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Harvest is more than just an agricultural event. It is a moving human metaphor. The very word conjures up a wide variety of images and feelings when it is heard, or when we experience it within the context of the colors and changing weather patterns of autumn. In our Northern hemisphere, harvest and autumn signal the energies of another school year, the coming of national holidays, and an overall sense of renewal in the face of “food and feast.” However, there is much more to the power of The Harvest than we often realize. There is a moving, even jarring, undercurrent that gives us cause to reflect as human beings in all of our various associations. In essence, “harvest as metaphor” subtly but definitively invites us, even goads us, to reflect deeply on what the seeds of our lives have been and are producing. In other words, the season that is now falling on the Northern hemisphere asks of us: “What is the harvest we are producing?” This is a very powerful question for each of us in research administration. It is the question that seems to thread together this edition of the Journal of Research Administration in a very moving way.

The manuscripts you are about to enjoy seem coincidentally to coalesce around new ways in which we as research executives, managers, and administrators serve as leaders for our various communities and institutions. The articles and reviews that follow challenge us to reflect on the “harvest” that we are producing for those whose research we serve. This challenging reflection begins importantly for us in the memory of our friend and colleague, Herb “Chuck” Cherm-side, who passed very unexpectedly from this life this past June. This edition of the Journal celebrates Chuck’s gifts to us in a very powerful and important way. Chuck was one of the true pioneers of our profession. He saw its complexities and its opportunities fully. He embraced them with a sense of enthusiasm and industry that is incomparable. His never ending dedication to the professionalization of research administration is something that has touched the lives of thousands --- and will continue to touch generations to come. Indeed, he left us in summer. And now it is in the autumn, in the time of “harvest,” that we are moved to reflect on who and what he has meant for us ----- only to taste most fully of the feasting of who and what we must be for others into the future. The seeds of what Chuck has done for us have come forth full. And now the tools are handed to us to continue to sow, and till and reap so that the feeding and feasting might continue.

In this edition of the Journal, you will find any number of manuscripts that I hope will stimulate your own reflections upon the harvest of your service in research leadership. Opening articles, dedicated to Chuck, address the professionalization of research administration. Subsequent articles will stretch your imagination into new areas of research administration leadership here and around the world. In the past 60 years of our profession, the seeds of management have burst above the soil in ways that no one would ever have predicted. Today we are policy analysts as well as financial managers. We are educators as well as trainers. We are ethicists as well as regulatory affairs specialists. We are strategic planners and entrepreneurs as well as operational officers. In short, our mission as research administrators is not just about providing “support.” Rather we have become part of the very fabric of
From the Editor’s Desk

senior leadership that is central to our institutions. But what does it mean, precisely to lead? Who are leaders anyway?

Perhaps 20 years ago, I read a text that made a real difference to me in how I understood organizations and the people who lead them. Permit me to borrow from that text to reflect with you a bit about the diverse ways that can portray the image of “leader.” Obviously, leaders are institutional officials. We have corporate responsibilities to the institutions we serve and those who have shaped those institutions as part of corporate life. Leaders are also community builders. Institutions are not made just of mortar and stone. Institutions are people-realities. Good leaders are dedicated to bringing together good people in good ways for the common good. Leaders are also signs and instruments. In this, leaders in a rare and important way embody the mission of the institution, its aspirations, its goals and its visions that benefit others. Leaders in addition are journeyers. They are “Prime Pilgrims,” so to speak, who have a clear and uncommonly brave openness to change and quality improvement even if revisions and reshapings raise up the deepest questions of all. Finally, leaders are servants. Institutions certainly need authorities who take responsibility. But truly “moral authority” is not something exercised from the top down, but from the bottom up. Leaders as servants are those who know the way and show that way first by example ever before doing it by exhortation or decree. Leadership certainly relies on native skills and abilities. But it is an art moreso than a science. It is a human reality ever before it is a theoretical construct whose characteristics can be summarized glibly in a self-help manual. In short, being a leader is an experience, a moment. It is a harvest --- not just the result of the techniques of planting. To know leadership means being given the time and the resources to realize one’s potential, and to reflect on how it might be deepened. One of those ways of learning the leadership potential that we each have is to reflect on the metaphors around us that show us the way.

This edition of the Journal of Research Administration will provide you with any number of powerful metaphors to reflect upon your own leadership potential and how you are being called to serve the needs of your community, and the growth of our profession. What crowns this edition is the image, the metaphor, the living memory of our friend and colleague, Chuck Cherm-side, whose leadership to and mentoring of thousands has enriched our profession in ways incalculable. His teaching and mentoring have been his harvest to us. And we have eaten full. But the harvesting and the feasting go on. They go on because the seeds now are planted in us........ and in future generations............ so that those who crave insight and support and creativity are fed what they need. Being committed to becoming research administration leaders can seem daunting. The articles to follow dispel that fear. It is clear that being such a leader into the future is a challenge but an exciting one. Or to paraphrase Emily Dickinson, “I think to lead may be a bliss, for those who dare to try.”
Fran Chandler
is currently the Associate Director of Research Services at Brock University and has been there for the last five years. She has a Bachelor of Environmental Studies in Urban and Regional Planning, a Bachelor of Education degree, a Masters degree in Social Welfare Policy and is currently a part time PhD student in Education with a focus on policy and leadership. Fran is also a certified social worker, teacher and professional planner. She has lived and worked in northern and southern Ontario, China and Ghana.

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At NYU, he served for many years as a director or member of the Institutional Review Board, the Institutional Animal Care and Use Committee and the Institutional Biosafety Committee. Ira was the first full time administrator of NYU’s NCI designated cancer center shortly following a major gift dedicating it as the Rita & Stanley H. Kaplan Cancer Center. From 1985 to 1987 he coupled this position with that of Administrator of the Department of Pathology.
Contributors

Ira has a Bachelor of Science degree in Biology and Chemistry from LIU, a Master of Public Administration degree and a Master of Science in Clinical Management degree from the NYU Graduate School of Public Administration.

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Educators for Social Responsibility and the
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Jennifer Shambrook, M.H.A. is currently serving the Society of Research Administrators International (SRAI) as the Chair of the Education and Professional Development Committee, and one of the Program Co-Chairs of the 2007 Annual Meeting in Nashville, Tennessee. Ms. Shambrook has served SRAI as Founding President of the Allegheny Chapter (1998-1999), President of the Northeast Section (2000-2001), and President of the Southern Section (2004-2005). Ms. Shambrook is keenly interested in professional development in research administration and has presented hundreds of seminars and workshops both in North America and internationally. She is a faculty member of the Department of Psychiatry and Behavioral Sciences at the Medical University of South Carolina and presently holds a dual position as both the Associate Chair for Research Administration and Co-Director of the Division of Public Psychiatry. She is a Ph.D. candidate in Community Health Promotion and Education at Walden University and a member of the Cherokee Tribe of Northeast Alabama. She was also one of the many mentees of Herbert “Chuck” Chermside, CRA.

Sally E. Sivrais holds the position of Research Manager at the Stephen M. Ross School of Business at the University of Michigan. Throughout her two decade career at the University of Michigan, Ms. Sivrais has specialized in departmental research administration. She has a wealth of experience working with the National Institutes of Health (NIH), National Science Foundation (NSF), and a variety of foundations. An important goal for her is to create and disseminate knowledge related to her field. Among her training accomplishments are one-on-one faculty development and staff mentoring. Ms. Sivrais has also published two collaborative papers in the Symposium proceedings of the Society of Research Administrators International.

Ms. Sivrais is currently working on a Masters of Science Degree in Human Resources and Organizational Development at Eastern Michigan University and has received a Bachelor’s degree in Political Science from the University of Michigan.

Carrie Disney is a Contract and Grant Specialist at the Geriatric Center/Institute of Gerontology at the University of Michigan. She began her second career in 1998 at the University of Michigan, specializing in pre-award research administration. She has extensive experience working with the National Institutes of Health (NIH), National Science Foundation (NSF), and a variety of foundations. Ms. Disney has conducted multiple training seminars and workshops, as well as having published two collaborative papers in the Symposium Proceedings of the Society of Research Administrators International.
Rosemary Stefiniw, RN, BS, CCRC
attained her Bachelor of Science in Business Administration from the College of St. Elizabeth and her Associate of Applied Science in Nursing from the County College of Morris. In addition to being a registered professional nurse, she holds certification as a Certified Clinical Research Coordinator through the Association of Clinical Research Professionals. She is a member of the Cancer Institute of New Jersey Curriculum and Education Committee. In May 2006, she did a Presentation to the Leukemia and Lymphoma Society “Participating in Clinical Research”.

Ms. Stefiniw has worked at Morristown Memorial Hospital, one of the Atlantic Health campuses for over 24 years in various nursing capacities. Currently she is the Manager of Oncology Research for Atlantic Health. In her this position, Ms. Stefiniw is responsible for implementing and achieving oncology research standards and goals for the organization. She is responsible for making sure that the timelines are met, the staff are well trained and knowledgeable regarding compliance and procedures. In addition, providing oversight for all regulatory, nursing and data management activities for adult oncology research conducted with industry and cooperative group sponsored trials.

Voice of Experience
VOE advances the tradition and service of the Journal of Research Administration by fostering consideration of and reflection upon contemporary issues and concerns in research administration as they arise from professionals in the field of service. 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. Our 2006 VOE Authors are: Ms. Lynne Chronister, Associate Vice Chancellor for Research, University of California, Davis, Dr. Elliott Kulakowski, President, Research Administration and Management Strategy Group (RAM), Dr. Victoria Molfese, Ashland/Nystrand Chair in Early Childhood Education and Professor in the Department of Teaching and Learning, University of Louisville. Dr. Molfese is also Associate Editor, Developmental Neuropsychology.
Contributors

Paul Waugaman

Center for Research in Early Childhood, Mr. J. Michael Slocum, senior member of the law firm of Slocum & Boddie, P.C., Dr. Cliff Studman, Director, Pie Squared Consultants, Mr. Paul Waugaman, Principal and co-founder of the Technology Commercialization Group (TGG). Ms. Chronister serves as the 2006 Senior Writer and Column Coordinator. The success of VOE for the profession depends directly on issues and emerging topics of interest as they are articulated from our colleagues. If you wish to contribute, please contact the Journal Editor at info@srainternational.org.
Herbert “Chuck” Chermside entered the emerging profession of research administration after attending his first Society of Research Administrators (SRA) meeting in 1969. The meeting was held one month prior to the completion of his bachelor’s degree. The former Marine used his G.I. Bill and six years of his life working toward that degree (M. Chermside, personal communication, June 29, 2006). He used his degree intentionally to seek out a job in research administration and begin a personal journey touching the lives of thousands. He worked not only to develop his own career, but also to establish research administration as a distinct genre in the broad field of administration. Chuck’s death left a sharp void in so many of us who considered him “Mentor.” His life, however, serves as a role model and clarion call to those who learned from him to fill that void. We, as a group, must take up his mantle and carry forward as a network of mentors as an honor and as an obligation to continue his quest on behalf of our emerging profession. To do this, we must simply follow his path.

To say Herbert “Chuck” Chermside was well known to the research community is an understatement. One need only go to the Guestbook pages of the Richmond Times-Dispatch (2006) to see how far-reaching Chuck’s influence extended. There are entries from hundreds of people, from three continents and almost every State in the Union. Many claimed to have considered him their mentor, although they may not have had the privilege of actually meeting him in person. I read and re-read those Guest Book entries and numerous articles on mentoring excellence while planning this tribute. My conclusion: Chuck’s life is the embodiment of what it means to be a mentor. Chuck was a mentor as much as he was a man, a native Virginian, a brunette, a Chermside… it was just what he was. He did not have to decide to be mentor; others only had to decide to be his mentee. It was in his genetic code. Mentoring was not a learned skill for Chuck; it was a God-given, natural talent.

We can learn to be good mentors by practicing the mentoring skills Chuck bestowed upon us. There is certainly a mentoring void with Chuck’s passing; and knowing Chuck, he would prefer that we fill it rather than feel it. He had a mission, a life purpose that was to share what he had learned with anyone and everyone that might benefit from that knowledge. It was important to him to see research administration advance as a profession. Even after retirement as Emeritus Director of Sponsored Programs from Virginia Commonwealth University, he spent his time reading regulations, answering the Research Admin Listserve questions, and giving presentations at professional meetings. Chuck’s participation in the leadership of the Research Administration Certification Council at the end of his career was not to benefit himself, but to share with others and encourage them toward excellence.
The Times-Dispatch Guestbook displays a continuous flow of certain descriptive words and phrases. These heartfelt expressions came from people who worked with him for years on a daily basis. These words were from those who enjoyed seeing him once or twice a year at professional meetings; those who had only spoken with him by phone; and those who never interacted with him but saved his answers to questions on the Research Admin Listserv. The words used to describe Chuck from various points of the globe were consistent. They were the description of what it means to be a good mentor. Repeatedly we read:

- **Chuck was a wealth of knowledge.** Chuck made it his business to know the regulations, the guidelines, the principles and even the history of our profession (as well as botany, ballroom dancing, and scouting, which were his other passions).

- **Chuck was generous.** Chuck did not hesitate to share his knowledge with anyone who sought an answer from him. He respected every human being and did not show favoritism. He did not share to impress; he did not share to advance himself. He shared because he genuinely enjoyed the act of sharing his knowledge.

- **Chuck was kind.** Chuck always seemed to appreciate being asked a question. It did not matter if he had just answered it a few minutes before in a presentation he was giving, or if the question seemed so basic that anyone should be able to answer it through common sense. Chuck answered with kindness and always made the individual feel as if they had honored him by seeking his advice.

- **Chuck had a great wit and sense of humor.** For those of us who were fortunate enough to know him, it is easy to picture his face in our minds. That face always has a smile. Chuck was ready to laugh, find the humor in a situation, and resolve differences in a genial manner.

- **Chuck has left a great void.** Another individual person cannot fill this void. This is why we must all work together to take up the mantle to serve others, to share what we have learned, to research thoroughly before we give an answer, and to be kind and generous to those that seek our help. None of these things can replace our beloved friend and mentor; but these things will honor Chuck and continue his mission. I urge you to learn one more lesson from Chuck by going to the Guest Book and reading the entries there (Richmond Times-Dispatch, 2006). They are a lesson in excellence in mentorship.

Chuck was active in Scouting for 25 years. He went to scouting camp every year to work with the boys, and this year was to be the same. Ken Lyons, Reservation Director at Camp Powhatan, Virginia, wrote in his guest book entry “We will leave an open bunk.” There will be an open bunk in many hearts and minds for years to come as we miss Chuck and think about his example. He was truly Everyone’s Mentor for research administration. Finally, to quote Bob Killoren of Penn State, let us all say with our hearts and our actions “Chuck, I salute you.”

**References**

Chermside, M. Personal communication to Jennifer Shambrook and Kobby Hoffman, June 29, 2006.

Author Note

This article is dedicated to the memory of our friend and colleague Herbert “Chuck” Chermside who unexpectedly passed away on June 22, 2006. Chuck was a staunch advocate of professional development and continuing education opportunities for research administration professionals. He was one of the research administrator pioneers who worked hard to establish the Research Administration Certification Council (RACC), an organization providing an opportunity for research administrators to certify through experience and testing that they have the fundamental knowledge necessary to be a professional research or sponsored programs administrator. This article was previously published as a paper in the 2005 Symposium proceedings of the Society of Research Administrators International. It was originally developed by the author based on his doctoral dissertation research in the Department of Educational Research, Technology, and Leadership in the College of Education at the University of Central Florida.

Abstract

The professional field of research administration faces critical challenges in maintaining and cultivating a talented group of skilled administrators in the new millennium. Universities have created increasingly complex bureaucracies to manage the dramatic rise in research funding and the complicated legal and regulatory requirements associated with receiving funding for research (Hanson & Moreland, 2004). As a result, the number of people employed in the field of research administration has increased. The value of certification in the field of research administration is not known. This study sought to determine whether those who have attained the Certificate in Research Administration (CRA) perceive a benefit to their careers and why most research administrators do not attempt certification. The primary research question studied is concerned with the relationship between perceived value of the CRA to research administration professionals and demographic characteristics. No research is available concerning the value of research administrators becoming certified through the Research Administrators Certification Council (RACC). This study will help to determine to what degree research administration professionals value certification, and will help in determining the perceived value of certification to different groups of research administrators. An analysis of the data will be provided and implications for future practice will discussed.
Delimitations and Limitations

The study is delimited to research administrators based in the Southeastern region of the United States as defined by the National Council of University Research Administrators (NCURA). This sample population was selected because the author is well known in this region due to previously held leadership positions attained as a result of membership voting, presentations made at various meetings, and participation in numerous other activities involving regional membership. It was anticipated that response rate to the survey administered would likely yield the best results if the aforementioned population was utilized. An additional delimitation pertains to the half of the sample population that has achieved certification because in order to be included in the study the Certified Research Administrator (CRA) must have achieved certification prior to February 1, 2005.

This study is limited since it is assumed respondents will answer the survey questions honestly. Furthermore, the accuracy and currency of the records obtained from the NCURA, SRA, and RACC could not be controlled.

Introduction

Certification programs are designed to confirm that individuals in a given profession possess the fundamental knowledge necessary to serve their employer and profession in the best possible manner. Gilley and Galbraith (1986) define certification as the process by which a professional organization or an independent external agency recognizes the competence of individual practitioners.

There is often a great deal of confusion associated with the term certification. For example, Bratton and Hildebrand (1980) emphasize that professional certification should not be confused with teacher education certification because the term teacher certification is a misnomer. Instead, it is a licensing mechanism regulated by a local body. Since teachers are required to hold a valid certificate in order to teach in the public school system, the teacher education certification is, in reality, a license to teach. Parker and Smith (2004) report that processes established for certifying and licensing practitioners share important credentialing related commonalities, but the primary difference often misunderstood is that licensure is mandatory and certification is voluntary. Galbraith and Gilley (1985) contend this confusion biases many educators regarding the certification issue and narrows the examination and discussion of professional certification. Penland (1982) asserts that this confusion has resulted in misunderstanding and frustration on the part of those concerned with the topic of professional certification and has impeded communication. Galbraith and Gilley (1985) maintain that certification, licensure, and accreditation each attempt to regulate the measurement of competencies, however; the methodology, population, and purposes of regulations differ. For example, in McCue (2003), Schoon and Smith indicated that licensure is the granting of a license by a governmental body to practice a profession, while certification is thought of as a means of promoting achievement within a discipline. Certification is not a property right to practice a profession; instead, it is a voluntary achieved standard of excellence for an individual.

According to Bratton and Hildebrand (1980) certification is often perceived as being the same as accreditation and licensure. Distinctions between certification, accreditation, and licensure need to be recognized in order to place professional certification in correct context and avoid confusion in use of terminology. The following table provided by Bratton and Hildebrand (1980) offers a succinct comparison of accreditation, licensure, and certification.
Table 1: Comparison of Accreditation, Licensure, and Certification

<table>
<thead>
<tr>
<th>Type of Credential</th>
<th>Recipient of Credential</th>
<th>Credentialing Body</th>
<th>Required or Voluntary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accreditation</td>
<td>Programs</td>
<td>Association/Agency</td>
<td>Voluntary</td>
</tr>
<tr>
<td>Licensure</td>
<td>Individuals</td>
<td>Political Body</td>
<td>Required</td>
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<tr>
<td>Certification</td>
<td>Individuals</td>
<td>Association/Agency</td>
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</tbody>
</table>

Introduction

Bratton and Hildebrand (1980) offer the following definitions to help clarify the distinctions between certification, accreditation, and licensure.

Certification – the process by which a professional organization or an independent external agency recognizes the competence of individual practitioners.

Accreditation – the process whereby an agency or an association grants public recognition to a school, college, or university, or specialized study program that meets certain predetermined qualifications or standards.

Licensure – a mandatory legal requirement for certain professions in order to protect the public from incompetent practitioners. Licensing procedures are generally established or implemented by a political governing body that prescribes practice without a license.

According to various authors (Bratton & Hildebrand, 1980; Mason, 1984; Galbraith & Gilley, 1986; McCue, 2003) certification is a voluntary achieved standard of excellence for an individual practitioner recognized by a peer group. The focus of this study falls under this category of credentialing identified in the literature as professional certification.

The Research Administrators Certification Council (RACC) was formed in conjunction with the Society of Research Administrators International (SRA) in 1993 with the primary purpose of certifying that an individual, through experience and testing, has the fundamental knowledge necessary to be a professional research or sponsored programs administrator (Research Administrators Certification Council, 2004). Since the RACC was formed in 1993, 501 research administration professionals have achieved certification (Research Administrators Certification Council).

This study sought to determine whether those who have attained the Certificate in Research Administration (CRA) perceive a benefit to their careers and why most research administrators do not attempt certification. The primary research question studied is concerned with the relationship between perceived value of the CRA to research administration professionals and demographic characteristics. Five research questions guided the investigation.

Statement of the Problem

The value of certification in the field of research administration is not known. Research administration professionals do not know whether certification has benefited the careers of those who have achieved it, or why most research administrators do not...
attempt certification. The primary focus of the study was concerned with the relationship between perceived value of the Certificate in Research Administration (CRA) to research administration professionals and demographic characteristics.

**Methodology**

An Internet-based survey instrument was developed to collect data from certified research administrators (CRAs) and non-certified research administrators. The survey collected demographic information to help describe the relationship between the demographic characteristics of the population and perception of value. A pilot study was conducted to determine the survey instrument’s work under realistic conditions. The survey instrument was then distributed via an electronic mail notification and included a link to an Internet site where the survey could be completed online. Three electronic mail requests followed by personal telephone calls to those who did not respond to the electronic mail requests resulted in a return of 230 usable surveys or an 83% rate of return.

The primary focus of the study was concerned with the relationship between perceived value of the Certificate in Research Administration (CRA) to research administration professionals and demographic characteristics.

**Population and Sample**

The population of respondents for this study included research administrators based in the Southeastern region of the National Council of University Research Administrators (NCURA). According to the NCURA (2005), 1,101 members are based in the Southeastern region.

A list of 501 research administrators who have achieved certification was obtained from the Research Administrators Certification Council (RACC), and the list revealed that 147 of the research administrators who have achieved certification are from the Southeastern region of the NCURA. These 147 individuals were selected to represent half of the overall sample population for this study. The other half of the sample population was randomly selected from a list of non-certified members based in the Southeastern region.

The list of certified research administrators provided by the RACC only included the names, affiliation, and city of the individuals. In order to obtain complete contact information for the certified research administrators, further research was necessary as RACC did not readily provide complete contact information upon request. NCURA and SRA membership databases were utilized in an attempt to find complete contact information for the 147 certified research administrators based in the Southeast region of the NCURA. A search of these two sources revealed contact information for 84 of the 147 certified research administrators based in the Southeast region of NCURA. A search of university Web sites provided the necessary contact information for 34 additional individuals. Contact information for the remaining 29 individuals was obtained through Internet searches, telephone calls, and through contacting individuals known to the researcher who were affiliated with the same organization as the CRA. Contact information was verified, edited, and resulted in a final count of 134 certified research administrators based in the Southeast region of NCURA.

The list of 1,101 research administrators based in the Southeast region of NCURA was used to draw a random sample of 147 non-certified research administrators. Sixty-eight (68) of the individuals included in the list of 1,101 were deleted since they were already included in the certified research
administrator sample population. The author of this paper was also deleted from the list of 1,101, leaving a total 1,032 non-certified research administrators based in the Southeast region of the NCURA from which a random sample of 147 was drawn. This resulted in 126 verified and willing participants.

Since there were more non-certified research administrators based in the Southeast region of NCURA to draw a random sample from, a second random sample of 21 was drawn in an effort to identify more respondents. The list the second random sample of 21 was drawn from was narrowed to 885 after the 147 from the first random sample were eliminated from the list. The second random sample resulted in 17 additional potential respondents that could be verified. Of the remaining 4 individuals identified in the second random sample, 2 could not be located, and 2 were unresponsive. Contact information was verified, edited, and resulted in a final count of 143 non-certified research administrators based in the Southeast region of NCURA.

A total of 277 potential respondents comprised the overall sample population for this study. 134 were identified as certified research administrators, and 143 were identified as non-certified research administrators. Each potential respondent was contacted by telephone or e-mail and notified that this study was in progress. Confirmation of contact information for all potential respondents was checked for accuracy and edited as necessary.

A third random sample of 5 was drawn from the list of non-certified research administrators after a situation arose subsequent to the initial distribution of the survey instrument. One of the potential respondents indicated it was the policy of that particular institution to receive Institutional Review Board approval for any study involving students or employees of that institution. Despite already having obtained the appropriate Institutional Review Board approval, the researcher was asked to refrain from sending additional surveys to students or employees of that particular institution unless Institutional Review Board approval from that particular institution was obtained for this study. Considering this circumstance the researcher elected to draw a third random sample of 5 since all the potential respondents from this institution were non-certified research administrators who could be replaced. One individual from this particular institution had already freely responded to the initial survey invitation, so their response was maintained. The researcher complied with the request from this institution by not resending the survey to any potential respondent from that institution. Contact information for all 5 of the potential respondents from the third random sample were verified, notified of the study, and identified themselves as willing participants in the study after being contacted by the researcher.

In summary, the population of respondents for this study included 277 research administrators based in the Southeastern region of the National Council of University Research Administrators (NCURA).

Summary and Discussion of the Findings

The summary findings and discussion of the data collected for the five research questions of this study are presented below:

Research Question 1

What is the perception of certified research administrators compared to non-certified research administrators in regard to the value of certification?
The relationship between the demographic characteristics of research administrators and the level of agreement in regard to the perceived value of the Certificate in Research Administration (CRA) was analyzed to determine if perceptions of value were different between CRAs and non-certified research administrators. There was a statistically significant difference (<.0006) between how CRAs perceive the value of certification and how non-certified research administrators perceive the value of certification. CRAs perception of the value of certification was significantly greater than that of non-certified research administrators.

Age, educational level, salary, and length of employment in the field of research administration were the demographic characteristics selected to compare the perceived value of certification between certified research administrators and non-certified research administrators. The interaction effect was found to be not statistically significant. The closest demographic characteristic to approach statistical significance (<.0562) was perception of value and educational level. Interaction effect is the variation among the differences between means for different levels of one factor over different levels of the other factor.

In response to the question, *Do you feel more knowledgeable as a research administrator as a result of becoming certified,* the overwhelming majority of the CRAs indicated they did feel more knowledgeable as a result of becoming certified. In response to the question, *Do you believe you would feel more knowledgeable as a research administrator if you were certified,* the majority of non-certified research administrators indicated that they would feel more knowledgeable, but it was by a much smaller margin as almost as many perceived that being certified would not make a difference.

Analyses of both summary data and selected demographic variables revealed that CRAs consistently perceived the value of certification to be greater than non-certified research administrators did.

**Research Question 2**

What is the relationship of demographic characteristics to the attainment of certification?

Age, educational level, salary, and length of employment in the field of research administration were the demographic characteristics selected to compare the perceived value of certification between CRAs and non-certified research administrators.

In regard to the demographic characteristic of age, there was a statistically significant relationship (<.0373) between age and certification status of research administrators. Of the respondents who indicated they were not certified, the majority indicated they were less than 39 years old. This indicates that younger non-certified research administrators may not value certification as much as those over 40. This may be as a result of being undecided in terms of their career, being unaware of the opportunity to become certified, or being employed at an institution that is not supportive of certification.
In regard to the demographic characteristic of educational level, there was not a statistically significant relationship (<.3729), although the pattern of the results was similar to the pattern formed by the statistically significant demographic characteristics. This indicates that non-certified research administrators who already hold a doctorate may feel they do not need to become certified, and CRAs with an Associate’s Degree or less education may feel they do need to become certified to show evidence of their expertise.

In regard to the demographic characteristic of salary, there was a statistically significant relationship (<.0001) between salary and certification status of research administrators. The majority of the respondents who indicated they were not certified earned less than $40,000 annually or more than $80,000 annually. This suggests that non-certified research administrators who earn less than $40,000 annually may not perceive certification as being valuable and those earning more than $80,000 annually may not perceive the need to become certified. The majority of CRAs earned between $40,000 and $80,000 annually. Less than 3%, or 3 of 108 CRAs, earned less than $40,000 annually.

In regard to the demographic characteristic of length of employment as a research administrator, there was a statistically significant relationship (<.0001) between length of employment in the field of research administration and certification status of research administrators. The majority of the respondents who indicated they were not certified were employed in the field of research administration for less than 10 years with most of them being employed in the field for between 3 and 10 years. This was important to note since the RACC required a minimum of three years of work experience in the field of research administration before research administrators became eligible to take the certification exam. Not only were research administrators ineligible to take the certification exam with less than 3 years of experience, the data revealed that they also did not take the exam after they became eligible. This leads to the conclusion that non-certified research administrators who are early in their careers are not becoming certified.

**Research Question 3**

To what extent do certified research administrators attribute their career advancement, self-confidence, and enhanced knowledge of the field to certification?

Certified and non-certified research administrators were asked a set of questions pertaining to their perceptions of certification being beneficial to their career in terms of eight characteristics and two specific questions pertaining exclusively to enhanced knowledge and confidence.

The summary findings and discussion of the data collected for the eight characteristics are presented below:

1. Eighty-five percent (85%) of the certified research administrators (CRAs) agreed or strongly agreed that others more fully recognize their ability to perform their job compared to 50% of the non-certified research administrators. This perception is consistent with the perceived value of certification being greater for CRAs than non-certified research administrators. Although there is a significant difference in perception between CRAs and non-certified research administrators, the majority of non-certified research administrators still agreed or strongly agreed that others would more fully recognize their ability to perform their job.
2. Seventy-nine percent (79%) of the CRAs agreed or strongly agreed that their prestige among individuals within their organization increased as a result of becoming certified compared to 43% of non-certified research administrators. This perception is consistent with the perceived value of certification being greater for CRAs than non-certified research administrators. The majority of non-certified research administrators did not perceive certification making a difference in terms of increased prestige among individuals within their organization.

3. Seventy percent (70%) of the CRAs agreed or strongly agreed that their prestige among individuals outside their organization increased as a result of becoming certified compared to 61% of the non-certified research administrators. Although there was a small difference in perception between CRAs and non-certified research administrators in regard to this characteristic, the majority of non-certified research administrators positively perceived the value of certification in terms of prestige among individuals outside their organization.

4. Sixty-seven percent (67%) of the CRAs agreed or strongly agreed that their prestige among superiors within their organization was greater as a result of becoming certified compared to 45% of the non-certified research administrators. This perception is consistent with the perceived value of certification being greater for CRAs than non-certified research administrators. The majority of non-certified research administrators did not think certification made a difference in terms of prestige among superiors within their organization.

5. Fifty-percent (50%) of the CRAs indicated no difference in regard to certification being beneficial in terms of increased professional opportunities for contributions compared to 46% of the non-certified research administrators. Forty-eight (48%) of the non-certified research administrators agreed or strongly agreed that they perceived a benefit. The perceptions of both CRAs and non-certified research administrators were similar in regard to certification being beneficial in terms of increased professional opportunities for contributions, but slightly more non-certified research administrators agreed or strongly agreed that there was a perceived a benefit.

6. Fifty-seven percent (57%) of the CRAs indicated no difference in regard to certification leading to increased job responsibilities as a result of certification compared to 61% of the non-certified research administrators. The perceptions of both CRAs and non-certified research administrators were similar in regard to certification leading to increased job responsibilities.

7. Thirty-nine percent (39%) of the CRAs agreed or strongly agreed that their salary increased as a result of becoming certified compared to 30% of the non-certified research administrators. Fifty-five percent (55%) of the CRAs indicated no difference that their salary increased as a result of becoming certified compared to 56% of the non-certified research administrators. The perceptions of both CRAs and non-certified research administrators were similar in regard to certification leading to an increase in salary.

8. Twenty-nine percent (29%) of CRAs agreed or strongly agreed that they would receive a promotion as a result of becoming certified compared to 31% of non-certified research administrators. Sixty-six percent (66%) of the CRAs indicated no difference that they would receive a promotion as a result of becoming certified compared to 55% of the non-certified research administrators. The perceptions of both CRAs and non-certified research administrators were similar in regard to certification leading to a promotion.

The summary findings and discussion of the data collected for enhanced knowledge and confidence are presented below:

In terms of enhanced knowledge, 74% of the CRAs indicated they do feel more knowledgeable as a research administrator as a result of becoming certified compared to 40% of the non-certified research administrators.
Although there is a significant difference of perception between CRAs and non-certified research administrators, the majority of non-certified research administrators still indicated they would feel more knowledgeable as a result of certification.

In terms of confidence, 74% of the CRAs indicated they felt more confident in their ability to do their work as a result of becoming certified compared to 36% of the non-certified research administrators. Thirty-eight percent (38%) of non-certified research administrators indicated they would not feel more confident in their ability to do their work as a result of certification.

**Research Question 4**

What reasons, if any, do non-certified research administration professionals give for not attempting certification?

Eighty-two percent (82%), or 96 of 117, of the non-certified research administrators provided a reason for not attempting certification, with 40%, or 38 of 96, indicating they did not believe there was any benefit to becoming certified. There was a tie for the second most popular reason for not attempting certification, with not having enough time and not being aware of the opportunity to become a CRA each garnering 11%, or 11 of 96, of the responses of reasons for not attempting certification. Despite the perception of the majority of non-certified research administrators doubting the value of certification, some of the reasons provided by non-certified research administrators suggest they are not opposed to the concept of becoming a CRA. As examples of this, none of the following are individual objections to the concept of certification: (1) a current employer does not support a research administrator’s effort to become certified, (2) a research administrator is not eligible to sit for the exam, and (3) a research administrator takes the exam but does not pass.

Overall, the majority of non-certified research administrators do not believe there is benefit to becoming certified. However, when all the other reasons for not attempting certification are closely examined, the responses taken as a whole indicate that as many non-certified research administrators may perceive a benefit to becoming certified as those who do not perceive a benefit. These data indicate that non-certified research administrators perceive some benefit to certification.

**Research Question 5**

What relationship, if any, exists between the value placed by certified and non-certified research administrators in a supervisory role when they evaluate the qualifications of applicants for positions in research administration?

The relationship between the value placed by certified and non-certified research administrators in a supervisory role when they evaluate the qualifications of applicants for positions in research administration and the perceived value of the Certificate in Research Administration (CRA) were analyzed. These data revealed that there is a statistically significant difference (<.0001) between the perceptions of CRA supervisors and non-certified research administrator supervisors regarding the value of certification.

Research administrators who were certified and who served in a supervisory role were more likely to include a preference for Certified Research Administrators (CRAs) when they advertised for research administration positions, give preference to CRAs when they hire, and were more likely to negotiate a higher starting salary for CRAs. They
also perceived hiring CRAs as being more beneficial to their organizations in terms of people within the organization more fully recognizing a CRAs ability to perform their job, increased credibility of the employee within the organization, increased credibility of the employee outside their organization, and increased professional contributions.

The perception of CRAs who was supervisors and non-certified research administrators who was supervisors was similar to those of CRAs and in general. CRAs perception of value in regard to the CRA was greater than that of non-certified research administrators.

Discussion of Findings

This study sought to determine the value of certification in the field of research administration and was concerned with the relationship between perceived value of the Certificate in Research Administration (CRA) to research administration professionals and demographic characteristics.

In terms of personal demographic characteristics, research administrators are an educated group of professionals, with 84%, or 189 of 226, holding at least a Bachelor’s Degree. The majority of respondents ranged in age from 30-59, with 90%, or 203 of 226, falling in this category. The majority of the respondents were from doctoral granting research universities, and they were classified as coordinators or professional staff with an annual salary of $40,001-$50,000 and had been employed in the field of research administration for 5-10 years. Most respondents initially became involved in the field of research administration by working in another area of the university not directly related to research administration and had transferred to a predominantly research administration position or had no related experience or expertise prior to becoming a research administrator.

The research revealed that CRAs and non-certified research administrators both held negative views of the value of the CRA with regard to some specific characteristics. For example, certification was perceived by both CRAs and non-certified research administrators as not making any difference in terms of increased job responsibilities, salary increases, and promotion. This indicated that research administrators in general doubted that certification would lead to increased job responsibilities, promotions, or salary increases.

There were also some positive views toward certification that were shared between CRAs and non-certified research administrators. Both groups perceived benefit in terms of prestige among individuals outside their organization increasing as a result of becoming certified and others more fully recognizing their ability to perform their jobs. These findings led to the conclusion that research administrators did not believe that their organizations internally value certification, whereas research administrators did perceive value external to their own organizations.

In terms of feeling more knowledgeable as a result of certification, 83% of CRAs and 45% of non-certified research administrators’ believed they would feel more knowledgeable as a result of certification. Despite this significant difference in perception, the majority of both CRAs and non-certified research administrators perception was that becoming certified would, or did, enhance their knowledge as research administrators.

The research revealed some differences in the perception of value of the CRA in terms of research administrators feeling that their prestige among individuals within their organizations would increase and
their prestige among superiors within their organization would increase as a result of becoming certified. CRAs overwhelmingly agreed or strongly agreed that their prestige was enhanced within their organizations, and non-certified research administrators perceived there would be no difference in their prestige. This leads to the conclusion that CRA’s perception of value is greater than that of non-certified research administrators’ perception of value in prestige among individuals and superiors within their organizations.

The research revealed two additional subtle differences in the perception of value in terms of increased professional opportunities to contribute and increased confidence in their ability to perform their work as a result of certification. Slightly more non-certified research administrators agreed or strongly agreed that certification would increase their professional opportunities for contributions, whereas CRAs perception was that there would be no difference in their opportunities for professional contributions. There was also a minor difference in feeling more confident in ability to do their work as a research administrator, with slightly more non-certified research administrators’ perceiving they would not feel more confident compared to CRAs dominant perception that they did feel more confident in their ability to do their work as a research administrator.

**Implications and Recommendations for Professional Organizations**

The National Council of University Research Administrators (NCURA) and the Society for Research Administrators International (SRA) are the two primary professional organizations dedicated exclusively to the field of research administration. Research administrators’ perceptions of NCURA and SRA professional development opportunities are extremely positive with 90% of respondents reporting positive or extremely positive experiences with professional development opportunities offered through these organizations. The Research Administration Certification Council (RACC) was established in conjunction with the SRA; however, there is no association with NCURA, and since the establishment of RACC in 1993 there has not been a strong coordinated effort between RACC and SRA that has been recognized by research administrators as being of vital importance to them personally or the profession in general. Professional organizations could potentially benefit from offering certification programs to research administrators through financial gain and being recognized as positively serving their membership (Knapp and Gallery, 2003).

There are many perceived positive implications of certification among research administrators, including enhanced prestige among individuals outside one’s own organization and enhanced personal knowledge. If RACC is to be widely recognized as a value to individuals and their respective institutions, it needs to be more closely aligned with the professional organizations that research administrators report having positive professional development experiences. Since the professional field of research administration emerged, it has consistently grown larger, and universities have been forced to pay close attention to the administration of research dollars and the fostering of the research enterprise in general. It is reasonable to assume hiring the most knowledgeable research administrators would be a high priority to universities. Since the vast majority of research administrators enter the profession with little or no experience in the field, it should be extremely important to employers to have high quality and comprehensive professional development opportunities readily available for newcomers to the field.
Even though both CRAs and non-certified research administrators doubt the value of certification in terms of increased job responsibility, promotions, and salary, CRAs report earning more money on an annual basis than do their non-certified counterparts. The only exception is those earning more than $80,000 annually. The majority of those earning more than $80,000 annually are not certified, and it is concluded that those individuals do not feel they need to become certified.

In summary, a comprehensive certification program in the professional field of research administration has strong potential to serve individuals, organizations, and sponsors of research in an effective and positive way. In order to accomplish this, a comprehensive certification program should be closely aligned with the two major professional organizations dedicated exclusively to the professional field of research administration.

Recommendations for Future Research

Further research is suggested in the following areas:

1. It is recommended that a replication of this study be done in another region of the United States to further validate the results.

2. It is recommended that a replication of this study be done on an international scale to further validate the results.

3. It is recommended that research be conducted to determine if curriculum at the university level should be developed in research administration management.

4. It is recommended that the primary professional organizations in support of research administration engage in research to determine how many people are involved in the profession of research administration to help make decisions in regard to continuing adult education.

5. It is recommended that research be conducted focusing on the employers of research administration professionals to determine if they would value being served by a Certified Research Administrator (CRA) through the Research Administrators Certification Council (RACC).

6. It is recommended that the primary professional organizations in support of research administration engage in research about specific needs and preferences of their membership.

Conclusion

The death of our friend and colleague Herbert “Chuck” Chermside leaves all research administrators with the professional responsibility of defining what it means to be a research administration professional. In his professional life Chuck consistently challenged us all to be the best we could be. He constantly thought of ways in which professional development and continuing education could enhance our profession. He not only thought about it, he acted on it. The responsibility of carrying on this legacy is now ours, and it is up to research administrators worldwide to constantly challenge ourselves to be the best we can possibly be.

References


Special Commemoration: Research Article


The Legacy of a Colleague: Reflecting on Who We Are and What We Do

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It has been more than two years since I “discovered” the Society of Research Administrators International (SRA). In that period, I have learned much from of the society and have tried to contribute what I can. Recently, I was invited to participate as a track leader for the upcoming annual meeting, and to be part of the Journal of Research Administration’s editorial team. This confluence of events in my relationship with SRA made me pause and reflect on this society of ours.

Why SRA?

I could not help but recall when a colleague first suggested to me that I should belong to SRA. I looked at the suggestion from the perspective of what I could gain from membership. What was in it for me? Would SRA collect my membership fee like some associations, and offer little in return? At first, I believed that SRA had nothing to offer to me, coming from human subject research. At superficial first glance, it appeared to me that SRA was very focused on university-type research.

The annual meeting in Salt Lake City, Utah changed my view. I looked at the program syllabus and selected the sessions and workshops that were likely to be meaningful and helpful to me in my practice. It took some time but I was able to find sessions. At the meeting, I was pleasantly surprised not only by the caliber of the programs but also by the people who presented and the people who attended. Conversation with members of both groups convinced me that this was not unusual, not the luck of the draw of one particular meeting. In other words, there was depth to SRA. Every interaction I have had with the SRA since has been full of opportunities to learn. I have gained information that validated my daily practice, tools that I have adopted or implemented from SRA’s offerings, and ideas that made me sit back and think. SRA has helped me to be more effective research administrator.
Who are we?

However, who am I? Better yet, who are we? For many, if not all, it appears that research administration found us rather than the other way around. We all seem to say that we were “drawn” into research administration. We all have our stories of the journey. Mine was the track of greatest resistance. I started as a Clinical Research Coordinator (CRC) in the early nineties. I coordinated clinical trials with complex protocols that advanced what we know in cardiovascular care. The work required clinical expertise and analytical skills. Conference presentations on clinical investigations and learning on my own served as my initial training in clinical research coordination. Little or no time was allocated for administrative functions. I would argue that most of my CRC colleagues had similar training. More often than not, training was trial and error, or worse: trial by fire! The administrative demands of a CRC can be daunting.

CRCs are usually involved in budgeting, supervising, and sometimes in hiring some of the clinical research team members. They may have little appreciation of what clinical trial agreements entail or the influence of agreement language on their practice. Nuances of indemnification, publication, intellectual property and other contractual elements are sometimes only glanced over. CRCs are usually more concerned that contracts are executed expeditiously so that their respective clinical trials can begin.

As they move forward with their research careers, CRCs may find themselves in the midst of the “research administrative jungle,” with little or no structured educational support or training from their own institutions. Research billing, allowable costs, indirect rate calculations or trial cost analyses may be left for the “finance guy,” who needs input from the CRCs to make budget models work. Some CRCs are expected to manage these activities themselves in a feel-your-way-through manner. I remember an NIH grant proposal budget in the early 90’s. Without effective training, I had no idea what a facilities and administration rate was, but was told that it was 25% and put it in without question. I also put postage and office supplies in the direct cost line. At other times early in my career, I was called on to use the disciplinary process on a subordinate for poor performance, and to interview a replacement for a budgeted position. I felt unprepared to handle all of these. These may have been “rookie” mistakes but they can certainly be avoided.

Literature confirms that my experience is more the rule rather than the exception. Fedor (2005) found out that CRCs are expected to “manage the full spectrum of research activities. CRCs require a wide range of technical, managerial, ethical and regulatory expertise” (p.6). She lists the main administrative functions, activities, and responsibilities of the CRCs (Table 1), confirming from an interview-based study that showed that most training was “on the job”. This lack of formal support and training can only add to the CRCs’ frustrations, and leads to job dissatisfaction and turnover among CRCs. Center Watch (2003) reports that the highest turnover rate among CRCs comes at one to three years of experience.
This phenomenon will only increase with the continued demand for clinical trials. Innovation in the practice and delivery of healthcare and the advance of basic science demand well-conducted clinical trials. Gambrill and Zisson (2005) reported that the clinical research industry grew 12.3% to $18.5 billion from 2003 to 2004. Combined with the almost $29 billion that the National Institutes of Health (NIH) budget (NIH, 2006), this increase may lead to a sudden and critical shortage of well-prepared CRCs needed to perform mandated procedures, collect data, coordinate research plans and manage the clinical trials that potentially improve lives. SRA can make a great difference here. SRA cannot totally reverse the trend, but it can positively affect it. SRA can embrace a group of professionals and help them avoid the mistakes that my colleagues and I made early in our early careers.

I go back to the earlier question: who are we? The short answer is that we are everything that is research administration! The diversity of background of SRA membership has been one of our strengths, but it can also be our Achilles heel if we do not continue to improve outreach both to our traditional membership and to new or emerging areas of specialty. SRA needs to expand its collaboration with other professional research associations and define itself as the “go to” association for all aspects of research administration and management. It needs to advertise the value of its workshops, sessions and
meetings, but also the diversity of its membership and the openness of its community to everything research administration.

These are exciting times for all of us. SRA is at the cusp of change, growing into a new executive structure, developing new core curricula for novice research administrators and Responsible Conduct for Research tracts. These will compliment the various certificate tracts, sessions, and workshops that SRA currently offers. We help make financial responsibilities, rules and regulations clear and manageable, but are also stewards of responsible conduct of research. We are integral participants in the research process. We are facilitators. We are problem-solvers. We embody my earlier short answer: we are everything that is research administration!

The Research Administration Professional

Themes of “Professionalization” of research administrators abound in our society. Certification in Research Administration (CRA) is available for those who want to validate and/or learn more about the art and science that we profess. One cannot speak of research administration certification without mentioning the name of its ardent advocate and pioneer: Herbert “Chuck” Chermside. Many of you know that Chuck passed on earlier this year. He left us his legacy in certification among a host of other things. He cherished helping us in research administration to the very end. In this edition of the Journal, Roberts (in press) eloquently wrote that Chuck’s death left us with the responsibility to define who we are. I offer that we are at the threshold of doing so. The textbook on research administration and management published by Kulakowski and Chronister (2006), and the emergence of graduate certificate program(s) underscore this. It will be only a matter of time before we have an accredited graduate degree in research administration in several universities with future research administrators carrying credentials of Master in Research Administration, (MRAs) at the end of their names.

I may be reaching too far with another notion. Can we consider a Fellowship in Research Administration? There are members right now who are worthy of such recognition, Fellow of the Society of Research Administration International, (FSRA). Some may question why we need this when we already have certification in research administration. I ask, why not both? Being a fellow of the society validates the personal achievements of our outstanding membership and elevates our profession that much more.

The choice of Quebec City for the upcoming meeting seems to say something: a city in which the old and the new exist in harmony points to SRA at a crossroad of its history and its future. The program promises to be the most comprehensive and inclusive ever. The passion and commitment of the chairs and the planning committee inspire awe. The committee boasts leaders in international research administration thought and a broad spectrum of professional and educational backgrounds. Strong focus on recruitment and retention, leadership and mentoring joins unflagging commitment to excellence in sessions and workshops about finance, regulations and compliance among others, there will be an equally. In addition, our Canadian colleagues are also excited to show what this wonderful city has to offer.

Under its new editorial structure, our journal positions itself to provide better resources for us and for future research administrators. It encourages scholarly ideas from all facets of research administration. Articles go beyond international borders, oceans and
professional backgrounds. I have had the advantage of reading them early in my duty as the Senior Manuscript Editor. I hope that you find them as interesting as I did. The vision for this journal pays homage to its tradition while reaching to support everything research administration. It helps to further define the profession. The commitment and dedication of the editorial staff is impressive. They volunteer their time and expertise to provide authors with extraordinary support and present the membership with the best articles about our profession. The vetting process is such that the contributors are assured careful consideration of their manuscripts all the way through.

**The Exciting Future**

My reflections have spanned fifteen years—from being a CRC to my current role as the research administrator for a healthcare system performing clinical research. This led me to be excited:

- Excited by the potential and the future of our profession.
- Excited by the contributions of other professions that enrich who we are.
- Excited by the growth potential.
- Excited by the challenges of our future!

Fulfillment will demand work and nurturing. Let us help and nurture each other. I hope that you all would agree.

**References**


Why Do Ethical Scientists Make Unethical Decisions?

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Note: All opinions expressed in this paper are solely that of the author and not of Weill Medical College of Cornell University or any other institution

Abstract

In light of the ever-increasing number of cases of research misconduct being highlighted in the media, this paper looks to consider what conditions exist that cause supposedly ethical scientists to make blatantly unethical decisions. Looking to understand the ethical breaches illustrated in some of the more publicized cases, three things become apparent. One is the need to explore basic core values, second is to agree on common definitions and concepts, and third is to recognize the many outside forces that may have influence on ethical conduct and decision-making. Can common moral ground among ideology, pedagogy and reality be found through mandatory ethics training? Free will and choice are part of the human condition - what are the forces that impact the ethics of those choices and how do we as a societal collective react when our revered scientific role models fall short?

Never let your sense of morals get in the way of doing what’s right.  
~ Isaac Asimov

In December of 2002, the Office of Science and Technology Policy defined research misconduct as “fabrication, falsification, or plagiarism (FFP)—the “high crimes”—in proposing, performing or reviewing research results (OSTP.gov). However, as discussed below some commentators suggest there is a much wider—and grayer—area of misbehaviors and faulty decisions that are not captured in this limited definition. If these troubling practices are allowed to continue unchecked they will eventually erode any attempt to establish a solid foundation of responsible conduct of research.
Research

Martinson, Anderson and de Vries (2005) state that serious misbehavior in research is important for various reasons, not least because it damages the reputation and undermines public support of science. They suggest that, in light of the public’s penchant for headline grabbing cases of scientific and medical misconduct, the research community can no longer afford to ignore the ever-widening array of integrity issues.

The question always is: “Why?”

Martinson, Anderson and de Vries (2005) surveyed several thousand early- and mid-career US scientists funded by the National Institutes of Health (NIH) and asked them to report their own behaviors. Although the survey did not attempt to link specific behaviors to specific incidents, the results yielded a range of questionable practices. These results force a closer examination of the “negative aspects of the research environment.”

The modern scientist faces intense competition for limited research grants, which can create many scenarios for compromise that extend well beyond FFP (Martinson, Anderson and de Vries, 2005). The survey authors state: “In ongoing analysis, not yet published, we find significant associations between scientific misbehavior and perceptions of inequities in the resource distribution processes in science.” These behaviors undermine the scientific process, could lead to “misuse of public monies,” and generally foster an environment that lacks integrity (Mitchell, 2005). Lower (2005) is more blunt: “Corporate America provides a research environment that is not particularly conducive to good scientists or good science.”

I suggest that there is more to the issue than a simple succumbing to the pressures of “publish or perish” or the demand “show me the money.” One needs to consider from where core belief systems come and how they may be affected by outside influences.

Values, beliefs, moral, ethics and integrity are intricately interwoven concepts and are consistently—albeit mistakenly—used synonymously. Benefiel (n.d.) says that values are learned from childhood. These are the beliefs that children absorb from those who raise them and from their immediate surroundings. Benefiel (n.d.) goes further to say that morals are the intrinsic beliefs developed from the value systems of how one “should” behave in any given situation and that ethics are how one actually does behave in the face of difficult situations that test one’s moral fiber.

Kidder (2005) talks about moral courage as, simply, the courage to be moral. To be considered moral, he says our moral fiber must adhere to one of five core moral values: honesty, respect, responsibility, fairness and compassion. As one attempts to examine past incidences of scientific misconduct, the inherent breaches of research integrity, and the prevailing conditions that cause ethical scientists to make unethical decisions, one needs to understand these basic or core values, agree on some common definitions, and recognize the influence of outside forces.

Kidder (1995) notes four basic paradigms of ethical decisions: 1) justice versus mercy – fairness, equity and even-handed application of the law often conflict with compassion, empathy and love; 2) short-term versus long-term – difficulties arise when immediate needs or desires run counter to future goals or prospects; 3) individual versus community – this can be restated as us versus them, self versus others or the smaller group versus the larger; and 4) truth versus loyalty – honesty or integrity versus commitment, responsibility or promise-keeping.
Certainly any one of these paradigms, if not several, can be applied when examining the motivation of those who commit unethical scientific acts. In the case of the University of Vermont and researcher Dr. Eric Poehlman, it was determined by federal prosecutors that Dr. Poehlman committed scientific misconduct by falsifying and fabricating research data in numerous federal grant applications and in academic articles from 1992 to 2002. According to a Boston Globe article (Goldberg and Allen, 2005), this was “the worst case of scientific fakery” to come to light in two decades. Colleagues of Dr. Poehlman, a top obesity researcher, speculate that either he buckled to an exaggerated perception of the pressure to publish papers and win grants to keep his laboratory going, or he was just so sure that he knew the right answers that he cut corners to get them.

According to a Boston Globe article (Goldberg and Allen, 2005) one of Dr. Poehlman’s lab technicians offered that he could not be sure what Dr. Poehlman was thinking, but that the benefits were clear – the fabricated data made his grant proposals more appealing and his papers more publishable, thus enabling him to be one of the better-funded researchers at the University of Vermont. If, in fact, Dr. Poehlman manipulated the system to maintain his lab, his determination to preserve what he had created overrode the necessity to learn and publish the truth.

Karcher (2004) contends that integrity is choosing ethics above personal benefit. The fact that “everybody does it” or “no one will ever know” is irrelevant. Actions should be based on values rather than personal gain. The question becomes muddied—and perhaps more than slightly rhetorical—if one’s value system puts personal gain above all else. Hymes (n.d.) states that people breach or ignore their respective code of ethics for the very base reason of greed. Greed, whether viewed as lusting after financial gain, material goods, knowledge, fame or power can be a major motivating factor for breaking or overlooking ethical boundaries.

I suggest that lusting for scientific fame (e.g., a Nobel Prize) was the motivation in both the 1984 case of Dr. Robert Gallo, famed NIH researcher who claimed to have discovered the AIDS virus, and the more recent case surrounding the death of 18-year-old Jesse Gelsinger, who died in a gene therapy experiment led by Dr. James Wilson of the University of Pennsylvania.

In both of these instances the motivation to achieve that-which-had-yet-to-be-done was a driving force for breaking the rules.

Those involved in the thick of the Gallo debacle felt powerless to reverse the course of events. The prevailing political climate of ignorance and denial created a scenario in which many in the US and abroad were forced to watch in horror as the number of AIDS-related deaths began to climb while scientists on both sides battled for scientific superiority. How many died needlessly while patent issues were being fought in the courts?

Luc Montagnier of the Pasteur Institute of Paris, whose lab many now acknowledge discovered the virus, is quoted as saying, “Scientists in the US are forced to produce results, which sometimes warps their sense of ethics” (Caton, 1995). This is consistent with the Martinson, Anderson, and de Vries survey results – that intense competition forces otherwise respectable scientists to act unethically in widely varying degrees.

Lakoff (2002) describes integrity as the virtue of being morally whole. In his view someone with integrity has consistent moral
principles; he suggests that it is the overall unity of moral principle that makes someone with integrity strong.

Yet how strong does a young scientist have to be to stand up to and blow the whistle on a world-renowned figure such as Gallo? Or stand up to one’s graduate advisor, mentor or lab director in a school setting? The power imbalance can be crushing—and it can destroy a career before it has begun. Is such strength too much to ask when society is unwilling to take such a stand?

Harris (1998) adds the genetics element into the morality mix. She claims that the long-held notion that a child’s personality or “character” is shaped or modified by his or her parents is not completely valid. Alternatively she claims there are two far more overpowering influences: one being genetics and the other being the influences experienced outside of the home. She contends that parents do not socialize children, that children socialize children, and therefore outside peer groups have a more powerful influence than parents.

Perhaps an argument can be made here about the influence of adult peer groups as well. If the scientific community as a whole is not willing to take a dramatic stand against breaches of scientific integrity—as illustrated by the dearth of peers in the scientific community willing to testify against Robert Gallo or the US government agency that was supporting the work—then what message is being sent? Is it that we as scientists know what we are doing and it is for a nobler purpose, therefore it is not necessary or warranted to punish those who cross the line in the name of the greater good of furthering science? This might be argued under a Utilitarian approach, doing the best for the greatest number, but certainly not from the perspective of moral rights. How many innocent subjects and patients were trampled in the race to be “first”?

Lower (2005) argues that it is time for the people to demand honesty and integrity in science. He faults what he calls “religious capitalism” for creating an unethical abyss into which many have fallen. He is not surprised that this seeming eruption of corruption in American science has come to surface under the George W. Bush administration. Lower suggests that there is plenty of evidence that the Bush administration appears to be on a mission to systematically eliminate honest scientists. Sweet (2002) feels that this is particularly true for scientists with the courage to disagree with policies set forth by an administration with an agenda—hidden or otherwise. Sweet offers as examples that two existing scientific committees were purged for opposition to the White House political and/or religious points of view: one studying federal protections for human research subjects is said to have angered Bush’s radical religious supporters; the other committee—charged with helping to protect public health—was jettisoned because it recommended that the FDA expand its regulation of the genetic testing industry, which previously had been free of oversight (Sweet, 2002).

In light of the building instances of “political interference” in scientific research, how can we expect to change behaviors that positively impact ethical decision-making? What are the rewards for “doing the right thing” when government has a slanted view of what is the right thing?

The messages are mixed at best. Many institutions (such as my own) mandate ethics training for trainees and/or specialized human subjects training for anyone submitting a protocol to the IRB. We compel
student scientists to attend a fixed number of sessions and complete a specific number of online assignments on various topics related to the responsible conduct of research (RCR). This is fine. We can state with a clear conscience that X-number of trainees completed some sort of ethics instruction in a given year.

The more troubling question is what impact, if any, does such mandatory training have on future behaviors and decision-making? Do our trainees make more ethical choices? Are we creating and supporting an institutional culture that encourages, nurtures and enables ethical science? Or is it an illusion?

I like to think that we work hard to create educational and professional venues, which support “doing the right thing because it is simply the right thing to do.” Yet sometimes perception and reality are two separate things.

As Fuchs and Macrina (2005) suggest, once we enter the realm of moral reasoning, we base judgments on what we ought to do and we assume that this is the right thing. Yet, acting morally is not always akin to acting legally. History is filled with indiscretions that, at the time, were legal but today would be considered highly unethical—if not outright unlawful. Fuchs and Macrina state that, in order to avoid repeating these historical breaches, scientists must strive to carefully examine the moral dimensions of current research practices. It is no longer a matter of abiding by the regulations. The regulations do not always cover every nuance, and—in the opinion of some—regulators are suspect at best because of questionable political and/or religious affiliations (Lower, 2005, Sweet, 2002, Crewdson, 1995). This is illustrated not only by the Gallo case orchestrated under the Reagan administration’s watch but most certainly by the ongoing interference of the current Bush administration.

The public trust is fragile. Once shattered it is difficult to repair. Perception is the key—sometimes it is the mere hint of a possibility of wrongdoing that can be the catalyst for disaster. Hoey (2003) cites that the problem in the Gelsinger case was not one of uninformed consent, misleading protocols, publication gag clauses, or the like. Rather, the issue became one of public perception. Once the family filed a suit against the University of Pennsylvania (UPenn), it was learned that James Wilson, the lead investigator, was also the president and major shareholder of the private company that held patents for the procedure in question and funded the research. It also was discovered that the university and some members of the board of governors also owned stock in the firm. Although Hoey (2003) asserts that these factors had no direct bearing on Jesse Gelsinger’s death, UPenn quickly settled the suit and Wilson resigned his university post. UPenn went a step further by instituting strict guidelines for clinical research that would prohibit faculty from participating if they or close family members have a material financial interest in a private company whose product(s) they are evaluating. Many other institutions have followed with similar guidelines.

Conflict of interest and commitment become a slippery slope for many researchers in search of funding. Guterman (2005) reports that over the past twenty years the proportion of research studies funded publicly has decreased significantly, while those supported privately have increased. This seems especially true in occupational and environmental health, where the field is dedicated to studying dangers to the public’s health and safety from the workplace and/or environment. Academic scientists in this field know
that business interests increasingly drive research agendas (Guterman, 2005). The government seems to give this work low priority, so scientists are forced to look to the private sector for research funding. How does the responsible scientist balance the paycheck with the findings that their sponsor’s product is actually a menace to public health and welfare? Guterman quotes Daniel T. Teitelbaum, a Denver doctor specializing in medical toxicology and occupational epidemiology, who says, “Industry doesn’t give you money to do research. Industry gives you money to do research that favors them.”

Therefore are corporate sponsors the villains? The money has to come from somewhere, but at what price to the public trust? Many feel journal editors are equally culpable. Guterman argues that some journals in occupational and environmental health do not require authors to reveal their funding source or any other possible conflicts of interest. Shuchman and Wilkes (1997) also place blame at the feet of irresponsible journalists who at best are careless in their reporting, if not deliberately misleading. Shuchman and Wilkes recommend that members of the research community take an active role in ensuring honest reporting. They suggest that scientists check institutional press releases for accuracy and clarity; medical journals and sponsors of medical meetings should seek expert advice on placing new information in the proper context; the scientific community must inform journalists of any potential conflict of interest; and finally, industry sponsorship of research and persons who speak or write about that research should be identified as such.

Research integrity issues are multi-faceted. There are many stakeholders, and these are not problems for researchers to tackle alone. All in the research community have a voice and an important role to play. As Martinson remarked at the conclusion of his survey, “We should be asking what kind of aspects in science are fostering [these questionable practices] and are there ways of addressing them to make them better” (Mitchell, 2005).

As citizens in a democratic society, we have a duty to hold issues of integrity—in science, business, politics, education, or elsewhere—to a very bright light. If we fail to do so, those who suffered and perished as result of the Nazi WW-II experiments, who were deceived in the Tuskegee Study of untreated syphilis, or who fell victim to research delays caused by the questionable actions of warring investigators or opposing political views in the early—or present—days of the AIDS epidemic did so in vain. To have learned these lessons only to discard them for the sake of corporate greed, Nobel-Prize-blind-sightedness, journalistic sensationalism or religious dogma is unacceptable.

Programs like the University of Pittsburgh’s “Survival Skills and Ethics” course have sought to address these issues for twenty years. They attempt to integrate ethics and the responsible conduct of research into every topic. The Department of Health and Human Services’ Office of Research Integrity offers institutions grant money to develop pilot programs to teach graduate students responsible conduct of research. The assumption is that if we make greater efforts to educate students about integrity issues, then the incidents of misconduct will be reduced. However, ethics education is not a one-shot deal.

Trainees in the Tri-institutional Responsible Conduct of Research Program (co-sponsored by Weill Medical College, Memorial Sloan-Kettering Cancer Center and The Rockefeller University since the early 1990s) lament:
You can’t force-feed someone ethics. You cannot transform someone into an ethical being in every instance by mandating course attendance and completion.

Rather, ethics education is an ongoing life-long process that individuals must choose as a way of life and that peers, mentors and colleagues must model. Regulations change from administration to administration, but good science must remain unspoiled by the political flavor of the month.

Can scientists find common moral ground among ideology, pedagogy and reality through mandatory ethics training? There is power in numbers and unity. For a single university to tackle this dilemma alone is as foolish as waiting for something to go drastically—and publicly—wrong. RCR training should not be viewed as “punishment.” Martinson cautions that it would be dangerous for a single institution to try and address research misconduct in isolation because this could put them at a “distinct disadvantage” in the competition with other universities for grants and other resources (Mitchell, 2005).

As sad a commentary as that is, competition between like-minded institutions is a reality that needs to be acknowledged and addressed in a way that does not dilute the importance of doing what is right for its own sake. Institutions should not allow the fear of losing funding to their competitors dissuade them from developing transparent policies and support training that address the issues of research misconduct.

To date there is no extant empirical data of which I am aware to support the belief that mandatory training affects ethical behavior and decision-making in a positive way. Of course, if I reach retirement without seeing my institution or one of my trainees in the headlines for scientific misconduct, that would be a victory of sorts. Moreover, I would be satisfied when I stop seeing cynical evaluation comments from trainees upon being “forced” to attend RCR programs. As scientists, administrators and educators we should strive for the day when the unanimous response will be “Ethics – wow, this is great stuff – I couldn’t possibly imagine my life as a scientist (or a person) without it!”

After examination of the issues that might cause ethical scientists to make unethical decisions, an all-inclusive remedy is not forthcoming. What becomes apparent is that the scientific research community has an obligation to take these issues to heart. More important than just teaching mandated course modules or adhering to federal guidelines or regulations, ethical behavior and decision-making has to be thought about, processed, openly discussed, modeled, and mentored. Each of us must live with the growing pains. The choices we ultimately make will impact us not only in the classroom or the lab but also throughout the fabric of our personal lives.

References


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Abstract

The Australian higher education sector has seen growing pressure for universities to be more accountable for the quality of both teaching and research. The emphasis for universities to seek greater financial support from external companies to sustain research activity results in the universities becoming ‘products and services’ providers. The University of South Australia (UniSA) has developed an ISO9001:2000 certified quality management system, which includes policy, systems and processes for managing research and consultancy projects. In this paper, the discussion focuses on both the implementation and application of the ISO9001:2000, as well as the role of this formal system as a key factor in improving strategies to gain a superior competitive position. The interpretation of the latter are framed by Turban, McLean and Wetherbe’s (2004, p116) definition of strategic advantage. The experiences of the University of South Australia (UniSA) in collecting and analysing data from industry or client feedback via annual client surveys, and reporting and using the information to assess and modify the extent to which clients value the services are described.

Introduction

Australian education continues to be faced with a number of challenges as it strives to provide the nation with advanced knowledge and innovative research and development (Australian Vice-Chancellors’ Committee, 2004). As a consequence of increased challenges and pressures, universities acknowledge that they belong to a ‘market’ that is becoming increasingly competitive. One area of university operations that has historically been overlooked in the “quality” forum is that of research. Currently, the Government measures are performance or “outputs” based, considering only successful higher degree research student completions, staff and student research publications and staff research income. There is, however, no opportunity for the research partner/client to provide “input” about the level of satisfaction with the experience.

In order to understand better the expectations of clients and to attain a superior competitive position, the University established an ISO9001 Quality Management system. The aim of
this paper is to provide an overview of an approach to improving research management by measuring and streamlining the processes that support research project activity. It is not the intent of this paper to provide the prescriptive methodology used to survey clients.

The first section defines the principles, requirements and intent of ISO, while the second section explores how ISO9001 is applied and implemented at UniSA and, importantly, reveals how a formal management system has been key in driving improvement strategies through the development of quality performance measures in relation to the services provided to its external research clients.

What is ISO?

In the pursuit of competitive advantage, it is increasingly important to identify the demands and values of current and potential clients (Menzer, Flint, Kent, 1999). As we enter the 21st Century, it is imperative that we consider the complexities of our environment such as technology, globalisation, competition, change, speed of change and complexity itself (Tetenbaum 1998) as these factors contribute to the challenges of our organisational existence. If organisations, including University Research Offices accept these complexities and challenges, we must then address them by seeing knowledge, or the attainment thereof, as a prerequisite for sustainability. How do we best address these conditions and challenges and achieve competitive advantage? How do we give rise to a sustainable future?

It would be naïve to suggest that ISO9001 is the complete answer; however, for UniSA, it does provide a formal management system and framework for identifying client requirements, setting organisational objectives, assigning responsibilities, managing human and material processes and monitoring the output of the system, including client satisfaction, with a view to continual improvement. This being the case, the formalised system enables controlled interaction with the environment in which we operate.

The ISO9000 model contains eight management principles designed to enable continual improvement. They are:

1. Client focus
2. Leadership
3. Involvement of People
4. Process Approach
5. Systems approach to management
6. Continual improvement
7. Factual approach to decision making
8. Mutually beneficial supplier relationships

Complementing these underlying principles is a series of requirements that need to be met in order to be certified (or registered, as it is often referred to in North America). They are:

1. Management Responsibility – Responsibility for the system rests with the ‘top management’ of the organisation, thus at a strategic level.
2. Resource Management – Sufficient human and physical resources are available to carry out the processes.
3. Product Realisation -- There are controlled processes in place to support and manage products/service provisions.
4. Measurement, Analysis and Improvement – Strategies are in place that allow the system to be measured objectively and which allow for collecting information about how the system is performing in relation to client requirements.
Unlike many of the ISO standards, ISO9001:2000 is a “generic” standard – that is it can be applied to any organisation, regardless of size or type. The model’s four requirements function similarly to the PLAN-DO-CHECK-ACT (PDCA) improvement process that was popularised by W. Edwards Deming. It is a process approach; therefore, its framework.

(Figure 1.1) illustrates how client requirements drive the input and how client satisfaction drives the output. The process approach emphasises the importance of understanding and fulfilling the requirements of the client, the need to consider processes in terms of added value obtaining results of process performance and effectiveness, and continual improvement of processes based on objective measurement (Joint Technical Committee QR-008, 2000).

Figure 1.1 Quality Framework.

As illustrated, the process based quality management system shows the significant role that clients have in defining requirements as inputs. The continual improvement of a quality management system is derived from monitoring the satisfaction of clients, by evaluating information relating to their perception, as it is this that determines whether an organisation has met the requirements of their client (AS/NZS ISO, 2000). By deploying this framework and abiding to the requirements of ISO9001:2000, UniSA has developed processes, policy and procedures to ensure the following results:

1. Client/Industry Partner requirements are defined and documented ensuring alignment between client expectation and UniSA’s perception of that expectation.

2. Project Management processes are developed to ensure the clients’ requirements are fulfilled.

3. Client feedback is obtained at the end of every research and consultancy project as well as via an annual survey as described in the Service Quality Perceptions part of this paper.

4. Objective measurement of client feedback and process effectiveness is used to assist with decision making, leading to continual improvement and superior competitive positioning.

Because quality is critically linked to an organisation’s success (Buzzell & Gale, 1987; Gronroos, 1990; Howat, Milne & Crilley, 1996), UniSA has developed a framework which includes a suite of tools and systems for managing its research and consultancy projects. The aim of these is to foster process consistency and to learn more about our clients.

To be able objectively to measure client satisfaction one must have a consistent approach. To this end, the Research and Innovation Services Office has developed policy and procedures for the project management of research and consultancy, along with mechanisms for the continual review and improvement of its processes. This approach is consistent with Johnson’s (1993) concept of ISO quality, suggesting that ISO9000 is focused on meeting client needs with a system that is appropriate, planned, controlled, documented and fully understood. Additional information may
be found at http://www.unisa.edu.au/res/bus-admin/default.asp

At a functional level, a reliable approach to the management, tracking and recording of research and consultancy projects has been achieved through the development of a web-based project management system called the Project Quality System (PQS). The PQS enables projects to be managed from proposal stage through to project completion as its process tracks and records client details, intellectual property opportunities, risk assessment, capacity approval, budget entry, and client feedback. It is this latter component, client feedback, which is most important as it enables us to assess how the services that we are delivering services are valued by our clients.

Service Quality Perceptions – The Clients’ Perceptions

The initial question to be addressed therefore is “What do our clients value or want in their interactions with UniSA’s research services?” Beginning in 2001, a portfolio of service attributes was identified by conducting two focus groups with external clients. The service quality issues shaped the development of a self-administered questionnaire (see Appendix A), that was subsequently, piloted with a sample of clients from the PQS database. The self-administered questionnaires use a tailored service specific version of SERVQUAL, a conceptual service quality model able to facilitate the monitoring of clients service quality expectations and performance (Parasuraman, Zeithaml & Berry, 1985 and 1988).

The adaptation of SERVQUAL is dependent on two variables: expected service and perceived service. The two variables are compared so that the “perceived service quality” is interpreted from the differences in degree and direction between perceptions and expectations. For example the service quality attribute for “employee enthusiasm” in 2003 had an importance rating of 5.1 and a performance rating of 4.9, resulting in a service quality gap of -0.2. The smaller the gap the better the alignment between the two variables – expected service and perceived service.

The inaugural survey study of external clients, conducted in March 2001, netted a response rate of approximately 40%. Subsequent factor analysis on the 2001 data set led to improvements to the questionnaire, which included the identification of three industry specific dimensions of service quality. These were categorised as “product/service delivery,” “human resources” and “assurance and reliability.” Each year since, the Research and Innovation Services Office has contracted an independent research centre, specialising in these types of studies, to survey our clients under the guidance of a pre-determined set of criteria. The response rate during the last four years has ranged from 34 to 40 per cent.

The first two annual surveys examined only UniSA’s service delivery. The study has since extended to include the Australian Technology Network Universities (ATN), of which comprises UniSA, Curtin University Perth, Queensland University of Technology (QUT), University of Technology Sydney (UTS) and the Royal Melbourne Institute
of Technology (RMIT) are members. The perceived advantage of extending the survey to several comparable institutions is that it enables benchmarking and identifies areas of best practice. Each participating organisation receives an individual report with their results and a separate section in which these are compared to the benchmark average.

This paper now examines a small sample of survey results which are considered to be key indicators listing areas of strength and areas that require monitoring or attention. Furthermore, it explores an area that was highlighted as “requiring further attention” and explains how the process was identified and improved.

Using a seven-point scale with a measurement range from Very Dissatisfied to Very Satisfied, survey respondents are requested to rate their levels of satisfaction. The attribute, (Figure 1.2) is a summary attribute that measures overall satisfaction.

The measurement above illustrates that overall satisfaction with UniSA has increased (6.00 in 2004 from a maximum of 7.00) from the previous surveys (5.91 & 5.65). Achieving 86% from a maximum score of 100% (i.e. 6.00 from 7.00) is considered a strength as overall satisfaction has increased by a total of 6% over a three year period and is above the ATN benchmark. It could be argued that a 6% improvement over three years can at best be considered small, however the validity of this argument would lose its strength when it can be seen that UniSA is achieving 81% from a maximum of 100% in 2002 and 84.4% from a maximum score in 2003. In other words UniSA believes that as it is scoring close to the available maximum available result it is difficult to achieve large percentage improvements within such a limited available scope.

**Figure 1.2 Overall Satisfaction with UniSA’s Research Services**

![Graph showing overall satisfaction with UniSA’s Research Services from 2002 to 2004.](image)

**NOTE:** Scale used for this question ranged from 1 ‘very dissatisfied’ to 7 ‘very satisfied’
Similarly, another positive summary attribute (Figure 1.3) is that of recommendation to others. The tool used to measure the extent to which clients would recommend UniSA to others is a five point scale that ranges from Strongly Not Recommend to Strongly Recommend.

Aggregating the UniSA scores for strongly recommend and recommend it can be seen that UniSA has achieved high levels of recommendation, which have remained consistent each year with results of 88% in 2002, 89% in 2003 and 89% in 2004. Furthermore through benchmarking with the ATN Universities UniSA is above the total recommendation benchmark score, which is further evidence that the service provision for this attribute is at a level where clients are willing to recommend UniSA to others.

The scale used in this part of the questionnaire ranges from 1 (disagree) to 6 (strongly agree). The importance mean refers to the extent to which respondents believe the particular service attribute is important to them. The performance means measure how the service attribute is perceived to be performing. These two means are used to calculate the client service quality (CSQ) gap for each attribute. By requesting respondents to rate their levels of importance and performance in relation to attributes of service quality, the 2004 survey highlighted a number of attributes that may be considered as competitive strengths, these are shown in table 2.1.

The benefits of these results are a confidence amongst researchers and research administration staff that their services are valued

### Table 2.1 Importance and Performance Ratings.

<table>
<thead>
<tr>
<th>CSQ Attributes</th>
<th>Importance</th>
<th>Performance</th>
<th>CSQ Gap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employee knowledge and experience</td>
<td>5.3</td>
<td>4.9</td>
<td>-0.4</td>
</tr>
<tr>
<td>Key contact person clearly identified</td>
<td>5.4</td>
<td>5.2</td>
<td>-0.2</td>
</tr>
<tr>
<td>UniSA’s working knowledge of industry requirements</td>
<td>5.2</td>
<td>4.9</td>
<td>-0.3</td>
</tr>
<tr>
<td>Assuring trust and confidentiality</td>
<td>5.3</td>
<td>5.1</td>
<td>-0.2</td>
</tr>
<tr>
<td>Flexible Approach</td>
<td>5.2</td>
<td>4.8</td>
<td>-0.4</td>
</tr>
</tbody>
</table>
by clients; use in external marketing; and knowledge of what processes can be maintained and which need improvement.

An area identified in the 2003 survey as needing further consideration was that of “administrative processes.” As the nomenclature suggests, this question focused on measuring clients perceptions of administrative support processes (legal, finance, ethics) of the research project using a scale from 1 (disagree) to 6 (very strongly agree). In 2003 the results of the survey identified a comparatively large gap between clients’ importance ratings and their perceptions of UniSA’s performance. The gap of -1.0 (importance 4.9 and perceived performance 3.9) was larger than the ATN benchmark and was also larger than that recorded in the previous year, which was -0.7. The relatively high importance rating of 4.9 reinforced that clients considered this aspect of service quality to be integral to the research project’s success.

To better understand “administrative processes” an external focus group study was conducted with the aim of obtaining detailed feedback from clients who had engaged in research projects. Using a “storybook” approach, participants were asked the following nine questions and were encouraged to write responses on cards and discussion was facilitated to generate more ideas and elaborate on key points:

1. When engaging in research projects with UniSA, what in general were the areas in which problems were experienced?
2. When you commenced a research project did you experience any administration problems?
3. In relation to these administration problems, what should UniSA improve and how?
4. Does your organisation have any “best practice” administration principles that UniSA might adopt?
5. How can you as a client help UniSA to deliver products and services on time and according to specification?
6. What would your organisation like to be asked by UniSA staff at the conclusion of a project?
7. What should be the feedback mechanism(s) for your organisation to provide suggestions back to UniSA staff after a project is completed?
8. How many feedback mechanisms should there be?
9. Any other thoughts/experiences?

Free text responses from the storybook methodology included: financial monitoring takes a number of calls to sort out, incorrect invoicing; financial processes are not timely especially the production of invoices; lack of clarity about processes for payment in joint research projects; financial arrangements not specifically established. Responses to these questions identified that financial processes used to support research and consultancy projects needed urgent consideration.

Furthermore free text responses from the survey (e.g. financial monitoring takes a number of calls to sort out; incorrect invoices) had reinforced this aspect of service quality as one requiring immediate attention.

To address the area of financial processes, an internal review was conducted on the processes that support the financial management of projects. A number of interviews were conducted with senior administrative staff and active researchers. Findings from these interviews were documented and reviewed with the aim of identifying common issues and opportunities.
Based on the findings, it became evident that the processes relating to invoicing correctly and on time needed immediate action. To improve the existing and inadequate processes, it was agreed in consultation with relevant stakeholders that all financial monitoring and invoicing would be standardised using the PQS milestone facility to manage financial matters. This initiative was chosen as the PQS is able to automatically remind appropriate staff via email that financial action needs to be taken based on pre-entered project deliverable and financial schedules. To ensure that staff act upon the PQS financial milestone invoice emails, staff in the Research and Innovation Services Office develop regular ongoing reports from the PQS database to monitor financial milestone completion and, where necessary, take appropriate action to ensure scheduled milestones relating to financial matters are satisfied.

In an effort to better comprehend and track financial processes, the 2004 survey instrument was modified whereby the “administrative processes” attribute was removed and replaced by two questions: one focusing on “financial processes” and the other on “legal processes.” The results of the 2004 survey project show that the gap (importance v performance) is smaller than the gap for the previously included “administrative processes.” The journey is just beginning. Building on what has been learned, it is understood that these findings are not conclusive, nor ends in themselves, but rather an ongoing study of client feedback and processes that support research and consultancy project management. Whether future results reinforce what is already learned remains to be seen. In either case, (confirm or refute), the ongoing study of process efficiency, effectiveness and client satisfaction gives rise to opportunities for improvement.

The survey discussed in this paper is an ongoing cost-effective source of manager and decision maker friendly information that enables us to better understand the service perceptions and expectations of our clients. Competitive advantage or superior market positioning is thus achieved through this identification of client values and demands.
References


Creating a Multi-Use Building for a Research Center: A Management and Operations Case Study and Critique

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Abstract
From 2001 to 2005, the Moores Cancer Center at the University of California, San Diego sought to translate an approved design for a multi-use research and clinic building into a functioning reality. This case study explores the contribution of financial planning and organizational management theory to the major transition into a new building. It describes cultural challenges, decisions, and key policy development techniques along the way. This paper specifically addresses metrics for establishing debt structuring, creative electronic communication systems, and policy formation for space eligibility, staff performance, and building maintenance. We seek to highlight the value of research administration in a major building program and to address the paucity of literature on this subject.

Introduction
The University of California, San Diego (UCSD) enjoyed heady times in 2001. In May the National Cancer Institute (NCI) awarded the Moores Cancer Center its sixth Cancer Center Support Grant (CCSG) for five years of continued support at a substantial increase in funding. In July, for the first time in its 23-year history, the center was granted status as an NCI-designated comprehensive cancer center. The construction of a major building assigned to the
The cancer center was in the final stages of planning and approval. This study summarizes a series of decisions and events that had an impact on that building over the next four years.

The 2000 CCSG application included the University’s commitment to construct a large, multi-use building consolidating the cancer center’s research, patient care and outreach activities. The center at that time was dispersed over 20 locations on the UCSD campus and in neighboring leased facilities. Its ambulatory patient care was conducted at two sites 20 miles apart. The building promise was long in coming and its delay threatened the survival of the center. Plans called for a building of 270,000 sq. ft., with the first floor housing a state-of-the-art ambulatory oncology center and the upper floors containing wet and dry labs. A large conference center and administration suite were also part of the plan. The design featured a striking exterior of glass and limestone, with stainless steel tiles chemically treated to reflect sunlight in different hues throughout the day. It would be one of the largest buildings on the UCSD campus, exceeding the size of the university hospital and buildings in Health Sciences. The plans had been granted concept approval in 1999, and the estimated cost was $100 million.

**Financing the Building**

The building commitment was made with the understanding that the entire cost of the research space would be underwritten with private funding (the clinical space was to be financed with $20 million from Medical Center reserves). While this was a development goal of unprecedented scale at UCSD, the Cancer Center Board and leadership accepted the challenge and proceeded to raise $50 million, including a naming gift from benefactors Rebecca and John Moores. But by fall 2001, potential sources had become scarce, and $30 million stood between further delay and groundbreaking. Debt financing was, reluctantly, the only option. The timetable was critical, as the building was considered essential to future NCI CCSG support.

To finance new construction, the University of California may advance funds to a campus to be repaid through indirect cost reimbursement on competing federal grants. This form of construction support, known as Garamendi financing (named for former State Sen. John Garamendi, who introduced the legislation to create the debt instruments), has its benefits and drawbacks (University of California, San Diego, 2002). While it allows urgent construction to proceed, repayment is subtracted from the indirect cost reimbursement available to the entire UCSD campus, including Health Sciences. Thus, the budgets of all divisions and departments are calculated on the balance of funds after debt reduction payments. In employing debt financing, the cancer center was charged with computing myriad models to determine if the building could sustain an estimated annual repayment cost of approximately $3 million.

**Form and Function of the Building**

The building was conceived with the primary goal of shortening the time and distance between discovery and clinical application of advances in cancer prevention and treatment. Much thought went into creative venues for small- and large-group meetings to facilitate collaboration and research sharing. A 110-seat auditorium with pre-function space, a café, 15 conference rooms, 12 terraces and multiple outdoor seating areas for the comfort of patients and staff were among the design features. Because of its spacious design, usable space shrunk from 270,000 gross sq ft to approximately 150,000 assignable sq ft. The first floor, containing about 34,000 sq ft, would be dedicated to patient case study.
care. Cancer prevention and control would be conducted in about 23,000 total sq ft of dry labs and examination rooms distributed on floors two and three. Clinical trials offices would be allocated about 5,000 sq ft, and administration, approximately 8,000. A 13,000 sq ft vivarium occupied most of the basement. A five-story, 62,779 sq ft laboratory wing contained approximately 15,000 sq ft on each of its 4 upper floors; the clinic would occupy the first floor. Public use areas of approximately 7,000 sq ft completed the assignable space.

Modeling the Debt Service

Foremost in building financial models was determining where and how much debt was needed and what savings in construction could be achieved. One option was to build shell space in designated lab areas, perhaps as large as whole floors. Another option was to shell the conference center pending a naming gift. Yet another option was to limit additional parking spaces. The engineers and architects cautioned that renovating shell space at a later date was far more costly than building it out in the initial construction. This advice would be weighed carefully against the workable debt ceiling. Ultimately, it was decided to complete the building during construction because of the incremental costs of deferred renovation.

Financial modeling began in earnest in October 2001, and continued through April 2002, in anticipation of a request for debt approval at the UC Regents meeting that May. A senior member of the business office used Microsoft Excel to build spreadsheet programs employing complex macros and links to facilitate modeling. The macros included formulas for percent of overhead toward debt multiplied by the term of the mortgage times the principal, the annual prorated increase in grant dollars, and the calculation for escalating start-up costs. The models included multiple metrics, such as amount and length of the financing, percentage of revenues to be allocated to debt service, time to and amount of optimal sponsored funding, and other avenues of revenue, including the lease of one to two lab floors to non-cancer center tenants. The limits of financing applied alternative scenarios of 10 to 30 years and amounts from $33 million to $47 million. The higher debt ceiling was to cover the funding gap of sequential payment and testamentary contributions as well as the build-out of the entire building. The percentage of revenue applied to debt ranged from 80% to 90%, in accord with Garamendi-type financing. Ramp-up grant revenue projections generally followed a schedule of 25% annual increments leading to capacity funding in four years. Included in the grant revenue projections was the backfilling of occupied space vacated by investigators transferring to the new building.

The final model would forecast a debt of $44.3 million to be repaid over 10 years from the projected building completion in 2005, with a four-year ramp-up of recruitments, starting with 25% to 100% of projected revenue from applicable grants beginning July 2002. Indirect cost revenue to debt service would be at the 80% level. Rent revenue from two lab floors was proposed, but this decision was later modified to limit cancer center space to three, not two lab floors, and thus leasing to only one, for a period not to exceed five years. Thus, while the potential occupancy by cancer investigators was temporarily limited, the requirement to meet debt service obligations was reduced. With start-up package obligations for 17 new lab recruitments estimated at $12 million, or $3 million per year for the first four years, it was projected that expenses would exceed revenues until year five of occupancy. The
The proposal was approved by the UC Regents at their May 15, 2002 meeting. The building project was officially launched.

**Planning for Cultural and Organizational Change**

Along with new opportunities, the building presented the cancer center with many challenges. Significant among these were consolidating the separate cultures of the medical center and the medical school under one roof; territorial disputes arising from adjoining, partitionless labs of up to 12 investigators on a research floor; the new proximity and threat to productivity of contiguous administration and faculty offices, and the ongoing financial needs of a considerably larger and more costly enterprise.

In July 2002 the cancer center director unexpectedly announced his plans to retire, effective December 31, 2002. Ground-breaking took place on November 8, 2002, with anticipated construction completion in 25 months. An interim cancer center director would monitor the building construction until November 2003, when the current director, Dennis A. Carson, MD, assumed the post. Shortly thereafter a staff management group was formed to plot the logistics of the transition. This committee, the Managers’ Workgroup, had many functions, including: 1) Human Resources; 2) Facilities Coordination and Management; 3) Operating Policies; and 4) Financial Planning and Management.

The human resources (HR) representative would seek to unite the previously separate cultures and numerous sub-cultures, and build common HR practices among the occupants of the building. The HR representative set out to establish and implement measurable performance standards, tie performance standards to business objectives and operational efficiencies, identify reward and recognition mechanisms for various levels of performance, and tie these rewards and recognition systems to business results (US Office of Personnel Management, 2001). Techniques to facilitate the cultural assimilation process included cultural and needs assessments, cross-sectional work groups, employee orientation resources, focus groups, town hall-type forums, and the development of communication models to build and sustain participation and excitement.

The facilities representative focused on the timeframe and implementation sequence, space assignment issues, move logistics, and coordination of move-in services.

The operating policies representative worked to develop a cancer center building manual that would establish a set of shared operating principles for all areas of the facility and address central building services, including security, waste disposal, and parking.

Finally, the financial planning and management representative sought to identify the costs to meet, the financial targets for debt reduction, and financial strategies and projections for ensuring adequate revenues through a combination of grant award and patient revenue, philanthropy, and auxiliary services. Models for debt reduction, developed using Microsoft Excel spreadsheets, were based on varying dollars per square foot, different levels of occupancy until full building occupancy was achieved, and other variances, such as the fluctuating grant revenue of occupants once space was granted.

A cross-section of the cancer center population, including occupants from different locations, sub-cultures, and programs, was invited to participate in functional work groups. All participants were notified that active involvement would be required to...
achieve established objectives. The functional work groups met weekly; the Managers’ Workgroup met monthly initially and bi-monthly thereafter. Sharing among the groups was essential to the planning process, as many areas that appeared separate were actually connected, either operationally or logistically. To keep leadership and other functional work groups apprised of initiatives and objectives, timelines, and progress, reports were developed for each area of the Managers’ Workgroup. Cancer center administrative consultants from institutions throughout the nation who had engaged in similar large-scale construction programs and transitions to multi-use buildings were invited to share their experiences with the Managers’ Workgroup. Consultant review of progress reports, building specifications, and agenda topics provided valuable information that would aid in the planning process.

**Communication as the Key to Change**

Communication was instrumental to the success of this endeavor, particularly in creating and sustaining excitement for and “ownership” of an entity both unknown to and larger than most cancer center employees were accustomed to. Consequently, one of the first actions was to add a transitions page to the cancer center’s website at http://cancer.ucsd.edu. This page was designed by various Managers’ Workgroup participants, built by the IT Director, and managed by the Member Relations Analyst. It was populated with photos of the evolving construction site, including a continuous real-time videocast, information on the project and proposed guidelines for operations, and a forum for suggestions and questions. To keep the UCSD community advised of progress and policies for occupancy, the site also included a new Space Management Policy and Application Form, floor plans of the facility to aid navigation and help occupants familiarize themselves with their new home, and a variety of occupant-related general information resources. Communication among a physically dispersed faculty, formerly transmitted via paper, e-mail and phone, now traveled the information highway of the cancer center’s Intranet, ONClINE. Proven effective approaches to improve communication, as established by Goodman, Cabral, Nemcek, and Powers (1996), included: (1) minimizing the impact of geographic separation on administrative services; (2) connecting personnel electronically; (3) developing compatible computer systems; (4) sharing common information, and (5) planning collectively.

To enhance cross-communication and help ensure the success of clinical operations, the Managers’ Workgroup, which included a representative from both the medical school Dean’s office and the Medical Center, actively participated in the transition planning meetings with a parallel medical center group comprised of specialists in various service and activity areas.

Flexibility and focus were invaluable to the success of this venture. Due to transitioning workforce members, fluctuating demands and unanticipated challenges, priorities evolved and efforts were refocused on addressing emerging issues and resolving unexpected problems. While planning oversight was under the auspices of the Associate Director for Administration in collaboration with the Director, the day-to-day planning and actualization of the transition were carried out by cancer center staff members through a combination of overtime, work reassignment and adjusted priorities. As no external consultants or additional personnel were hired to oversee the project and its many details, this responsibility was assumed by the HR Manager and the facilities representative, who became integral to the process.
As the construction project evolved and the transition planning and timeline progressed, issues required continuous attention: construction change orders; space usage, assignment, and occupants; security system and food service vendors; furniture selections and configurations for public, shared and office spaces; interior and exterior signage; parking for patients, visitors, staff, and faculty; operational details including telecommunications, copier and mail services, shipping and receiving; facilities maintenance; housekeeping; safety and fire code compliance; meeting room and public venues management, and publicity and events. Consequently, it was sometimes necessary to postpone planned initiatives to address issues requiring immediate attention.

Because space assignment was a Cancer Center senior leadership function, a Space Advisory Committee (SAC) was appointed by the Director in December 2003, with representation from members of the Manager’s Workgroup (including the chair).

The Managers’ Workgroup performed exceptionally. Despite changing priorities and challenges, workgroup participants not only made significant progress and contributions to their early objectives and initiatives, but also resolved a plethora of issues that would otherwise have been addressed by external consultants. This group also effectively navigated the university systems, working closely with such key offices as the Health Sciences Dean’s Office, Facilities Design and Construction, and Real Estate Development. While benefiting from “in house” knowledge and expertise, the project management approach involved higher risk, as responsibility rested with a few key employees. For example, had the HR Manager or the facilities representative been unable to continue in their roles, the transition would have been compromised. Any institution preparing for such a large-scale project should assess the availability, benefits and drawbacks of internal and external resources.

More difficult than other objectives was the task of merging the medical school and medical center cultures. Turf disputes, policies and priorities regularly interfered with movement toward a unified cancer center organization. Programmed organizational and individual change management was considered key to the overall effort to transform the cancer center from a widely dispersed setting to a physical site with integrated, coordinated systems for translational research and optimal patient care. The Deputy Director for Clinical Oncology/Medical Director successfully forged new working relationships.

By mid-2004, the work of the Managers’ Workgroup was turning increasingly to plans for occupancy. With new leadership, the vision for the building was changing. A former focus on the biological aspects of cancer was modified to allow for a greater emphasis on the chemistry and pharmacology surrounding experimental therapeutics. UCSD and San Diego are well-recognized sites of groundbreaking biotechnology, and the building is a natural setting to bring these strengths to bear on curing cancer. At a cost of $483,000, a number of lab bays were retrofitted to triple the number of chemical hoods. Priority recruitments targeted accomplished and promising lab scientists in drug discovery and design, while also seeking clinicians committed to advancing cancer treatment via investigator-initiated trials emanating from a cancer center lab and ending in the clinic.

**Space Metrics and Management**

By mid-2004 construction was proceeding as planned and tours of the building were regularly scheduled with prospective occupants.
The SAC had approved a research space application form and accompanying metrics by which to evaluate requests for space. Requests were submitted electronically and adjudicated at committee meetings. Because of the number of investigators seeking to move, and the limited amount of space committed to recruitment, not all requests could be filled. In approving requests for research space, the SAC employed the following criteria: the ratio of grant funding to square footage would follow the school policy; each bay of space would be accompanied by one office; no one would have two offices, and single-office occupancy required full-time service in the cancer center; core facilities would be allocated space equal to that used for their current operations. Consideration was also given to the cancer relevance of the applicant’s research, the applicant’s scientific productivity, and the potential for interdisciplinary collaboration within the cancer center. Clinic space was not originally allocated by the SAC; this activity is evolving. The clinic includes 24 exam rooms, an infusion center of 30 chairs and 10 beds, a hematology lab, research and patient pharmacy, patient and family resource room, two radiation chambers and CT simulator, mammography center, and MRI imaging.

After initial space assignments were completed and the cancer center assumed occupancy of the building on March 14, 2005 (approximately three months behind schedule), it was time to execute the move logistics sequence. The furniture was received and installed in phases based on the timelines established to move in the various occupant groups. Simultaneously, the security system was being installed, the telecommunications group was activating and expanding services, housekeeping was preparing the building, and electrical and plumbing contractors were adding and modifying outlets and fixtures to accommodate special research equipment needs. Many factors determined the order of occupant moves: location and lease status of occupants prior to move-in; location within the new building to avoid congestion with service elevators; ongoing work in certain areas of the building caused by construction change orders; the urgency of some groups to relocate; in-progress research experiments and grant application deadlines to minimize disruption; availability of specialists to move highly sensitive equipment requiring recertification and calibration, and readiness of on-site services and resources. Confirmation of each scheduled move was sent to groups providing services to the building, such as mail and copier services and telecommunications. In addition, a relocation handbook was issued to occupant groups approximately two weeks prior to their scheduled moves. The handbook, which streamlined communication of critical information, addressed move responsibilities and expectations, moving supplies, environmental health and lab safety, lab equipment, common areas and shared equipment, the building address, mail and ship-to codes, security, phone and data line information, and directions on how to move computers. In addition, representatives from the contracted move company met with each group approximately one to two weeks prior to the scheduled relocations. A process to address after-occupancy change orders was developed and implemented.

The building was dedicated on April 8, 2005. Despite the intense planning and anticipation that the Administration would be first to relocate and facilitate subsequent moves, a newly recruited investigator and his research team were the first occupants. The Administration assumed occupancy in mid-April. The clinic opened on July 9. Research moves were sequenced over four months, from May through August, and all were relatively
problem free. Aside from research space reserved for designated recruits, the building was at research and patient care capacity less than a year after completion. The fifth lab floor, originally assigned elsewhere, has been returned to the cancer center. Over 800 employees are now working in the building.

During and after the phased-in moves, planning continued to address a barrage of operational issues. An ad-hoc committee of occupants from all areas was devised to discuss building-related issues and identify solutions to shared problems. Additionally, a Service Excellence Committee, formed approximately one year prior to the move, continues to meet to focus on performance and service excellence and cultural assimilation.

A Patient Advisory Council (PAC) has been created to advise the cancer center leadership on patient and family perspectives, with the goal of becoming a top tier cancer center. The PAC is comprised of patients both on and off active treatment, family caregivers, and UCSD faculty and staff. To date, the PAC’s contributions to the cancer center feature recommendations on how to improve and humanize the cancer experience and ways to maximize excellence, including a Medal of Excellence award to recognize employees who help patients in a special way. The SAC continues to meet regularly to fulfill its review and space management responsibilities.

Lessons Learned
The decision to build out the entire building reduced add-on and retrofitting costs. Sustained, intensive planning, punctuated by flexibility and strong decision-making, were paramount. With an eye toward rapid completion and close monitoring, the building was brought in very close to target: a $105 million cost and a 28-month construction time. The move was relatively smooth, due primarily to the significant efforts devoted to planning. The building was intended to reduce the dispersion of research and clinical activity. While large in scale, however, its space assignable to growth was reduced because over 50% was committed to current operations, not new activities. The building is now fully occupied or obligated. The research occupants are already experiencing limitations on growth. Continuing communication was particularly valuable, and the web provided easy access without imposing on staff time. Time to consolidate information and develop transition resources was well invested. Re-engineering cultures and performance requires a longer horizon. In less than a year of operation, the building is clearly fulfilling a dream and fostering interactions unimaginable a very short time ago.

References


Case Study

Changing the Culture of Research Administrators at a Public University

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Authors Note
The impetus for this article was a January 12, 2004 Center for Positive Organizational Scholarship, Positive Link Session presented by Marvin Parnes, Associate Vice President for Research and Executive Director, Division of Research Development and Administration, Office of the Vice President for Research at the University of Michigan. This can be viewed at http://www.bus.umich.edu/Positive/POS-Research/pastpositivesessions.htm.

Abstract
The University of Michigan, along with most other major research universities in the country, has experienced a number of significant changes over the last decade. These changes, which include dramatic growth in research volume, advancements in technology, and increased regulatory and compliance requirements, have had a profound impact on the administration of the research enterprise. To respond to both internal and external changes, a group of senior leaders at the University stimulated the development of integrated programs to expand research administration education and training; foster professional identity among research administrators; and nurture a sense of belonging within the research community. This paper outlines the steps taken to change and sustain the research administration culture. Interlocking activities have been put into place based on the fundamental principles of how people learn (Beckhard & Pritchard, 1992) and the process of creating change (Kotter, 1995). These efforts have created a new culture of research administrators which emphasizes education, recognition, and collaboration.
Case Study

Introduction
The University of Michigan has a fairly decentralized operating environment for research administration. At the department level, over 800 staff are involved in the day-to-day administration of research. According to Jim Randolph, the Senior Associate Director of the Division for Research Development and Administration (DRDA), the University’s philosophy for research administration is “to surround the principal investigators with well-trained department level administrators who manage the administrative details and allow the investigator to focus on the science.” The central offices of the Office of the Vice President for Research (OVPR), Division for Research Development and Administration (DRDA), and Financial Operations Sponsored Programs Office (SPO) are the focal points for sponsored research administration.

Where vision, strategy, and other tactics can set an organization on the right path, senior leaders in OVPR, DRDA, SPO, and several departments across campus realized that to succeed over time, the research culture needed to change and become both positive and vibrant. The goal was to get research administrators, who had an uncertain status as a group, to believe they have the ability to respond to the changing environment by thinking and acting collaboratively (Lessons in Leadership, June 2006).

Inside an organization, functional units often develop their own unique cultures. This was the case at the University where culture clashes often occurred between the central sponsored projects office, departmental research offices, financial operations sponsored projects office, human resources, payroll, accounts payable, contract administration, and purchasing. Each different unit had developed its own perspective, set of values, and culture. Difficulties arose in coordinating and integrating the processes and organizational activities of research administration.

The newly envisioned research administration culture encompassed individuals working with any aspect of research administration within the multiple departments across campus. The characteristics of the culture included 1) minimal management levels, 2) informality and self-management, 3) employee ownership, 4) work teams, 5) participation, and 6) job rotation. Instead of hierarchical rules and procedures, what makes the research administration culture unique is teamwork, employee involvement programs, University commitment to employees, semiautonomous work teams, rewards on the basis of team (not individual) accomplishments, processes that encourage workers to voice suggestions, and an empowering environment for employees. Research administration leaders are viewed as mentors, team builders, and facilitators. (Cameron & Quinn, 2006).

Catalyst for Change

1) Dramatic Growth in Research Volume
The University of Michigan’s research expenditures have more than doubled from $386 million in 1994 to $778 million in 2005. The increased research volume led to doubling of departmental level research administration staff.

2) Technological Changes
The University has seen significant changes in the use of technology and software and the need for data security in managing research and other institutional administrative functions. The Internet, a multi-tier remote computing application database (PeopleSoft), and electronic grant submissions all have affected day-to-day research management. These changes have necessitated the distribution of
many central research administration functions to the department level. Decentralization has created a significant need for training and communication among department level administrators, as well as with financial coordinators and IT administrators.

3) **Regulatory and Compliance Environment**
From OMB Circular A-21 to human subjects policies, export controls, and the effects of the Sarbanes-Oxley Act, the sponsored research regulation environment has changed dramatically over the last decade. The government’s improved ability to track compliance (enhanced by its own use of improved technology) and the addition of new regulatory/compliance requirements has greatly impacted research administration. Research administrators at all levels need to be more educated about a wider variety of regulations and perform as educators and enforcers of those requirements closer to where the research is being conducted. Regulation and compliance are complex areas and lack of compliance comes with some potentially costly consequences.

**Methods**

*The University of Michigan’s Response*
A group of about ten senior leaders from across campus recognized the impact the changes would make on the University and decided to be proactive instead of reactive. They embarked on an integrated strategy to improve the research administration culture at the University of Michigan. This strategy was comprised of four components: 1) determining educational needs and creating training programs; 2) building a sense of community among research administrators; 3) creating cross-functional problem solving teams to encourage a collaborative environment; and 4) developing programs to recognize and reward individual and group research leadership.

![Figure 1. Model for changing a culture of research administration.](image)

1) **Education and Training**
A guiding coalition from central and department level administration was formed in 1997 to build a new culture around research administration. One of their earlier findings was that the University needed a comprehensive training program for research administrators. Since this was a culture change, research administrators were chosen to be the ones to develop their own programs and be the experts. The research administrators determined the curriculum and designed and developed the program. Senior leadership realized there would be a trade off between the time it would take the group to develop the programs versus the quality and sustainability of the training program. Experts could have been brought in from the outside and training could have been done in a few months. Instead, the decision was made to take time to build a sense of ownership and participation and address the areas of concern for the research community.

After two years refining the curriculum, a process which involved more than 100 colleagues, the Research Administrators Instructional Network (RAIN) was piloted. Nine years later, RAIN training continues to be offered three times a year. Participants are required to make a four week commitment – a full day of training each week. While
nearly 75 applications are received for each session, only 24 research administrators are selected for attendance. Since its inception in 1999, more than 500 research administrators have completed the RAIN program. It is increasingly common for research administration job postings at the University to list RAIN training as a desired qualification.

During the four day program, up to thirty central and departmental administrators present topics. In addition to the benefits of the comprehensive agenda, a sense of community and collaboration is encouraged by scheduled group lunches with the presenters and others in central administration. The current RAIN program agenda follows.

### Table 1. Sample RAIN Training Program Agenda

**DAY ONE**

*Introduction*

The Research Administration Environment

*Ethics and Compliance*

Openness in research; conflict of interest; human subject protection; laboratory animal care; occupational safety and health; non compliance and misconduct

*Lunch with Presenters*

*Electronic Research Information Resources*

Electronic RA; Central (DRDA) assistance; UM Research Information Website

*Role of the RA*

Clarifying your responsibility; Funding

**DAY TWO**

*Proposals for Sponsored Activities*

Intro to proposal development; proposal writing; pre-proposals; starting the proposal; subcontracts, purchase orders, consultants; costs; cost sharing

*Lunch with Project Representatives*

*Proposals for Sponsored Activities (continued)*

Internal proposal processing; Central (DRDA) responsibilities; budgets and justifications; pulling it all together

**DAY THREE**

*Initiation and Administration of Projects Award processing*

File organization and department databases; hardship accounts; award types; subprojects; cost-sharing

*Lunch with Account Representatives*

*Initiation and Administration of Projects Award processing (continued)*

Reconciling, encumbering, projecting, and reporting; post award changes; project close out; final reports

**DAY FOUR**

*Human Resources Management*

Appointment options; case studies; web resources; International employment issues

*Game*

HR Jeopardy

*Lunch and DRDA tour*

*Research Related Agreements, Intellectual Property and Confidentiality*

Regulatory compliance; public relations; lobbying; wrap up
In 2001 DRDA allocated funds to create a dedicated staff position to manage education and training programs. This training staff member identifies ongoing training needs, oversees the development of new programs, and coordinates program delivery for the research administration community. The existence of this position has been instrumental in creating an open environment for the flow of ideas and in implementing programs in direct response to both central and departmental administrator’s concerns.

DRDA and SPO have also collaborated to create additional training programs for new and experienced research administrators. Currently, fifteen programs, nine of which are listed below, are offered regularly. Enrollment in these programs has totaled over 2,500.

Table 2. Training Program Titles

<table>
<thead>
<tr>
<th>Research Proposal Writing Workshop</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry Sponsored Research: Working with DRDA</td>
</tr>
<tr>
<td>Grants.gov: Electronic Submission of Federal Grant Application</td>
</tr>
<tr>
<td>Introduction to Sponsored Projects Administration</td>
</tr>
<tr>
<td>Financial Administration of Federally Sponsored Projects</td>
</tr>
<tr>
<td>A-21 Expenditure Monitoring of Federally Sponsored Projects</td>
</tr>
<tr>
<td>Cost Accounting Standards Training</td>
</tr>
<tr>
<td>Post Award Administration of NIH NRSA Training Grants</td>
</tr>
<tr>
<td>Introduction to Budgets: Developing Grant Proposal Budgets</td>
</tr>
</tbody>
</table>

2) **Creating a Sense of Community**

The University of Michigan established the Research Administrators Network (RAN) in 2001. The Network is meant to provide continuing education in the area of research administration and enable departmental administrators to interact with each other and leaders in central administration. A planning committee, made up of mostly departmental administrators, sets the agendas for the quarterly meetings. Any research administrator is welcome to recommend or suggest new directions or agenda items for future RAN meetings. The meetings include an educational topic, as well as updates critical to the University research community. RAN meetings have an average attendance of 250. The meetings have become an effective and enjoyable tool for sustaining the research administration culture at the University.

As the new research culture grew stronger, employees made suggestions to improve their work and the work of other research administrators. Senior leaders empowered the research administrators by designating staff time to implement their ideas. Examples of suggestions from research administrators included creating a web-based research administrators’ ‘Toolkit’ to assist research administrators to quickly locate information related to their jobs (http://www.research.umich.edu/ralinks/index.html) and developing a website, RAN Online, to provide a place where research administrators can share documents, templates and ideas that may be of use to their colleagues.

The Toolkit has proven to be a success and is updated on a regular basis. RAN Online has not proved to be as useful. However,
succeed or fail, the response of development and implementation provided empowerment. Sharing information and problem solving online is not yet comfortable for many research administrators.

The *Toolkit* synthesizes information from the University’s main Research website (see Table 3 below) with useful links and information relevant to research administrator’s day-to-day work.

### Table 3. Toolkit Headings: Links for Research Administrators

<table>
<thead>
<tr>
<th>A-Z index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative Offices</td>
</tr>
<tr>
<td>Sponsored Projects Advisory Team</td>
</tr>
<tr>
<td>Forms</td>
</tr>
<tr>
<td>Funding/Sponsor Pages</td>
</tr>
<tr>
<td>Sponsored Project Award Database</td>
</tr>
<tr>
<td>Project Administration</td>
</tr>
<tr>
<td>Reference Materials</td>
</tr>
<tr>
<td>News</td>
</tr>
<tr>
<td>Research Administration Professional Development</td>
</tr>
</tbody>
</table>

#### 3) Cross Departmental Collaboration and Problem Solving

In October 2001, a Sponsored Programs Implementation Team (SPIT) was commissioned for two years to improve the administration of sponsored projects at the University. Specifically, SPIT was charged to validate a list of issues and priorities, to complete a situation analysis, and to deliver solutions. Many of these issues related to making central administration more responsive to the needs of departmental administrators. Others focused on maximizing the value of the new financial system (PeopleSoft). SPIT was a cross-functional representation of research administrators from the University of Michigan’s central and departmental level administration.

The SPIT model has created new leadership opportunities for departmental research administrators. After SPIT’s commission ended, a “Sponsored Projects Advisory Team” (SPA Team) was formed (http://www.spateam.umich.edu). The SPA Team’s basic purpose is to: discuss new issues and facilitate solutions, address specific problems as they arise, continue to clarify the roles and responsibilities of central and academic units, manage communications about research administration, and evaluate solutions and subsequent policy and procedure changes.

These types of team efforts have set the standard for collaboration between departmental research administrators and staff in central offices. The communication and, in some instances, cultural clashes which once hindered problem solving are being overcome with the use of the SPIT model. The existence of this committee has given staff in all departments across campus the sense of collective support and responsibility.
4) Recognition Programs
As part of the cultural change, the Office of the Vice President for Research (OVPR) established the annual *Distinguished Research Administrator* and OVPR *Exceptional Service Awards*. Nominations are requested campus-wide. The *Distinguished Research Administrator Award* honors individual staff members from any department at the University who have demonstrated distinguished service exemplifying the goals of professional research administration over a number of years. The OVPR *Exceptional Service Award* honors individuals from OVPR or the many units which report to OVPR, who have made outstanding contributions going beyond the ordinary fulfillment of the position’s job expectations. In addition to receiving an honorarium and an award plaque, these research administrators are recognized in front of their peers in an awards ceremony a RAN meeting.

**Results**
The success of the changing culture of research administrators has also impacted other units on the University of Michigan campus. The following are a few examples.

In June 2005, the University of Michigan’s Human Resources and Affirmative Action department changed the University-wide career family classification system to assist and enable departments to attract and retain competent and committed staff. ‘Research’ was added as an independent career family, which can be defined as a meaningful grouping of jobs commonly clustered within a career emphasis (http://careernavigator.umjobs.org).

A second effort was Financial Operations Sponsored Programs Office’s reorganization from a production line approach to a team approach, aligning with the departments. In part, this reorganization was in response to issues identified by the SPIT / SPA teams. The reorganization effort provided a service-oriented responsiveness to the operation, as well as bringing significant financial benefits to the institution, through improved tracking, invoicing, collection, reconciliation, and reporting. New staff initiatives included building teams aligned with institutional units, identifying training needs and how to deliver them, encouraging staff to get involved in professional organizations and in institutional activities, and job rotations.

A third example is the impact of the research administration culture on another newly forming campus-wide effort called Business Intelligence (BI) at the University of Michigan. The BI group is concerned with transforming enterprise data into information, and information into knowledge to enhance decision-making and to create actionable plans that drive effective business activity. Similar to the research administrators, Business Intelligence (BI) consists of a multidisciplinary group of individuals from numerous departments across campus. (http://www.businessintelligence.umich.edu). The BI culture model is based on the successful sustainable research administration model.

**Conclusions**
The University of Michigan has created a recognizable research administration culture, which is being used as a model for other internal functional groups. Research Administrators Instructional Network (RAIN) education is effective in building skills and knowledge. Research Administrative Network (RAN) meetings have provided a gathering place and training for the research community. The emphasis on networking has
created an environment where research administrators, holding many different job titles, are comfortable communicating with their peers to share information and to problem solve. The cross-functional problem solving teams (SPIT & SPA) have had a dramatic impact, not only by creating and implementing solutions to issues affecting administrators, but also by serving as a model for the process of crossing boundaries to solve problems. The Office of the Vice President for Research (OVPR) awards have brought University-wide recognition to the many contributions of research administrators.

The University of Michigan continues to refine its vision thus enhancing the culture of professional research administrators. New approaches are being developed for future success. Educational programs are created on an on-going basis. A new leadership development program is being designed collaboratively to prepare the next generation of research administration leaders. The Sponsored Programs Advisory Team has transitioned to new leadership and membership. New sub-teams are being formed to address specific complex issues. There is positive energy in the research community, making collaborative progress sustainable.

The strategy for building a research culture has transformed research administration. It is a model which could bring success to other colleges and universities that are responding to similar internal and external changes.

References


Abstract
Flexible Leadership: Creating Value by Balancing Multiple Challenges and Choices is the kind of book that individuals from all sectors can easily read, appreciate, and incorporate into their work lives. Co-authored by Dr. Gary Yukl and Richard Lepsinger, this book assumes both an academic and pragmatic approach to leadership. Written during a time that will be remembered for its emphasis on fiscal restraint, changing private and public sector rules, regulations and policies, its premise is that good leaders are expert at scanning their environment and knowing when to make adjustments. These individuals employ techniques that are not instilled but learned and allow them to know when they should lead or manage. They know how to build relationships that yield mutually positive results by nurturing leadership competencies at all levels within and outside their particular organizations. These leaders are found not only within the ranks of private business but also university administrators, researchers, and government policymakers, and are pivotal to ensuring the success of any enterprise.

University administrators know that each participant in the research cycle has a pivotal role to play in the success or failure of a project. I know this too. As a Program Officer who dispensed funds, a Research Coordinator who spent funds, and now a mediator between the two as Associate Director of an Office of Research Services, I am aware that each person has a unique opportunity to diminish or enhance cutting edge research. I also know that questionable leadership exhibited by any of these players can be as damaging to a project as questionable science.

Yukl and Lepsinger (2004) make this point clear in their book, *Flexible Leadership: Creating Value by Balancing Multiple Challenges and Choices*. They suggest that leaders from all levels are pivotal to individual and organizational performance. As part of a complex system of interactions occurring over time, they must balance competing demands while assessing the impact that each decision has on those individuals with whom they interact. Rather than seeing themselves as arbitrators of rules and regulations, Yukl and Lepsinger believe that excellent leaders know when to follow, collaborate, alter course, or concede.

They discuss their views by organizing their book into three major sections, each relating to their model of flexible leadership. Comprised of a total of 12 chapters, this book begins with *The Nature of Effective Leadership*. As an introduction, this chapter describes various types of
leaders and the myths associated with each. It lays the foundation for the remainder of the text by providing a brief overview of their model including a diagram consisting of four concentric circles radiating from a small inner core.

This inner circle, organizational effectiveness, is surrounded by another that is divided into three pieces, application and innovation, efficiency and reliability, and human resources and relations. The third circle is sliced into six and each relates to a particular leadership behavior or system that impacts on an organization. The outer ring entitled situational factors, is not subdivided and is placed there to signify the importance the authors attribute to the role that context or environment plays on any organization.

The ensuing 10 chapters are divided into four sections. The first section relates to the circles depicted in their model. These circles represent challenges associated with improving organizational efficiency and the types of leadership behaviors and management systems that can negatively or positively affect this efficiency. Section II is focused on the importance of assessing the external environment then making adjustments to invoke changes so as to maximize benefits or minimize challenges imposed by the environment within which the business exists. There is an emphasis on how effective organizations should seek to employ flexible leaders who absorb information from the environment, assess the impact then utilize existing systems and programs to facilitate the necessary adaptations. Section III focuses on human resources and relationships with an emphasis on how flexible leaders can support, recognize, empower, and build teams that interact positively to changing conditions so as to ensure the success of their enterprise.

The final section, Finding the Right Balance, looks at tradeoffs that must be made as the adapting process ebbs and flows in reaction to change. Chapter 12 provides the reader with guidelines and five competencies that should be considered when learning to be a flexible leader and ends with concluding remarks about flexible leaders who know what to do, when to do it and how it should be done. These guidelines include: building a commitment to a core ideology; building capable leadership and involving and empowering people at all levels; maintaining open lines of communication; employing a variety of reward systems that support several objectives; and supporting excellent leadership by example.

What makes this book of interest to many types of administrators is its assertion that leaders are not born but rather they can be taught. Most leaders must learn how to coordinate organizational systems and programs when changes are imposed upon them and how to apply their flexible leadership skills for problem solving. These individuals know how to involve appropriate participants from all levels from within and outside an organization who have an impact on each other and to focus their attention on the greater good of the organization as opposed to their own individual area of responsibility.

Yukl, a professor at the State University of New York at Albany, and Lepsinger, president of a consulting firm specializing in strategic management for business, have been active in the field of leadership since 1970 and are cognizant of the theories, techniques, and tools needed to ensure flexible leadership is effectively implemented. Richard Lepsinger has had experience in working with businesses to create and implement strategic plans and is a proponent of the 360° feedback method. Gary Yukl has written or
co-authored several books and articles on leadership and is the recipient of numerous awards for his work.

These authors employ a pragmatic approach to leadership in this book. Easy to read, it addresses issues in a manner that encourages aspiring leaders to appreciate the complex world of leadership while encouraging them to implement seemingly simple but effective approaches to problem solving. Their ideas can be used in a variety of settings and although most examples relate to the private sector, individuals working in the non profit, health and educational sectors can easily adapt these concepts to their institutions. For example, the authors talk about envisioning change, facilitating collective learning, monitoring the environment, and undertaking strategic planning. None of these tasks is exclusive to organizations in the business world and can be applied to almost any organization that strives to succeed.

What makes this book of particular interest to research administrators is the concept that leaders are not managers whose main goal is to ensure compliance with rules and regulations, but instead they strive to find solutions that will benefit individuals, teams and organizations. Excellent communicators, they gain the commitment of all members of a group. They know that their actions, based on Yukl and Lepsinger’s five competencies, in conjunction with a keen sense of situational awareness, are crucial to ensuring a positive outcome. They also know that they do not work in a vacuum and that developing the leadership capability of their colleagues, at all levels in their organizations, is equally as important as developing their own.

All stakeholders in the research administration field including university administrators, funding agents, researchers and collaborators, need to realize that they are all leaders involved in an enterprise ensconced within a sometimes unstable environment. Yukl and Lepsinger suggest that all players need to continually envision their success as they maneuver their way through the myriad of government regulations, systems and bureaucracies. Building their own leadership skills by assuming a variety of roles such as facilitator, follower or mentor, elevates university administrators to the position of leader, not manager. The authors’ guidelines for team building and managing systems and programs within organizations are noted in Chapters 9 and 10 and are of particular interest to individuals involved in all phases of the research enterprise.

Knowing when to manage, lead, or concede, is an important aspect of a research administrator’s skill set as we balance rules and regulations, assess risk, run interference, problem solve, and act as a source of information and support. Yukl and Lepsinger would suggest that all participants involved in research from university presidents to research assistants, are in an excellent position to assess the human, financial, social and cultural impact of their decisions and make decisions based on the greater good of the enterprise. They all should be taught the difference between leading and managing and, with the support of their superiors and subordinates, act accordingly.

For example, good leaders know when a management approach is needed. This is especially true in cases when adherence to ethical and safety guidelines is expected because high-risk research projects are involved. In the same instance, however, a leader is able to balance due diligence with the goals of the research project to ensure a positive outcome for participants, researchers, funding agencies, government regulators...
and the university. It is this balancing act that separates managers from leaders and elevates university administrators to the status of professionals. This status is enhanced by the acquisition of leadership competencies that include having situational and personal awareness, a systems approach to problem solving, a focus on what is really important, and personal integrity.

Yukl and Lepsinger provide an excellent overview of these competencies and illustrate them with business examples such as Southwest Airlines, an American company that has taken a lead in employee and customer satisfaction. By listening to employees, encouraging innovation and instituting changes based on their input, the company has been able to instill a culture of leadership where employees are encouraged to assume a variety of roles in their work day. Southwest is also mentioned as being an exemplary organization that scans the external environment then making “tactical changes without losing sight of the core competencies or disrupting its image.”

Much the same can be said about research offices in universities. Yukl and Lepsinger would probably agree that the image of leaders in the administrative field would not be tarnished if they assumed a flexible approach to coordination of research projects. Instead they would be lauded for their innovation and ability to foster a climate of trust and cooperation.
Abstract

*Responsible Research: A Guide for Coordinators* details the responsibilities included in performing clinical research. It is a valuable reference and resource for research administrators and managers with oversight of clinical research operations, especially for those unfamiliar with day-to-day routines and nuances of clinical research coordinators’ responsibilities. The book can serve as a required text educating new clinical research coordinators having clinical or regulatory research responsibilities. Lastly, for seasoned coordinators, it is a perfect reference guide to aspects of clinical research and helpful tool for clinical research certification preparation and review.

**Chapters 1 and 2: The Evolving Role of the Clinical Research Coordinator; Guiding Principles and Regulations**

The authors present historical information regarding the identity of clinical research coordinators (CRC) and background of their emerging role in these respective chapters. These chapters provide research personnel with a framework describing a CRC’s main responsibilities, activities, education, training, certifications and average compensation. They also show the impact of CRC training and certification on potential earning abilities. These chapters also provide a real world understanding of the difficulties facing the CRC and clinical research sites such as workload and turnover.

Also included in this area are contrasts and comparisons of regulatory authorities, i.e., the US Food and Drug Administration (FDA) and Code of Federal Regulations, and the European Union (EU) and Japan International Conference on Harmonization (ICH). Summations of the responsibilities and oversight of these regulatory bodies are given. A detailed reference list regarding these regulations and guidelines are provided. A brief discussion of the CRC’s responsibilities and how they relate to these guidelines is also available.
Chapters 3, 4, 5 and 6: Ethics and Human Subjects Protection; Responsible Conduct of Research; The Informed Consent Process; Pediatric Informed Consent and Assent

Chapters 3 through 6 focuses on the human subject providing historical information e.g., how the regulations and guidelines were established. These chapters also discuss components of ethical research and related responsibilities of the CRC providing examples for the research professional.

Seven areas of responsible research - conflicts of interest, mentoring, authorship and publication, data management, ethics and morality, research misconduct, and human subject protection - are discussed. These topics are reviewed in detail providing identifiable points for CRCs during their conduct of research.

As a CRC, the most important roles of the position is to ensure that research participants make a knowledgeable and educated decision to participate in the study that is being explained. Chapter 5 includes information regarding documentation and confirmation of understanding by subjects ensuring all parties are appropriately informed before the commencement of the clinical research study. The required elements of a consent document are listed, as well as the regulations describing each of these essential elements.

Pediatric research poses additional difficulties as the authors explain. Assuring the parent is educated and knowledgeable regarding pediatric clinical trials may be a difficult task. However, the CRC’s arduous task is to ensure that pediatric patients understands and agrees with their participation in the clinical research being presented to the best of their ability or cognitive level. Tables illustrate tips for child friendly language, questions to consider when preparing an assent and guidelines on how to handle compensation to the pediatric patient. Information in these chapters is clear, concise and can be practical tools.

Chapters 7, 8, 9, 10, and 11: Study Implementation and Start-up; Recruitment and Retention of Research Subjects; Documentation; Assuring Quality in Clinical Trials: Monitoring, Audits; and Inspections, Communication

Chapters 7 through 11 address practical aspects of conducting clinical research. Study designs and phases of clinical trials are provided for background to assist in the protocol evaluation. These guidelines help the CRC and other research personnel to understand the feasibility, practical and financial implications of the study. The authors provide a table listing many documents usually submitted to the Institutional Review Board (IRB) to prepare for opening a research study. Although many of these documents require IRB review and approval, some may need to be reviewed by other departments within the organization. Note: This reviewer recommends that your institution’s IRB policies and SOP’s be reviewed and adhered to when completing the documents necessary for IRB review. The tables provided are functional and practical in organizing a CRC for initial study implementation. They also assist a CRC in determining aspects and departments that should be included and trained along with the CRC for initiation of a clinical research study.

Chapter 8 describes issues that surround recruitment and provides options to assist in this area. It also explains the consequences of not meeting the contracted goals. Subject recruitment is discussed in terms of how it is affected by the study contract. The authors provide insight into how the multidisciplinary approach within an organization can
assist to ensure awareness and further participation. Tables that include questions and alternatives ways to recruit are included. The authors also provide information supporting advertising guidelines as well as discussing advantages and potential disadvantages of advertising and marketing the institution or research site. The necessary components to recruitment including screening, protected health information, informed consent, and randomization and blinding are neatly outlined. The detail provided is a practical guide to the mechanisms required to meet the obstacles that may prohibit meeting the goals of clinical research.

Chapter 9 provides an overview of documentation that is essential to the conduct of clinical research as well as associated definitions. This information is a realistic guide to all required documents indicating how best to set up files within the department of clinical research to guarantee compliance and aide in the monitoring and auditing processes. It further elaborates on the Adverse Event process and reporting, the differences in the classifications of Adverse Events and the necessary documentation needed from the CRC and Principal Investigator to ensure regulation compliance. Tables are included to simplify the information.

This chapter also discusses proper documentation, including how to correct errors and answer queries and data clarification forms. This topic is also addressed in relation to the monitoring and auditing process. In addition, this chapter addresses the important and costly issue of data retention and provides the reader with questions to ask the sponsor to ensure compliance and potential financial implications.

Chapter 10 also includes responsibilities of the clinical research team. The author lists and describes the regulations under which the monitor or Clinical Research Associate (CRA) is acting when visiting and reviewing the site. This information provides the CRC with the perspective of the CRA position that may enhance the working relationship. Differences between monitoring and auditing/inspections are discussed and the potential consequences are reviewed. Recommendations are provided on ways to prepare for each process and to supplement the CRC’s performance to provide quality data.

Chapter 11 emphasizes the importance of communication in the CRC’s role. The authors discuss, accounting for institutional or organizational differences, possible departments and personnel where an important role to communicate and the information to communicate. They further provide input on the significance that is placed on the team effort that clinical research entails. This effort can be achieved through active and effective communication. Lastly, effective communication with study participants and the potential issues and concerns that should be included during discussions with them regarding their participation in the clinical trial are examined.

Chapters 12 and 13 Learning: A Continuous Journey and Future Trends: the Professionalization of the CRC

Chapter 12 evaluates the vision for the CRC. Different means of obtaining the most optimal training for the clinical research coordinator are assessed. Various professional organizations and websites are listed for reference. The importance of CRC certification is discussed. Other career opportunities for the clinical research coordinator are presented.
The importance of the humanistic side of the CRC’s responsibilities are revealed and how it is maintained within the current environmental pressures set forth by regulations and sponsor demands. The authors emphasize the importance of the CRC’s role in the protection of human subjects through appropriate and adequate communication. CRCs can obtain this information through adequate and required training.

The book’s title, *Responsible Research - A Guide for Coordinators*, may lead the reader to believe that the focus and emphasis will be on the moral and ethical aspects of clinical research. Although ethics is the consistent underlying tone of why certain aspects of the position are necessary, the information included in the book encompasses a larger overview of the responsibilities of the clinical research coordinator that far surpasses the book’s title. With many contributors to this book, there are wide varieties of perspectives included. The book is written clearly and succinctly and is a valuable resource for the clinical coordinator both in the practical aspects of performing the job duties as well preparation for the CRC certification exam. I highly recommend this book to all research professionals with any interest in clinical research who have oversight of CRCs and the clinical research process. This book should be on every research administrator or manager’s credenza for understanding and reference!
This Voice of Experience column marks the second corporate “voice;” actually a “chorus” of voices of experience, sometimes singing in tune, but always singing lustily. However, we note with sadness the passing of our colleague, Herbert “Chuck” Chermside, the original “solo” voice of experience for several prior issues. Chuck was a role model for many and a source of information for all. We will miss Chuck and his contribution to research administration.

1. Dealing with Multi-Center Study Publication Clauses

Question: One of our clinical investigators is preparing to participate in a multi-center clinical trial. The sponsor is proposing an agreement that limits individual investigators’ publication rights prior to publication of a joint report on the trial. Is this common? What do other institutions do when they receive agreements with these provisions in them?

Answer: Most of multi-center clinical trial agreements prepared by pharmaceutical companies use the same clause. Apparently many of academic institutions accept a clause that restricts individual publication until a joint publication is prepared. Most participating investigators consider this reasonable, assuming that the joint report will be prepared and released promptly. Such clauses go on to say something like the following:

If such a multi-center publication is not submitted within twelve (12) months after conclusion of the study at all sites, or after the Sponsor confirms there will be no joint, multi-center publication, but not longer than twelve (12) months after conclusion of the study at all sites, University and Principal Investigator may publish individually in accordance with this Section. (Emphasis added).

http://www.ohsu.edu/research/rda/rgc/docs/cttemplate.doc

Some of us have a problem with provisions like this. We recently reviewed a presentation given by Susan Carney, Yale University; Theresa Colecchia, University of Pittsburgh; and BethLynn Maxwell; The University of Texas System; at the Association of American Cancer Institutions Annual Meeting in Washington, D.C. October 17-18, 2005. One of their slides says it all:

Multi-site/center clinical trial studies
– Preserve Institution/PI’s right to publish separately from multi-site joint publication after reasonable delay
– Reasonable delays permitted until joint publication is published OR 12 – 18 months after our study is over (whichever is shorter) (emphasis in the original).

It may seem like a small thing, but it is important to stand firm on the last point made by Colecchia, et al. Institutions need to have a firm deadline after which the lack of a multi-center publication is no longer a bar to publication at the individual institution. If the companies’ standard language is accepted, then the company can effectively prohibit publication, simply by not completing the study at one single site.

The University of Louisville model agreement, and the University of Texas sample agreement with Merck; both excerpted below, delete the “at all sites” language.

The U of L provision states:

**Notwithstanding the foregoing, U of L agrees that if the Research is part of a multi-center study, the first publication of the results of the Research shall be made in conjunction with the results from the Investigators at the other study centers. However, if a multi-center publication is not forthcoming within one year following completion of this Agreement study, U of L will be free to publish.**

research.louisville.edu/p-and-p/clinical-trial-agree-ULRF.doc

I am not completely convinced that the UT language is explicit enough in asserting the Institution’s right to publish at a firm point after completion of the UT study.

The UT provision states:

**It is understood that this study is part of a multi-center trial and INSTITUTION will be free to publish the results of its part of the study in collaboration with the other investigators in this trial, but with due regard to MERCK’s confidential information and materials. Subsequent to the multi-center publication or twenty-four (24) months after completion of the study, whichever occurs first, INSTITUTION may itself publish the results of the study, with due regard to MERCK’s confidential information.**

www.utsystem.edu/ogc/Intellectualproperty/contract/merck.htm

I also noted that the University of Texas is not consistent with the requirement that it be allowed to publish at a time based on completion at UT. The AstraZeneca Master agreement provides:

**In no event will the Institution or the Principal Investigator be so restricted after 18 months have elapsed since the completion of the Study at all centers.** (emphasis added)

www.utsystem.edu/OGC/Intellectualproperty/Contract/AZMASTER.doc

The secret to getting companies in a single industry to accept the position of academia is to present a united front on a reasonable approach to a matter where reasonable parties can disagree. If every academic medical center and every clinical research thought leader takes the same position, then the pharma companies will eventually come around. I have discussed this issue with two large pharma companies that have made it company policy to accept firm deadlines. I have also had extended negotiations with other pharma companies which are still fighting the battle to control the publication process. In each case, where negotiation was necessary, I heard the same refrain: “But XYZ institution accepts this language.” Perhaps academic institutions that perform clinical trials need to agree on a reasonable practice, and communicate that practice among themselves and with the pharma companies that support clinical trials. It seems that it is reasonable to academic medical centers to insist on the right to publish, absent a joint publication, either 12 or 18 months after the study ends at the institution. This seems like a reasonable standard of practice; much as assuring the
right to publish after a reasonable period for review became standardized in all university-industry research agreements in the 1980s.

2. Benchmarks for the Size Research Management Staff

*Question:* I am trying to find out if anyone has done any work on best practice or assessment of optimum dedicated admin support for academic researchers - e.g. in research centers or institutes. An academic colleague indicated optimum level of one administrative/ support staff member per 4 – 5 academic staff in an active and externally focused research center but I am not aware of any modeling or best practice assessment or benchmarking that has been done - have you heard of anything either for number of admin staff or levels of support?

*Answer:* This is an oft-asked question!

William Kirby and Paul Waugaman tried to deal with this issue in their national benchmarking work from 1998 through 2003, and developed some ratios which speak to the questions of practice and norms current at the time, but do not give a complete answer.

In a series of surveys, their studies showed participating institutions how their sponsored programs administration staffing and workload compared with the other institutions. Each participant had the opportunity to do comparisons and prepare their own studies using a flexible web-based data system (Fig. 1). Aggregate data was presented as ratios and showing median values for four groups of institutions, grouped by size of research expenditure. Here are some results from the 2000 survey that point to possible answers to the question (Figs. 2.1 - 2.4):

Each graph portrays the median value for the number of institutions in each size group, and the median value for the entire survey population (all participants). The bar on the left represents the value for all participants. The other bars represent a size group (measured size of sponsored program expenditures) with the largest on the left and the smallest on the right.
These graphs portray a pattern of results showing that research management at smaller institutions generally costs more and requires more people per units of business (investigators, awards, proposals, and active projects). These results are consistent for the other measures developed in these surveys. There are confounding factors, however. The data do not consider the cost and effort of decentralized research administrators, which may be greater at the larger institutions.


There are a number of other reasons why the data alone do not fully answer the question.

First, the numerators and denominators for these ratios may not comparable from institution to institution beyond the study. For example the definition of “faculty member” or “principal investigator” shifts widely, so it is very difficult to identify a comparable researcher base across a number of institutions. Likewise, it is hard to identify administrative staffing when staffing is spread across the institution; and at many levels, people have mixed responsibilities including research management. Support staff are often hidden is accounting or purchasing offices and miss being counted. The participants in these surveys worked very hard to standardize definitions, so comparisons within the population could be valid. Comparisons outside the study population may be difficult.
Second, there is a base level of service problem. There is a certain critical number of people that are needed to manage an externally sponsored research program, even a very small one. There is no consensus on how many people you need just to get your first grant or contract, but I am guessing its more than one person. This base level is driven in the US by Federal agency compliance and accountability requirements, and the magnitude of the research development job with multiple funding sources. For the sake of example, let’s say the base number is four people. This staff should be able to cope with a program from $0 - $20 million; or from 1 - 25 researchers (those who apply for or live from external support) \textit{(NOTE: these numbers are mine alone, not an accepted benchmark)}. This means that any ratio applied to a program of small size would be meaningless. Kirby and Waugaman’s benchmarking data support this. Staffing and cost ratios for institutions with smaller programs are higher than those for larger institutions.

Third, the “expected level of service” differs from academic institution to academic institution; and differs from academic institutions to independent research organizations. IRO’s tend to be a bit leaner in research management staffing in our experience because indirect cost recovery must cover all central expenses whereas academic institutions often have and use other sources of central staff funding. Expectations of service differ widely and influence what institutions are willing to invest in central and support staff.

Finally, understanding what functions are included in research administration is important when counting noses or full-time equivalents. Many institutions include technology transfer, managing IRB’s, research-related procurement and contracting, and financial management in their research administration head count. Others do not. Kirby and Waugaman approached this issue by establishing fairly conservative definitions for their participants which tend to understate the numbers but relate them closer to the output numbers.

The bottom line is there currently are few yardsticks or benchmarks which can be used objectively. The best approach is to look objectively at staffing levels at a handful of “peer institutions that do things the way you do, and count staff the same way you do in order to develop fair comparisons. be advertised.