ensure that the institutional culture promotes and facilitates excellence in the conduct of research. Through federally mandated committees such as the Institutional Review Board (IRB) and Institutional Animal

Care and Use Committee (IACUC), and through campus administrative units such as Environmental Health and Safety, research administrators approve and monitor the practices of researchers to help assure they comply with regulations governing the study of humans and vertebrate animals, as well as environmental protection. Through pre- and post-award services, research administrators help ensure the fiduciary responsibilities of the university and its personnel. Personnel involved in research funded by certain federal agencies now are required to receive education in the responsible conduct of research. Frequently, this responsibility also is being met by research offices. In the Office of Research at UC Davis, an experiment was conducted to expand the scope of education in responsible conduct of research to include laboratory management.

Protecting the Research Enterprise: Multiple Reasons for Providing Education in Scientific Management

While graduate students and postdoctoral scholars are likely to receive excellent education in their research discipline, they are less likely to receive formal education in the leadership and management skills essential for the day-to-day operation of a research program and laboratory (Pascal, 1998). Currently, academic institutions have invested limited resources in leadership and management education for graduate students and scholars because they expect this education to be provided adequately and equitably by faculty mentors. However, many mentors view such education as secondary to guiding the students' or scholars' research project. In addition, mentors sometimes lack education in management skills themselves, or the resources to teach the skills consistently and efficiently to their students and scholars. Also, they may lack experience to guide their students and scholars in developing professional skills for employment positions outside academia. A simple scan of advertisements for research positions will reveal that employers prefer applicants with good communication skills and an ability to work well within diverse teams. These and other highly desirable skills, such as problem solving, innovating, behaving with integrity, using best practices, and leading and managing research teams, are seldom taught formally in our universities, and no one mentor should be expected to meet all the various needs of his or her mentees.

Faculty researchers often have little or no education in managing laboratories with highly diverse people, but rely increasingly on the research work of international students and scholars. At the extreme, students from countries that have been battling over politics or religion for hundreds of years may be asked to work alongside one another. Educational programs are needed to develop the professional skill-set that enables scientists to overcome cultural, language, gender-orientation, ethnic, age, and other barriers to communication that can be encountered in a laboratory with a diversity of people. Studies have shown that, for complex tasks, a diverse team of skilled workers will outperform a homogeneous group of comparatively skilled and motivated workers if the diversity is managed effectively (Hayles & Russell, 1997).

There is growing need for researchers to mount rapid and highly collaborative and coordinated research responses to global crises. Translational and other collaborative research is becoming more important in a society that also is becoming more complex and global. Therefore,

educational programs are needed for researchers to develop skills for leading and participating in research that is highly collaborative.

A skeptical public requires greater assurances of the believability and significance of research results to help them decipher and resolve what often appear to be contradictory results among researchers. The evidence must be as irrefutable as possible so that the public can determine if the scientist's inferences drawn from the research warrant changes in their own personal behavior, level of advocacy for certain lines of research, or their financial support of those research lines through taxes, grants, contracts, commercialization, and gifts. Scientists have an obligation to learn, use, and advance "best" scientific practices and perhaps a growing need to follow strictly, for instance, the guidelines of the Good Laboratory Practices Act. This creates an opportunity for research administrators to help researchers enhance their understanding of the importance of documenting the quality and validity of research results, and to provide greater institutional resources for enabling increased documentation. The increasing complexity of research and the increasing costs and volume of research data further require many researchers to be better trained in efficient execution of their research (Kulakowski & Chronister, 2006). Of equal importance, researchers with good leadership and management skills, such as an ability to communicate to the public how their research fits into a larger context, will be better able to acquire support. Research administrators can have a vital role in creating the means to assist researchers in these endeavors, and in providing career-enhancing educational programs to help them meet the growing need to compete for and leverage resources. For instance, research administrators might better enhance the education of researchers in the protection, licensing, and commercialization of intellectual property, in part, because of its significance as a source of funding or revenue.

Development of leadership and management skills is essential for decreasing the costs of mismanagement, research inefficiencies, and incidents of misconduct. More importantly, these same skills can increase scientific discovery, innovation, mentoring, and global competitiveness. A recent national survey reports that scientists spend, on average, 42% of their time on administrative matters (Keen, 2006) – time that otherwise might be used for discovery and innovation. Programs supported by research administrators that would help their faculty in mentoring students and scholars might increase scholarship.

More funding agencies are investigating allegations of scientific misconduct. The U.S. Department of Health and Human Services (DHHS) established the Office of Research Integrity (ORI) to investigate allegations of misconduct of scientists funded by the National Institutes of Health (NIH). ORI requires recipient institutions to have a means of investigating allegations of research misconduct in collaboration with the agency, and for submitting the results of their investigations to the agency for review, further investigation, and judgment. Research administrators, through preventive educational programs, can lessen these costs.

NIH and other funding agencies require applicants to have education in responsible research to be eligible for certain awards. Applications for specific NIH funding programs must include documentation about how investigators have or will have met education requirements in the responsible conduct of research, including data acquisition, management, sharing, and

ownership; conflict of interest and commitment; collaborative science; human and vertebrate animal subjects; publication practices, responsible authorship, and peer review; and mentor and trainee responsibilities. Investigators and institutions not meeting the education requirements can lose funding.

Finally, the research enterprise is enhanced if researchers help reduce IRB and IACUC operating costs by submitting and effectively executing study designs that will accomplish their research goals while posing fewer compliance problems and requiring less review and monitoring.

Almost all institutions have departments of human resources that provide developmental education for faculty and staff, but these educational opportunities usually are not designed to address the specific needs of researchers, as described above, nor are they utilized widely by researchers.

The academic research enterprise could be enhanced and protected effectively and efficiently through institutional education programs for researcher development such as those developed by the LMI.

2. Significance

Described here is a new model for institutional mentoring of students and scholars that is equitable, accountable, and provides greater assurances of their employability. The intended outcome was a change in the culture of mentoring students and scholars to provide learning opportunities at the institutional level, while at the same time highlighting for research administrators the importance of laboratory leadership and management education to a university's research enterprise. The program described was not only a response to growing education requirements by funding agencies, but also designed to explore the extent to which research offices have responsibilities, perhaps obligations, to faculty, students, scholars, and staff for consistent and equitable access to educational opportunities and experiences for their professional development. The program expanded on existing curricula for responsible research education, to include education in the daily operations of research, because research integrity also requires scientists to be good stewards of the resources provided to them.

The LMI's program for postdoctoral scholars included education in best practices, research compliance, stewardship, communication, collaboration, problem solving, and mentoring. The program was designed to help support mentors' efforts to provide the best possible education for their postdoctoral scholars with a minimal time commitment. Ultimately, the education was expected to decrease costs of mismanagement and incidents of misconduct, increase science and engineering discovery and innovation, and make careers in science more satisfying and fulfilling.

The program was designed to give postdoctoral scholars a jump start into their research project while at the university and into their careers once they left. With more than 2200 laboratories, 3000 international students, and a highly diverse population of graduate students and postdoctoral scholars, UC Davis was an ideal location for initiating such a program.

3. Program Background and Steps of Program Development

In 2003 a committee appointed by the Provost and chaired by the Associate Vice Chancellor for Research, assessed risks to research compliance at UC Davis. A group from this committee conducted a survey of campus laboratories that revealed a need for educational programs to help scientists gain skills in managing and understanding people, budgets, and regulatory and compliance issues (Pascoe, et al., 2003).

In 2005, Howard Hughes Medical Institute (HHMI) and Burroughs Wellcome Fund (BWF) awarded UC Davis and 19 other institutions grants to participate in their "Partners in Scientific Management Program" to teach others how to teach courses in scientific management. The HHMI/BWF partners program grew out of a 2002 workshop at the HHMI campus, where approximately 100 junior scientists learned about scientific management to help jump-start their careers (BWF/HHMI, 2004). In 2005, HHMI and BWF offered the workshop for a second and last time to another group of approximately 100 junior scientists, in part, to provide the 20 partners with the materials and experience to propagate the instruction at their respective institutions. Although HHMI/BWF provided funding for the partners to participate in and observe the workshop, each institution was responsible for providing and funding similar workshops at its respective site before the end of 2007.

To meet this obligation, and recognizing the value of providing laboratory management education, the Office of Research and six of the campus Dean's offices contributed funds for the UC Davis program. The LMI was established in July 2005, and its Director was charged with both developing an annual, year-long program for postdoctoral scholars, and thinking programmatically to enhance the missions of the university and lead the way for other institutions. What developed included education beyond the initial targeted group of postdoctoral scholars and beyond the minimal regulatory requirements provided through traditional seminar series and on-line training. Some of the goals of the LMI included filling an education gap, meeting the University's responsibility to train and mentor, helping jump-start and advance careers, enhancing skills in laboratory research, meeting a perceived national and international training need, enhancing regulatory compliance, reducing risks of penalties and litigation costs, achieving greater research efficiencies, aiding recruitment and retention, and enhancing science and the work environment.

The LMI was envisioned as a national and international resource for researchers and research administrators. Its mission was to provide comprehensive leadership and management education to help ensure research productivity and quality while enhancing the safety and well being of laboratory subjects and personnel. The activities of the LMI were to develop, validate, deliver, evaluate, and disseminate new curricula that would help researchers obtain, through didactics and practice, the leadership and management skills they would need to be effectual and innovative in their chosen professions.

The formation of the LMI, and the availability of a competitive award program for postdoctoral scholars, was announced at a campus-wide seminar. Making the program competitive gave awardees, their mentors, and their College or School additional stature and, therefore, incentive

to apply. A unique aspect of the seminar was the inclusion of a performance by two acting students from the UC Davis Theatre and Dance Department, who played the roles of a postdoctoral scholar and graduate student working at a laboratory bench. The scene illustrated the need for laboratory management education in a realistic, humorous, and sometimes egregious way, and drew immediate interest in the program. The success of the theatrical performance resulted in articles in campus newspapers about LMI. A logo was created for LMI to enhance brand recognition, and an LMI website was established through which scholars could apply to participate in the program. A committee evaluated and selected the awardees from the pool of applicants.

4. Program Description

Program

For the initial LMI education program, 22 postdoctoral scholars were selected from more than 30 nominated by their mentors, representing the schools of Medicine and Veterinary Medicine, and the colleges of Agricultural and Environmental Science, Biosciences, Engineering, and Letters and Science. Each year the number of postdoctoral applications and awardees increased (to 24 then to 26).

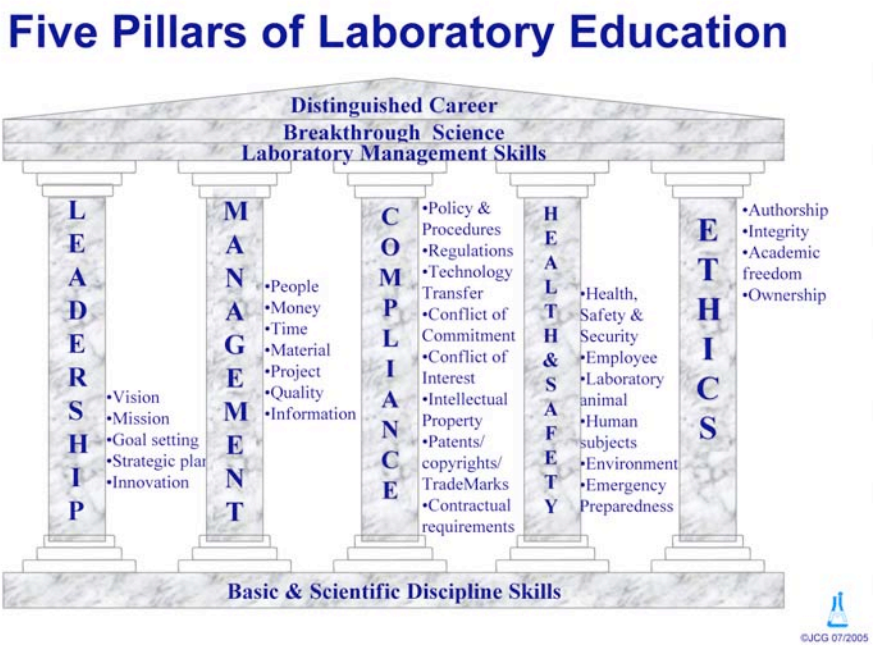
Postdoctoral scholars were the initial target group of researchers for receiving the LMI education because they often manage the day-to-day activities of academic research laboratories. In addition, they interact frequently with graduate and undergraduate students, technicians, institutional support staff, and their mentors. Therefore, the dissemination of education to postdoctoral scholars assumed a domino effect throughout the campus. Applicants were selected primarily on how they proposed to transfer what they would learn to other members of their laboratory and department. One postdoctoral scholar stated: "The LMI program is not about training 20-some postdoctoral scholars each year; it is about training more than 20 laboratories each year."

The program format was a two-day workshop followed by 12 monthly, two-hour evening sessions that focused on selected topics in depth. These closed sessions were confidential so the scholars could speak freely about their experiences. One of the authors (JCG) made four-hour visits to each scholar's laboratory for one-on-one learning and discussion outside the group sessions, and became for many of the scholars a confidante and mentor. Collaborative and social networks were formed during the program and have continued among some of the scholars.

Curriculum

The LMI curriculum for postdoctoral scholars was designed to build on their basic and scientific discipline skills, to include developing skills in leadership, management, compliance, health and safety, and ethics (Figure 1).

Figure 1
Laboratory Management Institute Five Pillars of Laboratory Education.



Several curricular themes emphasized (a) research professionalism and adherence to ethical principles, (b) stewardship of research resources, (c) self-assessment and improvement, (d) interpersonal and communication skills, (e) building working relationships with essential research support partners, (f) discovery and innovation, (g) mentoring and being mentored, and (h) placing research into a larger context.

Theme Teams

More than 30 UC Davis staff and faculty members agreed to make presentations during the two-day workshop. They met in small "theme teams" (e.g., health and safety, compliance, budget preparation and funds management) to discuss and coordinate their presentations. Health and safety topics included personnel roles and responsibilities, authorizations for research involving hazardous materials, and injury/illness prevention planning. Compliance topics included the work of IRBs and IACUCs, good practices guidelines, standard operating procedures, and responsible conduct of research (ethics and integrity). The budget preparation and funds management team discussed direct and indirect costs, authorization of expenditures, and changing budget allocations.

The curriculum drew, in part, on the BWF/HHMI (2004) guide, programs such as the University of Pittsburgh's "Survival Skills and Ethics Program," presentations by The Center for the Health Professions at UC San Francisco, articles in *Science Next Wave*, and *Naturejobs*, texts by Barker (2002), Sapienza (2004), Macrina (2005), and Cohen and Cohen (2005), and the extensive business leadership and management literature.

Unique Pedagogy

The LMI developed innovative education methods, such as *LabAct* learning, *LabScripts*, and *LabTrek,* which gave learners practice in developing professional skills in research. Practicing can be as essential to the scientist running a laboratory as it is to a musician preparing for a performance. Practicing leadership and management skills actively reinforces what one learns through less active means such as reading, listening, or even interacting with computer video.

LabAct Learning

LabAct learning allows participants to practice problem-solving solutions to real-life issues they face in their laboratories (Table 1), including personnel conflict, negotiating authorship, or complying with fiduciary or research regulations. *LabAct* learning is itself a laboratory in which participants use the scientific method to increase their problem-solving knowledge and skills. What is unique to *LabAct* learning, and what is appealing to researchers, is that the learning is based in the scientific method — hypotheses are tested, assumptions specified, controlled experiments performed, data collected, analyses made, and inferences drawn to help develop skills in running a research program.

LabAct learning uses a facilitator (*LabAct*ivator) and specialists who are professional actors (*LabAct*ors) to help participants experiment with multiple resolutions to issues that can arise in the research workplace. In this way, *LabAct* learning is a simulator for participants to learn important professional skills by practicing them in a safe, supportive environment before using them in real life. What separates *LabAct* learning from other education strategies is that the participants, not the leaders, define the issues and evaluate the success or failure of solutions they derive.

Step 1: Confidentiality.

The *LabAct*ivator first emphasizes the importance of confidentiality and respect in the *LabAct* learning laboratory so that participants feel they can speak openly about the issues.

Step 2: Identifying the issues.

The *LabAct*ivator asks participants to write about an issue they are facing or expect to face in their own laboratories, describing a specific situation in which the issue is raised, the organizational roles within the laboratory of the people involved and their relationship to one another, and any other information that would help clarify the issue. No information is used that might identify the specific people or location, and participants do not identify themselves as the author of the issue. Thus, *LabAct* learning is a blinded study. The *LabAct*ors then separate those issues that are unique from those that are common. They list these on a flip chart so each has an equal chance of selection for experimentation. The *LabAct*ivator simultaneously makes a brief presentation on such topics as the scientific method, teamwork, celebrating diversity, and changing outcomes by changing one's own attitudes, perceptions, and behavior.

Step 3: Selecting the issues for experimentation.

After the presentation, participants are shown the list of issues (referenced earlier in Table 1) and select those most useful to investigate with the scientific method. Once several key issues are selected, the *LabAct*ivator and *LabAct*ors solicit more specific information regarding the characters, setting, and circumstance. This important step gets the participants involved and, more importantly, provides reference points that help the *LabAct*ors make the experiment relevant and realistic.

Step 4: Portrayal of an issue.

The *LabAct*ors improvise the scene, illustrating the issue often in an egregious or humorous way, which helps define it and make it memorable. If the scene does not "ring true," refinements are made until it does.

Usually a scene involves two characters with opposing points of view, goals, principles, values, desires, expectations, personalities, compatibilities, or resources. The participants can experiment with the behavior of one character (the experimental person) but not with the other (a quasi-control). Usually, participants identify with the character whose behavior they will manipulate. The control is the real or perceived source of conflict — the character who hinders, blocks, counteracts, interferes, or prevents expression of the experimental character's morals or values (ethical conflict), or keeps him from reaching his goals. The behavior of the control can be influenced only by the behavior of the experimental character. The source of conflict need not be another person, but can be part of the physical, cultural, or social environment, or a destructive element in the individual's own nature (inner conflict).

In general, the scenes contain more than one point of conflict among the characters, but one underlying cause, which until enacted may be difficult to uncover. Often, the conflict among the characters results in tension, anxiety, fear, anger, and other emotional responses that the participants and *LabAct*ors comment on immediately after the scene. These comments contribute significantly to the instruction.

Step 5: Discussion of portrayal and suggested resolutions.

After the scene, the *LabAct*ivator invites comments and responses from the participants, and gathers their suggestions on different ways that the conflict might have been prevented, minimized, or resolved. Participants also are invited to specify any underlying assumptions they perceived the experimental character to be making that contributed to the conflict. Keywords from the discussion are written on a flip chart to label each potential resolution suggested.

Step 6: Resolution experimentation.

Using information from the discussion, the participants select one of the potential resolutions. The *LabAct*ors reenact the scene, but this time the experimental character uses the participants' suggestions to try to alter the response of the control. Following the scene, a discussion led by the *LabAct*ivator ensues to collect the opinions of the participants about what was or was not

successful. The *LabAct*ivator is careful not to bias or lead the discussion to a certain conclusion. All resolutions have the potential of working; participants judge them on their face value and what they perceive would work for them if they were having a similar conflict. The scene is replayed as long as time and potential resolutions allow.

Step 7: Participants as actors.

As participants gain confidence, they are invited to demonstrate ways to resolve issues themselves. This results in *embodied learning* (Fuller, et al., 2005), as participants experiment with changing their own behavior and determine for themselves if those changes are effectual and resonate with their sense of self. Thus, the group helps foster critical thinking and collective analysis of shared problems.

The *LabAct* learning sessions often are videotaped for subsequent use so the participants can see and, if necessary, modify future behavior. The videotapes also are used for other courses, on-line instruction, and demonstrations of the pedagogy. Participants are encouraged to record in writing what they have learned about themselves and others, and how they will prevent, minimize, or resolve a particular problem, conflict, or issue they are facing in their laboratory. From *LabAct* learning sessions, useful data are gathered for academic institutions, industries, and government regarding the kinds of issues next-generation researchers face in their academic laboratories, as well as an array of prevention and resolution strategies.

Step 8: Inferences.

At the conclusion of a *LabAct* learning session, the *LabAct*ivator asks the participants to identify those communication principles that might be applied to their own situations.

Benefits of *LabAct* Learning

LabAct learning experimentation provides an educational experience for learners to clarify and examine problems or issues pertinent to them, and can facilitate their insight, personal growth, and positive behavioral changes. *LabAct* learning experimentation shifts abstract concepts, such as integrity, into a simulated, lived experience, which allows the participants to observe or enact interpersonal conflict, witness or experience the success or failure of conflict resolutions, and determine which resolutions resonate best with their own personality. *LabAct* learning experimentation tests the hypothesis that changing another's attitude, perceptions, and behavior comes primarily from changing one's own. Many of the *LabAct* learning scenarios, although specific to a particular circumstance, become relevant on a broader level as issues of accountability, trust, choosing one's battles, being clear in communication, and other themes.

Plays have long been used by educators to convey concepts and teach behavior. However, with these forms of theatre, students are passive recipients and not active producers of the actions or topics to be enacted. *LabAct* learning experimentation is a new way of using the theatre arts, derived from other theatrical structures such as Forum Theatre (Boal, 1998), Playback Theatre (Fox & Dauber, 1999), and Psychodrama (Moreno, 1983).

Among other critical professional skills, *LabAct* learning sessions are a tool for modeling, identifying, discussing, and practicing individual, dyadic, and group communication skills, styles, and behaviors, and for analyzing communication within and across cultures, languages, dialects, and genders. Problems, disputes, misunderstandings, impasses, and conflicts among and between people and groups so often result from differences in communication skills, styles, and behaviors. *LabAct* learning sessions model verbal and nonverbal communication skills and behaviors that can make or break a communicator's message. These include word choice, thought organization, tone, voice speed, delivery, turn-taking in conversation, proper pronunciation, dialect and language use and active listening, eye contact, leaning in, open or closed body posture, nodding, position of listener relative to speaker, shared attentiveness to listeners and receivers of message. The roles of these critical communication elements are played out, analyzed and discussed.

LabScripts

From some of the issues and resolutions identified through *LabAct* learning experimentation (Table 1), program participants constructed scripts (*LabScripts*) to practice initiating discussion with their coworkers or mentors. *LabScripts* about topics that can be uncomfortable to discuss are used as examples for initiating what LMI called "courageous conversations." Courageous conversations on these and other topics can be especially difficult for students and scholars from differing cultures. Yet, in the culture of science, not speaking up can jeopardize the integrity of the research as well as important functional relationships in the laboratory. Later we discovered best selling books about these kinds of conversations with such titles as "Lifescripts" (Pollan & Levine 1996, 1999, 2004), "Crucial Conversations" (Patterson, et al., 2002), and "Fierce Conversations" (Scott, 2002, 2004).

LabTrek

The LMI used a project-management learning exercise conceived originally by Milton Datta (Emory University), with assistance from Martin Ionescu-Pioggia (BWF) and one of us (JCG). Briefly, it is an exercise in which a participant or team of participants can practice professional-development skills learned during LMI instruction. The object of the exercise is to choose one or more research hypotheses from a list that, upon testing, will provide preliminary data in support of a large grant to be submitted to a funding agency. Next, constrained by an operational budget, the participants must select from a list of experiments to perform and choose the necessary personnel to conduct the experiments successfully. During the exercise, unexpected but real events affect the outcome of these experiments as participants draw cards of misfortune and fortune. The repertoire of *LabTrek* exercises has expanded to include one in which participants practice developing a laboratory protocol.

In each of these practice activities, the learner obtains immediate feedback about the productivity, innovation, and discovery resulting from the quality of the interactions among the participants. As a result of these practice exercises, the learner builds self-confidence.

Table 1
Some Issues Raised and Addressed by Laboratory Management Program for Postdoctoral Scholars

Authorship, authorship, authorship
Squabbles over shared equipment
Dealing with administration
International female scholar afraid to approach mentor about her and husband's desire to start a family
Male postdoctoral scholar from patriarchal society behavior toward females in laboratory
Ethnic, language, and cultural silos of individuals working within labs
Opportunities outside academia (on average only 9% of postdoctoral scholars receive academic appointments)
Technology transfer and patent issues (proper documentation to facilitate patenting)
Mentoring of others in lab
Time management and follow-through
Achieving balance between work and one's other life
Communication/ethical issues related to interdisciplinary and collaborative studies
Situation-appropriate behavior
Resolving differences between labs in their mentoring/procedures (the comparisons mentees make between their lab mentor and others)
Difficulty in juggling different goals of persons in lab
How much time can a mentor afford to invest in mentee? How much to get involved? When over-involved? Where to draw the line?
Dealing with constant changing of processes in lab; dealing with change
Criteria for success in academia/industry
Innovation and discovery
Awareness of one's limitations and limitations imposed on them where they will be going
Supervision – how to do it; managing day-to-day activities in lab; dealing with the variety of people in the lab including visitors
How to hire and train personnel so they will fulfill their responsibilities
How to deal with protocol divergence
Personality issues – managing disruptive people
How to pick the right people – practical tips
Firing someone: how to do it; what documentation is needed? What rules/guides are there?
Meeting the needs and goals of mentee and mentor
How do you motivate (to have them do their work and meet deadlines)?
Improve efficiency – management style; differences between managing small v. larger labs
How to find and negotiate a job; career management
How to bring ideas for discussion and to resolve problems
How to become more independent, and an independent thinker
How to be candid, overcome shyness, or tone down the overtly gregarious

5. Program Assessment

LabCheck Observations

Using techniques published elsewhere (Goodger, et al., 1988), each of the postdoctoral scholars was interviewed, during four-hour walk-through visits of their mentor's laboratories, to record changes that occurred in their laboratories as a result of the education. These observations ranged from how participants developed standard operating procedures and signage for their labs to resolving complex issues related to diversity and life-work balance. Written anonymous comments and public comments by each of the three classes of postdoctoral scholars were almost unanimously positive; many gave the University permission to use their comments as testimonials.

The LMI curriculum and teaching method captured international recognition with a note in *Nature* (McCutcheon & Galland, 2006); a featured program in articles in *Science* (Aschwanden, 2007), *Cell* (Aschwanden, 2006), *The Scientist* (Grens, 2007), and *The Chronicle of Higher Education* (Brainard, 2006); and in an article published in the *POSTDOCket* newsletter of the National Postdoctoral Association (Galland & McCutcheon, 2006).

The accomplishments of LMI extended far beyond the annual postdoctoral program. During its three-year tenure, more than 1000 scientists, including more than 70 UC Davis postdoctoral scholars, participated in its educational programs. An annual 14-credit-hour Certificate Program in Scientific Management was developed which attracted scientists from as far away as West Africa. Also attending were representatives from the United States State Department, forensic laboratories, research hospitals, public health laboratories, national laboratories, and pharmaceutical companies. An annual day-long staff development course in laboratory management was initiated. LMI has provided workshops to various groups including undergraduate engineering students, both established and newly appointed medical school faculty, newly appointed faculty from multiple disciplines, research administrators, and veterinary degree students. A workshop in laboratory management was given to more than 300 international graduate students enrolling that year at UC Davis. Workshops in Laboratory Management were conducted at Harvard, UC Berkeley, The National Postdoctoral Scholars Association, Sigma Xi, Lawrence Livermore National Laboratories, Los Alamos National Laboratory, and Sandia National Laboratory. Two new graduate courses at UC Davis were developed, one in the Comparative Pathology Graduate Group for learning about managing biomedical research programs responsibly, and the other in the Department of Theatre and Dance for training *LabAct*ors. The Institute was awarded contracts to educate scientists from North Africa and to provide educational material to ORI.

Discussion

The LMI program for postdoctoral scholars did not come without opposition. Some faculty did not believe that they needed any institutional help in mentoring students. Some did not want to provide the release time for their postdoctoral scholars, or felt that the education would call into question their own practices. Some questioned the need for the expenditure of institutional funds and the quality of the instruction. Some expected their postdoctoral scholars to learn, as they had

learned, in the S*chool of Hard Knocks*. Some questioned the need for adding to an already full curriculum, while others thought that teaching human development disparaged the prestige of the university and likened the program to what might be offered at career development schools. Some felt that career skills either cannot be taught, or are too discipline-specific to be taught broadly. Some resented the administration for intruding on academic affairs under the purview of the faculty, while others were indifferent, thereby impeding any groundswell of support. Indeed, some opinions were changed, particularly after faculty experienced the newly acquired skills and knowledge sets of their postdoctoral scholars. Most of these changes in faculty attitudes were noted anecdotally. A more systematic and scientific assessment would be a valuable addition to future studies of changing the perceptions and attitudes of faculty when implementing new institutional programs such as the one described here.

Conclusion

Not only must researchers solve scientific issues in the laboratory but also a myriad of managerial issues, which often can be more perplexing. Research administrators can strengthen the research enterprise by providing educational programs that develop the managerial skills of researchers that will better enable them to establish, manage, and sustain their independent and collaborative research programs effectively and responsibly. These educational programs can impart critical information and skills in a way that is appealing, engaging, and dynamic. Practicing managerial skills before exercising them builds learner confidence. Creating curricular themes helps organize and formalize a heretofore unstructured body of knowledge in leadership and management for researchers and provides a framework for future learning. Offering the education centrally makes it uniformly assessable and consistent.

Initiating educational programs to enhance the managerial skills of researchers at an academic institution requires buy-in from administrators who would be stakeholders in such programs (e.g., administrators of research compliance, health and safety, faculty and staff development, business schools, and graduate studies), from staff who would support the program administratively and help develop its content, and from those faculty members who are categorized generally as early adopters of new programs who would influence others to participate. At UC Davis, the LMI was created largely through a top-down approach, followed by a groundswell of support generated by the postdoctoral scholars and faculty mentors who participated in the LMI educational programs.

A key success of the LMI program was that it gave postdoctoral scholars, an often neglected but essential group to the academic research enterprise, a forum to share experiences and grow professionally. One postdoctoral scholar reflected that the time she spent in the LMI program would be added to her lifetime total of happy moments.

It can never be known completely the extent to which the most beneficial discoveries and important academic innovations can be delayed as a result of unintended suboptimal management skills in the research laboratory environment. One can never expect that any institution or any research laboratory will always be capable of exercising the most optimal forms of leadership. However, growth in laboratory management is always an important, ongoing goal requiring continual quality professional development. It is the hope of the authors that research

administrators and educators will infer from the observations cited in this paper that they can reduce the risks of suboptimal management and promote the finest in laboratory leadership through actively enhancing the research skills of those involved in the research enterprise at their institutions.

References

Aschwanden, C. (2006). Learning to lead. *Cell, 125*, 407-409.

Aschwanden, C. (2007). Careers for postdoc scientists: Transferable skills and portable careers. *Science, 316*, 471-475.

Barker, K. (2002). *At the helm: A laboratory navigator, updated version.* Cold Spring Harbor, NY: Cold Spring Harbor Laboratory Press.

Boal, A. (1998). *Legislative theater.* New York: Routledge.

Brainard, J. (2006, November 10). Universities experiment with classes in scientific ethics: Pilot programs tackle a difficult topic amid questions about such education's efficacy. *The Chronicle of Higher Education,* pp. A22-A23.

Cohen, C., & Cohen, S. (2005). *Lab dynamics: Management skills for scientists.* Cold Spring Harbor, NY**:** Cold Spring Harbor Press.

Fox, J., & Dauber, H. (Eds.). (1999). *Gathering voices: Essays on playback theatre.* New Paltz, NY: Tusitala Publishing.

Fuller, A., Hodkinson, H., Hodkinson, P., & Unwin, L. (2005). Learning as peripheral participation in communities of practice: A reassessment of key concepts in workplace learning. *British Educational Research Journal, 31*(1), ,49-68.

Galland, J. C., & McCutcheon, J. R. (2006). New institute provides research leadership and management education for postdoctoral scholars. National Postdoctoral Association *POSTDOCket, 4*(2):5.

Goodger, W. J., Repp, S., & Galland, J. C. (1988). Toward developing an instrument for measuring milking management practices. *Acta Vet Scand Suppl. 84*:129-32.

Grens, K. (2007). Dealing with conflict. *The Scientist, 21*(2):26.

Hayles, R. V., & Russell, *A. M.* (1997). *The diversity directive: Why some initiatives fail and what to do about it.* New York, NY: ASTD/American Society for Training and Development; Irwin Professional Pub., McGraw Hill.

Howard Hughes Medical Institute and Burroughs Wellcome Fund. (2004). *Making the right moves.* Chevy Chase, MD: Howard Hughes Medical Institute.

Kean, S. (2006, July 7). Scientists spend nearly half their time on administrative tasks, survey finds. *The Chronicle of Higher Education.*

Kulakowski, C. E., & Chronister, L. U. (2006). *Research administration & management.* Sudbury, MA: Jones & Bartlett.

Macrina, F. L. (2005). *Scientific integrity* (3rd ed.). Washington, DC: ASM Press.

McCutcheon, J., & Galland, J. C. (2006). Actors as teachers. *Nature, 440*(7081):252.

Moreno, J. L. (1983). *The theatre of spontaneity* (3rd Ed.). New York: Beacon House.

National Bioethics Advisory Commission. (2001). *Ethical and policy issues in research involving human participants. Volume I: Report and recommendations of the National Bioethics Advisory Commission, August 2001. Bethesda, Maryland.* Retrieved April 24, 2007 from http://www.georgetown.edu/research/nrcbl/nbac/pubs.html

Pascal, C. (1998). *Management of biomedical research laboratories.* DHHS ORI Workshop, University of Arizona.

Pascoe, John et al. (2003). *Report of the sub-committee on research compliance*, University of California, Davis.

Patterson, K., Grenny, J., McMillan, R., & Switzler, A. (2002). *Crucial conversations: Tools for talking when stakes are high.* New York, NY: McGraw-Hill.

Pollan, S. M., &Levine, M. (2004). *Lifescripts.* Hoboken, NJ: Wiley.

Sapienza, A. M. (2004). *Managing scientists: Leadership strategies in scientific research* (2nd Ed.). Hoboken, NJ: Wiley-Lise, Inc.

Scott, S. (2004). *Fierce conversations: Achieving success at work and in life, one conversation at a time.* New York: : Berkeley trade paperback edition.

Wade, N. and Choe Sang-Hun. (2006, January 10). Researcher faked evidence of human cloning, Koreans report. *The NY Times.* Retrieved August 28, 2008 from http://www.nytimes.com

A Conceptual Framework for the Future of Successful Research Administration

Elizabeth M. Lintz, MA, CRA
Director, Grant Development and Sponsored Research
University of Maryland College of Education
3119 Benjamin Building
College Park, MD 20742-1121 USA
Tel: (301) 405-5884
Fax: 301-314-9890
Email: elintz@umd.edu

Author's Note

The author thanks Dina Sparks, Department of Education Policy Studies, College of Education, University of Maryland, for providing much appreciated feedback and guidance in all drafts of this paper. This paper is an expanded version of "A Conceptual Framework for Successful Research Administration" originally presented at the Annual Meeting of the Society of Research Administrators International 2007 Symposium, Nashville, TN.

Abstract

Research administration has experienced dramatic changes over the past decades. As scientific research has evolved, higher education institutions have tried to adapt, with varying degrees of success. This paper presents a conceptual framework based on six cornerstones of research administration: mission, information, communication, collaboration, transition or transformation, and outcomes. Within these cornerstones are key strategies that research administrators can apply according to their needs, resources, history, and goals. The purpose and importance of such a framework is to give research administrators a strategic role in leading their institutions into the highly competitive scientific research environment of the future.

Keywords: Research administration, grant administration, conceptual framework for research administration

Introduction

Historically, research administrators have largely been reactive to their environment. They reviewed proposals rather than creating them. They channeled proposals through the bureaucratic process rather than championing them toward award status. Recently, research administration has seen dramatic changes that affect fundamental aspects of the research administrator's role. Research administrators have become key participants in funded research strategic planning and leaders at the department, college, and university levels in attracting and managing external research dollars. The expanding nature of the research administrator position is attributable to increases in sponsored research dollars, competitiveness for those dollars, complexity of meeting sponsor funding requirements, and accountability for managing research dollars. To achieve

success in obtaining funding, research administrators must be knowledgeable in numerous areas – accounting, law, technology, academic content, clinical trials, economic trends, public and social policy, and global issues. Likewise, institutions must recognize research administrators as valuable assets, and be willing to incorporate non-academics into the top levels of institutional strategic planning.

This paper presents a conceptual framework for the future of research administration based on six cornerstones of effective management: Mission, Information, Communication, Collaboration, Transition or Transformation, and Outcomes. This model serves to assist both the seasoned research administrator and someone new to the field. The cornerstones also contain key strategies that institutional officials can adapt to their needs, level of resources, and funding goals.

Historical Context

A 1945 report to President Franklin Roosevelt by Vannevar Bush, Director of the Office of Scientific Research and Development, defended the government's increases in scientific investment and the existence of what would become the National Science Foundation (NSF). While Bush's report was not a blueprint for research administration, it nevertheless contains clues for the establishment and success of the field.

Bush identified medical schools and universities as primarily responsible for basic research, and uniquely positioned to improve society via ideals he considered germane: 1) diffusion and flow of scientific knowledge (including the international exchange of ideas); 2) application of basic research to particular problems (applied research); 3) discovering and developing talent in youth; and thus, 4) full employment.

While not specifically mentioning research administration, Bush recognized that, to achieve these goals, a group of professionals would be needed to ensure the continued flow of scientific research.

The Conceptual Framework

The framework is based on six cornerstones essential to pre- and post-award research administration: Mission, Information, Communication, Collaboration, Transition or Transformation, and Outcomes. This framework proposes that a unit's ability to apply these cornerstones and adapt its operations appropriately will help it determine its level of success in achieving goals. A unit may be defined as broadly as a central office or as narrowly as a department.

Mission

A Mission is central to the function of any entity, and may consist of single or multiple components. Institutions of higher education (IHEs) have multi-tiered missions because their purposes are so complex. The challenge for IHEs is to transition from a more traditional mission to one that addresses the changing nature of society and the communities they serve. Society expects IHEs not only to educate and develop future leaders, but to lead in critical research areas and technological development (as evidenced by the increasing numbers of university-industry

partnerships). Further, IHEs are increasingly expected to practice civic responsibility, both locally and globally. It is no longer enough to focus on teaching or on research in the abstract. Universities educate the world's students.

Essential Components for a Modern, Progressive Mission

Among the key elements essential to the IHE Mission are:

Education and critical inquiry. Education – of students, communities, and governments -- is the primary goal of IHEs. The education of students in critical inquiry ensures a future generation of researchers, who in turn may share their knowledge to the benefit of their communities and society as a whole in such varied specialties as education, public service, medicine, and law. Through innovative research, IHEs educate their communities, empowering them with knowledge born of discovery. Research administrators, in collaboration with IHE investigators and offices of public relations, convey findings from research and outreach activities to society. These findings in turn inform local, state, and federal governments as they address community issues.

Research. The goals of education and critical inquiry and research frequently overlap. The importance of research cannot be overstated, as it enhances current and introduces new knowledge to the potential benefit of every aspect of society. Nor can the importance of research administrators be overstated. In addition to helping investigators create proposals, research administrators ensure the accurate and efficient processing of awards from initial receipt to final closeout. By studying trends in funding, legislation, and policy, research administrators expand the knowledge base of investigators and help them focus on appropriate funding sources.

Civic responsibility. Formerly, IHEs existed to educate and conduct research. Today IHEs are expected to contribute to the difficult questions facing society, and to develop superior technology. IHEs have a civic responsibility, and the public is ready to hold them accountable for that role. Research administrators play a crucial role in ensuring research compliance with federal, state, and local regulations, as well as sponsor requirements. Through Responsible Conduct of Research (RCR) initiatives, research administrators have begun to take a proactive approach to problem solving.

Self-sustainability. Economic slowdowns create cuts in state budgets, which can reduce institutional budgets by millions of dollars. In turn, many IHE administrations rely on entrepreneurship to obtain funds, not only for research but for general operating support and capital projects. IHEs must find alternative ways to raise sufficient resources to ensure the continued quality education of their students. By collaborating with IHE development officers, research administrators help apply an entrepreneurial spirit in securing public and private funds for a variety of projects while maintaining high accountability standards. Partnerships with industry are one avenue for this endeavor.

Industrial and technological corporations increasingly collaborate with IHEs to tap the potential for research, development (e.g., patents, licensing), and other innovations. Both IHEs and corporations understand that these collaborations increase financial capital for all involved. In

addition, these partnerships build the human capital needed to advance global competitiveness, particularly in science, technology, engineering, and mathematics.

Information

Information is the second cornerstone of the conceptual framework. When developing or revising a strategic plan, early considerations should be given to the primary stakeholders involved for each part of the plan. This determination will guide a unit's method of employing this cornerstone. Different stakeholders require different information at different times and in different ways, depending on goals and expected outcomes. Information strategies need to be specific to each stakeholder's needs.

During pre-award processes, information is more than merely Request for Proposal (RFP) release dates and due dates. To achieve the greatest success possible, information must be obtained, tracked, and analyzed on several fronts: federal and local political climate; legislation and policy; sponsor funding priorities and trends; and the needs of the global community.

Additional information critical to post-award management includes trends toward greater accountability, outcomes of funded projects and programs, and lessons learned from institutional colleagues.

Communication

Communication is the third cornerstone. Once the appropriate information is obtained for particular stakeholders, it must be communicated in the most effective and efficient manner. Because communication can take many forms, and stakeholders differ in how they respond, information may travel through various channels. What works for one group may not work for another. To this end, research administrators should rely on several methods of communication – from e-mail to personal contact. Face-to-face contact is essential to maintain a true sense of collaborative teamwork and common purpose, and to eliminate the "us versus them" attitudes that engender negative feelings, both among research administrators themselves and between research administrators and investigators.

William M. Sullivan (1995), professor of philosophy, describes the "us versus them" phenomenon as negative interdependence. A unit or entity mired in negative interdependence realizes that "the prosperity depends upon close cooperation with the others…yet this seems to generate intensely distrustful, competitive, and hostile responses" (Sullivan, p. 136).

In order to combat negative interdependence, an entity would have to employ routine, effective key strategies that enable all stakeholders to "learn to cooperate, regulating and sharing responsibility for the collective effects of their individual actions" (Sullivan, p. 137). Successful key strategies would empower all parties to "develop the breadth of understanding, skills of cooperation, and willingness to share responsibility which enable them to turn the situation to their advantage" (Sullivan, p.141), thus resulting in positive interdependence.

Collaboration

The fourth cornerstone, Collaboration, is essential if the stakeholders within the research enterprise are to implement a complete, successful framework. Collaboration encompasses many of the ideals previously discussed. Collaboration can be defined narrowly or broadly, depending on the event (singular or continuous) in which stakeholders are involved. No stakeholder can operate singularly; each must cross boundaries to achieve his or her goals. Faculty and research administrators must collaborate to advance research agendas. Business managers and faculty must work together to ensure that pre- and post-award systems operate smoothly. Business managers and central research administrators must collaborate to convey policy and system changes in pre- and post-award processes.

To advance the ideals of Vannevar Bush, collaboration must extend beyond local entities into other, non-traditional realms. The increase in university-industry partnerships is one example, and coordination between public and private funding is another. IHE's and research administrators need to employ key strategies that enable partnerships to exist and excel.

Transition or Transformation

The fifth cornerstone is Transition or Transformation. Each unit must decide which kind of change to champion, depending on current conditions and future goals. A transition may be minor, involving relatively little movement from one level to another. A transformation, on the other hand, involves a complete reframing of ideals, structure, goals, use of human capital, and resources. Common to the two is adaptability. An entity's willingness and ability to adapt to new landscapes will determine what kind of changes need to occur. A unit that fails to follow trends and resists forward progress may find itself in need of a transformation, rather than a mere transition. It is more cost-effective to transition slowly than to transform in a hurry.

By becoming more proactive, the field of research administration has already effected a transformation. No longer merely a business office, the office of research administration has become an active partner in a process of inquiry. However, the bigger question is, how do research administrators help move their units into the future? How do research administrators transform the field itself into a strategic position to help universities and medical schools become stronger, healthier centers for research and translate basic research to applied fields?

Another transition or transformation that needs to occur is in the perception of research administrators, principal investigators and other players in the research arena. Here, collaboration paired with transition or transformation can reduce negative interdependence and increase positive interdependence. William M. Sullivan (1995) cites Benton MacKaye, founder of the Appalachian Trail, who felt the way to change people's "mental maps" is to change their "physical maps" (Sullivan, p. 230). People need to be able to envision the impact they have on the world and their connection to it. Once people can do that, MacKaye said, "they often become active stewards of the land they inhabit and love" (Sullivan, p.230). Research administrators need to view themselves outside the bureaucratic process of proposal-submitting, and become involved in the science proposed by investigators. Investigators need to view research administrators as active supporters of their research rather than policy-driven roadblocks. Research administrators have

a wonderful opportunity to follow ideas with investigators from initial concepts to completed projects. It is important that research administrators understand how the science they helped advance impacts current and future knowledge. When all participants are invested and engaged, there exists an environment for positive, sustainable common good.

As paper-based communications make way for electronic systems (e.g., Grants.gov, electronic effort reporting), research administrators can quell the fears this sweeping transformation can create.

Outcomes

Outcomes – defined as quantitative or qualitative results -- comprise the final cornerstone. A frequent mistake is considering only quantitative results; it is equally important to analyze and understand the seen and unseen, intended and unintended results of any efforts.

Quantitative Outcome Measures

Most colleges and universities have an office of institutional research whose responsibility is to measure and analyze standard variables that enable administrators to determine the level of activity and effectiveness in a particular area (e.g., enrollment, research, faculty productivity). For research, it is important to look at variables such as number of sponsored research dollars per full-time equivalent (FTE); expenditures per FTE; number of graduate students and postdoctoral students supported; number of proposals submitted; dollars requested; and number of awards. However, rather than mistake one or two high numbers as a sign of success, institutional administrators must seek additional measures of efficiency. Proposal submissions need to be strategic. The level of effort expended (pre-award) should relate to level of return (post-award).

Efficiency is the elusive measure. How do research administrators determine if they are efficient? It is not an easy question to answer, but benchmarking – which uses both quantitative and qualitative measures to assess effectiveness and efficiency -- may help. A lengthy discussion of benchmarking will not be undertaken here. (Waugaman, Kirby, and Tornatzky (2006), describe the process at length.) Suffice it to say, it is a reliable method that research administrators may utilize to establish both intra- and inter-institutional comparisons.

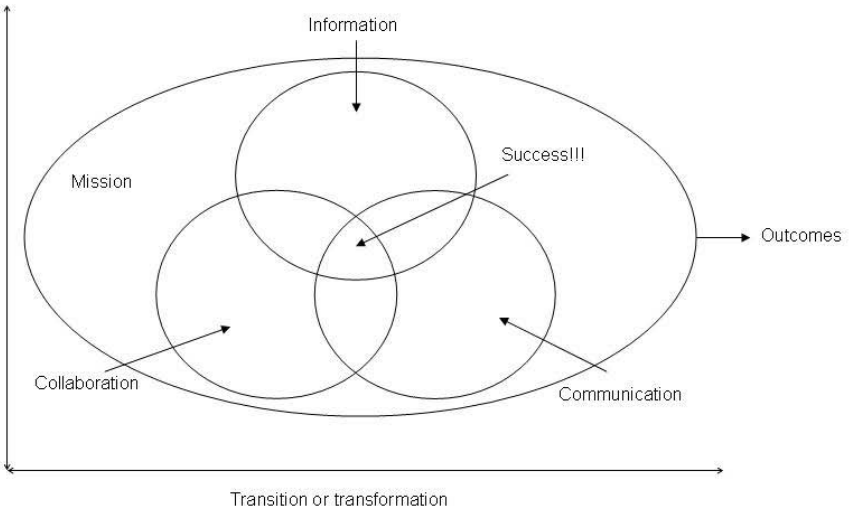
Qualitative Outcome Measures

In judging the success of each cornerstone, it is equally important to measure variables such as perception, satisfaction, and level of engagement or investment. For example, to achieve success during a transformative stage in a unit, institutional administrators should learn how satisfied the stakeholders are in their current positions, their perception of the changes, and what is needed to make the changes successful.

Outcome measures such as these may be obtained through surveys and focus groups, particularly with the assistance of offices of institutional research/assessment, with their extensive research backgrounds and experience in methodology.

Figure 1depicts the cornerstones of the conceptual framework, which builds on significant overlap of domains. The intersection and overlap of the components illustrate success. A unit is more poised to achieve its goals when it operationalizes all cornerstones correctly and efficiently. If the domains operate independently and without coordinated overlap, success can be tenuous.

Figure 1
The conceptual framework.



The degree of overlap varies according to the amount of resources invested in each cornerstone. For example, a unit rich in human capital (usually stakeholders) and financial resources would expect to have a larger overlap (or success) area than a unit with fewer engaged stakeholders and financial resources. It is not enough to define each cornerstone as it relates to a specific goal or set of goals. Administrators should employ a specific research process when defining each cornerstone and applying it to an event (see below).

Operationalizing the Cornerstones

Needs Assessment

A needs assessment guides the process of developing strategies to achieve particular goals or objectives. Before developing or expanding strategies for each cornerstone, it is important to remember that a needs assessment is a continual process. Research administrators should conduct a needs assessment during strategic planning to determine what resources are required to achieve stated goals. Further, needs assessments should be conducted for each unit and event—campus, college, department, faculty member, and proposal. The overall goal is to manifest the model at every level, especially during the preparation of what will be a successful proposal.

Four questions are integral to a needs assessment:

What do the stakeholders need?
What do the stakeholders want?
What existing processes and strategies work?
What is the best method of dissemination (e.g., information and services)?

Key Strategies

Regardless of its level of success, each unit can employ key strategies to achieve its mission and achieve upward mobility (See Table 1). Strategies are the tools that research administrators use in their day-to-day operations. Some key strategies, such as using free listservs, are very simple and require minimal investment. Others, such as professional development courses and certification, require a high level of financial or human capital. The ability of a unit to adopt certain key strategies depends on the level of investment it is willing to commit. Each cornerstone of the model has its own set of strategies available to research administrators. Some strategies may overlap within and across cornerstones, but some remain unique to each unit's specific experiences and needs. Those unique strategies will ensure maximum performance under each cornerstone. Repetition of key strategies within and across cornerstones is not a sign of redundancy, but rather an indication of symbiotic relationships -- an acknowledgement of agreed-upon strategies between pre- and post-award units.

Table 1
Mobility within the Conceptual Framework

Key Strategies by Cornerstone	Level of Resources or Investment
MISSION	
Pre: No involvement in campus mission development; no mission statements or underdeveloped mission statements; mission statement does not address overlapping offices/units; unspecified long-term goals; no evaluation of mission *Post:* No involvement in campus mission development; no mission statements or underdeveloped mission statements; mission statement does not address overlapping offices/units; unspecified long-term goals; no evaluation of efficiency/success in meeting goals/objectives	Minimum
Pre: Individual office/unit missions; specific 5-year plan with moderately defined objectives; infrequent evaluation of mission *Post:* Individual office/unit missions; specific 5-year plan with moderately defined objectives; infrequent evaluation of mission; infrequent evaluation of efficiency/success in meeting goals/objectives; employee satisfaction a consideration	Moderate
Pre: Significant involvement in campus mission development; ; individual unit/office missions reflect all aspects of campus mission; routine evaluation of mission/objectives; specific 5- and 10-year plans with measureable objectives; frequent evaluation of efficiency/success in meeting goals/objectives; external reviews conducted at regular intervals; employee satisfaction a significant consideration in developing pathways to success *Post:* Significant involvement in campus mission development; ; individual unit/office missions reflect all aspects of campus mission; routine evaluation of mission/objectives; specific 5- and 10-year plans with measureable objectives; frequent evaluation of efficiency/success in meeting goals/objectives; external reviews conducted at regular intervals; employee satisfaction a significant consideration in developing pathways to success	High
INFORMATION	
Pre: Listservs (sponsors, Grants.gov, professional associations, university research centers); newspapers, news outlets; Catalog of Federal Domestic Assistance (CFDA): Federal Register *Post:* Email, memos, Listservs (e.g.-NIH-Findings of Scientific Misconduct); Office of Management and Budget (OMB) Circulars	Minimum
Pre: Monthly publications & emails: Federal Assistance Monitor, Contracts and Grants Weekly, (e.g. Thompson Publishing Group); Campus-sponsored workshops *Post:* Informational publications (e.g. Single Audit Information Service); targeted trainings (campus-sponsored)	Moderate
Pre: Site licenses for large databases (e.g. The Foundation Center); high-end grant directories; sponsor-hosted workshops; grant-seeking and grant-writing courses *Post:* Specialized professional development for research administrators	High

COMMUNICATION	
Pre: Newsletters; email groups; face-to-face meetings; meetings with administrators; Web site	Minimum
Post: Paper-based systems; segregated professional development	
Pre: Routine meetings between administrative groups regarding research agenda, planning; increased use of electronic systems; established work groups focused on campus initiatives *Post:* Some mid-level electronic research administration systems; campus-sponsored workshops; work groups for post-award issues	Moderate
Pre and Post: High-end electronic research administration systems; full administrative commitment to Responsible Conduct in Research (RCR) initiatives *Post:* High-end publications detailing research endeavors and accomplishments disseminated nationwide; routine public relations plan implemented within local and national media outlets; specialized professional development for research administration staff	High
COLLABORATION	
Pre: Web sites; contacting other experts in the field; listservs *Post:* Segregated professional development; professional development for senior level staff only	Minimum
Pre: Campus personnel act as liaisons in setting up research groups; campus-sponsored research grant programs; research centers with interdisciplinary affiliated faculty *Post:* Integration of mid-level electronic research administration systems; campus sponsored professional development	Moderate
Pre: Faculty are highly entrepreneurial—actively seeking out partners with non-profits, industry, etc.; research incentive programs for centers or specific initiatives (e.g., Science, Technology, Engineering and Mathematics (STEM) *Post:* Full integration of electronic research administration; specialized online training modules for faculty and staff; specialized professional development and certification of research administration personnel	High
TRANSITION OR TRANSFORMATION	
Pre: "We've always done it that way…"; segregated offices with overlapping interests; lack of communication; lack of knowledge about colleagues; unwillingness of advance/learn; paper-based system dependence; lack of knowledge of campus objectives; lack of awareness of role in achieving objectives; "what happens once the money arrives is their problem." *Post:* "We've always done it that way…"; segregated offices with overlapping interests; lack of communication; lack of knowledge about colleagues; unwillingness of advance/learn; paper-based system dependence; lack of knowledge of campus objectives; lack of awareness of role in achieving objectives; "I can only do so much before and after my lunch hour."	Minimum
Pre: Coordination with post-award mission/personnel; interest in investment in mid-level electronic system(s); average knowledge/interest in science/principal investigators *Post:* Coordination with pre-award mission/personnel; interest in investment in mid-level electronic post-award system(s); average knowledge/interest in science/principal investigators	Moderate
Pre: Significant overlap and coordination with all post-award mission/personnel (even at local levels); significant interest in overlapping/cohesive e-systems for both pre- and post-award missions; hiring personnel with expertise in pre- and post-award areas *Post:* Significant overlap and coordination with all post-award mission/personnel (even at local levels); significant interest in overlapping/cohesive e-systems for both pre- and post-award missions; hiring personnel with expertise in pre- and post-award areas	High
OUTCOMES	
Pre: "We do what we can do for today;" no interest or strategy for measuring success, efficiency, etc. This is also a reflection of vague mission statements, lack of identity/common purpose *Post:* "We do what we can do for today;" most basic measures exist for measuring success; no measures for efficiency. This is also a reflection of vague mission statements, lack of identity/common purpose	Minimum
Pre: Routine internal auditing practices to measure success, efficiency as well as qualitative variables; some change occurs as a result of findings; stakeholders are given opportunity for input before changes are made; strategic planning in "go/no-go" decisions; some benchmarking practices *Post:* Routine internal auditing practices to measure success, efficiency as well as qualitative variables; some change occurs as a result of findings; stakeholders are given opportunity for input before changes are made; some benchmarking practices	Moderate
Pre: Routine internal auditing practices to measure success, efficiency as well as qualitative variables; external evaluations/audits are conducted at scheduled intervals (every 3-5 years); change occurs as a result of findings; stakeholders are given opportunity for input before changes are made; findings are made public to university community; significant strategic planning in "go/no-go" decisions; structured benchmarking practices *Post:* Routine internal auditing practices to measure success, efficiency as well as qualitative variables; external evaluations/audits are conducted at scheduled intervals (every 3-5 years); change occurs as a result of findings; some change occurs as a result of findings; stakeholders are given opportunity for input before changes are made; findings are made public to university community; structured benchmarking practices	High

Pre- denotes pre-award practices
Post- denotes post-award practices

Evaluation

A thorough evaluation is needed upon completion of each event. It is in the best interests of stakeholders to repeat positive history. Administrators should conduct the evaluation as it relates to each cornerstone to indicate how the use of key strategies affected the intended outcome(s) of the overall event.

Components of an evaluation stem from the original questions in the needs assessment:

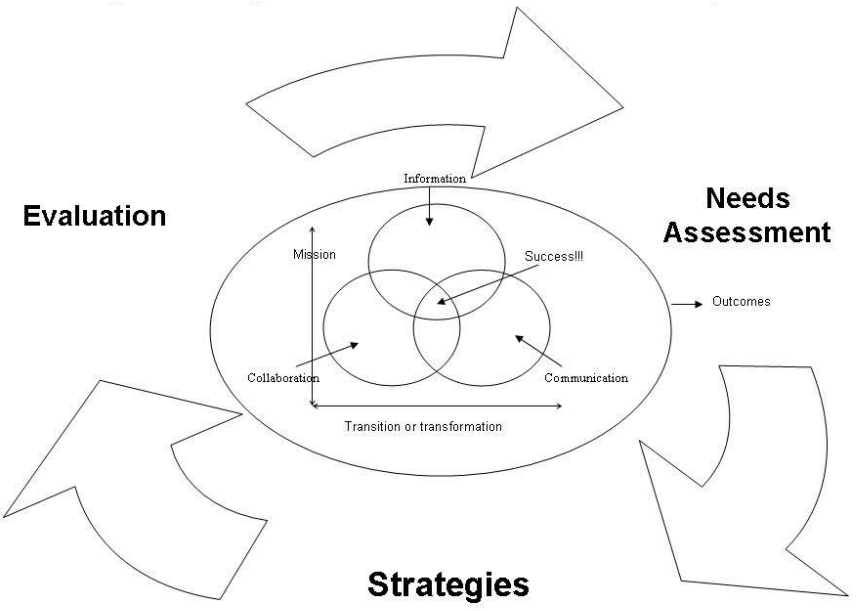
Were needs properly identified?
What were expected outcomes?
What worked/needs improvement?
Were services and information effectively and efficiently disseminated?

Identifying strengths and weaknesses in key strategies enables research administrators to learn from the past and implement stronger strategies for the future. During an evaluation, a unit can identify the current level of investment and develop other key strategies to move to the next level for greater success.

Just as important as the evaluation components are the roles and responsibilities of the individuals participating in the evaluation. Each stakeholder must be willing to accept responsibility for his or her role in the process and be willing to make improvements that may include additional responsibilities. If certain stakeholders are not willing to participate in the evaluation, it is incumbent upon each research administrator to do his or her own evaluation and maintain records of strategies that worked and those that need improvement. Effective evaluations can assist in improving performance for future events. Improved performance will garner increased trust and respect from faculty and other peers. In research administration, one must continually seek to improve knowledge, skills, and performance.

As Figure 2 illustrates, when a unit defines each cornerstone, completes a needs assessment, implements key strategies, and evaluates its performance, it has implemented the feedback cycle inherent in the conceptual framework adoption.

Figure 2
Full implementation of the framework and feedback loop.



As seen in Table 1, key strategies can be categorized according to cornerstone, by pre- and post-award relevance and by level of resources, although there is some overlap. This table is not exhaustive or mutually exclusive, but serves as a foundation. Research administrators should adapt strategies to each cornerstone, and then adapt again by level of resources (or investment) related to level of output (success). Generic strategies such as listservs or newsletters are the starting point. Depending on the cornerstone or the level of resources, these items should be made relevant to the stakeholder audience. Resources for the purposes of the conceptual framework discussed here include human capital, level of access to information, and willingness or ability to invest. Similarly, success includes, but is not limited to: number of proposals submitted; number of proposals funded; number of interdisciplinary collaborations and sub-awards; significant compliance with institutional, sponsor, and federal guidelines; number of highly trained (or certified) staff and senior research administration personnel, and effective management practices.

Theoretical Framework

One theoretical framework ascribed to by research administrators is servant leadership, the modern theory developed by Robert Greenleaf (2002). Servant leadership stresses the role of leaders as stewards of resources provided by an organization. The servant-leader focuses on serving others while advancing and achieving the goals and aspirations of the organization. While this theory does stress collaboration and trust-building, the connotation of the word servant calls to mind the idea of research administrators as just there to do as directed.

A more suitable theoretical framework for the model is the theory of successful intelligence. This psychological theory applied traditionally to education adopts a domain-general approach, which means its purpose is to apply a "general theory of cognitive and other skills that apply across subject-matter areas" (Sternberg, 2008, p. 150). The four main tenets of this theory are: a) definition of success; b) different paths to success; c) adapting to existing environments, shaping those environments and selecting new; and d) balancing abilities (analytical, creative, and practical).

Sternberg (2008) describes *definition of success* in relation to the individual in one's sociocultural context. This is relevant to research administrators and research administration, and allows application of the six cornerstones. Each research administrator needs to have a firm idea of what it means to be successful, not only in a personal sense, but also in the context of the larger unit or organization. A unit of research administration needs a firm idea of success for the unit itself, but also in context of the university's Mission and Outcomes.

Sternberg describes *different paths to success* as having the knowledge to understand there are no single pathways to success for any goal. Pathways may change as organizations or units change. In this model, *different paths to success* are key strategies, especially for Communication, Collaboration, Transformation, and a final needs assessment.

The third tenet, *adapting to existing environments, shaping those environments and selecting new,* involves staying current, looking ahead and preparing for changing conditions. The Transition or Transformation component is all about avoiding stagnation, and constant evolution.

The final tenet of Sternberg's (2008) theory is *balancing abilities.* Analytical abilities enable research administrators to plan, forecast, and measure outcomes, and solve problems. Creative abilities (program/project design, a sense of entrepreneurialism) engender great ideas. Practical abilities enable implementation of those ideas into action. These abilities serve as the foundation for Information, Communication, and Collaboration. Sternberg (2008) emphasizes that successful people need not be capable across all three, but discover ways to accommodate for strengths and weaknesses.

Sternberg's final point suggests a stronger commitment towards continuing professional development for research administrators at all levels. Continuing professional development helps create experts while at the same time addressing weaknesses. Capitalizing on strengths and developing expert research administrators will help diffuse negative interdependence. Professional development must remain continuous and consistent to be most effective. Central research administrators' levels of expertise should not be so far in advance of those at local levels. An environment characterized by limited and segregated professional development only breeds mistrust and discontent. Continuing professional development will increase engagement and investment among research administrators and lessen issues of retention and turnover.

For professional development to play such a critical role, it is important to have full administrative support from supervisors and senior research administration. Increased support will engage and motivate stakeholders. As stakeholders become more engaged, they are more than likely going to increase their participation and investment. Fully engaged stakeholders will support the unit's mission overall, and that will lead to more sponsored research funding. In the end, that is what research administration is all about.

Conclusion

The conceptual framework was developed to assist research administrators with improving their approach to research administration as a whole. If a unit is to grow and achieve greater success, research administrators must move beyond what is minimally required to get the job done. If the field of research administration is to grow and gain wider acceptance and respect, then research administrators need to prove that they can help a unit move beyond the status quo and be valuable stakeholders in promoting a unit's success.

Even highly successful units desire greater success. The conceptual framework is open to an individual unit's own interpretation and leaves room for creativity and entrepreneurialism. For the conceptual framework to be successful, it is incumbent upon each unit to determine the meanings of key concepts such as needs, strategies, and successes and then develop a more specific framework around those determinations.

References

Bush, V. (1945). Science: The endless frontier. Washington, D.C.: United States Government Printing Office.

Greenleaf, R. K., & Spears, L. C. (2002). *Servant leadership: A journey into the nature of legitimate power and greatness.* New York: Paulist Press.

Sternberg, R. (2008). Applying psychological theories to educational practice. *American Educational Research Journal,* 45(1), 150-165.

Sullivan, W.M. (1995). Work and integrity: The crisis and promise of professionalism in America. Stanford: Jossey-Bass.

Waugaman, P.G., Kirby, W.S., & Tornatzky, L.G. (2006). Performance measurement. In E. C. Kulakowski, & L. U. Chronister (Eds.), *Research administration and management* (pp. 137-147). Sudbury, MA: Jones and Bartlett Publishers.

Conflict: A Catalyst for Institutional Change

Debra Schaller-Demers, MSOM
Research Education and Communication Manager
Memorial Sloan-Kettering Cancer Center
Research and Technology Management Division
1275 York Avenue, Box 69
New York, New York 10065
Tel: 646 227-2282
Email: schalled@mskcc.org

Author's Note

This article was adapted from a paper originally presented for the SRA Symposium 2007 entitled: "You say conflict like it's a bad thing." This paper was based on a lecture originally presented at the Weill Cornell Medical College Research Coordinators' Network in December 2006, and at the Weill Cornell Masters Degree Program in Clinical Investigation July 2007 seminar series entitled: *Ethical, Social & Legal Issues in Responsible Clinical Research.* All opinions expressed in this article are solely that of the author and not of any particular institution and/or organization.

Abstract

This article focuses on perceptions and behaviors surrounding potential conflicts of interest and/or commitment on both personal and institutional levels. It references past cases, public reaction and subsequent policy decisions. Most people believe conflict to be negative, something to be avoided. While conflict might make one feel stressed, angry, scared, or confused, it can offer new and positive opportunities for change, learning, and growth. In that same vein, a potential conflict of interest or commitment is not inherently a bad thing. Conflicts within science are almost to be expected. In fact, often it means there is good work happening that will contribute to generalizable knowledge and benefit society. Therefore, there is no shame or crime in having external financial relationships. The shame is in allowing those relationships to potentially bias the work, create false presumptions and distort decision-making, or in hiding the fact that they exist in the first place. This paper endorses a proactive approach for dialoguing and developing effective conflict of interest policies that will ultimately lead to changes in people's perceptions as well as their behavior in conflict of interest situations.

Keywords: Conflict of interest, conflict of commitment, significant financial interest, equity holdings, conflict management, rebuttable presumption, commercialization of intellectual property, peer review

Introduction

Conflict, simply defined, is a state of disharmony between incompatible or opposing persons, ideas, or interests. When asked to close their eyes and envision a recent conflict, most people will experience a disheartening feeling. They may notice physical or emotional signs of distress (e.g., palpitations, rapid breathing, sweaty palms, shaking, tearing, etc.). Therefore they tend to assign

a negative connotation to conflict as a general concept. They view conflict as something to be avoided at all costs. But conflict is natural, and even when one acquires the skills to deal with it more effectively it continues to exist (ESR, 1998). It surrounds us on a daily basis, and while it might make us feel stressed, frustrated, angry, scared, or confused, it can offer new and positive opportunities for change, learning, and growth.

The same holds true for conflicts of interest and/or commitment within an organization. Again, by simple definition, a conflict of interest and/or commitment exists when there is a state of disharmony between one's responsibilities as an employee/member of a specific institution/organization and an outside entity. Both the American Association of Medical Colleges (AAMC) and the American Association of Universities (AAU) have adopted this definition: "The term individual conflict of interest in science refers to situations in which financial considerations may compromise, or have the appearance of compromising, an investigator's professional judgment in conducting or reporting research" (Broccolo & Klanica, 2006). Yet, dealing effectively with the conflict of interest situation can also lead to positive opportunities for change, learning, and growth.

In essence, a potential conflict of interest or commitment is not inherently a bad thing. Often it means there is good work happening that will contribute to generalizable knowledge and benefit society. External or extramural financial interests often drive the research in ways that internal funding alone cannot by providing a direction to research that will result in the largest possible positive impact on society. Kalichman and Macrina (2001) state that conflicts encountered through the scientific profession are to be expected, it is how they are handled that can lead to untoward, inappropriate, or bad outcomes. Therefore, there is no shame in having external financial relationships, whether as an individual or an institution as a whole. The shame is in allowing those relationships to potentially bias the work, create false presumptions and distort decision-making, or in hiding the fact that they exist in the first place.

Maintaining even minimal standards of research integrity is dependent upon protecting and preserving not only the integrity of the science, but that of the researcher and the institution. There is also a fundamental obligation to preserve and sustain the public trust. The public trust is a fragile thing and once shattered it is almost impossible to repair (Schaller-Demers, 2006). Bradley (2005) says there is a concern that an escalating climate of secrecy and economic competition is contributing to the public's loss of confidence in the integrity of science and scientists, if not an actual deterioration in the quality of the science. If one accepts that public trust is what drives public funding, it may be logical to assume that once public trust is eroded, public funding will erode as well (Cohen, 2002).

Broccolo and Klanica (2006) state that instances of research misconduct can be motivated by the types of financial and associational (non-financial) interests that give rise to potential conflicts of interest and that the media and the public cannot distinguish the difference between actual conflict and perceptions of conflict. That is why perception and appearances are so important. Hiding is never the answer, because upon close examination, it may be determined that an actual conflict of interest doesn't even exist. When conflicts are revealed after-the-fact, especially in cases where misconduct is alleged or unanticipated adverse events occur, the perceptions can be more damaging than the reality.

An elemental question is to what extent financial incentives affect professional judgment. Barnes and Florencio (2002) state that financial incentives can and do exert significant influence over human behavior. Sadly, when individuals' reputations and/or livelihoods are at stake, good judgment can succumb to avarice. Institutional judgment can become clouded when reputations and/or finances hang in the balance. Bradley (2005) says that universities have a strong sense of self-preservation when confronted with these types of situations. Therefore, they may be reluctant to cancel lucrative contracts or prohibit or restrict certain studies even though a faculty member may have a potentially serious conflict of interest. The University of Oklahoma and the University of Toronto are two examples of institutions where professional judgment was overpowered by financial considerations to the detriment of reputation and research (Barnes & Florencio, 2002). At St. John Medical Center in Tulsa, Oklahoma, there was a study that investigated an experimental vaccine for malignant melanoma. Both the Institutional Review Board (IRB) chair and the dean allegedly concealed from both the IRB and the Food and Drug Administration (FDA) a report from an outside consulting firm that found severe deficiencies with the melanoma vaccine study. They eventually halted the study, but not because of these negative findings, and stated in an annual report that there were no significant safety issues related to the melanoma vaccine.

At the University of Toronto, the former university president urged the Canadian Prime Minister and four other cabinet ministers to withdraw proposed drug patent regulations or Apotex, a pharmaceutical giant, would rescind its multi-million dollar donation earmarked for the University and its affiliated teaching hospitals.

Barnes and Florencio (2002) point out that even high-level officials like an IRB chair, a dean of medicine, or a university president can be distracted from their primary responsibilities due to the influence of financial interests. One would automatically assume that safeguarding human research subjects and preserving the integrity of research, researchers, and the institution would be paramount. Yet even those held in the highest esteem may misstep while chasing ever-shrinking research dollars.

Objectivity through self-reflection can be difficult to achieve and/or maintain. Doctors, researchers, and other academic professionals might question whether "gifts" from a pharmaceutical company or consulting agreements could influence them to prescribe that company's drugs, use a particular device, or contract for a certain service (Gilbert, 2006). As professionals, people do not want to believe that they can be subconsciously bribed. It is almost impossible to judge one's own behaviors or motivations accurately and without bias. Gilbert (2006) says that the brain cannot see itself fooling itself. Therefore, he thinks that the only reliable method for avoiding bias is to avoid the situations that produce it in the first place.

Avoidance and elimination are ways to handle conflict of interest situations. However, in the scope of scientific research that is not always what is in the best interest of the science (see rebuttable presumption). As is the case with most learned professionals, scientists are generally strong in their beliefs and will stand long by a hypothesis. Understandably this mindset might tempt them to hold tight to a particular research plan, especially when it has become their life's work. However, as we have now seen by the misjudgments of others, strong beliefs can sometimes lead to disaster – as proven by more than one now-infamous example.

In 2005, researcher James Wilson and the University of Pennsylvania (UPENN) were found complicit in the case of Jesse Gelsinger, a teenage volunteer who died in a gene therapy trial. In addition to numerous research misconduct violations, it was discovered after-the-fact that Wilson, the principal investigator (PI), held a 30% equity interest and UPENN a 3.2% equity interest in the sponsor of the trial. When another corporation acquired the sponsor, the PI reportedly made a return of $13.5 million and the university reportedly earned $1.4 million (Lemonick & Goldstein, 2002).

Paul Gelsinger (2001), Jesse's father, says that when he met with the head researcher for the first time after his son's death he asked him about his financial position in the trial. The researcher's response was that he was an unpaid consultant to the biotech company behind the research effort. Gelsinger accepted his word and continued to support him and his work. He now contends that the over-enthusiasm of the clinical investigators painted an unrealistic picture of the study's safety and efficacy. That enthusiasm blinded them to the ill effects that they were witnessing. Therefore, Gelsinger says "… I still support our need for clinical trials, but with this caution: Informed consent is only possible if all facets of the research endeavor are ethical and in the open." The death of Jesse Gelsinger stands as a tragic reminder that transparency and full disclosure serve to protect us all – the public-at-large (all potential subjects), the researchers, the sponsors, and the institutions.

Today's media, fortified by intensified government review, focus an easily influenced public's attention on misconduct. In this atmosphere, potential biomedical research conflicts receive heightened scrutiny – especially when human subjects are involved. Broccolo and Klanica (2006) say that the current challenge to institutions is to establish and maintain a conflicts of interest infrastructure that achieves the right balance between promoting and supporting a spirit of innovation (as supported by Bayh-Dole) on the one hand and adapting to the best practice standards that are emerging through society's call for reform on the other. Cohen (2002) reminds us that it is critical for relationships between academic medicine and industry to remain principled, protective of subjects, respectful of scientific integrity, and capable of withstanding public scrutiny. In other words, it is not sufficient to know your heart is pure, your science is impeccable, and your motives are completely altruistic -- you must be able to prove it on the front page of The New York Times.

Although federal (i.e., PHS, FDA, DHHS) conflict of interest laws and regulations may fall short of emerging best practices, it is still important to be cognizant of them as a basic foundation for developing institution-specific policies and procedures (Broccolo & Klanica, 2006). Understandably, institutions are concerned about the increasing administrative burdens placed on them by legislators and regulators who expect them to implement unfunded mandates, especially when these mandates may put the institutions at odds with their own faculty or scientists (Bradley, 2005). Yet, the bigger picture is obvious – without clear policies and procedures, the price to pay would be even higher.

Most institutions and organizations have some requisite set of procedures, guidelines, or policies that dictate how potential conflicts of interest and/or commitment should be handled. The problem is not that policies do not exist, but that communicating their expectations or improving the implementation of those policies might be improved. Commonly accepted methods for

handling a potential financial conflict of interest involve managing (disclosure), reducing, or eliminating.

Managing financial conflicts of interest has become more important in recent years as the emphasis on commercialization of intellectual property has increased. Researchers are now encouraged to commercialize and thereby increase their opportunity to benefit personally (Cohen, 2002). As researchers benefit, so do their institutions. Universities now regard technology transfer as an important revenue stream needed to bolster or replace decreasing support from state and/or federal agencies (Bradley, 2005). Developing an organizational culture that appreciates the urgency of compliance, while balancing its enthusiasm for innovation and discovery is the key to financial longevity, brand-name recognition, and public trust.

The AAMC's guidelines for managing individual and institutional financial conflicts of interest were developed in recognition of the unique challenges faced by medical schools and teaching hospitals. The central focal point of the guidance is the *rebuttable presumption* that no one with a significant financial interest in the outcome of a study can be allowed to conduct that research, unless there are compelling circumstances why the research cannot be otherwise conducted as safely or effectively (Cohen, 2002). Typically, these financial interests exceed a certain dollar amount or value threshold and/or involve a competing fiduciary obligation (Broccolo & Klanica, 2006). Since it is rare that the rebuttable presumption can be argued successfully, there are several other alternatives that can be used to reduce or eliminate the conflict.

To further confuse the issue, there are varying definitions of the word "significant" in terms of reporting external or extramural financial interests (consulting fees, honoraria, gifts, in-kind compensation, equity interests, royalties, etc.). The National Institutes of Health (NIH - PHS) defines significant as having aggregate value greater than $10,000 or a 5% equity ownership in a single entity, while the FDA has set the significance threshold at $25,000. This leads to confusion on the part of many researchers. Most investigators report what is required and necessary, but others may feel that they are suspect because they are being asked to disclose.

The Office of the Inspector General's (OIG) report (January 2008) on the NIH and Conflicts of Interest in Extramural Research has focused new attention on this growing concern. Its findings clearly illustrate a disconnect between what is reported to the institution in the first instance and to the federal government and the public in the second. NIH policy simply requires that an institution report that a significant (meaning of high value) conflict exists and that it is being dealt with when NIH funding is involved. The OIG found that the information being reported to NIH is incomplete, as it lacks sufficient details regarding the conflict and how it is being managed. NIH counter-argues that it is incumbent on the institution – not NIH -- to "police" and guarantee this process. Note: NIH has stated that institutions must disclose to them significant conflicts as defined by the institution's policy if the institution has a lower dollar value definition than NIH does.

It is this lack of specificity or unwillingness to take an authoritative stand that leads to confusion on the part of investigators and their institutions. The days of "don't ask, don't tell" are over. There is too much at stake. Years of ground-breaking research are now suspect because funding sources and equity or intellectual property rights were not reported with enough transparency.

The debate about whether or not to accept funding from certain industries and how much it might influence the outcome of the research is not new... If tobacco companies or "Big Pharma" sponsor research, will the results be automatically suspect? Many institutions take a hard stance against acceptance of funding from the tobacco industry. As reported in 2006, the University of California had received close to $2 million in grants and contracts from tobacco companies. As a result, a movement began to ban the university system from accepting such funding. Jaschik (2006) reports that the argument is not that the smoking industry promotes harmful products, although most would concur that it does, but that it uses university research to "deceive the public to such an extent that the research harms the university system." The opposing viewpoint says that any absolute ban on support from tobacco, or for that matter, any other specific source, would violate the tenets of academic freedom. This would create an untenable situation where university officials would be constantly put in the position of having to decide which sources were acceptable and which were not (Jaschik, 2006).

The American Cancer Society (ACS, 2008) maintains a policy in regard to the acceptance of funding from tobacco companies. It states that those who are funded by the tobacco industry for any project, or whose named mentors in the case of mentored grants are funded in the same vein, may not apply and will not be eligible for ACS research and training grants activated on or after July 1, 2005. It states further that those who accept tobacco funding during the tenure of an ACS grant must inform ACS of such funding and subsequently the ACS grant will be immediately terminated.

Might drug company dollars be perceived as influencing research results in much the same way as those of tobacco? Abramson and Starfield (2005) suggest that universities have little choice but to turn to commercial sources of funding, a notion supported by the numbers, which show that between 1977 and 1990, drug expenditures on research and development (R & D) increased six-fold. A large portion of these expenditures went to support university-based research.

Certainly there are strict regulatory controls overseeing pharmaceutical development as compared to the oversight mechanisms that exist within the tobacco industry. Therefore society's trust level is supported when it comes to drug R & D. Yet this dramatic increase in funding over the years certainly speaks to the possibility of biased or skewed results. The increase in spending alone is not an indicator of how the funding was used or if any of the researchers or institutions involved may have had a potential conflict of interest with the sponsoring company or agency. Additionally, if financial relationships did exist, there is no way to know from just the numbers if there were any contractual restrictions on publishing negative results. Yet, it is this very lack of explicit reporting and monitoring that helps foster negative perceptions. In the end, without much needed transparency, the process can become tainted and a lifetime of valuable research can become unnecessarily suspect.

The controversy becomes more intense as the loudest voices position themselves to be heard. Who should be the final arbiter of what is right when it comes to funding the scientific enterprise? How does policy, such as the one established by the ACS, reflect on the worthiness and validity of the scientific peer review process? As stated by Dovey (2004), the rigors of the peer review process, even in the most renowned science and medical journals, in addition to full disclosure requirements, aren't enough to convince some that published studies aren't tainted by

the dollars that made them possible. Dissatisfied with results that might undermine or contradict their own belief system, activists and politicians claim bias, and otherwise prestigious biomedical institutions and organizations are forced to backtrack, opting in some instances to "appease the advocates," rather than allow the established scientific method to determine good science from bad (Dovey, 2004).

While Dovey (2004) and others hold the peer review process in high regard, others (Abramson & Starfield, 2005) feel that the medical journals are "ill-equipped to withstand the drug companies' financial pressure, research and statistical capacity, commercial ties with the most recognized experts, and lack of transparency in the research they fund." Neal, Schwartz and Bowman (2005) concur, and say that a major limitation of the peer review process is its inability to effectively deal with conflicts of interest, especially in a context when "prestigious scientists may have similar biases." Therefore, they fear that reliance on the peer review process may allow damaging distortions to become ingrained in clinical practice and health policy.

Each of us, despite our role as members of a society dependent on those in the know in the research community, has to be able to determine what is "real" from what is "real, but paid for." Following the money trail allows us to be cognizant of the influences that may be at work behind the scenes. This is essential to understanding the motivations of those performing, interpreting, and reviewing the research. Readers, potential subjects, patients, and colleagues need to be able to make their own judgments about the likelihood that conflicts (real or potential) may have introduced bias in the research report or practice guideline (Neal, Schwartz, & Bowman, 2005).

This is further evidence that a clear and transparent process for disclosure is important. The science must be above any suspicion of hidden (or not so hidden) agendas. Everyone must be considered equally and subject to the same reporting mechanisms. It is prudent to require disclosure of any amount, and not be persuaded by a presumption that only significant amounts need to be reported. Broccolo and Klanica (2006) recommend abandoning the use of financial thresholds as triggers for disclosure and support requiring disclosure of interests of any value, using the thresholds instead as a guideline for the conflict committee (or other appropriate oversight body) when assessing management options.

Too often investigators get lulled into a false sense of security by thinking that their monetary gain is not significant enough to warrant reporting, or could not influence their results. This has led to many controversies of late, and a media frenzy of pointing fingers, opposing testimonies, and restrictive policies, such as the ACS ban on tobacco funding referenced above.

In any case where bias is in question, the benefits of conducting the research by the conflicted investigator and/or at the conflicted institution must be weighed against the risks of what that bias might incur (Barnes & Florencio, 2002). Conflict advisory panels or committees to oversee the reporting and make compliance recommendations are an important first screening mechanism to have in place before even Institutional Review Boards (IRBs) or Institutional Animal Care and Use Committees (IACUCs) evaluate a proposed project. It then becomes essential to both the financial survival and scientific reputation of the research institution to ensure that its conflict of interest policies, procedures, and practices are clear, effective, enforceable, and can stand up to any scrutiny.

Conclusion

To preserve, maintain, and foster research integrity and the public trust, academia will need to prove that it values the advancement of human knowledge more than short- or even long-term profit (Barnes & Florencio, 2002). Having policies and procedures to actively manage both individual and institutional conflict of interest situations earns good faith points in the eyes of those served by the research enterprise. Federal regulations are just the starting point and, as witnessed by the recent OIG audit of the NIH, even the government is taking a hard look at its own biases and weaknesses in this regard. The public, the courts, the media, and industry trade associations have all made it clear that just meeting the minimum standard is no longer acceptable (Broccolo & Klanica, 2006).

Regardless of the oversight mechanisms employed, education, training, and communication among all the constituents are vital. Conflicts of interest should not be treated like secrets, but disclosed and reported with consistency and regulated with parity.

Building an organizational environment that will support, sustain, protect, and give a voice to staff, faculty, and students alike is critical to the process. A culture that embraces the ideals of research integrity will allow for open venues to actively discuss conflict situations. These days, most comprehensive Responsible Conduct of Research (RCR) programs have a module on conflicts of interest and commitment, but learning does not begin and end in college or graduate school. Sometimes the most seasoned faculty members and top-level administrators need refresher lessons and reinforcement. Even mentors need mentors. If people feel they are a part of the solution and not just the problem, compliance rates should increase, as doing the right thing becomes the only way to do what needs to be done. Ideally, accurate and timely disclosure would become an automatic standard operating procedure.

Electronic database systems have made reporting and tracking less onerous and allow those responsible for compliance to have the most up-to-date information at hand. Yearly disclosure is standard, and the immediate reporting of changes that might occur during the year is critical to maintaining compliance.

Enforcing sanctions for noncompliance with the research conflicts policy can be challenging. While no one wants to interfere with good science, there are compliance standards that must be met for the protection of everyone involved. Creating clear procedures for reporting in an accurate and timely fashion on both an annual and on-going (study specific) basis will serve to bolster the enforceability and effectiveness of the policy. If sanctions are delineated in the policy, the institution must consistently enforce them. Broccolo and Klanica (2006) suggest that ties to annual renewals of medical staff or faculty status can be effective, as can suspension or termination of such status. On a study-by-study basis, IRB and IACUC approval can be held in abeyance until disclosure statements are complete and accurate, as can the execution of pending grants and/or contracts.

FASEB (2007) offers these three guiding principles: 1) Investigators must conduct research activities objectively; 2) Investigators must operate with transparency; 3) Investigators must be accountable to all stakeholders. We may also go one step further, and say that investigators are not the only ones who must operate in this forthright manner.

Institutions and all of the stakeholders (including the public, the media, regulators, students and trainees, technicians, legal counsels, technology transfer personnel, compliance officers, committee chairs/members, administrators, coordinators, and other research support staff) engaged in or affected by the research enterprise must embrace and internalize responsible conduct of research on many levels. It must become an ingrained part of the mission, the virtual raison d'être. Conflicts of interest issues dwell at the base of this ethical core. Allowing them to remain hidden or untouched will eventually erode the entire foundation of trust in the integrity of science. Dealing with them openly and actively will allow them to rise up and filter out into the mainstream where they belong. The result is a research enterprise above reproach – one that is responsible, accountable, and indisputably ethical.

References

Abramson, J., & Starfield, B. (2005, September-October). The effect of conflict of interest on biomedical research and clinical practice guidelines: Can we trust the evidence in evidence-based medicine? *Journal of American Board of Family Practice, 18*(5), 414-18.

American Cancer Society (2008, January). *Research Scholar Grants Policies and Instructions,* p. 7.

Barnes, M., & Florencio, P. (2002). Financial conflicts of interest in human subjects research: The problem of institutional conflict. *Journal of Law, Medicine and Ethics*, *30*:390-402.

Bradley, S. G. (2005). Managing competing interests. In F. L. Macrina (Ed.) F. L. *Scientific Integrity* (3rd Edition) (pp. 159-186). Washington, DC: ASM Press.

Broccolo, B. M., & Klanica, K. E. (2006, October 18). Conflicts of interest in human subject research: Adapting to evolving best practice standards. *The Bureau of National Affairs, Inc, 5* (20), 690.

Cohen, J. J., (2002). Managing financial conflicts of interest in clinical research. *Science and Engineering Ethics, 8*(3), 401-406.

Dovey, T. (2004, August 23). American Cancer Society a danger to science? American Council on Science and Health. Retrieved June 21, 2008, from: http://www.acsh.org/factsfears/newsID.432/news_detail.asp

Educators for Social Responsibility, Metro (ESR). (1998) Now known as Morningside Center for Teaching Social Responsibility. *Five key concepts of conflict resolution.*

FASEB - Federation of American Societies for Experimental Biology. (2007, July 20). COI Toolkit. Retrieved July 23, 2007, from: http://opa.faseb.org/pages/Advocacy/coi/Toolkit.htm

Gelsinger, P. (2001). Jesse's intent. http://www.circare.org/submit/jintent.pdf

Gilbert, D. (2006, April 16). I'm O.K., you're biased. *The New York Times.*

Jaschik, S. (2006, September 21). *Does tobacco money taint research?* Inside Higher Ed. Retrieved June 21, 2008, from: http://www.insidehighered.com/news/2006/09/21/tobacco

Kalichman, M., & Macrina, F. (2001). Responsible conduct of research education committee (RCREC) internet course. *Conflicts of Interest.* http://www.rcrec.org

Lemonick, M. D. & Goldstein, A. (2002, April 22). At your own risk. Retrieved June 30, 2007, from: http://www.time.com/time/magazine/article/0,9171,1002263,00.html

National Institutes of Health: Conflicts of Interest in Extramural Research. OEI-03-06-00460 (2008, January). Retrieved June 21, 2008 from: http://www.oig.hhs.gov/oei/reports/oei-03-06-00460.pdf

Neale, A.V., Schwartz, K. L., & Bowman, M. A. (2005, July 19). Conflict of interest: Can we minimize its influence in the biomedical literature? *Journal of American Board of Family Practice.*18: 411-413. Retrieved June 23, 2008, from: http://www.jabfm.org/cgi/content/full/18/5/411

Schaller-Demers, D. (2006, November). Why do ethical scientists make unethical decisions? *Journal of Research Administration.* Society of Research Administrators International. Volume XXXVII. No. 2. pp 35-42.

The Chronicle of Higher Education. (1999). *Canadian drug company withdraws most of a major gift to U. of Toronto,* A69. Retrieved June 30, 2007, from: http://chronicle.com/weekly/v46/i13/13a06902.htm

International Regulatory Review

The Human Tissue Act 2004

Reflections on recent changes in regulatory affairs in the United Kingdom

Birgit Whitman, PhD
Research Governance Manager
Research and Enterprise Development
Senate House, Tyndall Avenue
University of Bristol
Bristol, UK BS8 1TH
Tel: +44 (0) 117 3317130
Fax: +44 (0) 117 9298383
E-mail: birgit.whitman@bristol.ac.uk

Rachel Ginham, DPhil
Research and Human Tissue Specialist
Research and Enterprise Development
Senate House, Tyndall Avenue
University of Bristol
Bristol, UK BS8 1TH
Email: rachel.ginham@bristol.ac.uk

Mary Perkins, RGN, DHealth (cand)
Research and Development Manager
University Hospitals Bristol NHS Foundation Trust
Research and Effectiveness Department
Education Centre, Level 3
Upper Maudlin Street
Bristol, UK BS2 8AE
Tel: +44 (0) 117 342 0233
Fax: +44 (0) 117 342 0239
Email: mary.perkins@uhbristol.nhs.uk

David Langley, PhD
Director
Research and Enterprise Development
Senate House, Tyndall Avenue
University of Bristol
Bristol, UK BS8 1TH
Tel: +44 (0) 117 9288457
Fax: +44 (0) 117 9298383
Email: david.langley@bristol.ac.uk

Introduction

US Federal regulators have increased their oversight in areas that use human tissue, in particular targeting companies that remove tissue for use in medical procedures. The UK has recently undertaken a comprehensive review of the existing law that surrounds human tissue as a result of inquiries that identified a need to improve current practice. The inquiries related to a misinterpretation of legislation that led to a distressing and unacceptable situation for relatives of children and adults whose bodies, or part of their bodies, were used without their consent, after their deaths. The Retained Organs Commission (ROC) made recommendations for changes to the existing law (Department of Health, 2001a). The Human Tissue Act 2004 (HT Act) was created and relates to England, Wales and Northern Ireland. A separate Act, the Human Tissue (Scottish) Act 2006, is in place in Scotland.

This review explores the events leading up to the creation of the HT Act with a brief overview of the key points, remit and impact of the HT Act. *(Editor's Note: The term "remit" may be understood as scope or responsibilities.)*

The events leading to the development of the Human Tissue Act in the UK

Two public inquiries at the Bristol Royal Infirmary and the Alder Hey Children's Hospital were the catalyst for the creation of the HT Act in the UK. Both inquiries highlighted issues of consent, retention, and use of human tissue obtained from people after their deaths. The Isaacs Report summarised the findings from both inquiries and highlighted the fact that after people had died it was commonplace to find storage and use of their organs and tissue without proper consent being obtained (Department of Health, 2001a, 2001b, 2003).

These events caused much distress to relatives who were often unaware that organs had been retained. There was an urgent need to address this with a legislative review of the existing law to ensure that guidance for good practice in the storage and use of human tissue was developed and implemented. This review also served to restore public confidence and ensure that tissue obtained with consent would still be available for research and teaching purposes.

A public consultation was undertaken by the government as part of an overall legislative review to address this lack of attention to policies and procedures outlined in the existing legislation. The report (Department of Health, 2001c) summarised the changes necessary to the legal and regulatory framework to reflect advances in good practice and provided a *lessons-to-learn* approach. This made it clear that living patients would be required to consent to the retention and use of their organs and tissue for particular purposes beyond their diagnosis and treatment. There would also be mandatory consent for removal, retention, and use of tissue from the deceased given either by these people while still alive; or, in the event that they died without expressing their wishes, given by someone nominated by or close to them (Department of Health, 2001c). The independent Retained Organs Commission (ROC) was set-up as a recommendation from the legislative review and provided advice to the Government about the changes needed in the law, based on two rounds of consultations carried out in 2002 and 2003.

Summary of the HT Act 2004

The HT Act repeals and replaces a number of previous pieces of legislation. It provides a framework for regulating the storage and use of human organs and tissue from the living; and the removal, storage, and use of tissue and organs from the deceased for specified health related purposes and public display. In response to the ROC recommendations, the HT Act makes consent the fundamental principle underpinning the lawful retention and use of body parts, organs, and tissue from the living or the deceased for specified health related purposes and public display. (Human Tissue Authority, *Homepage,* n.d.; *Human Tissue Act,* 2004). The Human Tissue Authority (HTA) was established on 1 April 2005 under the HT Act and regulates the following activities:

1. Carrying out of an anatomical examination;
2. Making of a post-mortem examination;
3. Removal of relevant material from a deceased person;
4. Storage of relevant material from a deceased person (other than for a specific ethically approved project);
5. Storage of anatomical specimens;
6. Storage of relevant material from a living person for research (other than for a specific ethically approved project) or for human application;
7. Public display of a body or material from a deceased person.

The HTA has two principal statutory functions. The first is to inform the public and the Secretary for Health about issues within their remit. The second is to license and inspect according to their regulatory remit. The HTA provides guidance in the form of Codes of Practice covering the following areas (Human Tissue Authority, *Codes of Practice*, n.d.):

Code 1: Consent;

Code 2: Donation of solid organs, tissue and cells for transplantation;

Code 3: Post mortem examination;

Code 4: Anatomical examination;

Code 5: Removal, storage and disposal of human organs and tissue;

Code 6: Donation of allogenic bone marrow, peripheral blood stem cells and donor lymphocytes for transplantation;

Code 7: Public display;

Code 8: Import and export of human bodies, body parts and tissue.

The European Union Tissue and Cells Directive (EUTCD) also sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissue and cells intended for human application (The Commission of the European Communities, 2006). This Directive applies to the whole of the UK.

What is considered relevant material under the HT Act?

In Section 53 of the HT Act, the term "relevant material" is defined as material, other than gametes, which consists of or includes human cells, except for embryos outside the human body, or hair and nails from the body of a living person (Human Tissue Authority, 2004). The Human Fertilisation and Embryology Authority is responsible for regulating the use of human reproductive cells, that is gametes and embryos.

Consent is the fundamental principle

The principle of consent is fundamental to the HT Act. The flow chart (Figure 1) highlights that consent is not required for material that had been collected prior to the implementation of the HT Act on the 1st September 2006.

The need for a licence

The flow diagram (Figure 2) clarifies that in most instances a licence will be required to work with human tissue. The compliance report encompasses detailed information about consent, governance and quality, premises, facilities and equipment, and disposal. This will be verified in an inspection by the regulatory authority.

The flow diagram details the exemptions from the licensing framework. One major area of exemption is a specific project that is running under a favourable opinion from the National Research Ethics Service (National Patient Safety Agency, 2007).

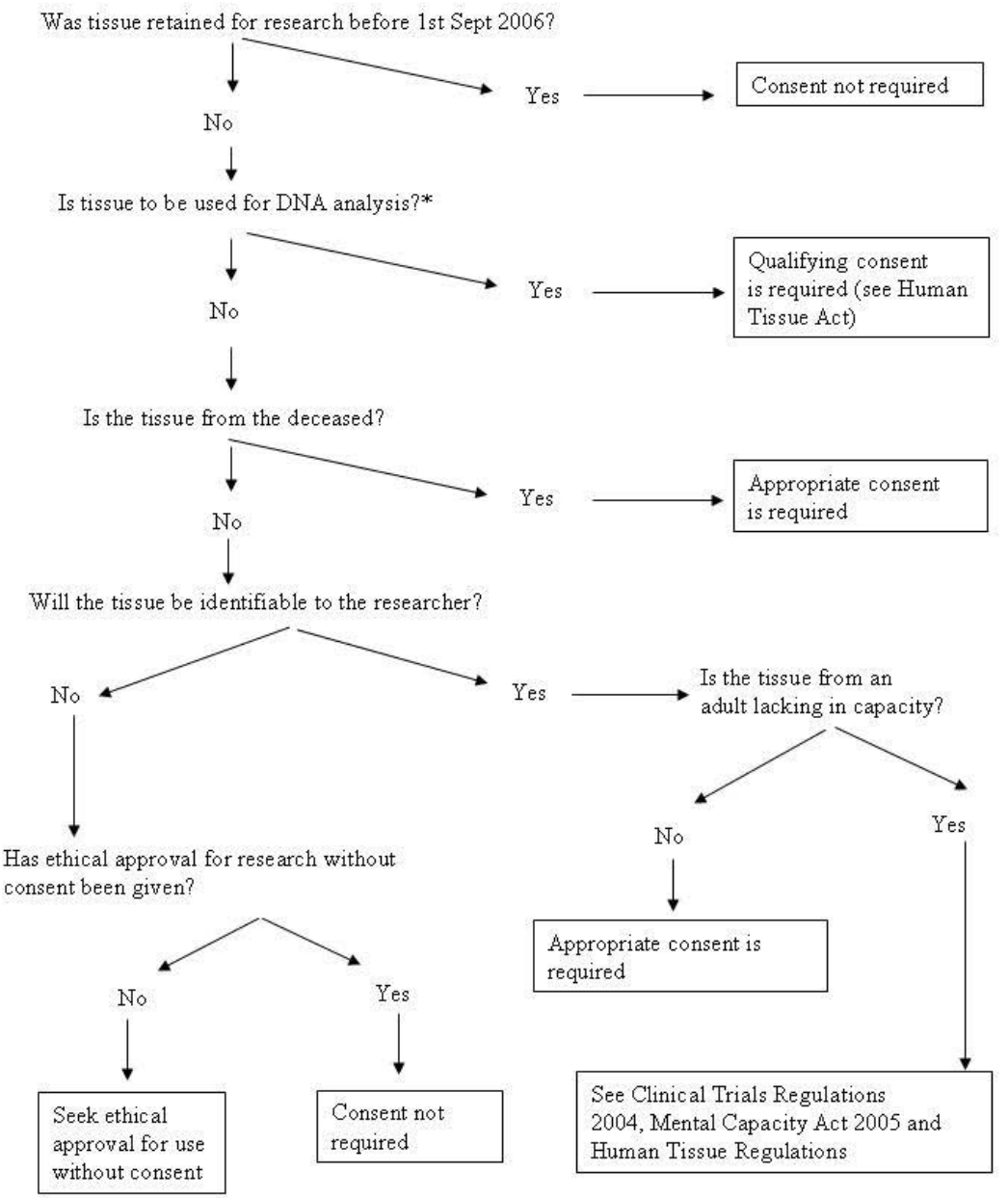
The role of a Designated Individual

Researchers working with tissue in the UK will be familiar with a new role that was created during the implementation of the HT Act. The Designated Individual (DI) is considered the gatekeeper of anyone using tissue that falls under the licensing remit of the HTA in one particular premise, more specifically within one postcode area.

Section 18 of the HT Act provides that it shall be the duty of the DI to secure:

1. That the other persons to whom the licence applies are suitable persons to participate in the carrying on of the licensed activity;

Figure 1
Content for removal of tissue and for retention and use of tissue.

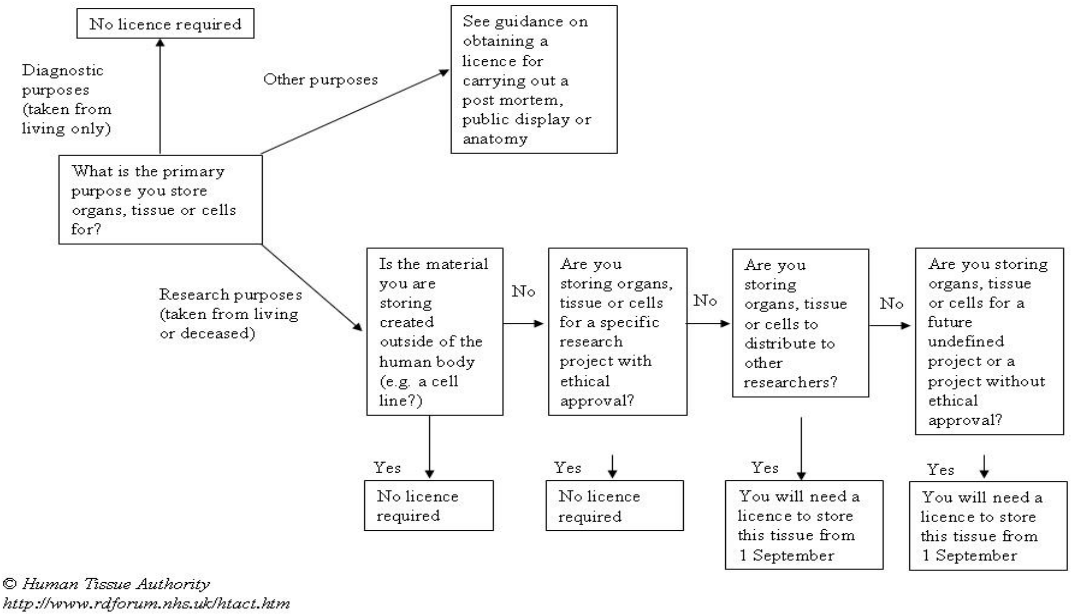


** This question applies UK-wide and includes nail, hair and gametes*
http://www.rdforum.nhs.uk/htact.htm; 19/07/06

2. That suitable practices are used in the course of carrying on that activity; and,

3. That the conditions of the licence are complied with.

Figure 2
Licensing requirement for working with human tissue.



The DI will complete the compliance report for the HTA and will be the point of contact for the desk-based assessment and inspection visits. Responsibility for all areas of the licence will lie with the DI with a personal liability. The DI ensures the consent process, training, governance arrangements, adequate facilities for storage and disposal according to the HT Act (Human Tissue Authority, 2006).

The Licence Holder

A Licence Holder can be an individual with managerial links to an establishment or a corporate body such as a university or hospital trust. In practical terms this means that a bigger organisation might have a Licence Holder as well as one or more DIs (Human Tissue Authority, 2006).

Persons Designated

A Persons Designated (PD), in the terms of the HTA, is a person to whom the licence applies. The PD does not have legal duties comparable to those of the DI.

Implementation of the HT Act at Bristol University

A Human Tissue Working Group (HTWG) was set-up to oversee the institutional processes and procedures to ensure compliance with the requirements of the HT Act. A baseline audit of current tissue holdings was performed across the institution to establish holdings exempt from supplying evidence of consent. The group raises awareness about the new legislation that would have an impact at the heart of the research and teaching culture. All DIs are invited to the HTWG to discuss compliance issues, best practice, training needs, and record keeping. The group receives high-level support from the University and reports to an executive Council Committee.

In preparation for the HTA's programme of inspection, the University initiated its own internal audit schedule. DIs cross-audit each other's licensed premises in accordance with this rolling programme. The objectives of the internal audits are to ensure that the activities on the premises satisfy the HT Act and relevant Codes of Practice. The internal audit team will work in close collaboration with the DI and the HTWG to identify practices that should be changed or improved. Training needs and resource requirements will be identified.

What impact does it have in the UK?

The HT Act has a profound impact on any activity that involves the use of human tissue. Due to the need for compliance with an extensive regulatory framework, it has touched at the heart of the research and teaching cultures as well as areas of public display, such as museums.

Understandably there have been resource implications for the implementation of the HT Act such as maintaining audit trails and implementing training programs for DIs and Research and Development staff. There has been a positive impact on the quality of research and on the quality of tissue holdings. Stakeholders involved in the use of tissue will now work within one framework in England, Wales, and Northern Ireland. It is possible to reassure the public that ethical considerations have been taken into account in the new legislation.

Conclusion

The HT Act was put into place to regulate the use of tissue and to ensure public confidence in the UK. Compliance with the HT Act is a resource intensive process and personal liability by DIs is a considerable risk to the individual as well as an institution.

From a global perspective it is necessary to explain the UK framework to people outside of England, Wales, and Northern Ireland. When research is conducted internationally, it is important to find a realistic way of understanding and translating the UK law into the framework of other countries. Such understanding and translation are critical to satisfying the legislative requirements of all stakeholders while facilitating innovative research and related works that involve the use of human tissue.

References

Department of Health. (2001, January 30 a). *The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol (Cm 5207(I)).* (Publication No. 0101520735). Retrieved July 30, 2008, from Department of Health website: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4009387.

Department of Health. (2001, July 18 b). *The royal Liverpool children's inquiry report.* (Publication No. HC [Session 2000-2001] 12-II). Retrieved July 30, 2008, from Department of Health website: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005937.

Department of Health. (2001, January 30 c). *The removal, retention and use of human organs and tissue from postmortem examination* (Series No. 0113225326). Retrieved July 30, 2008, from Department of Health website: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4064942.

Department of Health. (2003, May 1). *Isaacs report: The investigation of events that followed the death of Cyril Mark Isaacs.* (Publication No. 011322611X). Retrieved July 30, 2008, from Department of Health website: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4064681.

Department of Health. (2005, May 6). *The Human Tissue Act 2004: New legislation on human organs and tissue.* (Publication No. 267440). Retrieved July 30, 2008, from Department of Health website: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_4109578.

Human Tissue Authority. (2006, March 1). *A guide to licensing for designated individuals and licence holders.* Retrieved July 30, 2008, from Human Tissue Authority website: http://www.hta.gov.uk/licensing/guide_to_licensing_and_application/application_guide.cfm.

Human Tissue Authority. (n.d.). *Codes of practice.* Retrieved July 30, 2008, from Human Tissue Authority website: http://www.hta.gov.uk/guidance/codes_of_practice.cfm.

Human Tissue Authority. (n.d.). *Homepage.* Retrieved July 30, 2008, from Human Tissue Authority website: www.hta.gov.uk.

Human Tissue Authority. (2004). *Human Tissue Act 2004.* Retrieved July 30, 2008, from Human Tissue Authority website: http://www.hta.gov.uk/about_hta/human_tissue_act.cfm

National Patient Safety Agency. (2007). *National research ethics service.* Retrieved July 30, 2008, from National Patient Safety Agency website: http://www.nres.npsa.nhs.uk/.

The Commission of the European Communities. (2006, February 8). *Commission directive 2006/17/EC.* Retrieved July 30, 2008, from Department of Health website: http://www.dh.gov.uk/en/Publichealth/Scientificdevelopmentgeneticsandbioethics/Tissue/Tissuegeneralinformation/DH_4136920.

Book Review

Medical Apartheid: The Dark History of Medical Experimentation on Black Americans From Colonial Times to the Present (2006) Harriet A. Washington, Harlem-Moon, 510 pp.

Lori Walker MEd (cand)
Research Ethics Officer
Brock University
St. Catharines, Ontario, Canada

This year marks the fortieth anniversary of Martin Luther King Jr.'s death, so it is fitting that I am reviewing Harriet Washington's book *Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present.* As I reflect on this book, it is clear that we have made significant changes to the way we conduct research as a result of the public exposure to the kinds of abuses that Washington cites. These changes, however, are not enough. The exploitation of vulnerable populations continues to this day, and it is for this reason that this book is a *must read* for those of us involved in the administration of research.

Harriet Washington is a journalist, bioethicist, and scholar, whose manuscript chronicles the history of abuses in research specifically related to African Americans. She delivers a stark message: the health profile of African Americans is deplorable. America suffers from a racial health gap that "has riven [the] nation so dramatically that it appears as if we were considering the health profiles of people in two different countries -- a medical *apartheid*" (p. 20). According to Washington, this gap is perpetuated by an African American fear of medicine, which she refers to as *iatrophobia* -- coined from the Greek *iatros* (healer) and *phobia* (fear). In *Medical Apartheid*, Washington reveals the legitimate basis for this fear, exposing a dark history of abuse and medical experimentation on unwilling and unwitting African Americans spanning 300 years.

Medical Apartheid, winner of the 2008 National Book Critics Circle Award for Non-fiction, is a well-researched book that holds value for a variety of audiences. It has obvious implications for medical and public health professionals, but it is also an important read for researchers, educators, students, and research administrators, including those who work closely with human research ethics boards. People interested in Black history, social justice, women's studies and/or children's rights will find this book to be a rich resource as well.

Interweaving history, science, and culture, Washington takes complex information and makes it reader-friendly. She divides her book into three parts and 15 chapters. Part 1, "A Troubling Tradition," chronicles the medical exploitation of Blacks from slavery to the Tuskegee Syphilis Study, providing harrowing accounts of inimical medical practices which, for the most part, were

non-therapeutic and non-consensual. Washington goes beyond simply enumerating instances of abuse by providing insight into the contemporary social, political, and economic ideologies that cultivated and sustained the exploitation of African Americans. For example, she describes how scientific racism and social Darwinism were used to justify the claim that Blacks were different from Whites medically and biologically, thereby providing a rationale for slavery and a justification for the experimental abuse inflicted on Blacks.

In Chapter 7, "A Notoriously Syphilis-Soaked Race: What *Really* Happened at Tuskegee?," Washington traces the Tuskegee Syphilis Study from its benign origins as a treatment program intended to bolster the economic potential and self-sufficiency of Macon County to the formal 1997 presidential apology acknowledging the racist and immoral nature of the study that ensued. In this chapter, Washington writes that "Tuskegee remains the iconic symbol of racialized medical abuse," but she also notes that it is important to "separate fact from fiction [as] false beliefs generate false fears that exacerbate black aversion to medical treatment" (p. 178).

Washington effectively examines how the Tuskegee study was able to continue by situating it within the context of the time. She provides the reader with an informative, inside look at the political situation and describes both the successes and failures of the government-appointed ad hoc panel charged with investigating the study. While Tuskegee was America's longest and most infamous example of distributive injustice in research, Washington cautions against a "monomaniac" focus on this study. She clearly illustrates that the Tuskegee study was not an aberration, but part of a pattern of experimental abuse on African Americans "eclipsed in both numbers and egregiousness by other abusive medical studies" (p. 181).

In Part 2, "The Usual Suspects," Washington focuses on research conducted within the federal government and private sectors. The studies highlighted take place from the early twentieth century to the present day, and involve vulnerable populations such as African American women, children, soldiers, prisoners, and hospital patients.

Again, Washington is conscious of setting the historical stage and placing the studies that she cites within the confines of the time period. The twentieth century witnessed a refinement of earlier scientific racism that laid the foundation for eugenic theory to develop in a manner that disparaged African Americans and treated them as inferior (p. 191). According to Washington, this belief provided the justification needed for the unconscionable invasion of women's bodies and their reproductive rights. It also allowed the government and military to undertake studies on unwitting men, women, and children, exposing them to infectious agents, non-therapeutic vaccines, dangerous experimental technologies, and lethal doses of radiation.

Chapter 10, "Caged Subjects: Research on Black Prisoners," provides an historical account of research conducted in American penal institutions. Detailed descriptions of experimental abuse are interwoven with the poignant voices of prisoners who suffered pain and disfiguration from clinical, pharmaceutical, chemical, and cosmetic trials. Issues of distributive justice, informed consent, coercion and undue influence are underscored.

Part 3, "Race, Technology, and Medicine," provides chilling insight into modern genetic research, emerging diseases, and the "living weapons" of bioterrorism. However, Washington also strays

into the political realm. For example, Chapter 12, "Genetic Perdition: The Rise of Molecular Bias," begins by examining the use of DNA profiling by government and law enforcement agencies. While this discussion raises important questions about racial discrimination and the right to privacy, Washington's attention is diverted from bio-medical issues to criticism of the American judicial system.

Likewise, in Chapter 15, "Aberrant Wars: American Bioterrorism Targets Blacks," Washington deviates from her discussion about American scientists who use their own citizens as test subjects in the development of biological warfare to explore the issue of racial disparity in the treatment afforded Blacks and Whites after the 2001 Washington, DC anthrax scare. The racial inequality of the government's response to this crisis is evident, but the connection between this particular instance of domestic bioterrorism and medical research is unclear.

The remainder of this section refocuses on health issues, as Washington examines the racial impact of pharmaceutical labeling, the renaissance of tuberculosis, and the HIV pandemic. Not all of Washington's arguments are convincing, and some examples are not fully supported by evidence. For instance, she alludes to, but does not offer support for, racial underpinnings in the selection of two Black men as the first recipients of the AbioCor artificial heart in 2001 and 2002. It is not clear that this constituted a disproportionate use of Black subjects, as statistics cited by Washington are incomplete. Another example is found in the epilogue, where Washington fails to support her statement that "Third World women subjects of thalidomide trials for leprosy and AIDS were not warned of the horrible birth defects the drug can cause" (p. 391).

The subject of informed consent underlies Part 3 and continues into the epilogue, "Medical Research with Blacks Today." Washington cautions against the more subtle threats endangering individuals' rights to choose whether and when to participate in research. In interesting discussions about the interplay between medicine, ethics and law, she examines the conflation of *research* and *treatment* in emergency contexts, the power of the state over that of the legal guardians of orphaned and fostered children, and the government-sanctioned waiver of informed and voluntary consent in military studies.

Medical Apartheid serves to illuminate the devastating consequences that can result when one segment of the population regards another as *Other*. Washington provides hope for the reader that current human research ethics policies have evolved to the point where the worst research abuses are in the past. Nevertheless, the number and nature of experiments conducted post-Nuremburg is alarming, as is the thought that history may be repeating itself. The abuses that threatened African Americans in the past have been exported to Africa as "the Third World has become the laboratory of the West" (p. 390).

In her epilogue, Washington briefly addresses the role of Institutional Review Boards (IRBs), which are mandated to judge the scientific merit and ethical acceptability of human subject research. Given the wealth of evidence uncovered in this book, it is difficult to deny her assertion that IRBs have failed to perform their role of protecting the American public as a whole and African Americans in particular (p. 401). This scant look at IRBs placed near the end of the book may leave readers fearful, wondering if indeed we have learned anything from history. Many of

the abuses exposed in this book are recent; one wonders what role IRBs played in allowing these studies to take place and what justification the researchers may have used to gain approval.

The absence of information on research oversight stands in contrast to the detail that Washington provides throughout most of her book. Washington's approach to deconstructing iatrophobia is laudable, as she gleans data from medical journals, previously unpublished reports, and the oral history of perpetrators and victims. Applying a measured approach, she is cautious not to portray a simplistic story in which Blacks are the victims of villainous White researchers (p. 17). Washington notes that many of the perpetrators of injurious medical experiments were guilty of blind ambition rather than racist intent. Perhaps one of the most difficult truths Washington exposes is the dual face of abuse. The exploitation of Black subjects has made numerous medical advances possible while at the same time leading to deep-seated fears of medical intervention that remain to this day.

Washington suggests that efforts to devise policies that address disparities in African American health care are likely to be futile unless they acknowledge the past. Without a thorough understanding of the history of ethically flawed medical experimentation conducted on Black Americans, it will be difficult to reverse the distrust in the medical profession that has negatively affected their health-seeking behaviors (p.21). It is Washington's hope that this book will assist researchers and medical professionals to better understand the abuses that have been inflicted on vulnerable populations in the name of science. She also hopes that African Americans who read this book will be able to regain trust in the medical system, although one could argue that her formidable account of history may have precisely the opposite effect.

In spite of the dark history Washington exposes, she attempts to portray a message of optimism. Washington believes that African Americans should not be deterred from participating in medical research. Emulating Martin Luther King Jr.'s belief in openness and hope, she suggests that this population should effect a transformation in attitude to ensure that it benefits from the medical advances that only ethical therapeutic research initiatives have the potential to provide. She writes that "the challenge is to prepare the way for a new openness to medical research on the part of African Americans while maximizing their protections from abuse" (p. 386). Surely Dr. King would agree.

Voice of Experience

When Leadership Changes: Reflecting on the Way Forward In Research Administration

2008 Coordinator and Senior Writer
Victoria Molfese, PhD

2008 Authors
Lynne Chronister, MPA
Elliott C. Kulakowski, PhD
J. Michael Slocum, JD
Cliff Studman, PhD
Paul Waugaman, MPA

Voice of Experience advances the Journal's tradition of academic and professional excellence by considering contemporary issues and horizons in research administration. VOE is a celebrated feature column in each edition of the Journal. It is under the corporate authorship of some of the most distinguished and seasoned members of SRA International who lead research administration efforts around the globe. In this issue, VOE offers an interview with Mr. Philip V. Spina, MA, CRA, who in October completed his leadership as the first President of the Society elected for a two-year term.

Introduction

Changes in leadership always create moments of reflection. This is as true for organizations or local small local communities as it is for nations and governments. This year, the American people experienced a significant moment of leadership-change that has created a time of critical reflection upon the foundations of American life. More than any political platform, this past election year has been a moment to re-discover the core values and the core meaning of what it means to be a unique people with a unique way of life who are part of a global community. The Society of Research Administrators International has undergone its own change of leadership this year. It is a unique time of reflection and re-discovery. This reflection and re-discovery are not centered upon what it means to be a member of SRA. Rather it is a moment when the women and men of the Society are moved to reflect critically upon the meaning of the profession of research administration itself, and its mission for the act of research within our respective institutions and communities. In this edition of VOE, Philip Spina offers his reflections upon these very issues as he completes his two-year term as SRA International President.

An Interview with Philip V. Spina, MA, CRA: Reflections on The Way Forward

VOE:

This October, you came to the end of your term as SRA President. This Fall you also begin your thirtieth year in the profession of research administration. What do you believe are the most significant changes you have seen in research administration over the past 30 years?

PS:

There are three major changes in the past thirty years that strike me as particularly important.

The first is the definition, or perhaps I should say the emergence of a definition of research administration as a profession. Historically, a profession emerges from an occupation as the members define their profession in terms of education and professional training. The establishment of linkages between our professional organization and various accreditation organizations, certification programs and traditional educational organizations are first steps in a process of establishing and maintaining standards of excellence and expectations that govern our professional affairs. As a profession, we have defined the theoretical knowledge necessary to be a professional research administrator as outlined in the Body of Knowledge. The development and expansion of our professional expertise now requires us to work towards establishing and obtaining degrees and professional certifications as well as regular updating of skills through certified continuing education.

The second is the expansion of the profession. We are all aware of the continuing growth of the number of members in the Society of Research Administrators and other professional organizations dedicated to professionals serving the research community. We have added approximately five hundred new members to SRA in just the last two years alone. The expansion and diversification of our profession is actually far more complex than the growth in the numbers of individuals who recognize their participation in our field. In the time that I have been a member of SRA, we have seen expansion of the interest of the membership from proposal submission and award management to include the spectrum of integrity and ethical issues in research, intellectual property and technology transfer issues, safety issues, faculty and institutional development and even facilities operations and management. Our profession's development of the Body of Knowledge and the creation and continued growth of a professional certification program have enhanced the professional recognition of the research administrator not only in North America but globally as well.

The third significant change has been the pace and diversity of technological changes. In some ways, the technological changes have had impacts that counter-balance our efforts to professionalize research administration.

… Computerization: It is hard for me to imagine that I began my career as research administrator without a computer on my desk. Even more unimaginable, I had to walk to a library to review sponsor guidelines, regulations, and other documents on paper.

Clearly the emergence of "electronic research administration" has made it possible to submit a greater quantity of proposal to a broader spectrum of sponsors and manage a greater quantity of awards. I remain unconvinced that electronic research administration has added to the quality of the research. I wonder whether or not electronic research administration diminishes the researchers' view of the value of research administrators.

… Telecommunications: The recent SRA Salary Survey asked a question about employer provided PDAs (such as a Blackberry™) and cellular telephones. In any meeting, you can hear or feel the constant buzz of the telecommunications devices. Is it possible to be too connected?

We do not serve our researchers or our sponsors well by constantly responding to every inquiry with an immediate answer. Some issues require thoughtful consideration rather than an immediate answer. Additionally, we are increasingly seen as the providers of cookie cutter answers, While many professions have seen the emergence of electronic one size fits all solutions, reality is far different. This is particularly true in the research setting. After all, our primary products are answers to questions that have been never been asked before and more questions about the answers we just gave.

VOE:

Your answer suggests that research administration is still evolving into a profession. What do you think are the factors that make this continuing evolution possible?

PS:

When I became President at the SRA International Meeting in Quebec City, I told the members who were attending that we had three priorities. These were "education, education, and education." What the profession needs are qualitative and quantitative increases in the educational opportunities for our members. I believe that there are four major components that will facilitate the continued development and emergence of research administration as a profession.

1. Training – We need to continue to develop, offer, and refine our entry level basic curriculum for the new research administrator. Course work and instructional materials covering the critical elements of the Body of Knowledge have to be available in a variety of formats and forums so that new research administrators can be initiated in the field and have the knowledge necessary to serve their researchers and institutions.

2. Certification and Continuing Education – Beyond the basics, we need to offer opportunities for mid-career research administrators to explore the theoretical basis of research administration. These offerings need to focus on issues such as the social and cultural impact of research, the philosophical underpinnings of the ethical issues related to research, and moral and legal issues involved in conducting research across national and cultural boundaries. These offerings must be held to defined standards and must withstand careful review and scrutiny. This can be done in collaboration with organizations that offer continuing education certification and professional certifications.

3. Academic and professional development – I am absolutely convinced that our profession needs to help universities provide graduate degree programs or areas of concentration within graduate degree programs in research administration and management. This will enhance the recognition by our researchers that we are true partners in the research enterprise and provide added value to the members of the profession in the form of increasing compensation levels.

4. Scholarship – To make the three items above possible, we will need to conduct research about the field of research administration and its philosophical roots, cultural impact, and historical origins. This new knowledge will need to be critically reviewed by peers in the field, validated, and shared.

VOE:

Internationalization and collaboration are spoken of today in research very frequently. How are these areas expanding the traditional service and leadership of research administration?

PS:

Perhaps by other names, internationalization and collaboration have always been part of the research process. "Collaboration" is another way to speak of "inter-departmental," "interdisciplinary," or "multi-institutional" when describing the relationships between researchers. "Internationalization" is probably best understood as our awareness of the global nature of the marketplace for research results. Globalization always provides an important opportunity for research administrators to serve their researchers in ever new and unique ways. Let me to expand on these ideas.

1. Collaboration and Competition – Scientific collaboration, or for that matter any type of collaboration, is wholly dependent upon the individuals involved. What do the various members of the team bring to the table to advance the project? Can the project be done just as efficiently and effectively without the collaborators? What do we gain from collaboration? The reality is that research is a business and individual researchers gain both economic and reputational advantage from being the "first" to produce the results of their research. This is particularly true in the areas of research which result in protected intellectual property. The scientist who discovered the new pain medication, cancer drug, or medical device stands to receive significant financial rewards. The same is true of their institutions. Therefore, we balance the potential scientific gain which may result from collaboration against the potential financial impact of sharing the discovery with others.

2. Globalization – The market for research and research results has become global. This has increased the competition for research resources, increased the expenses of conducting research, and combined with the computerization and telecommunications revolution truly made research administration a 24/7 profession requiring new skills and different approaches to serve the research community.

3. I believe that we need to reshape or even re-imagine, rather than expand, our "traditional service and leadership" to meet the challenges of a more competitive, global research marketplace. We must serve as facilitators of research while balancing the differing and sometimes conflicting needs of our researchers, our institutions, our sponsors, and the people who will benefit from our research.

VOE:

What do you believe are the most serious challenges, both academic/scientific and administrative, for research institutions as we move into the future?

PS:

I believe the following are the most serious challenges:

Creating realistic expectations - Research administration is a "helper" profession. We add value by enhancing the productivity of our researchers and institutions. This means that the results of our effort must be measured qualitatively, not quantitatively.

Changing the presumptions about the issues of the ethical conduct of research – First of all, I feel compelled to state that the overwhelming majority of researchers and research administrators conduct their research in compliance with all applicable laws, regulations, and guidelines. Unfortunately, there have been and will continue to be instances of willful disregard for the standards of conduct dealing with the academic and financial standards of behavior. The perception that we can regulate and enforce standards of ethical conduct that will prevent waste, fraud, abuse, and misconduct are misguided and counter-productive. These serve to create a climate of mistrust and fear which limits the creativity of our researchers without providing the desired benefit. We must create a climate of integrity that is based on education and dialogue.

1. Financing the research enterprise – The total amount of financial resources that are available for research is limited. When we face dramatic increases in the costs of food, energy, health care, and housing as well as employment uncertainties, investing in research that may or may not immediately change our lives seems to be less important. For me, nothing could be further from the truth. I believe in the promise of tomorrow, the creativity of humanity, and our ability to explore, understand, and solve our problems.

2. Valuing the profession – our work matters. The efforts we make to facilitate research, streamline and eliminate unnecessary rules, regulations, and administrative limits, and create a climate of integrity, free our researchers to be more creative and productive.

Finally, I have every confidence that, under the leadership of Dr. Pamela Miller, SRA will continue to be the premier organization fostering excellence in research administration globally. It has been my privilege to serve the Society of Research Administrators International for the past two years as its President. I want to thank the headquarters staff, the leadership, and the members for their support, encouragement, and patience. Together we have brought a set of major changes to SRA and improvements to the profession.

Postlude

Lost in Translation and Political Will: Research and Policy as a Means to Advance Human Rights

Carmen J. Head, MPH, CHES
Director, School Health Programs
Society for Public Health Education
Washington, DC
Email: CHead@sophe.org

My grandfather, Fred L. Tyson, was a subject of the U.S. Public Health Syphilis Study at Tuskegee. The Syphilis Study remains the most infamous biomedical research study conducted in this country. Like many of the other 300 men in the study, my grandfather was an uneducated sharecropper. Many of the protocols and ethical standards that are in place today to protect human research subjects are a direct result of the abuse of power, loss of life, and breach in trust that occurred during this thirty-five year study.

My grandfather was fortunate to be a study survivor who went on to live a long life after his involvement in the study. As a child, I enjoyed listening to his stories about growing up poor in Tuskegee, in the early 1900s. Often times, he would end his stories by offering words of wisdom and lessons he learned from past life experiences. I vividly remember his colorful stories and how they would invoke my imagination as a girl. Today my heightened sense of compassion for impoverished communities and the need to explore past and current socioeconomic trends and their impact on human rights is due in part to my grandfather's stories.

Societal ills that continue to plague our world such as unequal health status and education attainment, poor living conditions, and oppression through violence are sustained through a plethora of wide reaching issues. Many of these challenges are created and sustained by longstanding root causes. Some of these complex determinants have been in place since the earth's earliest civilizations. Their vigour and continued existence do not suggest to me that solutions, cures, or common ground cannot be discovered. They signify the need for the development of multifaceted approaches driven by research to cultivate social change.

The broad overarching goals of research are to identify errors to previous thoughts, solutions to existing problems, and explanations for unanswered questions. Research also provides estimations or projections for what may lie ahead. The field of research will continue to be a catalyst for change and progress as many of the world's questions biologically, philosophically, and socially, have yet to be answered. While the need

for research continues, many challenges exist in unleashing its full power to influence or create social change.

Jan L.A. van de Snepscheut once said, "In theory, theory and practice are the same thing. In practice they're not." Not only does this quote make the most compelling case for examining how we as researchers and practitioners dialogue with one another on the same issue, it highlights the ever pressing need for us to strengthen the translation of research findings to practitioners and beyond.

Since data and trends are the most pressing and significant factors that guide the creation and analysis of anything from effective medical therapies to environmental policies; it is not surprising that researchers, from all fields, play a dynamic and critical role in improving human rights. The more difficult questions ask how to:

…translate and disseminate research findings such as unequal access and racism to world audiences to strengthen momentum for a more humane world;

…form a more unified bond between researchers and practitioners that celebrates differences while allowing both research and practice methods to be made malleable based on research and practice recommendations;

…convene researchers from different fields to explore and identify environmental, economic, and biological commonalities among the world's communities; and

…engage and influence the world's policymakers, religious, and opinion leaders in an effort to create new laws and regulations, provide resources where lacking, and promote political and moral will.

Creative approaches to these questions must be identified and strategically implemented to assist efforts seeking to uplift humanity. As we explore these innovative approaches it is important to ask an important final question, how can each field of research play a greater role in the struggle for human rights. As we face a world that becomes smaller with each passing day through technology; a nation (the United States) that becomes more racially and ethnically diverse; environmental trends that indicate the need to address energy resources; and a world population that's poverty rate continues to be a looming threat to our health and economic development; let us recognize our shared role in shaping our future through research.

Many public health organizations have rallied and shouted the battle cry, "Health is a human right." Public Health research is paramount in working towards the elimination of racial and ethnic health inequities. Since 1967, the Society for Public Health Education (SOPHE) has embraced an Open Society that charges the organization to respect diversity and seek social justice and health equity for all.

SOPHE, where I am currently employed, has been in involved in addressing health inequities though multiple channels which include: creating resolutions that help guide research, policy, and education efforts; educating policy makers on the need for increased resources and funding to address the nation's disease prevention efforts; strengthening pre-professional public health programs; and engaging communities in research to create and implement effective programs and services. SOPHE's mission is to provide leadership to the profession of public health education and to contribute to the health of all people and the elimination of disparities through advances in health education theory and research, excellence in professional preparation and practice, and advocacy for public policies conducive to health.

My favorite story from my grandfather ended with him saying to me: "Your actions today will impact your future." I oftentimes think back to that advice in my life's work in improving health outcomes of disadvantaged communities through the implementation of effective resources and policies. As we continue in our life's work, let us be ever mindful of the power and the obligation that we have as researchers and research administrators to impact the world we live in positively – for ourselves and for future generations.

How does your research tool stack up?

1. Where does the information come from?

A. Research Administrators submit best practices, articles, links, regulations and research. The more information you submit, the more reference value you will get out of this living library.

2. Is it backed by an International Association?

A. Yes. The Society of Research Administrators is a nonprofit organization exclusively dedicated to the education and professional development of Research Administrators like you.

3. How often is it updated?

A. With a team of editors on hand, the Society of Research Administrators can ensure the information you submit is posted quickly and accurately.

4. Is it easy to use?

A. Yes. Simply start with one of the six key research administration categories. From there find articles, links, regulations and resources that help you find the information you need – *fast*.

Introducing the SRA International

Body of Knowledge

– built for Research Administrators, by Research Administrators.

SRA International
Body of Knowledge

www.srainternational.org

SRA International 2009 Educational Opportunities Save the Date!

Research
WITHOUT BORDERS

SRA INTERNATIONAL 2009
SEATTLE, WASHINGTON OCTOBER 17-21

SECTION MEETINGS

April 4-8, 2009
Northeast Section Meeting
Sheraton Inner Harbor
Baltimore, Maryland

May 2-5, 2009
Midwest Section Meeting
Sheraton Hotel & Sioux Falls
Convention Center
Sioux Falls, South Dakota

May 17-19, 2009
Southern Section Meeting
Sheraton Oklahoma City
Oklahoma City, Oklahoma

June 11-17, 2009
Western Section Meeting
Marriott Hotel and Marina
San Diego, California

Check the SRA Web site for more information and to learn about upcoming Chapter Meetings in your area.

www.srainternational.org

RAM Strategy Group, Inc.

Research Administration and Management

Our mission is to:

Maximize Value of Our Client's Research and Technology Efforts

and allow researchers to do world class research.

- **Strategic Planning, Implementation and Evaluation**
- **Interim Leadership**
- **Clinical Trials Management**
- **Policies and Procedures Development**
- **Pre- and Post-Award Management**
- **Regulatory Compliance**
- **Research Management Training**
- **Technology Transfer**
- **Technology Commercialization**

We provide client-based and customer-delivered results. We care about you, your satisfaction and your success.

Contact: RAM Strategy Group, Inc:
Email: info@RAM-strategy-group.com
Phone: 435-615-7190

Need staff support to reduce backlogs and improve performance?

We listen. We partner.
We focus. We deliver.

Huron Consulting Group is a leading provider of **performance improvement & interim staffing support** for research institutions. Our professionals work collaboratively with your staff to address needs related to:

Performance Improvement

- Review staffing levels & organization structure
- Review & redesign processes
- Develop training & education programs
- Develop standard operating procedures

Interim Staffing

- Proposal review
- Account set-up
- Subcontract development
- Invoice preparation & submission
- FSRs & close-outs
- Accounts receivable & cash management

For more information contact:

Joe Taylor
312-583-8744
jtaylor@huronconsultinggroup.com

Shandy Husmann
312-583-8757
shusmann@huronconsultinggroup.com

Huron
CONSULTING GROUP

Huron Consulting Group helps clients effectively address complex challenges that arise in litigation, disputes, investigations, regulatory compliance, procurement, financial distress, and other sources of significant conflict or change. The Company also helps clients deliver superior customer and capital market performance through integrated strategic, operational, and organizational change. Huron provides services to a wide variety of both financially sound and distressed organizations, including Fortune 500 companies, medium-sized businesses, leading academic institutions, healthcare organizations, and the law firms that represent these various organizations.

1-866-229-8700
www.huronconsultinggroup.com

Experience.**Redefined.**™

Society of Research Administrators International
Serving the Profession Since 1967
1901 North Moore Street, Suite 1004
Arlington, VA 22209
www.srainternational.org